Traumatic Elbow Dislocations

Gijs I.T. Iordens

TRAUMATIC ELBOW DISLOCATIONS

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This thesis was realized at the Trauma Research Unit, Department of Surgery, Erasmus MC, Rotterdam, The Netherlands.

Part of this research was financially supported by grants from the European Society for Surgery of the Shoulder and the Elbow (SECEC/ESSSE), the AO Research Fund of the AO Foundation (No. S-09-99D), and the Osteosynthesis and Trauma Care (OTC) Foundation (No. 2010-DHEL).

Printing of this thesis has been financially supported by:
- Erasmus MC, Afdeling Heelkunde
- Erasmus Universiteit Rotterdam

ChipSoft
Pro-Motion MEDICAL
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Nederlandse Vereniging voor Heelkunde
Samen met
Johnson & Johnson MEDICAL

ISBN: 978-94-6299-248-1

Cover design by Maurik Stomps
Layout and printing: Ridderprint BV, Ridderkerk, the Netherlands

TRAUMATIC ELBOW DISLOCATIONS

Traumatische ellebooglUxaties

PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de rector magnificus

Prof.dr. H.A.P. Pols

en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op
woensdag 23 december 2015 om 13:30 uur

door

Gijsbert Ioan Timon Iordens
Geboren 26 april 1981 te Amsterdam

Erasmus University Rotterdam

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Voor Moes

TABLE OF CONTENTS

PART I

General introduction

General introduction, aim and outline of the thesis

1

GENERAL INTRODUCTION

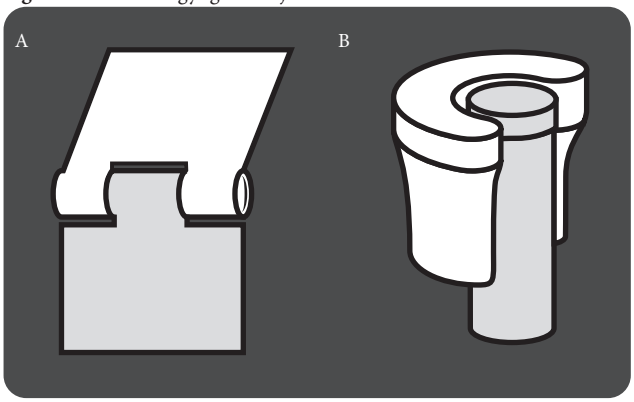
Epidemiology

The elbow is the second most common major joint to dislocate after the shoulder in the adult population. [1, 2] Elbow dislocations account for approximately 11 to 28% of all elbow injuries. The incidence varies between 5.2 and 6.1 per 100,000 person years. [2-6] There is a female sex preponderance and the injury is mostly sustained to the non-dominant hand. [3, 7]

Kinematics

Together with the shoulder the elbow plays a crucial role in positioning the hand in space. The degrees of freedom of the elbow, being a trochlear (pivoting / pro- and supination; **Figure 1**) and ginglymoid (hinge / flexion and extension) joint is relatively constrained but loss of range of motion in the elbow joint has significant impact on activities of daily living and therewith quality of life. [8-10]

Figure 1. A trochleogynglimoid joint



The elbow is trochleogynglimoid joint which combines hinging (flexion and extension; A) and pivoting (pro- and supination; B).

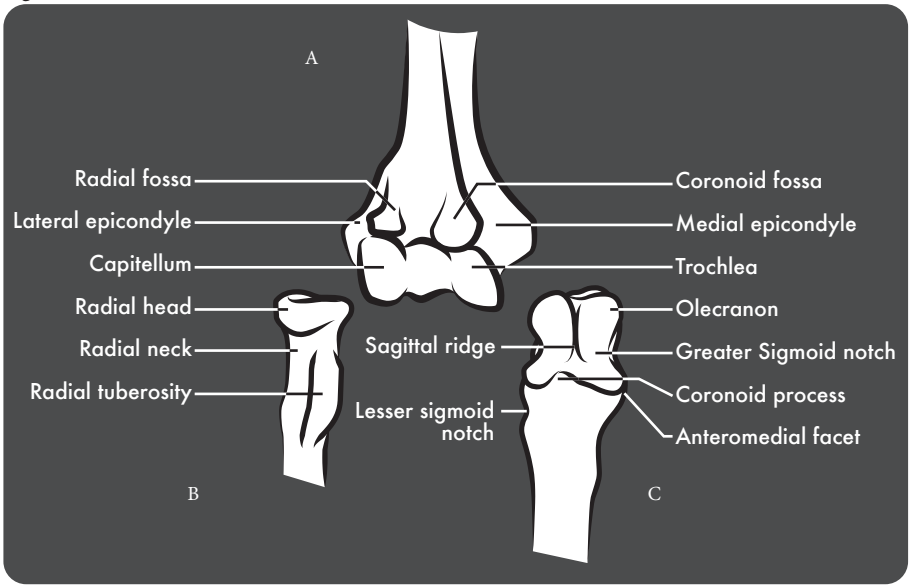
Relevant anatomy and stability

The stability of the elbow is largely dependent on the integrity and congruency of the joint. It is a highly constrained joint which relies on a complex interaction between bony articulations, capsuloligamentous structures and dynamic muscle restraints. [11, 12]

From an osseous point of view the elbow is constructed of three articulations; the ulnohumeral, the radiocapitellar and the proximal radioulnar joint. The most important osseous stabilizer is the ulnohumeral joint. Congruent articulation of this joint is responsible for as much as 50% of the stability of the elbow. [13] The coronoid process acts as a buttress for posterior directed forces to the forearm. In addition, the medial facet

of the coronoid process plays an important role in stability during varus stress. [14-17] The radial head also neutralizes posteriorly directed forces (radiocapitellar joint) and in collaboration with the radioulnar joint it facilitates forearm rotation. Furthermore, the radial head plays is an important stabilizing factor during valgus stress. [18] The osseous stabilizers are shown in Figure 2.

Figure 2. The three bones of the elbow

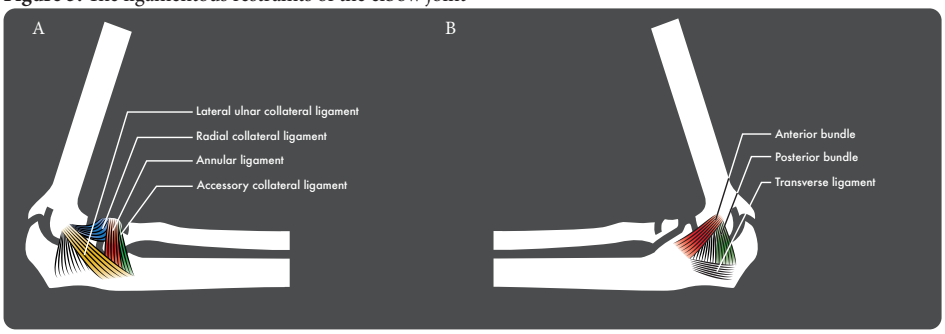


The distal humerus (A), the proximal radius (B) and the proximal ulna (C).

Ligamentous restraints contribute to the stability of the elbow joint (Figure 3). The most important ligamentous structures are the medial collateral ligament complex (MCL), the lateral collateral ligament (LCL) and the joint capsule. The MCL is situated on the medial aspect of the elbow joint. Its main function is to retain contact between the trochlear articular surface of the distal humerus and the trochlear notch of the ulna. [19] The MCL consists of three separate segments; the anterior bundle (AMCL), the posterior bundle (PMCL) and the transverse ligament. The latter does not span the joint and therefore does not contribute to ligamentous stability, rather it is thought to be an insertion site for the joint capsule. Moreover, together with the posterior bundle it contributes to the floor of the cubital tunnel. [12] The AMCL and the PMCL together are responsible for 30% and 55% of the restraint to valgus load in extension and 90° flexion, respectively.[12, 13] The greatest portion of these resistant forces are provided by the AMCL, which makes it the primary stabilizer to valgus stress; consequently, the radial head acts as a secondary stabilizer. [18, 20] An elbow with an intact MCL complex remains stable, even after removal of the radial head. [12]

The lateral collateral ligament (LCL) is positioned on the lateral side of the elbow and its main function is to maintain contact between radial head and capitellum, in other words, to prevent posterolateral instability of the elbow joint. This makes it the primary restraint of external rotation and varus load at the elbow. [12, 19, 21] The LCL consists of four components; the radial collateral ligament (RCL), the lateral ulnar collateral ligament (LUCL), the annular ligament (AL) and the accessory collateral ligament (ACL).[22]

Figure 3. The ligamentous restraints of the elbow joint

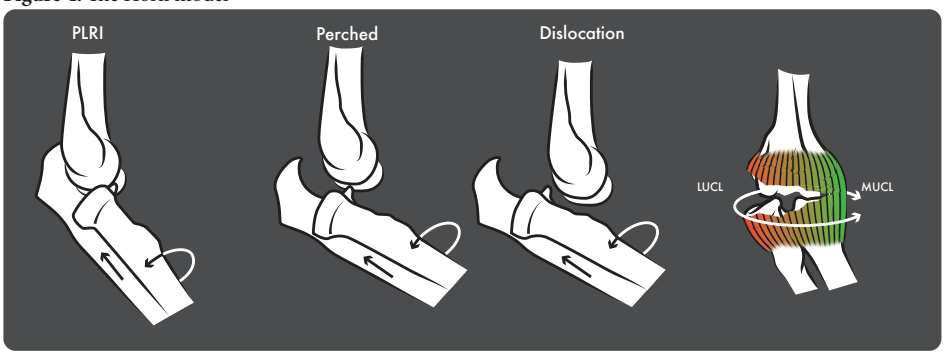


Viewed from lateral (A) and medial (B).

Biomechanical and cadaveric studies of the elbow and its ligamentous stabilizers led to the concept that dislocation is the final stage of three sequential stages of elbow instability. It starts with posterolateral rotation during which soft-tissue disruption progresses from lateral to medial. This sequence of events, the concept of posterolateral rotatory instability (PLRI), is best illustrated by the Horii model and accounts for the most commonly seen (postero)lateral elbow dislocations (Figure 4). [21, 23, 24] The opposite mechanism holds true for more infrequently encountered (postero)medial disocations. [14, 16] Some authors even state that a dislocation as a result of PLRI can occur while the MCL remains intact. [21] A recent study on elbow dislocations *in vivo,* however, challenged this principle. They reviewed 62 videos of traumatic elbow dislocations and concluded that extension, axial load, external rotation, and a deforming valgus moment are the ingredients for a typical elbow dislocation. They suggest that the anterior bundle of the MCL, rather than the LCL may be the initial site of soft tissue disruption. [25]

Both LCL and MCL are actually a thickening of the joint capsule which makes it hard to clinically differentiate between these anatomically contiguous structures. Nevertheless, the joint capsule also contributes to stability. In full extension its contribution to stability under valgus stress is almost 40%. In 90 degrees flexion its role in valgus load stability is less important (10%). [12, 13, 26]

Figure 4. The Horii model



The Horii model displays the concept of PLRI and the three stages of elbow dislocation and soft-tissue disruption progressing from lateral to medial. [23]

In addition to stability derived from bony and capsuloligamentous structures, the dynamic stability provided by muscles also plays an important role. Dynamic stabilizers are represented by the elbow flexors (M. biceps brachii, M. brachialis and M. brachioradialis), the elbow extensors (M. triceps brachii and M. aconeus), the forearm flexor-pronators and the forearm extensors. These muscles span the elbow joint and support the static stabilizers by applying compressive load over the joint when contracted. [12, 18, 23, 27, 28]

Dislocations

Elbow dislocations occur as a result of a fall on the outstretched hand and are divided into simple (*i.e.* without associated fractures) and complex dislocations (*i.e.* with associated fractures). In contrast to complex dislocations, simple dislocations of the elbow joint are generally stable following reduction. [29, 30] Additionally elbow dislocations can be classified according to the direction of the displacement of the forearm relative to the humerus. Posterior and posterolateral elbow dislocations comprise almost 90% of all elbow dislocations. [31, 32] Posteromedial and medial dislocations are more uncommon, while anterior and divergent dislocations are very rare.

The majority of simple elbow dislocations can be treated non-operatively whereas complex dislocations usually require surgical intervention in order to reestablish a concentric and stable joint. Indications for surgery in acute elbow dislocations are unsucsessful closed reduction, fractures contributing to instability which require open reduction and internal fixation, intra-articular bone fragments or loose bodies, open dislocations, concomitant neurovascular injury, or recurrent post-reduction instability with dislocation. [11, 33-35] It is known from previous studies that prolonged immobilization following an elbow dislocation leads to stiffness of the joint. [29, 30, 32, 36, 37] The optimal

after-treatment in terms of whether to immobilize or not, remains a subject of debate for both simple and complex elbow dislocations.

Associated fractures

Due to disruption of the capsuloligamentous constraints, joint stability following elbow dislocation is to a large extent dependent of bony articulation. Therefore, the presence of additional fractures considerably affects post-reduction stability. A commonly encountered fracture in complex elbow dislocations is the radial head fracture. The presence of the radial head is especially important in patients with disruption of the AMCL. Most authors advocate that displaced (>2mm) or comminuted radial head fractures should be treated by open reduction and internal fixation (ORIF) if this is feasible and is expected to provide enough stability. Otherwise the radial head should be excised and replaced by radial head prosthesis. [11, 34, 35, 38-42]

The coronoid process plays a key role in stability of the elbow. Fractures of this structure are rarely isolated injuries as they are frequently associated with collateral ligamentous injury or other fractures. As a rule, coronoid fractures are often pathognomonic for a period of instability. [16, 17, 43] For instance, a dislocation which is associated with a fracture of the anteromedial facet of the coronoid process, should lead to a high level of suspicion for valgus instability as the anteromedial facet serves as an insertion site for the AMCL, the primary constraint against valgus stress. [16, 22, 44] O'driscoll *et al.* developed a comprehensive classification for fractures of the coronoid process not only taking size, but more importantly, also taking anatomic location into account. Type 1 fractures involve only the tip of the coronoid process. Type 2 fractures involve the anteromedial facet of the coronoid. Type 3 fractures involve the base and body of the coronoid. Due to MCL involvement, type 2 fractures are known to jeopardize stability of the elbow. Likewise, type 3 fractures that involve more than 30% of the coronoid process can cause serious instability, even with repaired or intact collateral ligaments. [14, 17, 34, 45, 46] In order to adequately restore elbow stability, coronoid fractures that are likely to contribute to elbow instability should be considered for open reduction and internal fixation. [16, 17, 34, 35, 39-42, 46-48]

An elbow dislocation with the presence of fractures of both radial head and coronoid process is called a "terrible triad" injury. The combination of fractures with disruption of ligamentous constraints is associated with considerable instability. Fractures are frequently managed by ORIF or prosthesis and if instability persists either ligamentous reconstruction or hinged external may be indicated. [16, 39, 42, 48-51] Some authors even advocate standard ligamentous repair. Whether immediate surgical repair of the injured ligaments in complex elbow dislocations is an absolute requirement, as well as the role of a hinged external fixator, remain subjects of debate.

The articulation between the olecranon and trochlea of the humerus is the most important osseous constraint of the elbow joint. Consequently a fracture of the olecranon after an elbow dislocation leads to substantial instability. Resection of the olecranon has been reported, nonetheless stable fixation of the fracture in order to restore the contour and dimensions of the trochlear notch is the key to optimal treatment. [40, 52-54]

AIM

The general aim of this thesis was to study the optimal treatment for simple and complex elbow dislocations in terms of functional outcome, range of motion, quality of life, adeverse events and healthcare consumption with associated costs. Furthermore it aimed to give insight in the trends in incidence and costs of injuries to the upper extremity in the Netherlands and to validate the Dutch translation of the most commonly used elbow questionnaire.

OUTLINE OF THIS THESIS

General introduction

Chapter 1 provides a general introduction to the subject of this thesis. It elucidates the anatomical aspects of the elbow and its stability and gives insight into the mechanisms of elbow dislocations. Furthermore it describes the aim of this thesis. **Chapter 2** describes recent long-term population-based trends in the incidence of upper extremity injuries in the Dutch population between 1986 and 2008 and gives a detailed overview of the associated health care costs. **Chapter 3** focuses specifically on the trends in incidence and costs of elbow dislocations between 1986 and 2008.

Treatment and evaluation of simple elbow dislocations

Chapter 4 describes the protocol a randomized controlled trial (RCT) comparing early mobilization with plaster immobilization in patients with a simple elbow dislocation. The results of this RCT are discussed in **Chapter 5.** There are no available studies that report the burden of simple elbow dislocations on direct and indirect healthcare costs, let alone whether early mobilization might play a role in reducing these costs. **Chapter 6** assesses the cost-effectiveness of early mobilization versus plaster immobilization in patients with a simple elbow dislocation. **Chapter 7** aimed to investigate the reliability, validity and minimal clinically important difference of the Dutch version of the Oxford Elbow Score (OES) in patients with non-surgically treated elbow injuries.

Treatment of complex elbow dislocations

Chapter 8 describes the protocol of a multicenter prospective study evaluating functional outcome in patients with acute complex elbow dislocations and residual instability, who were treated with a hinged external elbow fixator and early mobilization. The results of this prospective study are discussed in **Chapter 9**

General discussion and future perspectives

Chapter 10 discusses the performed research. Furthermore the author hypothesizes on future perspectives of research in this field with an emphasis on early mobilization and a conservative approach towards ligamentous injury after elbow dislocations. **Chapter 11** summarizes the performed research in both English and Dutch.

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Trends in incidence and costs of injuries to the shoulder, arm and wrist in The Netherlands between 1986 and 2008

Suzanne Polinder *, Gijs I.T. Iordens * , Martien J.M. Panneman,
Denise Eygendaal, Peter Patka, Dennis den Hartog, Esther M.M. Van Lieshout

* Both authors contributed equally

BMC Public Health. 2013 Jun 1;13:531.

2

ABSTRACT

Background

Upper extremity injuries account for a large proportion of attendances to the Emergency Department. The aim of this study was to assess population-based trends in the incidence of upper extremity injuries in the Dutch population between 1986 and 2008, and to give a detailed overview of the associated health care costs.

Methods

Age-standardized incidence rates of upper extremity injuries were calculated for each year between 1986 and 2008. The average number of people in each of the 5-year age classes for each year of the study was calculated and used as the standard (reference) population. Injury cases were extracted from the National Injury Surveillance System (non-hospitalized patients) and the National Medical Registration (hospitalized patients). An incidence-based cost model was applied in order to estimate associated direct health care costs in 2007.

Results

The overall age-adjusted incidence of upper extremity injuries increased from 970 to 1,098 per 100,000 persons (13%). The highest incidence was seen in young persons and elderly women. Total annual costs for all injuries were 290 million euro, of which 190 million euro were paid for injuries sustained by women. Wrist fractures were the most expensive injuries (83 million euro) due to high incidence, whereas upper arm fractures were the most expensive injuries per case (4,440 euro). Major cost peaks were observed for fractures in elderly women due to high incidence and costs per patient.

Conclusions

The overall incidence of upper extremity injury in the Netherlands increased by 13% in the period 1986-2008. Females with upper extremity fractures and especially elderly women with wrist fractures accounted for a substantial share of total costs.

BACKGROUND

Upper extremity injuries account for a substantial proportion of all injury patients visiting the Emergency Departments (EDs). Besides the impact of upper extremity injuries on health and daily life, they impose an economic burden on the community.

The upper extremity consists of the shoulder (*i.e.*, clavicle and scapula), upper arm (i.e., proximal humerus and humeral shaft), elbow (*i.e.*, distal humerus, proximal radius and ulna), forearm (*i.e.*, ulna and radius), wrist (*i.e.*, distal radius and ulna, carpal bones), and hand (*i.e.*, metacarpal bones and the phalanges). Injuries seen in the upper extremity include fractures, dislocations, sprains, contusions, wounds, and superficial lesions.

Population-based knowledge on the economic impact of upper extremity injuries is essential for the allocation of health care services, optimization of preventive measures and research purposes; it also provides a forecast for the future. Most epidemiologic studies on upper extremity injuries primarily focused on one distinct subgroup such as a separate type of injury, anatomical region, or age group. [1-15] In most studies, data from single hospitals or regional data were used [2-4, 8, 9, 12, 13, 16, 17]. Few publications used a national injury database. [6, 7, 10, 11, 14, 18, 19] Data regarding the associated health care costs are generally lacking. Some studies report direct costs of upper extremity injuries, mostly fractures. [9, 19-23] No papers reported on both incidence trends and costs of all injuries to the upper extremity.

Due to budgetary restraints and increasing costs for health care services, economic analyses are becoming more important. The aim of this study was to examine recent long-term population-based trends in the incidence of upper extremity injuries in the Dutch population between 1986 and 2008 and to give a detailed overview of the associated health care costs in 2007.

METHODS

Data sources

For this retrospective study data were collected for all upper extremity injuries in The Netherlands in the period 1986-2008. Upper extremity injuries were defined using the International Classification of Diseases, ninth revision (ICD-9-CM). All codes in Chapter 17 (Injuries and Poisoning, codes 800-999) related to fractures (810-819), dislocation (830-839), sprains and strains (840-848), open wounds (880-887), superficial injuries (910-919), and contusion (920-924) at the shoulder, arm and wrist area were included. An overview of the ICD-9-CM codes is shown in Table 1. For this study, the upper extremity was separated into shoulder, arm, and wrist. The shoulder region

included the clavicle and scapula. The arm region included the upper arm, the elbow, and the forearm. The wrist region included the distal radius, the distal ulna, and the carpal bones.

Table 1. Injuries to the shoulder, arm, and wrist as encoded in the ICD-9-CM

Type of injury	ICD-9-CM codes
Shoulder	
Fracture clavicle/shoulder	810, 811
Dislocation shoulder/AC-joint	831
Open wound clavicle/shoulder	880.00, 880.01
Superficial injury/contusion clavicle/shoulder	912, 923.00, 923.01
Arm	
Fracture upper arm	812.0, 812.1, 812.2, 812.3
Fracture elbow	812.4, 812.5, 813.0, 813.1
Dislocation elbow	832
Fracture forearm	813.2, 813.3, 813.45, 813.8, 813.9
Open wound arm	881.00, 881.01
Superficial injury/contusion arm	923.1
Wrist	
Fracture wrist	813.40, 813.41, 813.42, 813.44, 813.51, 813.52, 813.54, 814
Sprained/dislocated wrist	833, 842
Open wound wrist	881.02, 882
Superficial injury/contusion wrist	914, 923.2

Injury cases were extracted from the National Injury Surveillance System (LIS) [24] and the National Medical Registration (LMR) [25], to include non-hospitalized and hospitalized patients, respectively. The LIS is based upon 13 geographically distributed Emergency Departments (EDs) in the Netherlands, resulting in a representative 12% sample of injury-related ED visits. The adherence population of the participating hospitals in this study is representative for the Dutch population in age and gender structure. [24] The LMR collects data from all Dutch hospitals regarding hospital admissions, admission diagnosis, length of hospital stay, gender, age, and trauma mechanism. With a missing value rate of less than 5% (except 12% for 2007), the LMR data have almost complete national coverage, and were extrapolated to full national coverage. [25]

Calculation of incidence rates and trends

The age-specific incidence rates were calculated in 5-year age groups. For each age group the absolute number of upper extremity injuries was registered in the LIS database. Because the absolute number was obtained from a sample, the figures were weighted in order to create national estimates. An extrapolation factor was estimated

by comparing the number of admitted injury patients in the LIS database with the total number of admitted injury patients as recorded in the LMR. The age- and sex-specific incidence rates per 100,000 person years were calculated based upon the Dutch mid-year standard population. The mid-year population sizes for all age-groups were obtained from Statistics Netherlands. [26] "Direct standardization" was used in order to calculate age-adjusted incidence rates. [27] The average number of people in each of the 5-year age classes for each year of the study (1986-2010) was calculated. This number was used as the standard (reference) population, as described previously. [28-30] The overall growth in the number of hospital admissions was calculated for 2008 in percents relative to the year 1986.

Calculation of costs

The incidence-based Dutch Burden of Injury Model was used in order to measure and describe the health care costs resulting from injuries occurring during a specified period. [27] For each individual injury group patient numbers, health care consumption, and related costs were calculated using the LIS database, the National Hospital Discharge Registry, and a patient follow-up survey conducted in 2007. [31, 32] In this model, the age- and injury-specific costs are based upon the estimated health care supplied to the individual patients. Health care costs of injuries were calculated by multiplication of the incidence, health care volumes (*e.g.*, length of stay in hospital or institution, the number of outpatient visits, General Practitioner visits, home care hours, and physical therapy treatments), and unit costs (*e.g.*, costs per day in hospital). All unit costs were estimated according to national guidelines for health care costing. [33] All costs in this study were calculated over the year 2007. Costs are calculated every five years; the 2007 data were the most recent data available. Despite the 12% of missing data entries for 2007, detailed cost information was available for all patients in the database.

RESULTS

Incidence

Between 1986 and 2008, a total number of 3,711,600 patients (1,844,300 males and 1,867,300 females) visited an ED with an upper extremity injury, comprising 42% of the total injury-related ED visits in The Netherlands. The overall (*i.e.,* males and females combined) age-adjusted incidence of upper extremity injuries increased by 13%, from 970 in 1986 to 1,098 in 2008, with a peak in 1999 of 1,250 per 100,000 persons (Figure 1). Since 2005, the incidence increased again, especially in children.

Injuries to the upper extremity appeared to be age- and gender-related. Women were more likely to sustain an injury to the upper extremity. Over the past two decades, a

mean incidence rate for women of 1,042 per 100,000 person-years was seen, compared with 987 per 100,000 for men (Figure 1). Both boys and girls in the age of 5-14 years had a relatively high incidence of upper extremity injuries, especially of the wrist and arm (Figure 2). From the age of 45 onwards, the incidence rate of upper extremity injuries in females increased. In older males, this peak was visible from the age of 80 years onwards.

Figure 1. Age-adjusted incidence (per 100,000 person-years) of upper extremity injuries in the period 1996-2008. Data are shown for males and females separately.

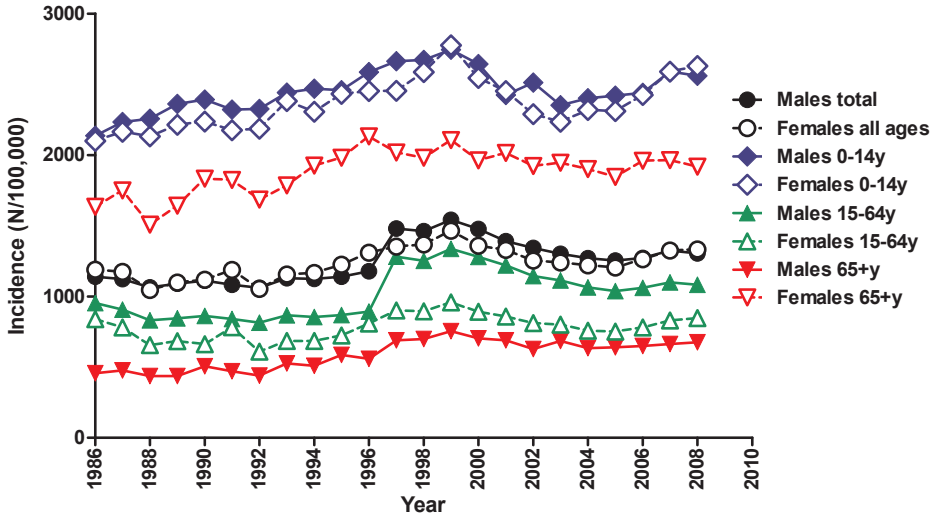
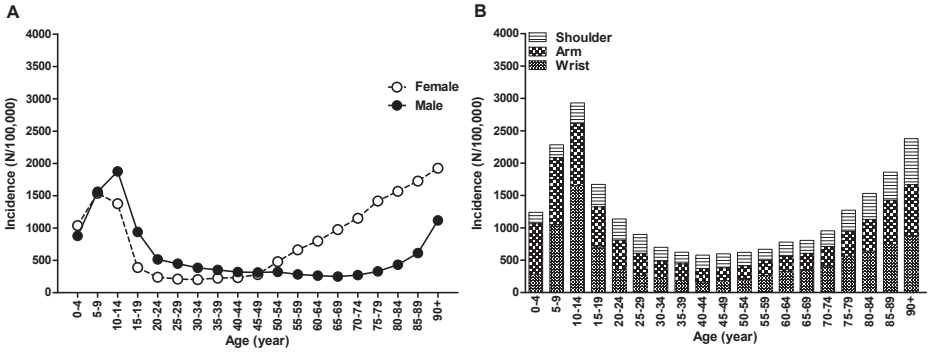


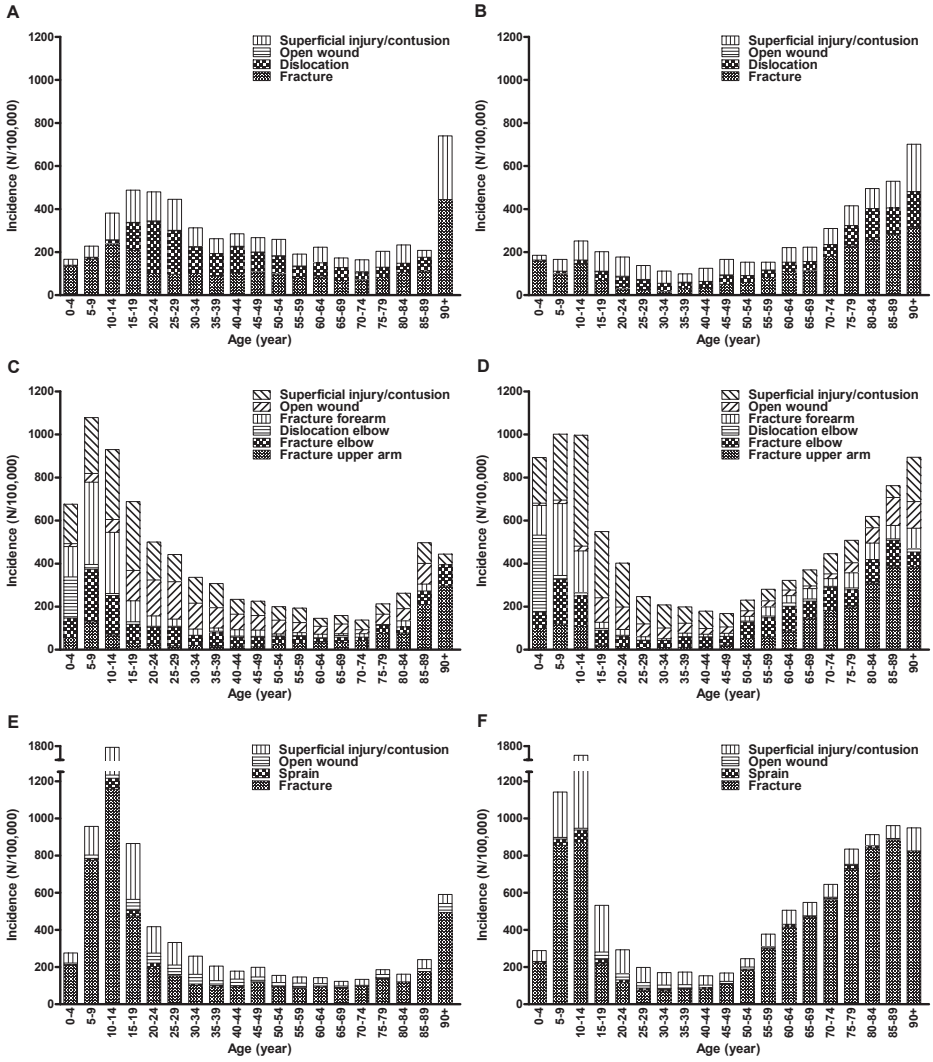
Figure 2. Age-adjusted incidence (per 100,000 person-years) of upper extremity injuries in the period 1996-2008. Data are shown by age and gender (A) or anatomic location (B).



The relatively high incidence of upper extremity injuries among boys (aged 10 – 14 year) was mainly attributable to wrist fractures; 1,157 per 100,000 person-years (Figure 3); dislocations and fractures of the shoulder/clavicle were also abundant. Most upper

extremity injuries in older women resulted in a fracture, mainly in the wrist and to a lesser extent also in the upper arm (Figures 2B and 3). Superficial injuries/contusions were the most abundant injury in the arm region (32% in males, 33% in females), followed by fractures of the forearm (21% and 20%). Fracture injuries were mainly observed injury in the wrist and shoulder areas and were seen in 61% and 41% of the injuries to the wrist and shoulder, respectively. Wrist fractures occurred more frequently in females than in males (290 versus 206 per 100,000). During the study period, the incidence of wrist fractures increased by 24% in males and by 10% in females.

Figure 3. Age-adjusted incidence (per 100,000 person-years) of the shoulder (A-B), arm (C-D) and wrist (E-F) by age. Data for 2007 are shown. Data are shown for males (A, C, E) and females (B, D, F) separately.



Costs

The total health care costs of upper extremity injuries in The Netherlands were €290 million a year, of which 190 million euro were paid for injuries sustained by women (66%; Table 2). Mean costs per patient were €1,150 for males and €2,180 for females. The total health care costs varied substantially between the different injury subtypes. Overall, fractures comprised 53% of all upper extremity injuries but accounted for 76% of the total costs.

Women with wrist fractures accounted for 21% of total costs of upper extremity injuries. The total health care costs for wrist fractures were €83 million making them the most expensive injuries. This seemed mainly attributable to the high incidence (Table 2). Upper arm and shoulder fractures represented 5% and 10% of all injuries, respectively. However, with total costs of over €40 million each, they were the second and third most expensive injuries. Fractures of the wrist, shoulder, and upper arm accounted for almost 60% of total costs. With average costs of €4,440 per case, upper arm fractures represented the most expensive injury per case in both men and women.

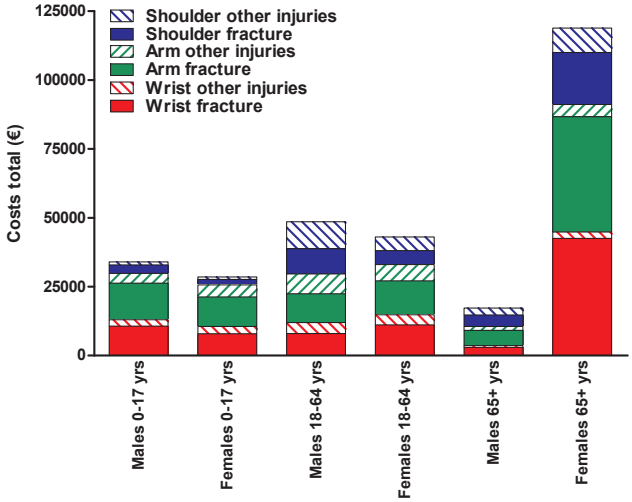
A substantial difference in costs between males and females was noted. For almost all injury groups total costs were higher for females, except for open wounds (Table 2). Costs were generally higher due to higher incidence rates and higher mean costs. An average upper extremity injury in women aged 65 years or older was with €4,310 per case approximately €1,400 more expensive than the same injury in men.

Figure 4 shows the total cost per type of injury by gender for three age groups. Although the total costs for the male population under the age of 65 was slightly higher than for their female peers, the total costs for females aged 65 years or older was almost seven times higher than the corresponding age group in males, mainly due to fractures and dislocations.

Table 2. Total cost and cost per case of all injuries of the upper extremity

	Overall			Males			Females		
	N cases	Total cost (€)	Cost per case (€)	N cases	Total cost (€)	Cost per case (€)	N cases	Total cost (€)	Cost per case (€)
Shoulder	**38,776**	**70,418,210**	**1,820**	**23,324**	**29,811,080**	**1,280**	**15,452**	**40,607,130**	**2,630**
Fracture	16,647	42,422,680	2,550	9,646	16,434,470	1,700	7,001	25,988,220	3,710
Dislocation	10,167	17,499,320	1,720	6,938	8,643,750	1,250	3,229	8,855,570	2,740
Open wound	281	282,830	1,010	215	222,210	1,030	66	60,620	920
Superficial injury/ contusion	11,681	10,213,380	870	6,524	4,510,650	690	5,156	5,702,720	1,110
Arm	**67,674**	**121,060,450**	**1,790**	**32,652**	**41,426,120**	**1,270**	**35,022**	**79,634,330**	**2,270**
Fracture upper arm	9,038	40,143,150	4,440	3,088	8,789,630	2,850	5,949	31,353,520	5,270
Fracture elbow	11,809	28,225,280	2,390	5,163	8,517,370	1,650	6,646	19,707,910	2,970
Dislocation elbow	3,625	4,174,760	1,150	1,482	1,478,510	1,000	2,143	2,696,250	1,260
Fracture forearm	11,266	25,894,070	2,300	5,992	12,034,840	2,010	5,274	13,859,220	2,630
Open wound	9,542	8,277,780	870	6,327	4,893,220	770	3,215	3,384,570	1,050
Superficial injury/ contusion	22,395	14,345,420	640	10,600	5,712,550	540	11,795	8,632,870	730
Wrist	**67,540**	**98,791,390**	**1,460**	**30,630**	**28,584,230**	**930**	**36,910**	**70,207,160**	**1,900**
Fracture	44,019	83,208,720	1,890	18,819	21,657,900	1,150	25,200	61,550,820	2,440
Sprain	2,478	1,946,670	790	1,172	852,820	730	1,306	1,093,860	840
Open wound	3,305	3,127,140	950	2,288	1,955,250	850	1,017	1,171,890	1,150
Superficial injury/ contusion	17,737	10,508,860	590	8,350	4,118,270	490	9,387	6,390,590	680
Total	**173,989**	**290,270,050**	**1,670**	**86,605**	**99,821,440**	**1,150**	**87,384**	**190,448,620**	**2,180**

Figure 4. Total costs related to injuries of the shoulder, arm and wrist. Data for 2007 are shown, subdivided into three age groups for males and females.



DISCUSSION

Upper extremity injuries accounted for 42% of all injury-related visits to the Emergency Departments (EDs). In the past 25 years the overall incidence of upper extremity injuries in the Netherlands increased by 13%. Throughout the years, the incidence was age and gender related. The increase in incidence of upper extremity injuries is most evident in patients aged 60 years and above. Fractures are the most expensive type of injury, especially in women.

Our data demonstrate an evident influence of age and gender on the incidence of certain upper extremity injuries. The 10-14 year old boys group is prone to wrist fractures, as shown before. [34, 35] During this age, an increased calcium demand combined with maximal skeletal growth and an increased physical activity leads to more fractures. [35] Young males have a higher upper extremity injury incidence than females of the same age, which seems in line with previous findings that young males experience more road traffic incidents and sports trauma. [12, 19] Women suffer significantly more fractures when aged 65 years and over, which seems attributable to the increasing occurrence of postmenopausal osteoporosis in elderly women. [5, 6, 15, 36] An equal rise in humeral fractures in females of this age-group supports this. In addition, the higher rate of falls may also explain the rise in fractures in the elderly. [29, 30]

Several studies describe incidence rates on injuries that were also included in the current study. Since these used another reference population form the standardization, absolute numbers may differ. However, trends remain indicative. Lofthus *et al.* reported that incidence rates on wrist fractures in females aged 50 and over range from 554 to 1,098 per 100,000. [16] This seems slightly higher than the incidence found in our study (average 489, range 430-621 per 100,000), but this may be due to differences in the reference population. In literature, dislocation of the glenohumeral joint ranged from 11.2-27.0 per 100,000 person years. [14, 37, 38] This is lower than the incidence (51.2 per 100,000) found in our study, which also contained dislocation of the acromioclavicular joint. In accordance with our data, all studies displayed a higher incidence of shoulder dislocations in men than in women. [14, 37, 38]

Even though the age-adjusted incidence rates for men and women were similar, the total costs of upper extremity injuries for females almost doubled those of males. This huge difference is for a considerable part attributable to the higher costs per case in females and the female preponderance in the older Dutch population (Statistics Netherlands). [26] Over 75% of total costs were attributable to fractures, making them the most expensive injuries. The majority of the costs for fractures were accounted for by women (69%). Fractures were expected to have the highest costs of all injuries, due to possible hospital admissions, surgical intervention, plaster treatment, X-rays, longer rehabilitation, and physical therapy. An explanation for the extensive costs of fractures

in the elderly females could be that osteoporotic bones of postmenopausal women fracture more severely. [38] Such fractures may require more radiological evaluation and more extensive or expensive surgical interventions. Also, new surgical techniques may have lowered the threshold for surgical interventions. In addition, surgery performed in osteoporotic bone has a higher failure rate which may result in an increased rate of revision surgeries. [39] A final explanation for the higher costs of fracture care in the elderly women could be that they outlive their partners, which may increase the chance of extended nursing home admission or home care.

To the best of our knowledge, this is the first population-based study to show trends in incidence and cost of fourteen different injuries of the upper extremity at a national level. A few other studies presented cost information of upper extremity injuries, of which most concern high-risk groups [9, 21] or economic evaluation studies of treatment interventions. [40, 41] Only Meerding *et al.* calculated costs of fractures of the wrist, the clavicle/shoulder, and the upper arm in the Netherlands. [19] After applying a correction for inflation, Meerding *et al.* reported €1,080 for wrist fractures, €1,130 for clavicle/shoulder fractures, and €3,200 for upper arm fractures, as opposed to €1,890, €2,550 and €4,440, respectively, in the current study. The higher costs as observed in the current study may be attributable, at least partly, to a higher number of patients receiving operative treatment for fractures. Higher current costs for (new or improved) implants can also not be ruled out. Finally, recent improvement in the data sources on home and nursing care and on operative interventions may have resulted in a more accurate, most likely higher, estimate of costs in our study.

The main strength of our study is that we used up-to-date population-based data over a longer, continuous time-period. The use of data from a representative national sample of outpatients using data from a national registry is a more reliable representation of the health care problem than extrapolating data from one clinical trial or one hospital only. [24] Although the registrations in the LIS-database only cover 12% of the Dutch population, international validation studies have shown that the mathematical model that was applied for the calculation of the overall Dutch data has a high level of completeness and validity. Meerding *et al.* showed that there was a close agreement between de cases recorded in the LIS and the hospital's discharge system. [24] Lyons *et al.* reported that there was a particularly good agreement between the extrapolated data from the LIS and the actual incidences of hospital admissions for injuries. [42] Another strength of our study is that it presents comprehensive estimates of health care costs, including all relevant health care sectors (*i.e.*, hospital inpatient care, medical procedures, rehabilitation clinics, and nursing homes). The model uses data from the LIS, the National Hospital Discharge Registry, and a patient follow-up survey conducted in 2007. Unfor-

tunately, when performing the follow-up survey, it was not known that 2007 was a year with relatively more missing data. However, due to the very large sample of the survey and the use of a uniform coding method, it was possible to compare the healthcare use and related healthcare costs of all types of upper extremity injuries. [32]

A limitation of the cost model is that indirect health care costs, such as absenteeism and work disability were not taken into account. This could be a suggestion for future research. Furthermore, there may be some statistical uncertainty due to underreporting of combined injuries. For example, patients with wounds concomitant with a fracture will be reported as fractures, not as wounds. Moreover, only patients who visited the ED were recorded in the LIS and LMR databases. Therefore patients who visited their general practitioner were not included.

CONCLUSIONS

There has been a 13% rise in incidence of upper extremity injuries in the Netherlands over the past two decades. These injuries constitute a substantial part of all injury-related ED visits and impose a burden on health care costs. The incidence of upper extremity injuries seems strongly age and gender related. Fractures are the most common injuries and they impose the greatest burden on health care costs, especially in women. Current treatment programs of especially frequently occurring injuries and injuries associated with high costs need to be evaluated in order to assess if health care cost reduction is feasible.

ACKNOWLEDGEMENTS

This project was supported by grants from the European Society for Surgery of the Shoulder and the Elbow (SECEC/ESSSE), the AO Research Fund of the AO Foundation (No. S-09-99D), and the Osteosynthesis and Trauma Care (OTC) Foundation (No. 2010-DHEL).

None of these granting organizations was involved in data collection, data analysis, or the preparation of or editing of the manuscript.

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Trends in incidence and costs of elbow dislocations in the adult population in The Netherlands between 1986 and 2008

Gijs I.T. Iordens, Esther M.M. van Lieshout.

Unpublished data

3

BACKGROUND

Elbow dislocations account for approximately 11 to 28% of all injuries to the elbow and reported incidence rates in literature vary between 5.2 and 6.1 per 100,000 person years. [1-4] However, there is no available data on the trend in incidence of elbow dislocations. The same accounts for the associated healthcare costs. The aim of this sub-analysis of data from a previously published article [5] was to examine the recent long-term population-based incidence trend of elbow dislocations in the adult Dutch population between 1986 and 2008 and to give a detailed overview of the associated health care costs in 2007.

METHODS

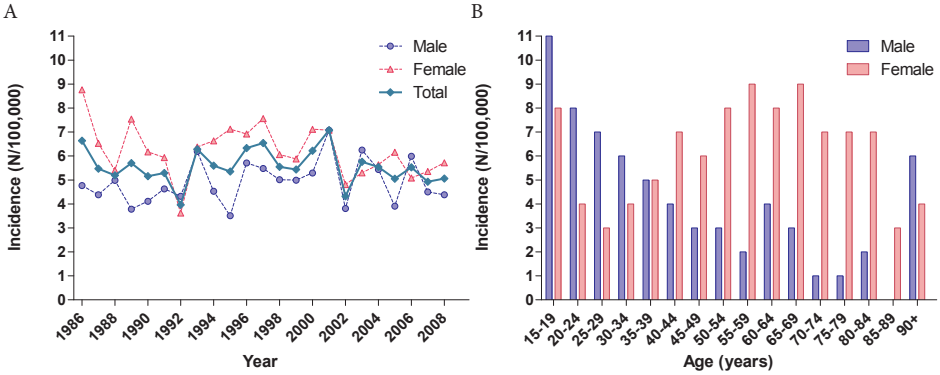
For this retrospective study we used data of a previously published study that reported on both incidence trends and costs of all injuries to the upper extremity. [5] Injuries were defined using the international Classification of Diseases, ninth revision (ICD-9-CM) and were extracted from the National Injury Surveillance System (LIS) [6] and the National Medical Registration (LMR). [7] All unit costs were estimated according to national guidelines for health care costing. [8] All costs in this study were calculated over the year 2007 as these were the most recent data available. A more detailed description of the data collection and the calculation of incidence trends and costs can be found in the original article. [5]

RESULTS

Incidence

Between 1986 and 2008 16.239 patients reported to the emergency department with elbow dislocations. The incidence rate of elbow dislocations varied from 4 to 7 per 100.000 person years between 1986 and 2008 and demonstrated a rather stable trend over this period (Figure 1A). The mean incidence rate was 5.6 per 100.000 person years. Two relative peaks in incidence rate were observed; one in the young adult male and female population (aged 15 – 19 years) and a second in middle aged females (aged 50 – 70 years; Figure 2B).

Figure 1. Incidence-rate of elbow dislocations in The Netherlands

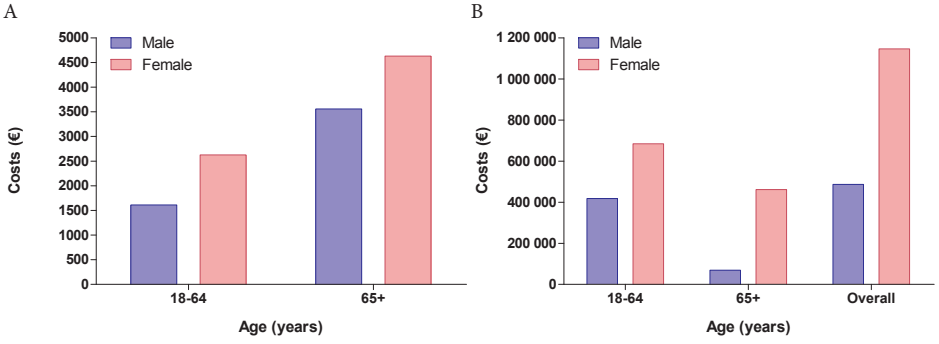


Trends in incidence-rate (N/100,000 person years) of elbow dislocations in the Netherlands between 1986 and 2008 (A). Data are also shown by age and gender (B)

Costs

The total costs for elbow dislocations were € 1.63 million per year. The majority of these costs were accounted for by the female population (€ 1.14 million *versus* € 0.49 million). The average costs per case were € 2.555 and costs per case were higher for females than for men (€ 3.174 *versus* € 1.751).

Figure 2. Costs for elbow dislocations in The Netherlands



Costs per case (A) and total costs (B) in 2007. Data are shown by age group and gender.

DISCUSSION

The mean incidence rate for elbow dislocations in the adult population between 1986 and 2008 was 5.6 per 100.000 person years with a preponderance for females. The total costs for elbow dislocations were €1.63 million. The average costs per case were € 2.555.

The incidence rate for elbow dislocations in current analysis resembled those of previous studies which ranged from 5.2 to 6.1 per 100,000 person years. [1-4] For this sub-analysis only patients of 18 years of age and older were included as this was most applicable to the population as will be discussed in this thesis. This implies that nursemaids elbows and elbow dislocations in children and the adolescent population are not taken into account. Furthermore, there may be some statistical uncertainty due to underreporting of combined injuries. For example, patients with complex elbow dislocations (with associated fractures) might have been reported as fractures instead of elbow dislocations. This may have led to underestimation of the incidence rate.

To the best of our knowledge this is the first report on the associated healthcare costs for elbow dislocations. The total costs for elbow dislocations in females doubled those of males. This was mainly attributable to both a higher incidence rate and higher costs per case for females. Higher costs per case could be explained by osteoporotic changes in the female population leading to a higher rate of complex elbow dislocations. Complex elbow dislocation are challenging injuries which often require operative treatment and longer follow-up, consequently increasing costs per case and therewith total costs. [9-12] This might also explain the fact that costs per case of elbow dislocations (€ 2.555) did not differ from those of elbow fractures (€ 3.297; data not shown) as much as one would expect. This study did not take into account indirect health care costs, such as absenteeism and work disability. This may have led to an underestimation of the total costs.

Although not the most common of injuries, costs per case for elbow dislocations approximate those of elbow fractures. Detailed information on healthcare costs are gaining importance as the burden of health care costs threatens to exceed the financial resources available. Moreover, accurate incidence rates are valuable for research purposes. It is helpful in the estimation of the duration and feasibility of a trial.

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PART II

Treatment and evaluation of simple elbow dislocations

Protocol: Functional treatment versus plaster for simple elbow dislocations: A randomized trial

Jeroen de Haan, Dennis den Hartog, Wim E Tuinebreijer, Gijs I.T. Iordens, Roelf S. Breederveld, Maarten W.G.A. Bronkhorst, Milko M.M. Bruijninckx, Mark R. De Vries, Boudewijn J. Dwars, Denise Eygendaal, Robert Haverlag, Sven A.G. Meylaerts, Jan-Willem R. Mulder, Kees J. Ponsen, W. Herbert Roerdink, Gert R. Roukema, Inger B. Schipper, Michel A. Schouten, Jan Bernard Sintenie, Senail Sivro, Johan G.H. Van den Brand, Hub G.W.M. Van der Meulen, Tom P.H. Van Thiel, Arie B. Van Vugt, Egbert J.M.M. Verleisdonk, Jos P.A.M. Vroemen, Marco Waleboer, W. Jaap Willems, Suzanne Polinder, Peter Patka, Esther MM van Lieshout, Niels WL Schep

BMC Musculoskelet Disord. 2010 Nov 12;11:263.

4

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 a simple dislocation, treatment options include immobilization 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 or hinged brace. Theoretically, functional treatment should prevent stiffness without introducing increased joint instability. The primary aim of this randomized controlled trial is to compare early functional treatment versus plaster immobilization following simple dislocations of the elbow.

Methods/Design

The design of the study will be a multicenter randomized controlled trial of 100 patients who have sustained a simple elbow dislocation. After reduction of the dislocation, patients are randomized between a pressure bandage for 5-7 days and early functional treatment or a plaster in 90 degrees 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. Function, pain, and radiographic recovery will be evaluated 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 heterotopic 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 immobilization, surgical treatment of ruptured collateral ligaments, functional treatment, or combinations. There is little available literature about treatment of elbow dislocations. One randomized 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 immobilization, 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 immobilization, 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 immobilization after reduction showed a larger ROM after shorter immobilization, 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 immobilization for more than two weeks following reduction may lead to limited ROM. [12, 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 immobilization 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 immobilization in adult patients who sustained a simple elbow dislocation. Secondary aims are to examine the effect of functional treatment versus plaster immobilization 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 AND DESIGN

Study design

The FuncSiE trial will follow a multicenter, randomized 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 randomized within one week. Participants will be allocated to one of two treatment arms using a web-based randomization program that will be available 24 hours a day. Variable block randomization 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 treat-

ment 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:

- Adult men or women aged 18 years and older (with no upper age limit)
- 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
- Provision of informed consent by patient

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

- Polytraumatized patients
- Patients with complex, pathological, recurrent or open dislocations
- Additional traumatic injuries of the affected arm
- Patients undergoing surgical repair of collateral ligaments of the dislocated elbow joint
- Patients with an impaired elbow function (i.e., stiff or painful elbow or neurological disorder of the upper limb) prior to the injury
- Retained hardware around the affected elbow
- History of operations or fractures involving the elbow
- Patients with rheumatoid arthritis
- Likely problems, in the judgment of the investigators, with maintaining follow-up (e.g., patients with no fixed address)
- 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 90°. 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 heterotopic 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): heterotopic 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:

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

- 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.

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.

Table 1. Schedule of events

	Screening	Enrollment	Baseline	1 week (3-10 d)	3 weeks (11-28 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
Informed Consent		X							
Randomization		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

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 immobilization. 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,

Randomized 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.

Acknowledgements

The Oxford and Isis Outcomes, part of Isis Innovation Limited, are acknowledged for their kind support. This project was supported by a grant from the European Society for Surgery of the Shoulder and the Elbow (SECEC/ESSSE).

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Early mobilization versus plaster immobilization of simple elbow dislocations: Results of the FuncSiE multicenter randomized clinical trial

Gijs I.T. Iordens, Esther M.M. Van Lieshout, Niels W.L. Schep, Jeroen De Haan, Wim E. Tuinebreijer, Denise Eygendaal, Ed F. Van Beeck, Peter Patka, Michael H.J. Verhofstad, Dennis Den Hartog, on behalf of FuncSiE Trial Investigators

Br J Sports Med. 2015 Jul 14. [Epub ahead of print]


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ABSTRACT

Background/Aim

To compare outcome of early mobilization and plaster immobilization in patients with a simple elbow dislocation. We hypothesized that early mobilization would result in earlier functional recovery.

Methods

From August 2009 to September 2012, 100 adult patients with a simple elbow dislocation were enrolled in this multicenter randomized controlled trial. Patients were randomized to early mobilization (n=48) or three weeks plaster immobilization (n=52). Primary outcome measure was the Quick Disabilities of the Arm, Shoulder, and Hand (*Quick*-DASH) score. Secondary outcomes were the Oxford Elbow Score, Mayo Elbow Performance Index, pain, range of motion, complications, and activity resumption. Patients were followed for one year.

Results

Quick-DASH scores at one year were 4.0 points in the early mobilization group *versus* 4.2 [95% CI 1.2 to 7.2] in the plaster immobilization group. At six weeks early mobilized patients reported less disability (*Quick*-DASH 12 [95% CI 9 to 15] points *versus* 19 [95% CI 16 to 22]; $p<0.05$) and had a larger arc of flexion and extension (121° [95% CI 115 to 127] *versus* 102° [95% CI 96 to 108]; $p<0.05$). Patients returned to work sooner after early mobilization (10 *versus* 18 days; $p=0.020$). Complications occurred in 12 patients; this was unrelated to treatment. No recurrent dislocations occurred.

Conclusions

Early active mobilization is a safe and effective treatment for simple elbow dislocations. Patients recovered faster and returned to work earlier without increasing the complication rate. No evidence was found supporting treatment benefit at one year.

BACKGROUND

With an incidence of 5.2 to 6.1 per 100,000 person years, the elbow joint is the second most common major joint to dislocate in adults. [2-4] An elbow dislocation without associated fractures is considered a simple dislocation. [5-7]

Traditionally, the elbow is immobilized in a long arm cast after closed reduction. However, immobilization may result in stiffness and contracture of the elbow joint.[5, 8-11] Simple dislocations may also be treated with early mobilization following closed reduction.[12-17] Although elbow experts appreciate and acknowledge the importance of early mobilization, it is not common practice worldwide yet. In the Netherlands more than 60% of simple elbow dislocations are still treated with plaster immobilization for at least three weeks.[18]

Current evidence on the merits of early mobilization over immobilization in a long arm cast has a low level of scientific evidence. Moreover, some physicians fear persistent instability after early mobilization. A systematic review including only one RCT (n=50) found no difference in flexion-extension arc at one year; less extension limitation was observed at three months in the early mobilization group.[9, 15] Observational retrospective studies showed better results for pain and range of motion (ROM) at six months following early mobilization.[9, 16, 17]

The low scientific level of evidence and methodological issues with the previous studies stress the need for more clinical studies. The FuncSiE trial (FUNCtional treatment *versus* plaster for SImple Elbow dislocations) was designed to compare patient-reported outcome after early mobilization versus three weeks of plaster immobilization in patients with a simple elbow dislocation. Primary outcome measure was the *Quick* Disabilities of the Arm, Shoulder, and Hand (*Quick*-DASH) score. We hypothesized that early mobilization would result in earlier functional recovery without increase in recurrent dislocation or persistent instability.

METHODS

Setting and participants

The FuncSiE trial was a multicenter, parallel group randomized study. Twenty-two hospitals in The Netherlands participated. All patients aged 18 years or older with a simple elbow dislocation and successful closed reduction were included after provision of written informed consent. Patients were excluded if they 1) were polytraumatized; 2) had a complex (*i.e.*, associated with fractures), recurrent, or open dislocation; 3) had additional traumatic injuries of the affected arm; 4) required surgical intervention; 5) had a history of impaired elbow function (*i.e.*, stiff or painful elbow or neurological

disorder); or 6) had fractures or surgery of the affected elbow in the past. Patients with expected problems in maintaining follow-up or with insufficient comprehension of the Dutch language were also excluded. The trial was approved by the Medical Research Ethics Committees or Local Ethics Boards of all participating centers. The study protocol is available online.[19]

Randomization and masking

Eligible patients were informed about the trial while being in the Emergency Department. Patients who signed informed consent were randomly assigned in a 1:1 ratio to receive early mobilization or plaster immobilization. The randomization sequence, stratified by center and with random block sizes, was computer generated at the coordinating hospital. Randomization was done by an independent central telephone operator, concealing treatment allocation from the recruiting investigator. Masking participants or investigators to the allocated treatment was not possible. In order to reduce bias, the follow-up measurements were standardized. Radiographs were blinded and evaluated independently by two assessors (GITI and DDH).

Intervention

The dislocated elbow was reduced under local, regional, or general anesthesia or without anesthesia, depending upon the preference of the surgeon. In the early mobilization group, the affected arm was put in a bandage for up to seven days. Patients were allowed to use a sling to relieve pain during the first few days. Early active movements within the limits of pain were started after two days according to a predefined protocol.[19] During the first three weeks, passive stretching was not allowed. In the plaster group the elbow was immobilized for three weeks in full above elbow cast. After removal of the plaster physical therapy was initiated according to a standardized protocol.

Assessments and follow-up

Follow-up data were obtained during outpatient visits at one, three, and six weeks, and at three, six, and 12 months after randomization. At each visit, the investigators ascertained clinical data from the patient files and patients completed a questionnaire on the level of pain. From six weeks onwards, the investigators measured the elbow ROM at both sides. At those times, patients were asked to complete a set of patient reported outcome measures (PROMs) and to complete a questionnaire with additional questions on health care consumption (*e.g.*, physical therapy) and resumption of activities of daily living (including work and sports). Radiographs of the elbow were made at the time of presentation to the hospital (baseline), after reduction, and at the follow-up visits at one week and one year. The X-ray at 12 months was used for determining the

amount and location of heterotopic ossification and the grade of degenerative joint changes. All data were collected prospectively and were entered into a central database.

The primary outcome measure was the *Quick*-DASH (Disabilities of the Arm, Shoulder and Hand) score.[20, 21] Secondary outcome measures were the Oxford Elbow Score (OES),[22-24] the Mayo Elbow Performance Index (MEPI),[25] pain level (Visual Analog Scale, VAS), Range of Motion of the elbow joint, and the rate of secondary interventions and complications. A detailed description of these questionnaires can be found in the trial protocol.[26] Heterotopic ossifications were classified from X-rays at one year according the classification of Broberg and Morrey.[27]

At baseline, intrinsic variables such as age, gender, American Society of Anesthesiologists' (ASA) classification, tobacco and alcohol consumption, comorbidities, dominant side, medication use, and work and sports participation were collected. Also, injury related variables (such as the affected side, mechanism of injury, and type of dislocation) and intervention related variables (such as the time between dislocation and reduction) were recorded.

Statistical analysis

Sample size calculation was based upon the assumption that the mean *Quick*-DASH would be 12.5 (SD 15.0) in the plaster immobilization group.[16] The FuncSiE trial was designed to enrol 100 patients, yielding 80% power to detect a treatment difference of at least 7.5 points (mean 5.0, SD 7.5) with a two-sided significance level of 0.05 and anticipating a 20% loss to follow-up.

Since there were hardly any missing data imputation was not needed. Normality of continuous data was assessed by inspecting the frequency distributions and the homogeneity of variances was tested with the Levene's test.

Chi-squared analysis was used for statistical testing of categorical data. Continuous data were analyzed using a Mann-Whitney U-test. P-values <0.05 were regarded as statistically significant.

Continuous outcomes that were repeatedly measured over time were compared between treatment groups using linear mixed-effects regression models. These multilevel models included random effects for the intercepts of the regression model and time coefficient of individual patients. Since the outcome measures were not linearly related with time, the time points were entered as factor. The models included fixed effects for treatment group, involvement of the dominant side, and gender. The effect of age was non-significant in all models and age was therefore not included. As the participating hospitals used similar treatment strategies, site was also not included in the model. The interaction between treatment group and time was included in the model to test for differences between the groups over time. For each follow-up moment, the estimated marginal mean was computed per treatment group and compared post hoc using a

Bonferroni test to correct for multiple testing. Absence of overlap in the 95% confidence interval around the marginal means was regarded as significant at $p<0.05$.

Analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 20. Analysis was by intention to treat and all statistical tests were two-sided. The trial is registered at the Netherlands Trial Register (NTR2025).

RESULTS

Patient and injury characteristics

Between August 25, 2009 and September 18, 2012, 108 patients were screened for eligibility, of which 100 were included; 13 hospitals included <5 patients, seven included 5 to 10 patients, and two included 10 or more patients. Of the included patients, 48 patients were assigned to early mobilization and 52 to plaster immobilization (Figure 1). All patients received the allocated treatment. One patient in the plaster group was lost to follow-up after six months, and six patients did not show up at one follow-up moment (four in the early mobilization and two in the plaster group; Figure 1). Randomization resulted in similar baseline and injury characteristics in the two groups (Table 1), except for a relative predominance of patients with comorbidities in the plaster group, and the dominant side was affected more frequently in the early mobilization group.

Patient-reported functional outcome and pain

The *Quick*-DASH, OES, MEPI, and pain scores improved over time in both treatment groups (Figure 2). Table 2 shows the results of the mixed-effects regression model for the interaction of treatment with time (indicating difference in speed of recovery between the groups) as well as the estimated marginal mean scores for the efficacy outcomes at six weeks; at that time a difference between the groups was expected. The mean *Quick*-DASH score diminished from 12 points at six weeks to 4 points at 12 months in the early mobilization group, and from 19 to 4 points in the plaster group (Figure 2A). The difference was significant ($p<0.05$) at six weeks follow-up, but not at later time points. The interaction between treatment and time, representing a change in treatment effect over time (and thus in recovery speed) was also significant ($p_{interaction}=0.002$). A similar change in treatment effect over time was found for the *Quick*-DASH work module score ($p_{interaction}=0.003$; Figure 2B).

The OES increased from 72 points at six weeks to 93 points at 12 months in the early mobilization group and from 66 to 95 points in the plaster group (Figure 2C). Significantly higher OES function scores were noted in the early mobilization group at six weeks (86 *versus* 73 points; $p<0.05$) but not at later time points (Figure 2D). Patients

in the early mobilization group recovered faster ($p_{interaction}$=0.013 for overall score and <0.001 for function).

The MEPI was consistently between 84 and 97 points in both groups (Figure 2E; $p_{interaction}$=0.068).

Patients reported significantly more pain at the affected arm in the early mobilization group at one week only (mean VAS 3.2 [95% CI 2.7 to 3.6] *versus* 2.2 [95% CI 1.8 to 2.6] for the plaster group; p<0.05) (Figure 2F). Analgesics use was similar in both groups; 16 (33%) patients in the early mobilization group and 12 (24%) patients in the plaster group used analgesics (p=0.372).

Figure 1. Flow chart of the study

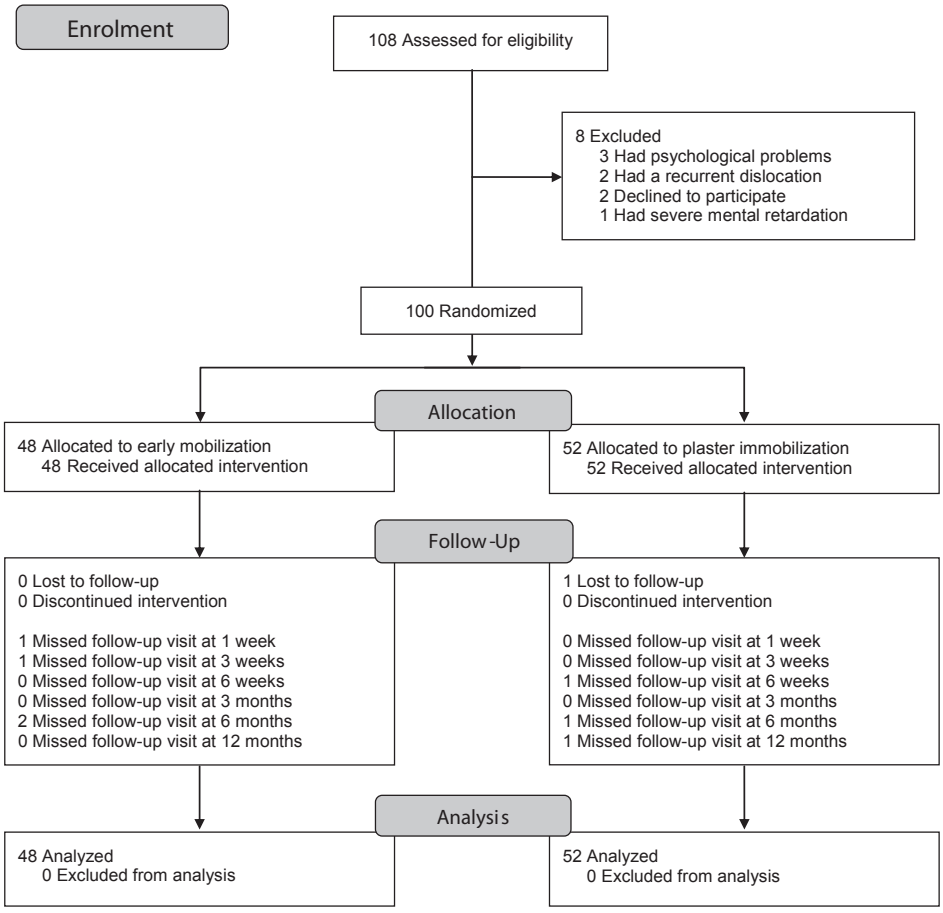


Table 1. Characteristics of trial participants by treatment group

	Early mobilization N=48	Plaster immobilization N=52
Patient characteristics		
Male[1]	22 (46%)	20 (39%)
Age[2] (year)	43 (16)	47 (14)
BMI[2] (kg/m^2)	25.0 (4.7)	26.4 (4.4)
Smoking[1]:		
Current	10 (21%)	12 (23%)
Past	13 (27%)	13 (25%)
Never	25 (52%)	27 (52%)
Alcohol consumer[1]	34 (71%)	35 (67%)
Alcohol consumption (units/week)[3]	3 (0-10)	3 (0-7)
Comorbidities[1]	12 (25%)	24 (46%)
Number of comorbidities[3]	1 (1-1)	1 (1-2)
Medication use[1]	11 (23%)	19 (37%)
Number of medications[3]	2 (1-2)	2 (1-4)
Independent living[1]	44 (92%)	50 (96%)
Household composition[1]:		
Alone	10 (21%)	10 (19%)
Alone with children	1 (2%)	3 (6%)
With partner	18 (38%)	19 (37%)
With partner and children	13 (27%)	17 (33%
With family/student house	6 (13%)	3 (6%)
Activities of daily living		
Work participation (N patients)	32 (67%)	32 (62%)
Exertional level:		
Light, mainly sedentary	13 (41%)	11 (34%)
Medium work	3 (9%)	7 (22%)
Heavy or very heavy work	16 (50%)	14 (44%)
Work participation (hours/week) [3]	36.0 (24.0-40.0)	36.0 (24.0-40.0)
Sports participation (N patients)	37 (77%)	36 (69%)
Sports participation (hours/week)[3]	6.0 (3.5-8.8)	6.0 (3.1-7.8)
Injury characteristics		
Right side affected[1]	26 (54%)	27 (52%)
Dominant side affected[1]	24 (50%)	22 (42%)
Type of dislocation		
Posterolateral	27 (56%)	29 (56%)
Posterior	8 (17%)	10 (19%)
Lateral	5 (10%)	5 (10%)
Posteromedial	3 (6%)	3 (6%)
Medial	0 (0%)	1 (2%)
Low energy trauma[1]	45 (94%)	48 (92%)

Table 1. Characteristics of trial participants by treatment group (continued)

	Early mobilization N=48	Plaster immobilization N=52
Accident scene[1]:		
Sports/recreation	21 (44%)	20 (38%)
Accident at home	14 (29%)	13 (25%)
Traffic accident	10 (21%)	15 (29%)
Accident at work	2 (4%)	4 (8%)
Violent assault	1 (2%)	0 (0%)
Treatment characteristics		
Number of reduction attempts[3]	1 (1-2)	2 (1-2)
Reduction in operating room[1]	5 (10%)	1 (2%)
Reduction anesthesia[1]:		
IV valium	21 (44%)	17 (33%)
General anesthesia	10 (21%)	8 (15%)
Intra-articular	3 (6%)	12 (23%)
None	6 (13%)	9 (17%)
Other	6 (13%)	6 (12%)
Regional/plexus	2 (4%)	0 (0%)

Data are presented as [1] N (%), [2] mean (SD), or [3] median (P_{25}-P_{75}).

* In six patients for whom stability was tested, the pivot shift test was not performed (three in each group).

Range of motion

Figure 3 shows changes in ROM. The corresponding estimated marginal means at six weeks and results of the regression model are shown in Table 2. The mean flexion-extension arc increased from 121° [95% CI 115 to 127] at six weeks to 142° at 12 months [95% CI 136 to 148] in the early mobilization group. In the plaster group, the arc increased from 102° [95% CI 96 to 108] to 138° [95% CI 133 to 144]; Figure 3A). A significant difference was noted only at six weeks, which was mainly attributable to differences in the angle of extension (Figure 3C). Likewise, the loss of ROM of flexion and extension (compared with the contralateral side) was significantly larger in the plaster group at six weeks (39° [95% CI 34 to 45] *versus* 21° [95% CI 15 to 27] after early mobilization; $p<0.05$; Figure 3E). At longer follow-up the motion limitation had resolved. Flexion-extension improved faster in the early mobilization group ($p_{interaction}<0.001$ flexion-extension arc, <0.001 for extension, and 0.001 for loss of flexion extension).

The pronation-supination arc was consistently between 169° and 174° in both treatment groups (Figure 3B). At six weeks follow-up, the mean angle of supination was significantly larger in the early mobilization group (mean 87° [95% CI 85 to 89] *versus* 83° [95% CI 81 to 85] in the plaster group; $p<0.05$; Figure 3D). The plaster group also showed a significantly greater loss of ROM of pronation and supination at six weeks (3.8° [95% CI 2.4 to 5.2] *versus* 0.2° [95% CI -1.3 to 1.6]); Figure 3F). Supination and ROM loss improved faster in the early mobilization group ($p_{interaction}=0.030$ for both).

Table 2. Treatment effect over time and outcome at six weeks follow-up by treatment group

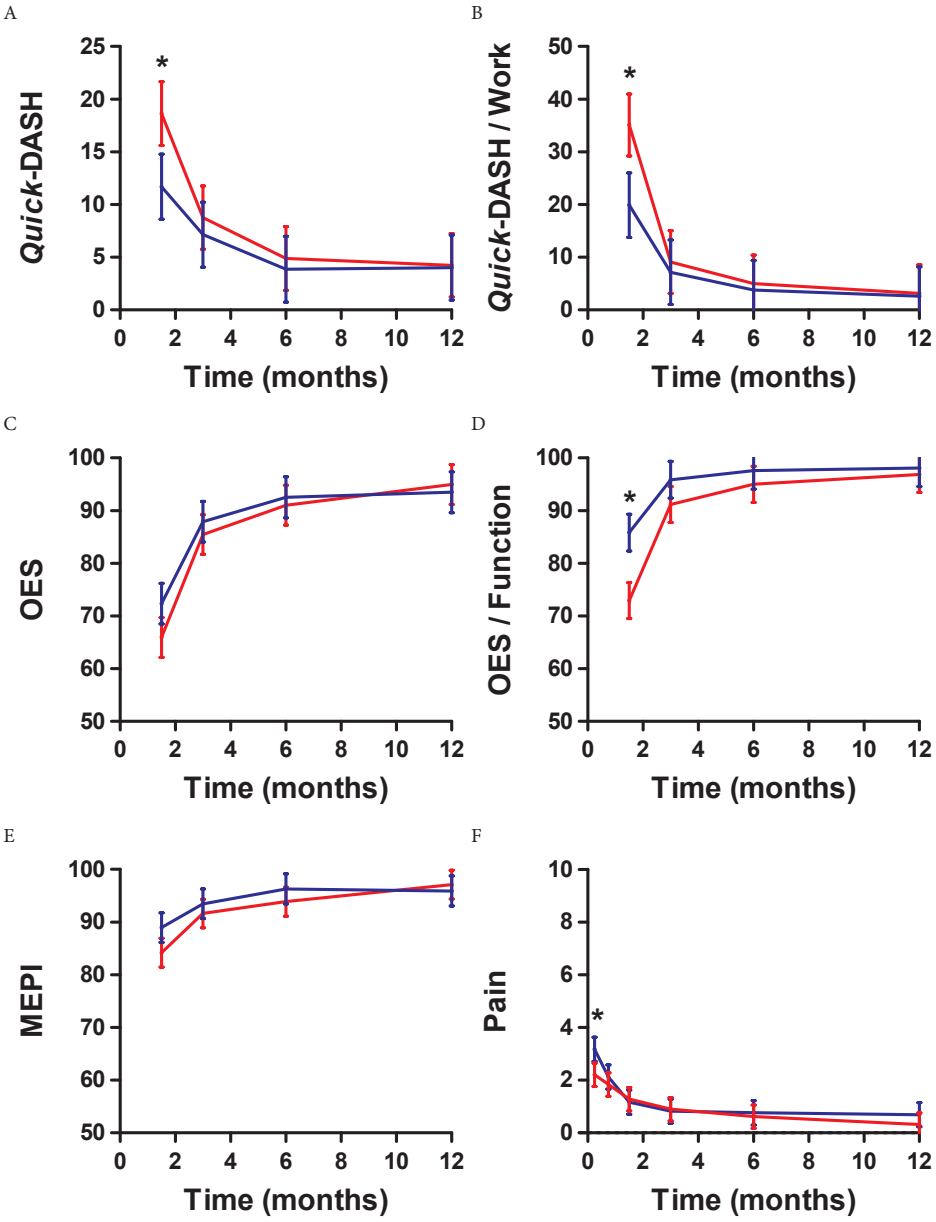
	Treatment effect over time		Outcome at six week follow-up	
	F-value	**$P_{interaction}$**	**Early mobilization N=48**	**Plaster immobilization N=52**
Patient reported outcome measures:				
Quick-DASH:				
Overall score	**5.103**	**0.002**	**12 (9-15)**	**19 (16-22)**
Work	**4.731**	**0.003**	**20 (14-26)**	**35 (29-41)**
Sports	1.449	0.229	41 (33-49)	52 (44-60)
MEPI	2.397	0.068	89 (86-92)	84 (81-87)
OES:				
Overall score	**3.662**	**0.013**	72 (68-76)	66 (62-70)
Pain	1.343	0.261	74 (70-79)	73 (68-77)
Function	**6.952**	**<0.001**	**86 (82-89)**	**73 (70-76)**
Psychosocial	1.102	0.349	57 (51-63)	52 (47-58)
VAS (1 week) Affected side	**2.353**	**0.040**	**3.1 (2.7-3.6)**	**2.2 (1.8-2.6)**
VAS (6 weeks) Affected side	**2.353**	**0.040**	1.2 (0.7-1.6)	1.2 (0.8-1.7)
Range of motion (degrees):				
Angle:				
Flexion	2.021	0.111	133 (130-137)	127 (124-131)
Extension*	**11.858**	**<0.001**	**12 (9-15)**	**25 (22-29)**
Pronation	0.100	0.960	86 (85-88)	86 (84-88)
Supination	**3.014**	**0.030**	**87 (85-89)**	**83 (81-85)**
Arc:				
Flexion-Extension	**7.715**	**<0.001**	**121 (115-127)**	**102 (96-108)**
Pronation-Supination	0.819	0.484	173 (170-177)	169 (165-172)
Loss of ROM:				
Flexion-Extension	**5.692**	**0.001**	**21 (15-27)**	**39 (34-45)**
Pronation-Supination	**3.026**	**0.030**	**0 (-1-2)**	**4 (2-5)**

Changes in recovery pattern were assessed in the multivariable model. Results are shown by the F-value of the interaction term in the model (treatment * FU moment) and its p-value ($P_{interaction}$). Data of the outcome at six weeks are shown as the estimated marginal mean with 95% confidence interval after six weeks follow-up adjusted for involvement of the dominant side and gender. If the intervals did not overlap, this is indicated in bold face. The Arc of ROM is shown for the affected side, loss of ROM is calculated by subtracting the angle of the affected side from the contralateral side.

Quick-DASH, Disabilities of the Arm, Shoulder, and Hand; MEPI, Mayo Elbow Performance Index; OES, Oxford Elbow Score; ROM, Range of Motion; VAS, Visual Analog Scale.

* Extension is measured as deficit from neutral position (0°).

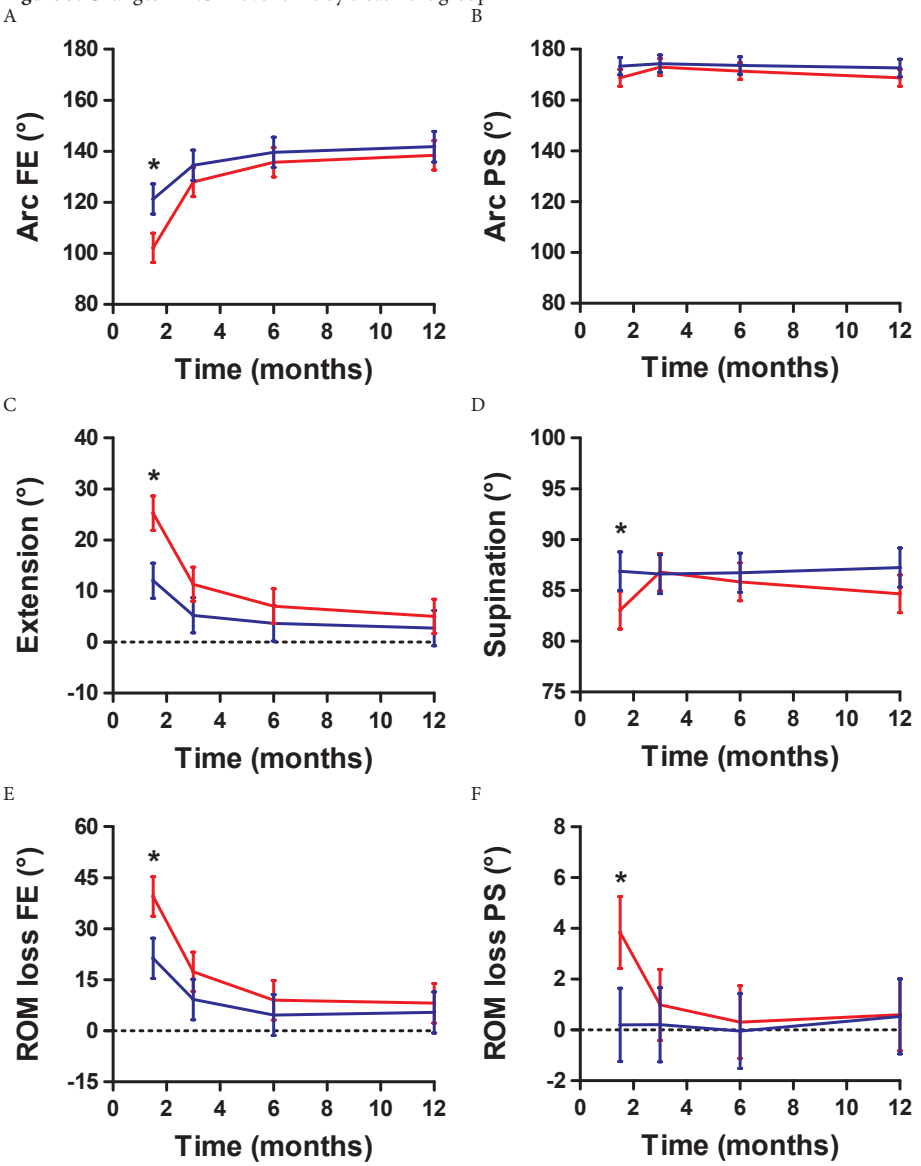
Figure 2. Changes in functional outcome scores and pain over time by treatment group



(A) Disabilities of the Arm, Shoulder, and Hand (*Quick*-DASH) overall score, (B) *Quick*-DASH score for the work optional module, (C) Oxford Elbow Score (OES) overall score, (D) OES score for the sub-domain function, (D) Mayo Elbow Performance Index (MEPI), and (F) pain (VAS, Visual Analog Scale) over time. The VAS score is reported for the affected arm. Higher scores represent more disability (*Quick*-DASH), better functioning (OES and MEPI), or more pain (VAS).

Data are shown as mean with the corresponding 95% confidence interval, adjusted for involvement of the affected side and gender. Blue lines represent the early mobilization group; red lines represent the plaster immobilization group. *p<0.05 (Bonferroni test).

Figure 3. Changes in ROM over time by treatment group



(A) Arc of ROM (Range of Motion) of flexion and extension, (B) Arc of ROM of pronation and supination, (C) angle of extension and (D) angle of supination over time are shown for the affected side. Higher arcs and angles represent better ROM. (E) Loss of ROM of flexion and extension and (F) loss of ROM of pronation and supination are calculated by subtracting values for the affected side from the contralateral side. Lower values indicate less motion restriction compared with the contralateral side.

Data are shown as mean with the corresponding 95% confidence interval, adjusted for involvement of the affected side and gender. Blue lines represent the early mobilization group; red lines represent the plaster immobilization group. *p<0.05 (Bonferroni test).

Resumption of work and sports

Table 3 shows the patients' resumption of work and sports. Forty-eight patients reported sick due to their injury. Although the rates of work and sports resumption at one year after early mobilization did not differ significantly from that after plaster immobilization, the early mobilization group returned to work earlier (median 10 *versus* 18 days; p=0.027).

Table 3. Resumption of work and sports by treatment group

	Early mobilization N=48	Plaster immobilization N=52	P-value
Work participation:			
Work absenteeism (N patients) [1]	22 (69%)	25 (78%)	0.572
Resumption at 12 months (N patients) [1]: No			
Partial	0 (0%)	1 (4%)	0.637
Fully	1 (4%)	1 (4%)	
Time-full resumption (days) [2]	21 (96%)	23 (92%)	
Percentage of baseline hours resumed at 12	10 (5-16)	18 (8-41)	0.027
months (%)[2]	100 (100-100)	100 (100-100)	0.376
Sports participation:			
Resumed activities at 12 months (N patients) [1]	28 (76%)	27 (75%)	1.000

Data are presented as [1]number (%) or as [2]median (P_{25}-P_{75}) and were analyzed using a Chi-squared test and Mann-Whitney U-test, respectively.

Complications and secondary interventions

Complications occurred in 12 patients and three underwent a secondary surgical intervention; no association with treatment was observed for both complications (p=0.640) or surgical interventions (p=1.000). In the early mobilization group, two patients reported pain without evident cause; one of these patients received five days of plaster immobilization, and one patient underwent arthrolysis to resolve motion restriction and pain. Another patient in the early mobilization group had a brachialis muscle rupture, and two patients had an ulnar nerve palsy; all three were treated non-operatively. In the plaster group five patients reported with discomfort or pain due to the plaster. One patient reported with an ulnar nerve palsy which was treated with ulnar nerve release, and one patient complained of persistent wrist pain requiring a diagnostic arthroscopy. The latter revealed cartilage degeneration, without instability of the distal radial-ulnar joint.

Radiological evaluation

Table 4 shows the radiological evaluation by treatment. At one year after trauma, radiographs were taken for 83 patients. Fifty (60%) of these showed heterotopic ossifications (55% in the early mobilization group versus 65% in the plaster group (p=0.377). Only three grade 3 ossifications were found, all occurred in the plaster group.

Table 4. Radiological outcome at one year by treatment group

	Early mobilization N=40*	Plaster immobilization N=43*	P-value
Joint incongruency	0 (0%)	0 (0%)	1.000
Heterotopic ossifications	22 (55%)	28 (65%)	0.377
Grade 1 (small, immature)	2 (9%)	1 (4%)	0.221
Grade 2 (small, mature)	20 (91%)	24 (86%)	
Grade 3 (large, mature)	0 (0%)	3 (11%)	
Grade 4 (ankylosis)	0 (0%)	0 (0%)	

Data are presented as N (%) and were analyzed using a Chi-squared test.

* Radiographs were not made for eight patients in the early mobilization group and nine in the plaster immobilization group.

Heterotopic ossifications were classified according to Broberg and Morrey.[27]

DISCUSSION

This study showed that treating a simple elbow dislocation with early mobilization resulted in earlier recovery and work resumption than immobilizing the elbow joint for three weeks. At six weeks follow-up, patients in the early mobilization group reported significantly better *Quick*-DASH and OES functional outcome scores, and a larger arc of ROM of flexion and extension. No evidence supporting treatment benefit at one year was found. Complications and secondary interventions were similar in both treatment groups. No residual instability, subluxation, or secondary dislocations were found.

Comparison with other studies

Functional outcome of simple elbow dislocations is generally good; however, residual stiffness may occur.[11, 28-30] The only RCT comparing early mobilization and plaster immobilization showed a significantly higher percentage of patients with a normal extension at three months in the early mobilization group.[15] The ROM values in the current study were in line with other studies.[29, 30] Absence of treatment effect at one year was also noted by Riel *et al.*, who found no difference in ROM after eight years of follow up.[8]

The functional outcome scores of our study were equivalent with Anakwe *et al.*.[29] De Haan *et al.*, however, reported slightly inferior *Quick*-DASH, MEPI, and OES scores. This is likely attributable to the inclusion of patients with complex elbow dislocations (49%) in their study.[30] The observation that early mobilization resulted in less disability and better function than plaster immobilization during the early phases of recovery was in line with the hypothesis and with previous studies.[9, 15-17] Given similar outcome scores at one year in the current study, superiority of early mobilization on the long term, as shown by Maripuri *et al.* (better *Quick*-DASH and MEPI scores at 2-5 years) and others is not to be expected.[9, 16]

Another finding supporting superiority of early mobilization was the shorter period until full-time work resumption. This difference, which could not be attributed to differences in exertional levels, emphasizes the relevance of early mobilization from a patient's perspective and has also been described before.[16] Earlier work resumption will reduce societal costs.

Patients in the early mobilization group reported a 1-point higher pain score only at one week. As analgesics use was the same in both groups, this small difference can be considered to be of little clinical relevance.

As expected, none of our patients showed recurrent instability. In 11 published studies (502 patients),[5, 8, 10, 11, 14-17, 29-31] only three recurrent dislocations (0.6%) were reported; two occurred after plaster immobilization and one after early mobilization.[14, 16, 30]

Strengths and limitations

The current study had some limitations. In addition to eight excluded patients, at least seven more patients have been missed during the enrolment period, possibly due to unfamiliarity of local hospital staff with the trial. A second limitation is that the ROM was measured from six weeks onwards. The six weeks visit was chosen since it was the first standard of care visit moment after removal of the plaster. For future studies, earlier measurement of the ROM would be recommended; it would provide baseline data for the plaster group as well as a more detailed view on the early recovery pattern. A final limitation relates to other sources of bias. Patients completed questionnaires on work absence and health care use at fixed time points. Should recall bias have occurred, it will be limited and non-selective. It was not possible to blind patients, physicians or researchers for the allocated treatment, which may run a risk of ascertainment bias. The blind (and duplicate) review of radiographs, the use of a standardized ROM protocol, and keeping the statistician blinded for treatment was meant to prevent this bias as much as possible.

An important strength of this study is the exceptionally high follow-up rate which can be explained by the fact that all follow-up moments at all sites were attended by the researcher. If patients declined coming to the hospital, a meeting was arranged at their home or work.

Conclusions

Early mobilization is a safe and effective treatment for simple elbow dislocations. It resulted in earlier recovery of elbow function and range of motion than after plaster immobilization. As a consequence, patients were able to resume work earlier. Early mobilization did not result in recurrent dislocation or persistent instability of the elbow. No evidence was found supporting treatment benefit at one year. The earlier recovery is relevant for patients but also from a societal perspective.

ACKNOWLEDGEMENTS

The Oxford and Isis Outcomes, part of Isis Innovation Limited, are acknowledged for their kind support. Dr. Yvonne Vergouwe and Dr. Gerard Borsboom (Erasmus MC, Dept. of Public Health) are greatly acknowledged for their assistance in the multilevel analysis. Mr. Kiran C. Mahabier, Mr. Harold Goei, Mr. Gerben De Reus, and Mrs. Liza Van Loon are acknowledged for their assistance in data collection.

SOURCES OF FUNDING

This project was supported by a grant from the European Society for Surgery of the Shoulder and the Elbow (SECEC/ESSSE). This organization was not involved in the trial design, patient recruitment, data collection, data analysis, data interpretation, publication decisions, or in any aspect pertinent to this study.

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Early mobilization versus plaster immobilization of simple elbow dislocations: A cost analysis of the FuncSiE multicenter randomized clinical trial

Gijs I.T. Iordens, Esther M.M. Van Lieshout, Suzanne Polinder, Denise Eygendaal, Michael H.J. Verhofstad, Niels W.L. Schep, Dennis Den Hartog, on behalf of FuncSiE Trial Investigators

Submitted


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ABSTRACT

Background

To our best knowledge no studies have reported the burden of simple elbow dislocations on health care costs. It is unknown whether or not early mobilization after reduction might play a role in reducing these costs.

Hypothesis/Purpose

The primary aim of this study was to assess and compare the total costs (direct health care costs and indirect costs due to los of production) after early mobilization versus plaster immobilization in patients with a simple elbow dislocation. The secondary aim was to evaluate cost-effectiveness. It was hypothesized that early mobilization would not lead to higher direct and indirect costs than plaster immobilization.

Study design

Randomized Controlled Clinical Trial

Methods

This cost-effectiveness study used data of a multicenter randomized clinical trial comparing early functional treatment with plaster immobilization in patients after simple elbow dislocations (FuncSiE trial). From August 25, 2009 until September 18, 2012, patients aged 18 years or older with a simple elbow dislocation from three academic and 19 non-academic hospitals were recruited and randomized to early mobilization (immediate motion exercises; n=48) or three weeks plaster immobilization (n=52). Follow-up was one year. Primary outcome were the total costs at one year. Analysis was by intention to treat. The trial was registered at the Netherlands Trial Register (NTR2025).

Results

100 patients were included; one patient was lost to follow-up after six months. *Quick*-DASH was lower in the early mobilization group at six weeks, but not at later time points. There were no significant differences in health-related quality of life measured with the EQ-5D, SF-36 PCS, and SF-36 MCS between the two groups throughout the 1-year follow-up. Mean total costs per patient were €3,624 in the early mobilization group versus €7,072 in the plaster group (p=0.094). Shorter work absenteeism in the early mobilization group (10 versus 18 days; p=0.027) did not lead to significantly lower costs for productivity loss (€1,719 in the early mobilization group versus €4,589; p=0.120).

Conclusion

From a clinical as well as a socio-economic point of view, early mobilization should be the treatment of choice for a simple elbow dislocation. Plaster immobilization has inferior results at almost double costs, and should therefore be abandoned.

BACKGOUND

The elbow is the second most commonly dislocated joint in adults and mostly occurs in young and active persons, thus affecting the working population. [1-3] Simple elbow dislocations (*i.e.*, dislocations without associated fractures) have better long-term functional outcome than complex elbow dislocations (*i.e.* dislocations with associated fractures). [4] Nevertheless, a simple elbow dislocation is a disabling injury which causes considerable pain and loss of range of motion on the short-term, which impedes the ability to perform daily activities such as work.

Previous studies demonstrated that immobilization of the elbow post reduction for more than three weeks may impair functional outcome, and suggested that early mobilization may give superior results. [5-10] Nonetheless, the majority of simple elbow dislocations in the Netherlands is treated with a long arm cast for at least three weeks. [11] For this reason the FuncSiE trial was conducted, which compared clinical outcome of early mobilization and plaster immobilization in patients with a simple elbow dislocation. The results of this study showed that early mobilization resulted in earlier recovery of elbow function, range of motion, and work resumption (unpublished data available as supplementary material). These results provided a definitive answer to an unresolved clinical question. The results justify the design of a treatment guideline from a clinical point of view. Faster recovery work resumption also support the societal relevance of early mobilization.

However, there are no studies that report the burden of simple elbow dislocations on direct and indirect health care costs, let alone to what extent early mobilization is able to reduce these costs. The aim of this study was to assess the direct and indirect costs and the cost-effectiveness of early mobilization versus plaster immobilization in patients with a simple elbow dislocation. It was hypothesized that early mobilization would not lead to higher costs.

METHODS

This cost analysis used data of a multicenter randomized clinical trial comparing early mobilization with plaster immobilization in patients after a simple elbow dislocation (FuncSiE trial). The trial is registered at the Netherlands Trial Register (NTR2025) and the study protocol is published elsewhere. [12] The study was approved by the Medical Research Ethics Committee or Local Ethics Board of all participating centers. All patients gave written informed consent.

Patients

Patients were recruited from August 25, 2009 until September 18, 2012. Inclusion criteria were an age of 18 years or older, a simple elbow dislocation which was successfully reduced by closed means. Exclusion criteria were polytraumatized patients, recurrent or open dislocation, additional traumatic injuries of the affected arm, an indication for surgical intervention, history of impaired elbow function (*i.e.*, stiff or painful elbow or neurological disorder), or a history of surgery or fractures involving the elbow, or expected problems with maintaining follow-up (*i.e.*, patients with no fixed address or insufficient comprehension of the Dutch language).

Randomization, intervention, and follow-up

Patients were randomly assigned in a 1:1 ratio to receive early mobilization or plaster immobilization. In the early mobilization group, the affected arm was put in a pressure bandage for up to seven days. Patients were instructed early active movements within the limits of pain after two days according to a predefined protocol. [12] In the plaster group the elbow was immobilized in a long arm cast for three weeks. After removal of the plaster physical therapy was initiated according to a standardized protocol.

Data were obtained during out-patient visits at one, three and six weeks, and at three, six, and 12 months after randomization. The primary outcome measure was total costs, consisting of direct costs (*i.e.*, costs for treatment and intramural care) and indirect costs (*i.e.*, costs for lost production). Use of health care resources was collected from the study case report forms and the patients' hospital register. All patients completed a health care consumption questionnaire at baseline and all follow-up visits from six weeks onwards. The questionnaire included questions on the number of visits to the physical therapist, general practitioner, and medical specialist, admission to hospital, rehabilitation center or nursing home, medication use, and the use of home care. The questionnaire also included questions concerning work absenteeism and resumption.

The primary clinical outcome measure was the *Quick*-DASH (Disabilities of the Arm, Shoulder and Hand) score, which will be converted to a 0-100 scale with higher scores indicating greater disability. [13, 14] Secondary outcome measures included the health-related quality of life using the EuroQol-5D (EQ-5D) [13] and Short Form-36 (SF-36). [14] The use of the EQ-5D is recommended for assessing quality of life in trauma patients especially for economic assessments higher scores indicating better quality of life. [15, 16] The scores for the physical and mental components of the SF-36 were converted to a norm-based score and compared with the norms for the general population of the United States. [14] As there were no significant differences in *Quick*-DASH score and quality of life scores between the two groups at one year, no cost-effectiveness and cost-utility ratio could be calculated. Therefore, a costs minimization analysis was performed.

Cost measurement

The total direct and indirect costs of both treatments were analyzed from a societal perspective and included the following costs: 1) intramural care costs for the primary intervention; 2) intramural care costs during follow-up; 3) intramural care costs for diagnosis and treatment of adverse events; 4) out of hospital care costs for rehabilitation; and 5) indirect costs due to productivity loss. Costs were calculated by multiplying the volumes with the corresponding unit prices (Table 1). Hospital costs for the primary intervention and costs during follow-up consisted of fixed and variable costs. As no patients were admitted to a nursing home or rehabilitation clinic, these costs were zero for all patients. Lost productivity was represented by the hours of work absenteeism.

The costs for use of the operating room included cost for personnel, anesthesia (not including the wage of the anesthesiologist) and overhead costs. An estimation of these costs was made by calculating the means of the fixed cost prices, which were derived from four participating hospitals (one academic and of three regional hospitals). Cost prices for other health care resources were derived from the Dutch manual on cost research. [17] Unit costs for all diagnostic procedures were derived from the Dutch Health Care Authority (NZa, Nederlandse Zorgautoriteit). Medication costs were calculated using standard unit prices as described by the CVZ (College voor zorgverzekeringen; Health Care Insurance Board; online available at www.medicijnkosten.nl). Indirect costs due to productivity loss were calculated using the friction-cost method, which assumes that initial production levels restore after some period of adaption, taking economic circumstances into account. [18]

Statistical analysis

Analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 21 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Armonk, NY). Analysis was by intention to treat and all statistical tests were two-sided. Since there were hardly any missing data imputation was not needed. Normality of continuous data was assessed by inspecting the frequency distributions and the homogeneity of variances was tested with the Levene's test. Chi-squared analysis was used for statistical testing of categorical data. Univariate analysis of continuous data was done using a Mann-Whitney U-test (non-parametric data) or a Student's T-test (parametric data). P-values <0.05 were regarded as statistically significant. Accelerated bootstrapping was used for pair-wise comparison of the mean differences in all hospital costs, out of hospital costs, indirect costs and total costs between the two treatment groups. The number of replications was chosen to be 1,000.

Continuous outcomes that were repeatedly measured over time were compared between treatment groups using linear mixed-effects regression models. These multilevel models included random effects for the intercepts of the regression model and time coefficient of individual patients. Since the outcome measures were not linearly related with time, the time points were entered as factor. The models included fixed effects for treatment group, involvement of the dominant side, and gender. The effect of age was non-significant in all models and age was therefore not included. The interaction between treatment group and time was included in the model to test for differences between the groups over time (*i.e.*, differences in recovery time). For each follow-up moment, the estimated marginal mean of the *Quick*-DASH score, the EQ-5D utility score and the SF-36 physical component summery (PCS) and mental component summery (MCS) scores were computed per treatment group and compared post hoc using a Bonferroni test to correct for multiple testing. Absence of overlap in the 95% confidence interval around the marginal means was regarded as significant at p<0.05.

RESULTS

One hundred patients were included in the trial, 48 patients were assigned to early mobilization and 52 to plaster immobilization (Figure 1). All patients received the allocated treatment. At one year follow-up complete cost data were available for 99 patients; one patient in the plaster group was lost to follow-up after six months. Apart from a relative predominance of patients with comorbidities in the plaster group, and more frequently affected dominant side in the early mobilization group, randomization resulted in similar baseline and injury characteristics in the two groups (Table 2).

Table 1. Data sources, sources of valuation and unit prices of all cost categories

Cost categories	Unit	Number of fixed units for EM / PI	Source of data	Source of valuation	Unit price (€)
Hospital costs – Primary intervention					
Emergency department visit	Visit	1/1	Hospital registry	Cost manual	€ 161.12
Radiology / diagnostics					
X-ray [1]	X-ray	3/3	Hospital registry	NZa	€ 51.07
CT-scan	CT-scan	Variable	Hospital registry	NZa	€ 202.14
MRI	MRI	Variable	Hospital registry	NZa	€ 256.79
Ultrasound	Ultrasound	Variable	Hospital registry	NZa	€ 76.64
Arthrogram	Arthrogram	Variable	Hospital registry	NZa	€ 126.86
Anesthetics / sedation	Case	Variable	Study/hospital registry	CVZ	€ 2.00 [2]
Plexus block / regional anesthesia	Case	Variable	Study/hospital registry	Hospital data	€ 82.00
Reduction in operating room					
Surgeon	Minute	Variable	Study/hospital registry	Cost manual	€ 2.41 [3] / € 1.83 [4]
Anesthesiologist	Minute	Variable	Hospital registry	Cost manual	€ 2.41 [3] / € 1.83 [4]
Operating room [5]	Minute	Variable	Study/hospital registry	Hospital data	€ 14.75 [3] / € 11.87 [4]
Treatment					
Plaster	Plaster	0 /1	Study registry	Hospital data	€ 127.18
Plaster change at one week	Plaster	0 /1	Study/hospital registry	Hospital data	€ 158.60
Pressure bandage	Pressure bandage	1/ 0	Study registry	Hospital data/www.medischservice.nl	€ 15.21
Sling	Sling	1/1	Study registry	Hospital data/www.medischservice.nl	€ 15.00
Admission days	Days	Variable	Study/hospital registry	Cost manual	€ 464.15[3] / € 613.53[4]
Visit out-patient clinic or plaster room [6]	Visit	2/2	Study/hospital registry	Cost manual	€ 68.29 [3] / € 137.64 [4]
Hospital costs – Follow-up					
Visit out-patient clinic [7]	Visit	4/4	Study/hospital registry	Cost manual	As displayed above
Radiology / diagnostics [8]	Study	1/1	Study/hospital registry	NZa	As displayed above

Table 1. Data sources, sources of valuation and unit prices of all cost categories (continued)

Cost categories	Unit	Number of fixed units for EM / PI	Source of data	Source of valuation	Unit price (€)
Hospital costs - Adverse events / revision surgery					
Visit out-patient clinic or plaster room [9]	Visit	Variable	Study/hospital registry	Cost manual	As displayed above
Radiology / diagnostics [10]	Study	Variable	Study/hospital registry	NZa	As displayed above
Operating room [5]	Minutes	Variable	Hospital registry	Hospital data	As displayed above
Surgeon	Minutes	Variable	Hospital registry	Cost manual	As displayed above
Anesthesiologist	Minutes	Variable	Hospital registry	Cost manual	As displayed above
Type of surgery					
Arthrolysis [5]	Procedure	Variable	Hospital data	Hospital data	€ 47.10
Ulnar nerve release [5]	Procedure	Variable	Hospital data	Hospital data	€ 56.91
Arthroscopy wrist [5]	Procedure	Variable	Hospital data	Hospital data	€ 220.17
Admission days	Days	Variable	Study/hospital registry	Cost manual	As displayed above
Out of hospital costs – Follow-up / rehabilitation					
General practitioner	Visits	Variable	Study registry	Cost manual	€ 29.88
Physical therapy	Visits	Variable	Study registry	Cost manual	€ 38.41
Home care	Hours	Variable	Study registry	Cost manual	€ 37.35
Indirect cost					
Work absenteeism Males < 35 years	Hours	Variable	Study registry	Cost manual	€ 25.00
Work absenteeism Males ≥ 35 years	Hours	Variable	Study registry	Cost manual	€ 39.00
Work absenteeism Females < 35 years	Hours	Variable	Study registry	Cost manual	€ 24.00
Work absenteeism Females ≥ 35 years	Hours	Variable	Study registry	Cost manual	€ 30.00

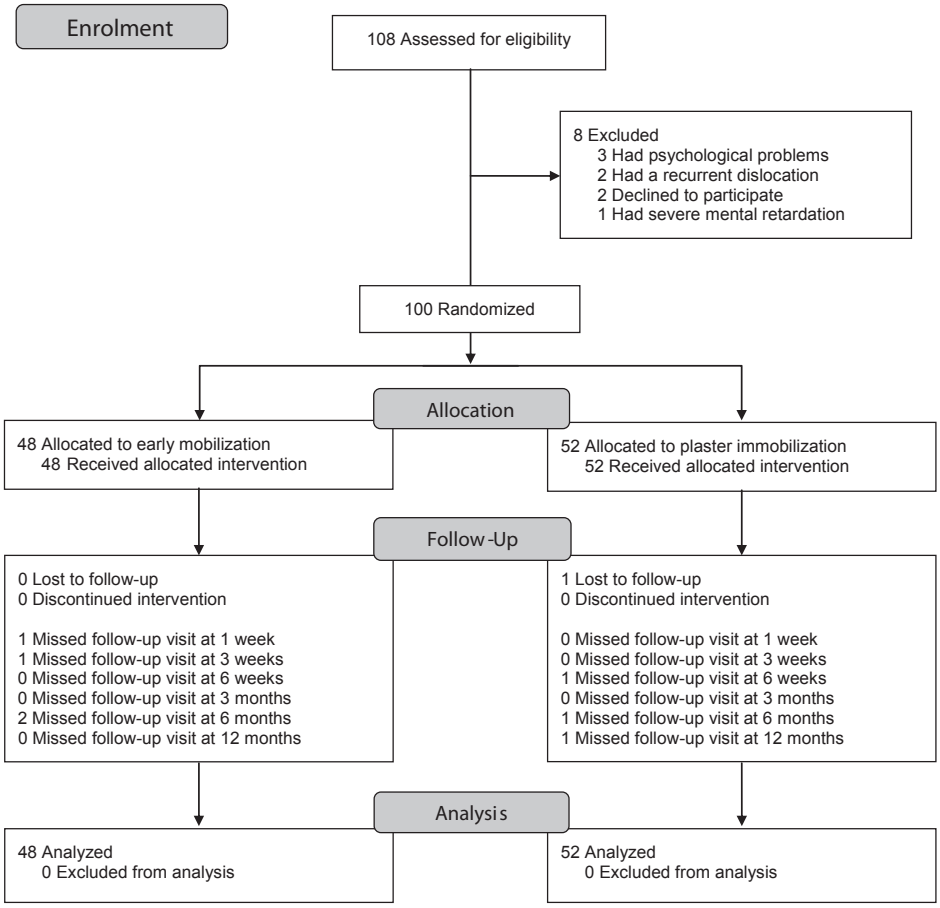
Number of units for fixed costs are displayed for EM (Early mobilization) and PI (Plaster immobilization); [1] Protocolled radiographs prior to and after reduction and after one week; [2] Due to the low costs of medication an estimated average of €2 was maintained per case of Anesthetics/sedation; [3] General hospital; [4] Academic hospital; [5] Protocol cost, only materials (OR use, anesthesiologist and surgeon wages not included) Average time for plexus block 15 minutes. Average operating time for arthrolysis, ulnar nerve release and arthroscopy of the wrist were 240, 190 and 75 minutes, respectively; [6] Protocolled visits at one and three weeks; [7] Protocolled visits at six weeks, three months, six months and one year; [8] Protocolled radiographs at one year; [9] Visits as a result of adverse events; [10] Diagnostics as a result of adverse events;

Table 2. Characteristics of trial participants by treatment group

	Early mobilization N=48	Plaster immobilization N=52
Patient characteristics		
Male[1]	22 (46%)	20 (39%)
Age[2] (year)	43 (16)	47 (14)
Body mass index [2] (kg/m^2)	25.0 (4.7)	26.4 (4.4)
Comorbidities[1]	12 (25%)	24 (46%)
Number of comorbidities[3]	1 (1-1)	1 (1-2)
Medication use[1]	11 (23%)	19 (37%)
Number of medications[3]	2 (1-2)	2 (1-4)
Independent living[1]	44 (92%)	50 (96%)
Household composition[1]:		
Alone	10 (21%)	10 (19%)
Alone with children	1 (2%)	3 (6%)
With partner	18 (38%)	19 (37%)
With partner and children	13 (27%)	17 (33%
With family/student house	6 (13%)	3 (6%)
Activities of daily living		
Work participation (N patients) [1]	32 (67%)	32 (62%)
Work participation (hours/week [3]	36.0 (24.0-40.0)	36.0 (24.0-40.0)
Sports participation (N patients) [1]	37 (77%)	36 (69%)
Sports participation (hours/week)[3]	6.0 (3.5-8.8)	6.0 (3.1-7.8)
Injury characteristics		
Dominant side affected[1]	24 (50%)	22 (42%)
Reduction in operating room[1]	5 (10%)	1 (2%)
Reduction anesthesia[1]:		
IV valium	21 (44%)	17 (33%)
General anesthesia	10 (21%)	8 (15%)
Intra-articular	3 (6%)	12 (23%)
None	6 (13%)	9 (17%)
Other	6 (13%)	6 (12%)
Regional/plexus	2 (4%)	0 (0%)

Data are presented as [1] N (%), [2] mean (SD), or [3] median (P_{25}-P_{75})

Figure 1. Flow chart of the study



Quick-DASH-score and quality of life

The *Quick*-DASH score at one year was 4 points (95% CI 1 to 7) in both groups. However, at six weeks follow-up the *Quick*-DASH score was significantly better in the early mobilization group 12 points *versus* 19 points, respectively (Table 3). No statistically significant differences in health-related quality of life measured with the EQ-5D and SF-36 between the two groups was noted throughout the 1-year follow-up (Table 3). The EQ-5D was consistently between 0.82 and 0.89 during follow-up. The SF-36 PCS varied between 42 and 53 and the SF-36 MCS varied between 55 and 59 throughout the whole follow-up. Both component summary scores remained within the population norm of 50±10 (SD) points, and were independent of treatment.

Table 3. *Quick*-DASH score and health-related quality of life at all follow-up moments by treatment group

Outcome score	Follow-up	Early Mobilization N=48	Plaster immobilization N=52
Quick-DASH	6 weeks	**12 (9 – 15)**	**19 (16 – 22)**
	3 months	7 (4 – 10)	9 (6 – 12)
	6 months	4 (1 – 7)	5 (2 – 8)
	12 months	4 (1 – 7)	4 (1 – 7)
EQ-5D Utility Score	6 weeks	0.86 (0.83 – 0.89)	0.82 (0.79 – 0.85)
	3 months	0.87 (0.84 – 0.90)	0.86 (0.84 – 0.89)
	6 months	0.88 (0.86 – 0.91)	0.88 (0.85 – 0.91)
	12 months	0.88 (0.85 – 0.91)	0.89 (0.87 – 0.92)
SF-36 PCS	6 weeks	45 (43 – 48)	42 (40 – 44)
	3 months	52 (50 – 54)	50 (48 – 52)
	6 months	53 (50 – 55)	52 (50 – 54)
	12 months	53 (51 – 55)	53 (51 – 55)
SF-36 MCS	6 weeks	56 (54 – 58)	59 (57 – 61)
	3 months	57 (55 – 59)	57 (55 – 59)
	6 months	57 (55 – 59)	56 (54 – 58)
	12 months	55 (53 – 57)	56 (54 – 58)

Data are shown as the estimated marginal mean with 95% confidence interval adjusted for involvement of the dominant side and gender. If the intervals did not overlap (indicating statistical significant difference between the treatment groups) it was indicated in bold face. EQ-5D, EuroQoL 5D; *Quick*-DASH, Disabilities of the Arm, Shoulder, and Hand; SF-36, Short Form-36; PCS, Physical Component Summary score; MCS, Mental Component Summary score.

Health care costs

Total costs and costs per category are shown in Figure 2 and Table 4. The mean total costs per patient were €3,624 (95% confidence interval (CI) 1,966 to 5,281) in the early mobilization group versus €7,072 (95% CI 3,444 to 10,701) in the plaster group. Although early mobilization was €3,449 less expensive than plaster immobilization, this difference was not statistically significant (p=0.094).

The costs for the primary intervention were €551 (95% CI 510 to 591) in the early mobilization group versus €856 (95% CI 551 to 1,161) in the plaster immobilization group (p=0.058). Due to the identical, protocolled follow-up there was no difference in the follow-up costs; €382 (95% CI 349 to 415) in the early mobilization group versus €399 (95% CI 364 to 434) in the plaster group (p=0.481). Details concerning adverse events are shown in Table 5. Adverse events occurred in five patients in the early mobilization group versus seven patients in the plaster immobilization group. Costs for diagnosis and treatment of adverse events were €166 (95% CI -147 to 478) in the early mobilization group versus €263 (95% CI -153 to 678) in the plaster immobilization group (p=0.712). The main determinant in the costs for adverse events were costs for surgery. This applied to three patients, one in the early mobilization group (€4,744) versus two in the plaster immobilization group (€3,007 and €1,687).

The out of hospital costs during follow-up and rehabilitation were €806 (95% CI 465 to 1,147) in the early mobilization group versus €966 (95% CI 660 to 1,271) in the plaster group (p=0.483). These costs were mainly due to physical therapy (€738 versus €808; p=0.693; data not shown). This can be explained by the fact that most patients in both groups attended physical therapy to some degree.

Figure 2. Mean total costs and costs per cost category by treatment group

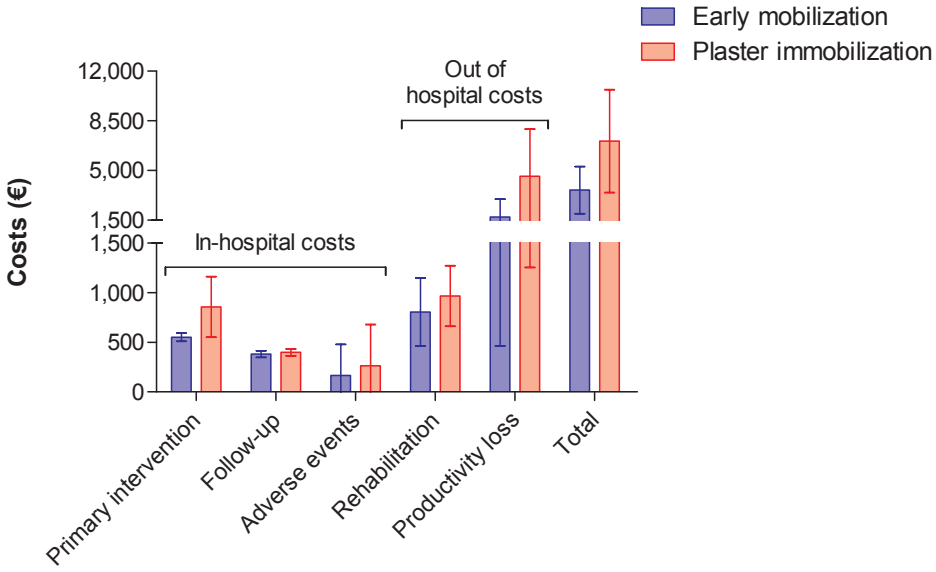


Table 4. Total costs and costs per cost category by treatment group

Cost categories	Early mobilization N=48	Plaster immobilization N=52	Difference	p-value
Direct costs	€ 1,904 (1,303 – 2,505)	€ 2,483 (1,822 – 3,144)	- € 579	0.198
In-hospital costs	€ 1,098 (785 – 1,411)	€ 1,517 (1,004 – 2,031)	- € 419	0.173
Primary intervention	€ 551 (510 – 591)	€ 856 (551 – 1,161)	- € 305	0.058
Follow-up	€ 382 (349 – 415)	€ 399 (364 – 434)	- € 17	0.481
Adverse events / revision surgery	€ 166 (-147 – 478)	€ 263 (-153 – 678)	- € 97	0.712
Out of hospital costs (Follow-up / Rehabilitation)	€ 806 (465 – 1,147)	€ 966 (660 – 1,271)	- € 160	0.483
Indirect costs (Productivity loss)	€ 1,719 (465 – 2,974)	€ 4,589 (1,258 – 7,920)	- € 2,870	0.120
Total	**€ 3,624 (1,966 – 5,281)**	**€ 7,072 (3,444 – 10,701)**	**- € 3,449**	**0.094**

Data are shown as the mean costs per patient with 95% confidence interval given between brackets and were analyzed with a regression analysis after bootstrapping.

Productivity loss

Details concerning work absenteeism are displayed in Table 5. Work absenteeism did not differ significantly between both groups, although the early mobilization group reported slightly less absenteeism (69% versus 78%; p=0.572). Patients who were treated with early mobilization resumed work eight days sooner than did patients that were treated with plaster immobilization (10 versus 18 days; p=0.027). The associated mean costs for lost productivity in the total study population were €1,719 (95% CI 465 to 2,974) in the early mobilization group versus €4,589 (95% CI 1,258 to 7,920) in the plaster group. Despite the large difference of €2,870 in favor of early mobilization, this did not reach statistical significance (p=0.120). When considering only patients that reported sick, the mean costs for productivity loss per absentee were €3,751 (95% CI 1,174 to 6,329) in the early mobilization group and €9,546 (95% CI 2,955 to 16,137) in the plaster group (p=0.115).

Table 5. Adverse events, secondary interventions and work participation by treatment group

	Early mobilization N=48	Plaster immobilization N=52	P-value
Adverse events [1]	5 (10%)	7 (13%)	0.640 [a]
Secondary interventions (N patients) [1]	1 (2%)	2 (4%)	1.000 [a]
Secondary interventions (N interventions) [1]	1 (2%)	2 (4%)	1.000 [a]
Arthrolysis	1	0	
Ulnar nerve release	0	1	
Arthroscopy of the wrist	0	1	
Work participation			
Work absenteeism (N patients) [1]	22 (69%)	25 (78%)	0.572 [a]
Resumption at 12 months (N patients) [1]:			
No	0 (0%)	1 (4%)	0.637 [a]
Partial	1 (4%)	1 (4%)	
Fully	21 (96%)	23 (92%)	
Time-full resumption (days) [2]	10 (5-16)	18 (8-41)	0.027 [b]
Hours resumed at 12 months (% of baseline) [2]	100 (100-100)	100 (100-100)	0.376 [b]

Data are presented as [1]N (%) or as [2]median (P_{25}-P_{75}) and were analyzed using a Chi-squared test and Mann-Whitney U-test, respectively.

DISCUSSION

The FuncSiE trial already showed that patients following a simple elbow dislocation demonstrate earlier recovery of elbow function when treated with early mobilization compared with plaster immobilization. As a consequence, early mobilized patients were able to resume work eight days earlier. Current data demonstrated that the *Quick*-DASH score and health-related quality of life at one year were similar in both groups.

Early mobilization showed a consistent trend towards being a less expensive treatment than plaster immobilization for all cost categories studied, yet the difference did not reach statistical significance.

Surprisingly, there was no statistically significant difference in costs for physical therapy between the two groups, despite earlier recovery of elbow function in patients that were treated with early mobilization. This could be explained by the fact that both groups received physical therapy according to an identical treatment protocol. Therefore, these data do not allow to reliably answer the questions whether earlier functional recovery after early mobilization consequently leads to less physical therapy in terms of frequency and duration and whether in that way a reduction in care costs might be realized.

Unfortunately, these data did not allow to calculate the cost-effectiveness and cost-utility ratio of early mobilization as there was no statistically significant difference in *Quick*-DASH score or health-related quality of life at one year follow-up between both groups. On the other hand, there is no relevance in performing a cost-effectiveness or cost-utility analysis for a treatment that leads to earlier functional recovery at almost half the costs per patient (€3,449 less expensive). A second drawback of this study concerns the absence of significance in differences between costs in both groups. This was mainly caused by the fact that only three patients underwent surgery as a result of adverse events. This led to excessive total costs for these patients compared with patients who healed uneventfully. These outliers caused considerable variation in costs which could falsely have led to the conclusion that the study lacked power. Moreover, sample size calculation of the trial was performed from a clinical perspective rather than for cost-calculation purposes. Statistically significant difference in total costs could have been demonstrated provided each treatment group should have encompassed 134 patients ($\beta = 0.8$, $\alpha = 0.05$ and two-sided testing).

A strength of this study is the data completeness. Moreover, patients were followed during the entire rehabilitation process, thus giving a truthful reflection of the actual total costs following a simple elbow dislocation. Furthermore, this is the first study to assess the burden of simple elbow dislocations on direct and indirect health care costs and health-related quality of life. Additionally, there is currently no literature reporting the influence of early mobilization on reducing these costs. The incidence rate of elbow dislocations in the Netherlands was recently found to be 5.6 (per 100,000 person years). [2] The difference of €3,449 in total costs was not statistically significant, but changing treatment protocols for simple elbow dislocations could, in the current Dutch population (16.8 million persons [19]), reduce the care costs by at least 3.2 Million Euro per year, supporting the societal relevance of early mobilization.

In conclusion, early mobilization of adult patients with a simple elbow dislocation leads to earlier functional recovery and might reduce costs by approximately 50%.

From a clinical as well as a socio-economic point of view, early mobilization should be the treatment of choice for this injury.

ACKNOWLEDGEMENTS

This project was supported by a grant from the European Society for Surgery of the Shoulder and the Elbow (SECEC/ESSSE). This organization was not involved in the trial design, patient recruitment, data collection, data analysis, data interpretation, publication decisions, or in any aspect pertinent to this study. Kiran C. Mahabier (research physician) and Harold Goei, Gerben De Reus and Liza Van Loon (medical students) are acknowledged for their assistance in data collection.

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Minimal clinically important difference and other measurement properties of the Oxford Elbow Score in patients with a simple elbow dislocation

Gijs I.T. Iordens, Dennis Den Hartog, Wim E. Tuinebreijer, Denise Eygendaal, Niels W.L. Schep, Michael H.J. Verhofstad, Esther M.M. Van Lieshout, on behalf of FuncSiE Trial Investigators

Submitted


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ABSTRACT

Objective

The aim was to evaluate the reliability, validity, and responsiveness of the Dutch version of the Oxford Elbow Score (OES) in patients with a non-operatively treated simple elbow dislocation.

Study Design and Setting

Data of a multicenter randomized clinical trial (n=100) were used. Reliability was calculated using Cronbach's alpha expressing internal consistency. Construct- and longitudinal validity were calculated by testing hypothesized correlations between all (sub)domains of the OES and *Quick*-DASH (Disabilities of the Arm, Shoulder and Hand) score, Mayo Elbow Performance Index (MEPI), pain level (Visual Analog Scale, VAS), EuroQol-5D (EQ-5D) and Short Form-36 (SF-36) using Spearman's Rho (rank correlation) coefficients. The minimal clinically important difference (MCID) was assessed using anchor-based and distribution-based methods. Floor and ceiling effects were also evaluated.

Results

The OES demonstrated adequate internal consistency (Cronbach α, 0.916). Construct validity and longitudinal validity were supported by a high degree of correctly hypothesized correlations. Anchor- and distribution based MCID values for the OES total score were 8.22 and 11.96 points, respectively. The OES demonstrated a ceiling effect from six months onwards.

Conclusions

The Dutch version of the OES is a reliable, valid, and responsive instrument for evaluating elbow-related quality of life. The anchor-based MCID was 8.22 points.

Clinical trial registration number

Netherlands Trial Register; NTR2025

INTRODUCTION

Musculoskeletal elbow injuries may influence health and quality of life.[1-3] Physicians have traditionally been focused on objective parameters such as radiographic healing or range of motion when evaluating recovery following elbow injuries. However, patients' own appreciation of recovery may differ from the judgment of the treating physician.[4-6] Patient-reported outcome measures (PROMs) are increasingly important for assessing outcome following elbow injuries, both in daily practice and in clinical research.[7]

The best elbow-specific questionnaire currently is the Oxford Elbow Score (OES). This originally English patient-reported questionnaire measures injury-related quality of life in patients following surgery of the elbow joint.[8-10] Recently, the OES was translated into Dutch according to the guideline for Cross Cultural Adaptation of Self-Report Measures and validated for its reliability, validity and responsiveness.[11-14] Limitations of that study were a small sample size and heterogenic population consisting of operatively and non-operatively treated patients. The OES has been shown valid and reliable for the assessment of outcome after elbow surgery.[15] However, measurement properties including the minimal clinically important difference (MCID) for patients with non-operatively treated elbow injuries are not available. The aim of the current study was to evaluate the reliability, validity, and responsiveness of the OES in adult patients with a non-operatively treated elbow dislocation.

METHODS

Study data

Data of a multicenter randomized clinical trial comparing early functional treatment with plaster immobilization in patients after a simple elbow dislocation (FuncSiE-trial) were used. The trial is registered at the Netherlands Trial Register (NTR2025). The study protocol is described elsewhere.[16] The study was approved by the Medical Research Ethics Committees or Local Ethics Boards of all participating centers.

Patients

Patients were recruited from August 25, 2009 until September 18, 2012. Inclusion criteria were 1) age of 18 years or older; 2) a simple elbow dislocation with successful close reduction; and 3) written informed consent. Exclusion criteria were 1) polytraumatized patients; 2) recurrent or open dislocation; 3) additional traumatic injuries of the affected arm; 4) surgical intervention; 5) impaired elbow function prior to trauma (*i.e.*, stiff or painful elbow or neurological disorder); 6) previous operations or fractures involving the elbow; and 7) expected problems with completing follow-up (*e.g.*, insuffi-

cient comprehension of the Dutch language). Baseline characteristics were gender, age, body mass index (BMI), affected side, hand dominance, and educational attainment. Patients completed a set of questionnaire during outpatient visits at one (pain only), three (pain only), and six weeks, and at three, six, and 12 months after randomization.

Questionnaires

The PROMs used were the *Quick*-DASH (Disabilities of the Arm, Shoulder and Hand) score,[17, 18] Oxford Elbow Score (OES),[6, 10, 12] Mayo Elbow Performance Index (MEPI),[19] pain level (Visual Analog Scale, VAS), EuroQol-5D (EQ-5D),[20] and Short Form-36 (SF-36).[21]

Region-specific questionnaires

The OES is a 12-item, three domain (elbow function, pain and social-psychological; 4 items each) questionnaire, reflecting injury-related quality of life..Each domain is transformed into a 100-point metric scale with higher score representing better outcome.[15] The same accounts for the total score. The OES was translated from English into Dutch in compliance with translation guidelines.[10, 12-14] Permission for 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/).

The *Quick*-DASH is a shortened version of the DASH-score and contains 11 items. It reflects both function and pain in persons with musculoskeletal disorders of the upper extremity. To be able to calculate a score, at least 10 of the 11 items must be completed. The score is measured on a 100-point scale with higher score representing greater disability.[17, 18]

The MEPI consists of four domains: pain (one item, maximum score 45 points), range of motion (20 points), stability (one item, 10 points), and function (5 items, 5 points each). Each domain is transformed into a 100-point scale with higher score representing better outcome.[19]

Generic health-related quality of life questionnaires

The SF-36 is a validated health survey with 36 questions that represent eight health domains (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), 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) that are combined into a physical and a mental component scale (PCS and MCS, respectively). The score ranges from 0-100 with higher scores representing higher quality of life. The scores are converted and compared with the norms for the general population of the United States.[21] The SF-36 is the most widely

evaluated patient-reported outcome measure for assessing general health.[22] A validated Dutch version is available.[23]

The EQ-5D-3L is a validated descriptive system of health-related quality of life consisting of five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each domain has three possible answers: no problems, moderate problems, or extreme problems. In addition, the individual's rating of his/her quality of life state is recorded by means of a standard Visual Analog Scale (EQ VAS). Higher scores represent better health-related quality of life.[20, 24] A validated Dutch version is available.[20]

Statistical analysis

Analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 21, and are reported in compliance with the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines. Descriptive statistics was used in order to describe the main characteristics of the study participants.

Reliability

Reliability can be expressed in internal consistency, which is a measure of the extent to which items within a questionnaire (sub-)scale items are correlated, thus are answered by the respondents the same way.[4] For every (sub-)scale, the correlation between the items was calculated using Cronbach's alpha. A value between 0.70 and 0.95 was considered as an acceptable level of internal consistency.[4]

Validity

Validity is the degree to which a PROM measures the construct it is supposed to measure. As there was no gold standard in the current study, the validity of the OES was expressed in terms of the construct validity validity. Construct validity refers to the extent to which scores on a particular measure relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured.[25, 26] Normality of continuous data was evaluated from frequency histograms (Q-Q plots). The construct validity was assessed by determining the correlation of the OES (sub)domains with subdomains of the DASH, MEPI, SF-36, and EQ-5D using Spearman's Rho (rank correlation). Correlation coefficients above 0.6, 0.6 to 0.3 and less than 0.3 were considered high, moderate, and low correlations, respectively.[27] Construct validity was given a positive rating if at least 75% of the results were in line with the predefined hypotheses.[4, 28]

Responsiveness is defined as the ability of a questionnaire to detect clinically important changes over time.[29] Longitudinal validity can be considered to be a measure of responsiveness. Longitudinal validity is the degree to which change scores of a

particular measure relate to changes of the "golden standard" or to changes of other instruments.[30] Analogous to construct validity, longitudinal validity was assessed by testing predefined hypotheses about expected correlations between changes in OES (sub-)scales and changes in the DASH, MEPI, SF-36, and EQ-5D.[4, 28] Change scores were calculated as the difference in score at six weeks and 12 months. Predefined hypotheses for both construct and longitudinal validity are given in appendix 1 and were made in consensus between three authors (GITI, DDH, and EMMVL).

Minimal clinically important difference

The minimal clinically important difference (MCID) is defined as the smallest change in score to be measured which patients perceive as important.[31] An anchor-based method was used as this gives a better indication of the importance of the observed change to the patient.[4] In addition to the PROMs patients completed a transition item (anchor question) reflecting patient-reported judgment of change in the general condition of their elbow. The question was: How would you judge the condition of your elbow, compared with the last time you completed this questionnaire? The item scored from 1 "completely recovered" through 2 "much better", 3 "slightly better", 4 "no change", 5 "slightly worse", 6 "much worse", or 7 "worse than ever". An anchor is judged as useful if a correlation ($r > 0.29$) between the anchor and the change score of the PROM could be demonstrated using a Spearman's Rho (rank correlation).[4, 9, 32, 33] The corresponding change score (score at previous follow-up subtracted from the score at time of completion of the transition item) for patients who answered the transition item as "slightly better" can be considered the MCID.[30] Current data did not allow an adequate distribution-based analysis of the MCID as this requires a test-retest analysis. As a substitute for the test-retest analysis we used the change scores for patients who reported "no change" on the transition item. The SEM was calculated by dividing the standard deviation of the mean difference between both measurements ($SD_{change)}$ by the square root of two.[34] This could be considered as a measure of absolute measurement error.[4] Subsequently, the SDC was calculated by multiplying the 1.96 by the SEM and by the square root of two.[4]

Floor and ceiling effects

The presence of floor or ceiling effects makes it impossible to discriminate deterioration in patients with the lowest possible score and improvement in patients with the highest possible score, respectively. A floor or ceiling effect was considered as present if more than 15% of the patients in a sample size of 50 patients achieved the lowest or highest possible score, respectively.[4]

RESULTS

One hundred patients were included, of which 48 were treated with early mobilization and 52 with plaster immobilization for three weeks. One patient was lost to follow-up and six missed one follow-up visit. Baseline characteristics are displayed in Table 1.

Table 1. Baseline characteristics

Characteristics	Total population N=100
Male	42
Age (years)	46 (32-59)
Body Mass Index (kg/m^2)	24.6 (22.4-28.4)
Right side affected	53
Dominant side affected	46
Highest education	
Elementary school	2
Course-based education	13
Vocational education	15
Secondary vocational education	26
Senior secondary vocational education	8
Higher education	26
University	10

Data are shown as median (P_{25}-P_{75}) or as a number.

Reliability

The Cronbach's alpha of total OES and all subdomains ranged from 0.827 to 0.916 and, representing excellent internal consistency (Table 2). *Quick*-DASH and SF-36 demonstrated Cronbach's alpha values between 0.741 and 0.923 indicating adequate internal consistency. Internal consistency of the EQ-5D and MEPI was inadequate as it did not reach the Cronbach's alpha threshold value of 0.70.

Validity

Construct validity is shown in Table 3. The calculated Spearman's Rho (rank correlation) coefficients were in line with predefined hypotheses in 37 of the 42 (88%) values, indicating good construct validity. As expected, strong correlations between all subdomains of the OES and other physically orientated questionnaires (DASH, MEPI, and SF-36 PCS) were observed.

Longitudinal validity is displayed in Table 4. The calculated Spearman's Rho (rank correlation) correlations were in line with predefined hypotheses in 34 out of the 42 (81%) values, indicating adequate longitudinal validity.

Table 2. Internal consistency of the instruments used

Instrument	N	Number of items	Cronbach's alpha
OES Total	394	12	0.916
Pain	394	4	0.827
Function	394	4	0.839
Social-psychological	394	4	0.856
Quick-DASH	394	11	0.898
MEPI Total	392	6	0.295
EQ-5D	393	5	0.611
SF-36 Total	394	35	0.906
PF	394	10	0.870
RP	394	4	0.902
BP	394	2	0.777
GH	394	5	0.783
VT	394	4	0.741
SF	394	2	0.802
RE	394	3	0.923
MH	394	5	0.820
SF-36 PCS	394	21	0.876
SF-36 MCS	394	14	0.858

PF, physical functioning; RP, role limitations due to physical health; BP, bodily pain; GH, general health perceptions; VT, vitality, energy, or fatigue; SF, social functioning; RE, role limitations due to emotional problems; MH, general mental health; PCS, physical component summary; MCS, mental component summary.

Minimal clinically important change

Anchor- and distribution-based MCID values are displayed in Table 5. The transition item demonstrated adequate correlation (*i.e.*, r >= 0.3) with the change scores of the total OES score, all OES subdomains and the DASH. The MCID was 8.22 points for the OES total instrument, 7.35 points for the OES pain subdomain, 5.59 points for OES function, and 11.73 points for OES social-psychological. The MCID for the *Quick*-DASH change score was -1.54 points. The SDC (distribution-based MCID) was 11.96 for the OES total and 12.87, 14.05, and 25.04 for the OES pain, function, and social-psychological subdomains, respectively.

Floor and ceiling effects

None of the PROMs evaluated showed a floor effect. From six weeks onwards the MEPI, VAS, and EQ-5D US demonstrated a ceiling effect (Figure 1); 32%, 29%, and 29% of the patients, respectively, reported the maximum score. From three months onwards the *Quick*-DASH demonstrated a ceiling effect; 29% of the patients reported the maximum score. The OES as a total score demonstrated a ceiling effect only from six months onwards; 27% of the patients reported the maximum score.

Table 3. Construct validity of the instruments used (correlation of scores)

		OES			
		Pain	**Function**	**Social- psychological**	**Total**
OES	**Function**	0.625 (0.561;0.682)			
	Social-psychological	0.718 (0.667;0.763)	0.702 (0.648;0.749)		
	Total	0.865 (0.838;0.888)	0.796 (0.757;0.830)	0.948 (0.937;0.957)	
DASH		-0.700 (-0.747;-0.646)	-0.732 (0.775;-0.683)	-0.739 (-0.781;-0.691)	-0.797 (-0.830;-0.758)
MEPI		0.643 (0.581;0.698)	0.612 (0.546;0.670)	0.612 (0.546;0.670)	0.672 (0.614;0.723)
VAS pain		-0.659 (-0.711;-0.599)	**-0.560 (-0.624;-0.488)**	**-0.558 (-0.622;-0.486)**	-0.651 (-0.704;-0.590)
SF-36	**PF**	0.400 (0.314;0.480)	0.536 (0.462;0.603)	0.462 (0.381;0.536)	0.501 (0.423;0.571)
	BP	0.686 (0.629;0.735)	**0.567 (0.496;0.630)**	0.629 (0.565;0.685)	0.687 (0.631;0.736)
	PCS	0.601 (0.534;0.661)	0.612 (0.546;0.670)	0.628 (0.564;0.684)	0.678 (0.621;0.728)
	MCS	-0.117 (-0.213;-0.019)	-0.051 (-0.149;0.048)	**-0.099 (-0.196;-0.000)**	-0.114 (-0.210;-0.016)
EQ-5D	**US**	0.532 (0.457;0.599)	0.550 (0.477;0.615)	0.539 (0.465;0.605)	0.593 (0.525;0.653)
	VAS	0.169 (0.071;0.263)	0.253 (0.158;0.343)	**0.217 (0.121;0.309)**	0.237 (0.142;0.328)

Spearman rank correlation coefficients are given for all possible combinations, with the 95% confidence intervals between brackets; N= 395 for all correlations except for the MEPI (N=391) and EQ-5D VAS (N=394); r>0.6 indicates strong correlation, 0.3<r>0.6 moderate correlation, and r> 0.6 weak correlation. Bold and underlined correlations were not hypothesized correctly; PF, physical functioning; BP, bodily pain; PCS , physical component summary; MCS, mental component summary; US, utility score; VAS, visual analog scale.

Table 4. Longitudinal validity of the instruments used (Correlation of change in scores between six weeks and 12 months)

		OES			
		Pain	**Function**	**Social- psychological**	**Total**
OES	Function	**0.317 (0.127;0.485)**			
	Social-psychological	0.453 (0.280;0.598)	0.534 (0.375;0.662)		
	Total	0.704 (0.588;0.792)	0.760 (0.661;0.833)	0.861 (0.799;0.905)	
DASH		-0.450 (-0.595;-0.276)	**-0.687 (-0.779;-0.566)**	-0.519 (-0.650;-0.357)	-0.680 (-0.774;-0.557)
MEPI		0.388 (0.203;0.546)	**0.381 (0.195;0.540)**	0.373 (0.186;0.534)	0.471 (0.299;0.614)
VAS pain		**-0.372 (-0.531;-0.187)**	-0.324 (-0.491;-0.134)	-0.319 (-0.487;-0.129)	-0.407 (-0.560;-0.227)
SF-36	PF	**0.245 (0.049;0.423)**	0.514 (0.351;0.646)	0.407 (0.227;0.560)	0.495 (0.329;0.631)
	BP	0.412 (0.233;0.564)	0.240 (0.044;0.418)	0.379 (0.195;0.537)	0.395 (0.213;0.550)
	PCS	**0.194 (-0.005;0.378)**	0.394 (0.212;0.549)	0.387 (0.204;0.544)	0.380 (0.196;0.538)
	MCS	0.204 (0.006;0.387)	-0.003 (-0.201;0.196)	0.05 (-0.150;0.246)	0.105 (-0.095;0.297)
EQ-5D	US	0.358 (0.172;0.520)	0.473 (0.303;0.614)	0.421 (0.243;0.572)	0.496 (0.330;0.632)
	VAS	0.142 (-0.059;0.332)	0.351 (0.163;0.514)	**0.250 (0.053;0.428)**	**0.294 (0.100;0.466)**

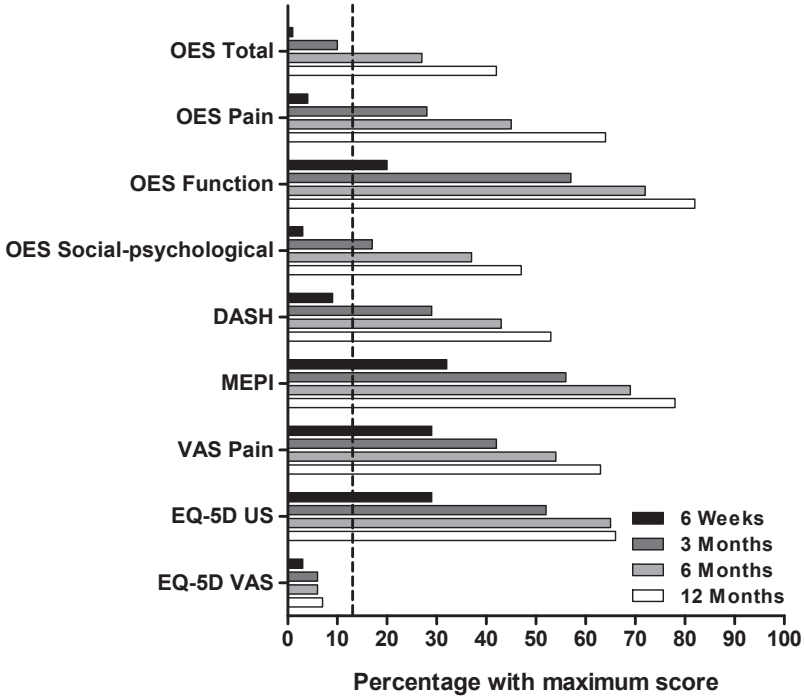
N= 98 patients for all correlations except for the MEPI (N=96) and EQ-5D VAS (N=97). Rest of table caption is identical to Table 3.

Table 5. Anchor- (MCID) and distribution-based (SDC) minimal important change values

		Anchor-based approach "slightly better" (N=57)	Distribution-based approach (N=31)		
		MCID (95% CI)	SD_{change}	SEM	SDC
OES	Pain	7.35 (3.33;11.36)	6.57	4.64	12.87
	Function	5.59 (1.96;9.23)	7.17	5.07	14.05
	Social-psychological	11.73 (7.57;15.89)	12.78	9.03	25.04
	Total	8.22 (5.71;10.74)	6.10	4.32	11.96
DASH		-1.54 (-2.40;-0.69)	2.74	1.94	5.37

MCID, minimal clinically important change; SD_{change} , standard deviation of the change score of patients that reported "no change" on the transition item; SEM, standard error of measurement; SDC, smallest detectable change**.**

Figure 1. Ceiling effects of the instruments used



N= 99 for all instruments at 6 weeks, N=100 at 3 months (except for the MEPI (N=99)), N=97 at 6 months (except for the MEPI (N=96)), and N=99 at 12 months (except for the MEPI (N=97) and EQ-5D VAS (N=98)). The dotted line represents the acceptable 15% of patients with the maximum score as proposed by Terwee *et al.*[31]. The SF-36 BP, PF, PCS and MCS did not demonstrate a ceiling effect and are not displayed. None of the instruments demonstrated a floor effect.

DISCUSSION

This study showed that the OES is a reliable and valid instrument for the evaluation and follow-up of patients after a simple elbow dislocation that was treated non-operatively. The anchor-based MCID was 8.22 points.

The reliability of the OES (Cronbach's alpha 0.916) was comparable with published values.[10, 13, 35] The OES had the highest Cronbach's alpha of all PROMs studied, making it the most reliable questionnaire. This is in agreement with previous studies.[8] The MEPI demonstrated inadequate internal consistency which had also been shown previously.[36] The OES proved its validity by demonstrating strong correlations with the DASH, MEPI, and SF-36 PCS. The latter is a novel observation, as no data were available on the correlation between the OES and SF-36 PCS. The correlation with the DASH and MEPI has been published before for patients who had undergone elbow surgery.[9, 15] There is no available literature concerning the validity of the OES in non-operatively treated patients. The correlation in change scores between the subdomains of the OES and DASH are comparable with data from Dawson *et al.*[9] Change scores of the OES also correlated strongly with change scores of the DASH. Remarkably, the change scores of the OES only correlated moderately with the MEPI. This could be explained by the fact that the MEPI demonstrated significant ceiling effects from the first follow-up onwards, which enables a questionnaire to reveal actual changes over time.

The interpretability represented by the MCID was 8.22 for the total OES score. The MCIDs for the OES pain, function and social-psychological subdomains (7.35, 5.59, and 11.73 points, respectively) were lower than for patients who underwent elbow surgery (17.41-19.23, 9.23-9.64, and 17.79-18.30 points, respectively) as reported before.[9] Although the number of 14 patients who answered "slightly better" on the transition item was much lower than the 57 patients in the current study, the difference in population most likely explains the difference in MCID.[4] MCID values are known to differ depending on patient population and the type of injury and intervention.[9, 33] Although the MCID for the OES in this study was evaluated in a cohort of patients with a simple elbow dislocation, one may expect that the MCID can be extrapolated to also be useful in the evaluation of other non-operatively treated elbow injuries.

The MCID for the *Quick*-DASH was only -1.54 points. This is hard to believe for a scale that runs from 0 to 100, especially as previously published anchor-based MICD values for the DASH-score ranged from 8 to 16 points.[37-41] The most plausible explanation for this is again the fact that already on the first evaluation (six weeks) the *Quick*-DASH showed a ceiling effect, which implies that subtle impediments and changes cannot be measured from that point onward. This emphasizes the need for elbow-specific questionnaires like the OES for the less severe types of injuries. The

OES also demonstrated a ceiling effect, however not before the six months follow-up moment, at which time patients were recovered to the largest degree.

Ideally, the MCID should be larger than the smallest detectable change (SDC) in order to be able to differentiate between "real" change and change caused by measurement error.[4] For the OES and DASH the SDC was larger than the anchor-based MCID. A previous study that also used both anchor- and distribution-based methods for calculating the MCID, also found that SDC values were higher than anchor-based MCID values.[9] This might lead to the conclusion that the observed anchor-based MCID values are unreliable as they fall within the range that could be due to chance. The SEM in the current study was calculated with the corresponding change scores of patients that answered "no change" on the transition item as a surrogate for test-retest values. This could have introduced some bias, which might have influenced the SDC value. Future studies should include an adequate test-retest analysis in order to be able to calculate a true SEM. Nevertheless, the anchor-based MCID values are the closest estimate of actual clinical change, therefore the MCID values in current study are of definite value.

This study has some limitations. First, the relatively long time between the follow-up moments hindered an adequate test-retest analysis. Furthermore, it could also have led to recall bias with regard to the transition item. However, the interval for the transition item in the only other study that analyzed the MCID of the OES using an anchor-based approach was at least six months.[9] Secondly, the transition item for the MCID analysis included "completely recovered" was a heterogeneous group. This group included patients who 1) were already completely recovered at the previous follow-up visit; 2) truly experienced no change; or 3) reported complete recovery for the first time but actually improved little/much since the previous follow-up. For future studies the outlying answers (*i.e.*, "completely recovered" and "worse than ever") should be left out.

Strengths of this study were its sample size and homogenous patient population. Furthermore, to the best of our knowledge, it is the first study to validate the OES for patients with elbow injuries treated non-operatively. Previous studies focused primarily on operated patients.[9, 10, 13, 14, 35]

In summary, the OES has proven to be a reliable and valid instrument for evaluating elbow-related quality of life in patients who sustained a simple elbow dislocation. Whereas validity was known for surgically treated elbow injuries, this study demonstrated the OES is also valid for elbow injuries treated non-operatively. The OES is a useful instrument for research purposes, and could play an important role in daily practice. The anchor-based MCID facilitates statistical power analysis and sample-size calculations for future clinical studies.

ACKNOWLEDGEMENTS

The Oxford and Isis Outcomes, part of Isis Innovation Limited, are acknowledged for their kind support. Kiran C. Mahabier, Harold Goei, Gerben De Reus, and Liza Van Loon are acknowledged for their assistance in data collection.

Funding

This project was supported by a grant from the European Society for Surgery of the Shoulder and the Elbow (SECEC/ESSSE). This organization was not involved in the trial design, patient recruitment, data collection, data analysis, data interpretation, publication decisions, or in any aspect pertinent to this study.

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PART III

Treatment of complex elbow dislocations

Protocol:

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

Niels W.L. Schep, Jeroen De Haan, Gijs I.T. Iordens, Wim E. Tuinebreijer, Maarten W.G.A. Bronkhorst, Mark R. De Vries, J. Carel Goslings, S. John Ham, Steven Rhemrev, Gert R. Roukema , Inger B. Schipper, Jan Bernard Sintenie, Hub G.W.M. Van der Meulen, Tom P.H. Van Thiel, Arie B. Van Vugt, Egbert J.M.M. Verleisdonk, Jos P.A.M. Vroemen, Philippe Wittich, Peter Patka, Esther M.M. Van Lieshout, Dennis Den Hartog

BMC Musculoskelet Disord. 2011 Jun 9;12:130.


8

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 reduction 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 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 because of residual instability. 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 yield quantitative data on the functional outcome in 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 reduction and internal fixation (ORIF) [3] or primary arthroplasty in case of a non-reconstructable radial head fracture.

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 immobilization.

A period of plaster immobilization 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 plaster immobilization 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 a satisfactory functional outcome at one year.

METHODS AND 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 for residual instability following fracture fixation 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 postoperatively. Patients meeting all inclusion criteria and none of the exclusion criteria will be included before discharge or 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:

- Men or women aged 18 years and older (with no upper age limit)
- 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)
- Patient was treated with a hinged external fixator after ORIF and/or arthroplasty of the radial head due to persistent instability
- 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 pivot shift test for posterolateral rotatory stability) is included in the protocol.

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

- Patients with a concomitant distal humeral fracture
- Patients with additional substantial traumatic injuries of the affected upper limb
- Patients who underwent repair of the collateral ligaments
- Patients with an impaired elbow function (i.e., stiff or painful elbow or neurological disorder of the upper limb) prior to the injury

- Retained hardware around the affected elbow
- Likely problems, in the judgment of the investigators, with maintaining follow-up (e.g., patients with no fixed address will be excluded)
- 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

The external fixator used is the Orthofix® Elbow Fixator (Orthofix Verona, Italy). The surgical approach to the fracture site 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 after one year. [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, repositioning or removal of the fixator, 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 deficits)

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:

- 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.
- 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 of the coronoid process according to Regan & Morrey [24], and fracture classification of the radial head according to Mason & Johnston. [25]
- 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 take place 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, 27]

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. [28, 29] 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 (randomized) 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 Reduction 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).

ACKNOWLEDGEMENTS

The Oxford and Isis Outcomes, part of Isis Innovation Limited, are acknowledged for their kind support. This project will be supported by a grant from the Osteosynthesis and Trauma Care (OTC) Foundation and by a grant from Dutch Added Value BV

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Good functional recovery of complex elbow dislocations treated with hinged external fixation: A multicenter prospective study

Gijs IT Iordens, Dennis Den Hartog, Esther MM Van Lieshout, Wim E Tuinebreijer, Jeroen de Haan, Peter Patka, Michael HJ Verhofstad, Niels WL Schep,

On behalf of the Dutch Elbow Collaborative

Clin Orthop Relat Res. 2015 Apr;473(4):1451-61


9

ABSTRACT

Background

After a complex dislocation, some elbows remain unstable after closed reduction or fracture treatment. Functional aftertreatment with a hinged external fixator theoretically allows collateral ligaments to heal without surgical reconstruction. However, there is a lack of prospective studies that assess functional outcome, pain, and ROM.

Question/purposes

We asked: (1) In complex elbow fracture-dislocations, does treatment with a hinged external fixator result in reduction of disability and pain, and in improvement in ROM, function, and quality of life? (2) Does delayed treatment (7 days or later) have a negative effect on ROM after 1 year? (3) What are the complications seen after external fixator treatment?

Patients and Methods

During a 2-year period, 11 centers recruited 27 patients 18 years or older who were included and evaluated at 2 and 6 weeks and at 3, 6, and 12 months after surgery as part of this prospective case series. During the study period, the participating centers agreed on general indications for use of the hinged external fixator, which included persistent instability after closed reduction alone or closed reduction combined with surgical treatment of associated fracture(s), when indicated. Functional outcome was evaluated using the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH; primary outcome) score, the Mayo Elbow Performance Index (MEPI), the Oxford Elbow Score, and the level of pain (VAS). ROM, adverse events, secondary interventions, and radiographs also were evaluated. A total of 26 of the 27 patients (96%) were available for follow up at 1 year.

Results

All functional and pain scores improved. The median QuickDASH score decreased from 30 (25^{th}–75^{th} percentiles [P25–P75], 23–40) at 6 weeks to 7 (P25–P75, 2–12) at 1 year with a median difference of 25 ($p < 0.001$). The median MEPI score increased from 80 (P25–P75, 64–85) at 6 weeks to 100 (P25–P75, 85–100) at 1 year with a median difference of 15 ($p < 0.001$). The median Oxford Elbow Score increased from 60 (P25–P75, 44–68) at 6 weeks to 90 (P25–P75, 73–96) at 1 year with a median difference of 29 ($p < 0.001$). The median VAS decreased from 2.8 (P25–P75, 1.0–5.0) at 2 weeks to 0.5 (P25–P75, 0.0–1.9) at 1 year with a median difference of 2.1 ($p = 0.001$). ROM also improved. The median flexion-extension arc improved from 50° (P25–P75, 33°–80°) at 2 weeks to 118° (P25–P75, 105°–138°) at 1 year with a median difference of 63° ($p < 0.001$). Simi-

larly, the median pronation-supination arc improved from 90° (P25– P75, 63°–124°) to 160° (P25–P75, 138°–170°) with a median difference of 75° ($p < 0.001$). At 1 year, the median residual deficit compared with the uninjured side was 30° (P25–P75, 5°–35°) for the flexion-extension arc, and 3° (P25–P75, 0°–25°) for the pronation-supination arc. Ten patients (37%) experienced a fixator-related complication, and seven patients required secondary surgery (26%). One patient reported recurrent instability.

Conclusion

A hinged external elbow fixator provides enough stability to start early mobilization after an acute complex elbow dislocation and residual instability. This was reflected in good functional outcome scores and only slight disability despite a relatively high complication rate.

Level of Evidence

Level IV, therapeutic study.

BACKGROUND

Complex elbow dislocations, with injuries to osseous and ligamentous structures, are an important cause of instability of the elbow. [1] The goal in management of complex elbow dislocations is to reconstruct a stable joint that tolerates a functional aftertreatment.[1-4] Elbows with residual instability frequently are treated with primary ligament repair with or without plaster immobilization. However, ligament repair has its disadvantages. Overtightening or malpositioning of the ligaments beyond the isometric point may contribute to stiffness and instability. Furthermore, ligament repair increases the risk of ulnar nerve injury and necessitates an extensive surgical approach. [5-7] Moreover, ligamentous repair may not be sufficient to stabilize the elbow in such a way that immediate active movement is tolerated. [4, 8] Plaster immobilization is unattractive, because earlier studies found that mobilization is essential during healing of injured ligaments because the functional load on the collagen fibers prevents contracture and the risk of stiffness.[9-15] Another alternative is the hinged external fixator, which stabilizes the elbow and protects the elbow against valgus and varus stress and allows flexion and extension. Theoretically, this will allow the ligaments to heal without additional reconstruction and without compromising a functional aftertreatment.

Rationale

Previous reports on ROM and patient-reported outcome scores after the use of a hinged external fixator in these types of injuries show promising but varying results. [3, 16-20] This is mostly because the majority of these studies were small retrospective case series. There is a lack of prospective studies regarding the use of a hinged external fixator in patients with instability after a complex elbow dislocation.

The aim of our study was to prospectively evaluate patients with acute complex elbow dislocations and residual instability who were treated with a hinged external elbow fixator and early mobilization in terms of (1) functional outcome; and (2) fixator-related adverse events.

Study Questions

We attempted to answer the following questions: (1) In complex elbow fracture-dislocations, does treatment with a hinged external fixator result in reduction of disability and pain, and in improvement in ROM, function, and quality of life? (2) Does delayed treatment (7 days or later) have a negative effect on ROM after 1 year? (3) What are the complications seen after external fixator treatment?

PATIENTS AND METHODS

Study Design and Setting

This study was a prospective multicenter case series. Surgeons representing 15 hospitals participated. All surgeons were selected based on their clinical case experience with this type of injury and the hinged elbow fixator. We assessed patients for eligibility for this study between December 15, 2009, and December 13, 2011.

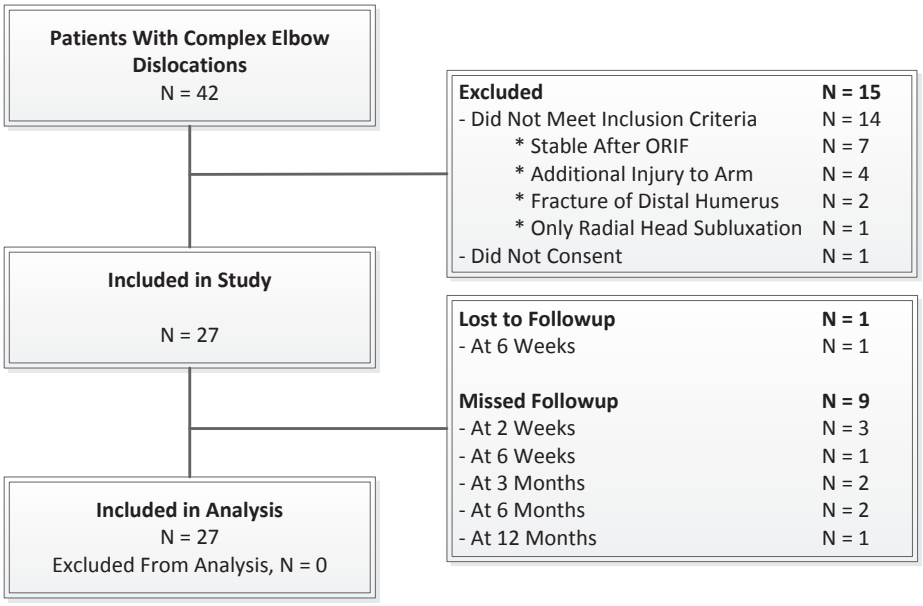
Participants/Study Subjects

During the study period, the participating centers agreed on general indications for use of the hinged external fixator, which included (1) residual elbow instability after open reduction and internal fixation of all associated fractures and/or radial head replacement, or (2) persisting postreduction elbow instability of dislocations that were accompanied by fractures that did not require fracture treatment. Inclusion criteria for the study were patients 18 years or older with a complex elbow dislocation who were treated with a hinged elbow fixator (Orthofix1 elbow fixator; Orthofix International, Bussolegno, Italy; FDA approved since September 15, 1999) for instability after closed reduction alone or closed reduction combined with open treatment of associated fracture(s) when indicated. A complex elbow dislocation was defined as any type of elbow dislocation with fractures of the radial head, coronoid process, or proximal ulna (olecranon). Residual instability was defined as spontaneous redislocation of the joint, or as redislocation during flexion and extension or the pivot shift test. Valgus or varus laxity without (sub)dislocation was not defined as residual instability and was not considered an indication for fixator placement. These tests were performed in the operating room directly after surgery. For patients who had closed reduction alone, spontaneous redislocation was used as an indication for fixator placement. [21] Exclusion criteria were pathologic fractures, preexistent injuries of the affected arm, collateral ligament repair, a fracture of the ipsilateral distal humerus, and additional traumatic injuries to the affected arm (ie, ipsilateral distal radius fracture). Patients with insufficient understanding of the Dutch language or patients for whom problems in maintaining follow up were expected also were excluded. All patients gave written informed consent to participate in this study, which was approved by the medical research ethics committees of all participating hospitals. The study protocol was published elsewhere. [22]

During the study period, 42 patients experienced a complex elbow dislocation and were screened for eligibility. Fifteen patients were excluded: seven patients had a stable elbow after open reduction and internal fixation, four had additional injuries to the ipsilateral arm, two had a fracture of the proximal humerus, one had only a subluxation of the radial head, and one did not consent to participate (Figure 1). Twenty-seven patients from 11 hospitals were included (Table 1). Those 27 patients were treated by

14 different surgeons. Eight surgeons treated only one patient, three surgeons treated two patients, one surgeon treated three patients, one surgeon treated four patients, and one surgeon treated six patients. The majority of the patients were female (52%) with a median age of 52 years (25th–75th percentiles [P25–P75], 38–59). All but one patient completed 1 year follow up. This patient died of a nonsurgery-related accident and completed only 6 weeks of follow up.

Figure 1. The study flowchart is shown.



ORIF = open reduction and internal fixation.
Data are provided as *median with the first and third quartiles given between parentheses or as †patient numbers with the percentage given between parentheses; ‡type of dislocation unknown because of prehospital reduction or absence of prereduction radiographic images when reduction occurred at another hospital; ASA = American Society of Anesthesiologists.

Table 1. Baseline characteristics

Characteristic	N = 27
Female[†]	14 (52%)
Age (years)[*]	52 (38–59)
BMI (kg/m^2)[*]	26 (23–28)
ASA score[†]	19 (70%)
1	7 (26%)
2	1 (4%)
3	
Tobacco use[†]	7 (26%)
Alcohol use[†]	19 (70%)
Injury to dominant arm[†]	13 (48%)
Type of dislocation[†]	
Posterior	14 (52%)
Posterolateral	10 (37%)
Lateral	1 (4%)
Unknown[‡]	2 (7%)
Associated fractures[†]	
Radial head	9 (33%)
Radial head + coronoid process	9 (33%)
Coronoid process	6 (22%)
Radial head + coronoid process + olecranon	1 (4%)
Radial head + olecranon	1 (4%)
Coronoid process + olecranon	1 (4%)
Radial head fractures[†][23]	20 (74%)
Mason I	2 (10%)
Mason II	5 (25%)
Mason III	13 (65%)
Coronoid process fractures[†][24]	17 (63%)
Regan and Morrey I	11 (65%)
Regan and Morrey II	5 (29%)
Regan and Morrey III	1 (6%)
Olecranon fractures[†][25]	3 (11%)
Mayo IIIa	1 (6%)
Mayo IIIb	1 (6%)
Monteggia fracture	1 (6%)
Operative fracture treatment[†]	19 (70%)

Fracture Characteristics

Nine patients (33%) presented with a terrible triad injury defined as an elbow dislocation accompanied by fractures of the radial head and coronoid process (Table 2). Nine patients (33%) had an isolated fracture of the radial head. In six patients (22%), the dislocation was accompanied by an isolated fracture of the coronoid process. One patient (4%) had combined fractures of the coronoid process and olecranon, one patient (4%) had combined fractures of the radial head and olecranon, and one (4%) sustained fractures of the radial head, coronoid process, and olecranon. In 20 patients (74%) at

Table 2. Characteristics of the 27 patients in order of inclusion

Patient number*	Sex	Age (years)	Trauma mech-anism	Fracture (classification)	ORIF	Radial head prosthesis	Adverse events	Secondary surgery	1-year Quick-DASH	1-year OES	1-year FE arc (degrees)	1-year PS arc (degrees)
1	M	39	LET	R(II)	R	-	Wound infection Limited ROM	None Arthrolysis	4.6	90	65	180
2	F	60	LET	R(III)	-	+	None	None	0.0	100	115	180
3	M	56	LET	C(II)	C	-	Ulnaropathy	Ulnar nerve release	6.8	92	115	180
4	F	50	HET	R(I), O (Monteggia)	O	-	None	None	11.4	60	120	180
5	M	35	LET	R(III), C(I)	R	-	None	None	2.3	98	130	180
6	F	65	LET	R(II), C(II)	-	-	Incongruent joint	Replacement HEF	29.6	73	120	165
7	M	41	HET	R(II), C(I)	R	-	Pin-tract infection Joint crepitus	None ROH (radius)	2.3	96	135	160
8	M	54	LET	R(III), C(II), O (IIIb)	C,O	+	Late infection	ROH (olecranon + radius)	9.1	88	115	160
9	F	53	LET	R(III), C(I)	R	-	Incongruent joint Pin-tract infection Limited ROM	Replacement HEF None Arthroplasty	22.7	67	80	160
10	F	64	LET	R(II)	-	+	None	None	0.0	98	150	170
11	M	30	HET	C(II)	-	-	HEF malfunction Persistent instability	Replacement HEF LCL reconstruction	20.5	58	115	170
12	F	57	LET	R(III), C(I)	-	+	None	None	6.8	92	125	160
13	F	66	HET	R(III)	R	-	Incongruent joint Pin-tract fracture ulna	Replacement HEF None	11.4	77	60	170
14	F	54	LET	C(II), O (IIIa)	O	-	None	None	0.0	88	120	170
15	M	31	LET	R(I), C(I)	C	-	Septic arthritis Pin-tract fracture humerus	Debridement Plate humerus	11.4	81	105	155

Table 2. Characteristics of the 27 patients in order of inclusion (continued)

Patient number*	Sex	Age (years)	Trauma mech-anism	Fracture (classification)	ORIF	Radial head prosthesis	Adverse events	Secondary surgery	1-year Quick-DASH	1-year OES	1-year FE arc (degrees)	1-year PS arc (degrees)
16	M	43	LET	C(III)	-	-	Pin-tract infection	None	4.6	81	125	165
17	F	64	LET	R(III), C(I)	R	-	None	None	NA	NA	NA	NA
18	F	80	LET	R(II), C(I)	R	-	Incongruent joint	Replacement HEF	6.8	92	105	145
19	M	57	LET	R(III)	R	-	None	None	13.6	90	145	170
20	M	26	HET	R(III)	-	-	Incongruent joint (3)	Replacement HEF (3)	18.2	71	110	170
21	F	47	HET	R(III)	R	-	None	None	2.3	96	110	170
22	F	48	LET	R(III), C(I)	R	-	Pain	ROH (radius)	9.1	98	145	165
23	F	29	LET	R(III)	R	-	None	None	0.0	94	145	160
24	M	37	HET	C(I)	-	-	Pin-tract infection	None	6.8	69	80	160
25	M	24	LET	R(III)	R	-	None	None	9.1	90	100	170
26	F	52	LET	C(I)	-	-	None	None	15.9	73	150	155
27	M	49	HET	C(I)	-	-	None	None	0.0	98	150	170

* Patients 6, 11, 16, 20, 24, 26, and 27 were treated conservatively; ORIF = open reduction internal fixation; OES = Oxford Elbow Score; FE = flexion-extension; PS = pronation-supination;; LET = low-energy trauma; HET = high-energy trauma; R = radial head (Mason classification[23]); C = coronoid process (Regan and Morrey classification[24]); O = olecranon (Mayo classification[25]); ROH = removal of hardware; HEF = hinged external fixator; LCL = lateral collateral ligament;

least one of the fractures required open treatment, and seven patients underwent only closed reduction before hinged external fixation. Time to surgery was a median of 6 days (P25–P75, 1–10).

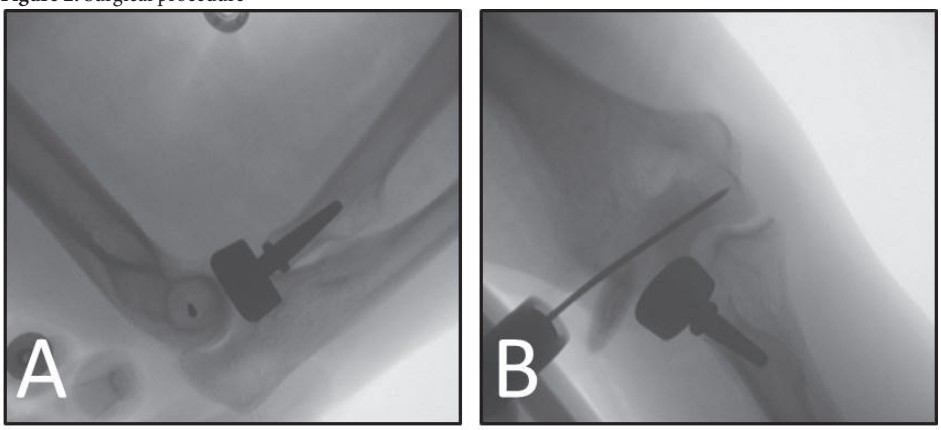
Surgical Procedure

If instability was present after fracture treatment, a hinged external fixator was mounted. With the elbow in 90° flexion, the central axis of rotation was located by overlapping the capitellum and trochlea in a lateral fluoroscopic image. Perfect overlap of these structures resulted in a circle with the center of this circle representing the axis of rotation. Along the axis of rotation, a 2-mm K-wire was inserted. Its position was confirmed on the AP and lateral planes (Fig. 2). The central connecting unit of the external fixator then was applied over the K-wire. The lateral aspect of the humerus was exposed by an approximately 4-cm incision just distal to the insertion of the deltoid muscle taking the radial nerve into account. The humeral screws were inserted and the clamp cover was tightened. Subsequently, the ulnar screws were drilled laterally through a 4-cm incision. After tightening this clamp, the image intensifier was used to check reduction and congruency of the joint and alignment of the fixator. Flexion and extension were required to go smoothly without compromising congruency during movement. A good indicator for perfect alignment was the K-wire, which had to have no resistance in the center of the connecting unit during motion of the elbow. Furthermore, no widening of the joint space was accepted during flexion and extension on AP and lateral view radiographs. Finally, the link-locking screws were tightened, the K-wire removed, and the wounds on the upper arm and forearm approximated.

Aftercare

A protocol of supervised active and passive extension, flexion, and pronation and supination exercises was started immediately after surgery if tolerated (Fig. 3). [22] After 6 weeks, the external fixator was removed in the outpatient department without any form of anesthesia. All patients received 50 mg indomethacin twice daily for 6 weeks as heterotopic ossification prophylaxis, unless NSAIDs were contraindicated. A proton pump inhibitor also was administered.

Figure 2. Surgical procedure



Locating the center of rotation by overlapping the trochlea and capitellum of the humerus projecting them as a perfect circle. The center of this circle is considered the axis of rotation (A). The depth of the K-wire is checked in AP view. Care should be taken not to drill too deep in order to avoid harming the ulnar nerve.(B)

Outcome Assessment and Data Collection

Follow up data were collected at 2 weeks, 6 weeks, 3 months, 6 months, and 12 months after surgery. Standard radiographs of the elbow were made at the time of admission, within 48 hours after surgery, and at each follow up.

Variables, Outcome Measures, Data Sources, and Bias

The primary outcome was the Quick-Disabilities of the Arm, Shoulder and Hand (*Quick*DASH) scores after 1 year, reflecting functional outcome and pain. [26, 27] Secondary outcome measures were level of pain measured with a VAS, the Mayo Elbow Performance Index (MEPI) [25], the injury-related quality of life measured with the Oxford Elbow Score [28, 29], and health-related quality of life measured with the SF-36. [30] Scores for the SF-36 physical and mental component summaries were converted to a norm-based score and compared with the norms for the general population of the United States. [30] Permission for translation and use of the Oxford Elbow Score for this study was obtained from Oxford and Isis Outcomes, part of Isis Innovation Limited (http://www.isis-innovation.com/). In addition, ROM was measured using a goniometer. All physical examinations were performed by an investigator or research assistant from the principal site in the presence of the treating surgeon. Complications and secondary interventions were recorded. Radiographs were evaluated by two observers independently (GITI, DDH) for type of dislocation, type of fractures, joint congruency, fracture consolidation, and the presence of heterotopic ossifications. Radial head fractures were classified using the Mason classification. [23] Fractures of the coronoid process were classified according to the Regan and Morrey classification.[24] Fractures of the olecranon

were classified according to the Mayo classification. [25] Fractures were considered healed if one of the following three criteria were met: (1) bridging of fracture by callus/bone trabeculae or osseous bone; (2) obliteration of fracture line/cortical continuity; or (3) bridging of fracture at three cortices. Heterotopic ossifications were classified as present if there were immature calcifications, small mature ossifications, large mature ossifications, or complete bone bridging/ankyloses. [31] Radiographic results showed that 18 (78%) of patients showed radiographic healing and that 13 (57%) of patients showed signs of heterotopic ossifications at one year (Table 3).

Table 3. Radiographic results at 1 year

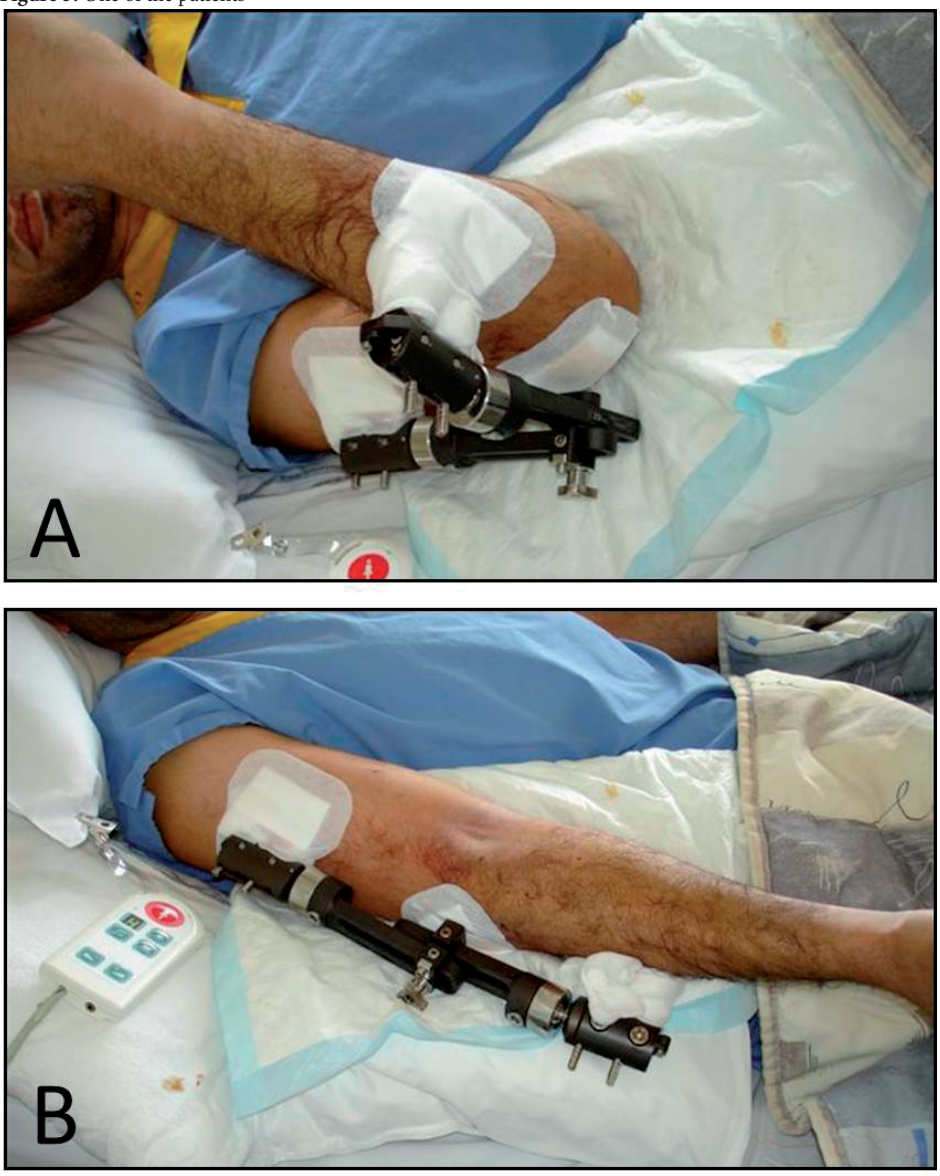
Characteristic	N = 23
Fracture consolidation	
Yes	18 (78%)
No	3 (13%)
NA	2 (9%)
Heterotopic ossifications	
Yes	13 (57%)
No	10 (43%)

Radiographs at one year were not available for 4 patients. None of the patients showed radiographic signs of instability at 1 year; NA = not applicable (these patients had a radial head fracture treated with radial head replacement).

Statistical Analysis

Data were analyzed using SPSS Version 20.0 (Chicago, IL, USA). Normality of continuous data was tested with the Shapiro-Wilk test and by inspecting frequency histograms (Q-Q plots). Descriptive analysis was performed to describe baseline characteristics (intrinsic, injury, and intervention-related variables) and outcome measures. Continuous data are reported as medians and percentiles (nonparametric data) or as means and SD (parametric data) and categorical data as numbers with percentages. A Wilcoxon signed rank test was used to compare functional outcome scores at 1 year with those at the first follow up measurement (ie, 2 weeks for ROM and 6 weeks for the QuickDASH, Oxford Elbow Score, MEPI, and SF-36). A Mann-Whitney U test was performed to assess statistical significance of difference in ROM between patients who received early treatment (ie, within 7 days after initial injury) and those who received delayed treatment (ie, 7 days or later after initial treatment). A p value less than 0.05 was considered the level of statistical significance.

Figure 3. One of the patients



A study patient is shown with his arm in (A) full flexion and (B) in extension immediately after surgery.

RESULTS

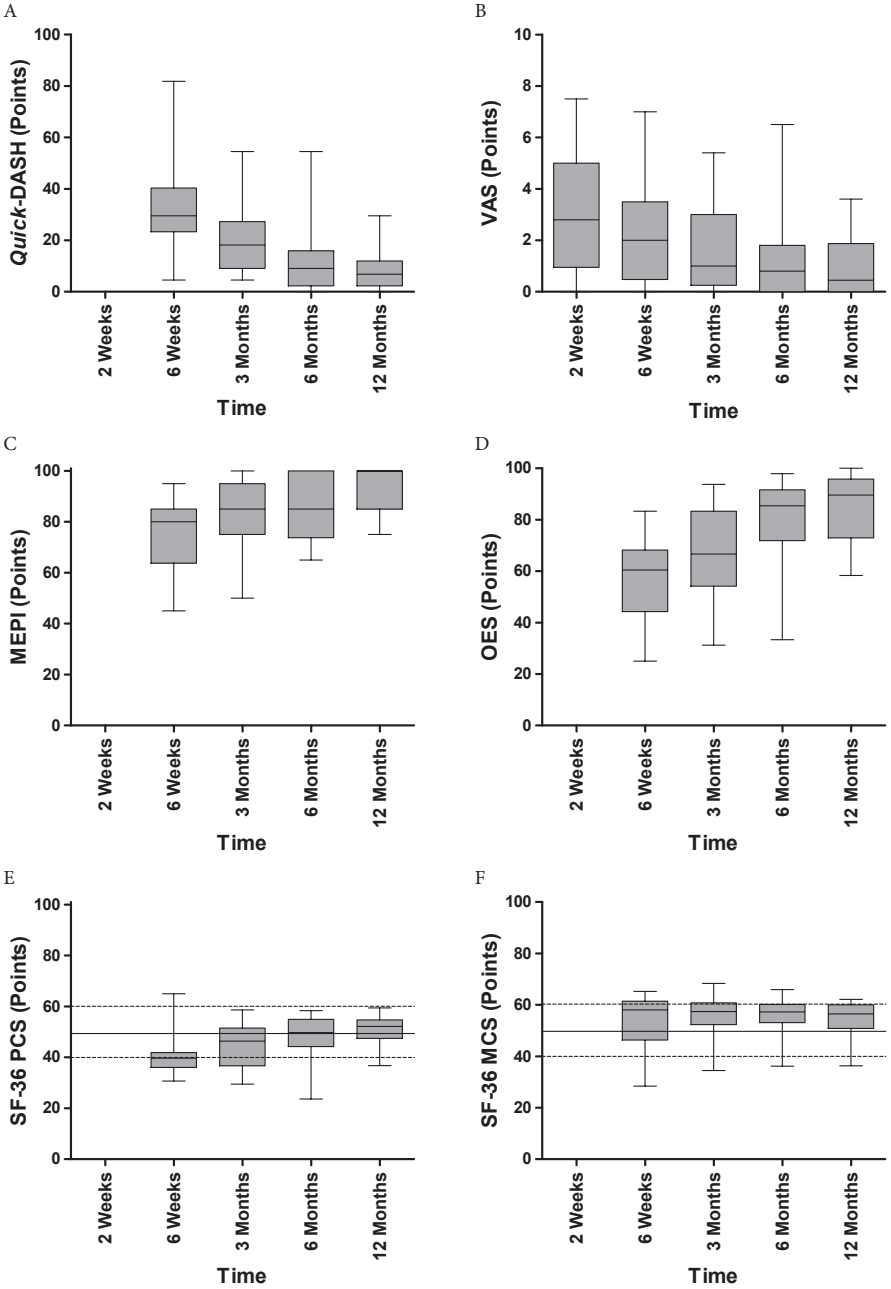
Patient-reported Pain, Functional Outcome, and Quality of Life

All outcome measures except for the SF-36 Mental Component Summary improved after the initial assessment (Fig. 4). The median QuickDASH score decreased from 30 (P25–P75, 23–40) at 6 weeks to 7 (P25–P75, 2–12) at 1 year with a median difference of 225 ($p < 0.001$). The median level of pain (VAS) decreased from 2.8 (P25–P75, 1.0–5.0) at 2 weeks to 0.5 (P25–P75, 0.0–1.9) at 1 year with a median difference of 22.1 ($p < 0.001$). The median MEPI increased from 80 (P25–P75, 64–85) at 6 weeks to 100 (P25–P75, 85–100) at 1 year with a median difference of 15 ($p < 0.001$). The median Oxford Elbow Score increased from 60 (P25–P75, 44–68) at 6 weeks to 90 (P25–P75, 73–96) at 1 year with a median difference of 29 ($p < 0.001$). The median SF-36 Physical Component Summary increased from 40 (P25–P75, 36–42) at 6 weeks to 52 (P25– P75, 47–55) at 1 year, with a median difference of 14 ($p < 0.001$).The SF-36 Mental Component Summary, however, remained similar (6-week median 58 [P25–P75, 46–61], 1-year median, 56 [P25–P75, 51–60], median difference, 22; $p = 0.784$).

Range of Motion

ROM for flexion-extension and pronation-supination arcs improved during follow up (Fig. 5). The median flexionextension arc improved from 50° (P25–P75, 33°–80°) at 2 weeks to 118° (P25–P75, 105°–138°) at 1 year, with a median difference of 63° ($p < 0.001$). The median flexion improved from 100° (P25–P75, 90°–110°) to 140° (P25–P75, 129°–145°), with a median difference of 33° ($p < 0.001$) and the median extension improved from 40° (P25–P75, 30°–60°) to 20° (P25–P75, 0°–26°), with a median difference of -30° ($p < 0.001$). Similarly, the median pronation-supination arc improved from 90° (P25–P75, 63°–124°) to 160° (P25–P75, 138°–170°), with a median difference of 75° ($p < 0.001$). The median pronation improved from 55° (P25–P75, 33°–85°) to 83° (P25–P75, 75°–85°), with a median difference of 15° ($p = 0.001$) and the median supination improved from 30° (P25–P75, 20°–45°) to 80° (P25–P75, 68°–85°), with a median difference of 45° ($p < 0.001$). At 1 year, the residual deficits compared with the uninjured side were 30° (P25–P75, 5°–35°) for the flexion-extension arc and 3° (P25–P75, 0°–25°) for the pronation-supination arc. The study population was divided into a group that was treated within 7 days after initial injury (early treatment, $n = 14$) and a group that was treated 7 days or later after initial injury (delayed treatment, $n = 13$). There was a 15° difference in the arc of flexion and extension favoring the early treatment group after 1 year: 128° (P25–P75, 114°–145°) versus 113° (P25–P75, 80°–119°), respectively ($p = 0.02$). This difference was attributable mainly to the greater extension deficit in the late treatment group: 8° (P25–P75, 0°–25°) for the early treatment group versus 25° (P25–P75, 13°–30°) for the late treatment group ($p = 0.03$).

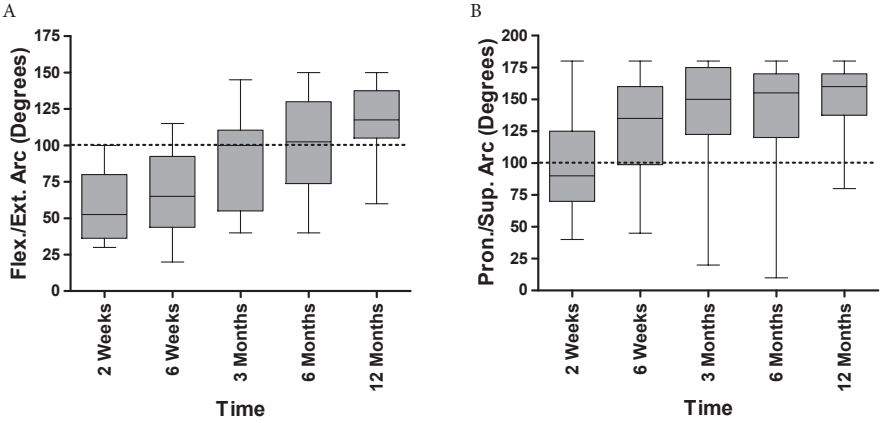
Figure 4. Changes in PROMS



Changes during followup in the (A) QuickDASH score, (B) pain, (C) Mayo Elbow Performance Index (MEPI), (D) Oxford Elbow Score (OES), (E) SF-36 Physical Component Summary (PCS) score, and (F) SF-36 Mental Component Summary (MCS) are shown.

The dotted lines in the (E-F) SF-36 PCS and MCS represent the US population norm of 50±10 (SD) points. All outcome scores except for the SF-36 Mental Component Summary show improvement with time.

Figure 5. Changes in (A) arcs of flexion-extension and (B) pronation-supination during follow up are shown



The dotted lines represent functional elbow ROM on positional and functional tasks as reported by Morrey et al.[32] ROM shows improvement with time.

Fixator-related Complications

Ten patients (37%) experienced 12 fixator-related complications, requiring secondary intervention in seven patients (26%) (Table 2). Five patients (19%) had elbow incongruency resulting from fixator malalignment. In all patients incongruency was recognized between 5 and 25 days after fixator placement. In these five patients, seven procedures for fixator replacement were required, all of which occurred on the same day or the first day after incongruency was recognized. One patient experienced a hardware defect which required fixator replacement. Four patients (15%) had a pin-tract infection, of whom two patients were treated with oral antibiotics alone. The other two patients required débridement in the outpatient clinic combined with antibiotic treatment. One patient had a pin-tract fracture of the ulna that was managed conservatively (leaving the fixator in situ) and one patient had a pin-tract fracture of the humerus 5 months after removal of the fixator, requiring plate fixation. No redislocations occurred after removal of the fixator; however, one patient had chronic posterolateral rotatory elbow instability and required a lateral collateral ligament reconstruction.

DISCUSSION

Residual instability after a complex elbow dislocation is a serious condition with potentially life-changing sequelae and its treatment poses a challenge, even for experienced surgeons. The goal in management of complex elbow dislocations is to reconstruct a stable joint that tolerates functional aftertreatment. [1-4] A hinged fixator may be used to achieve this. Previous studies reported promising but variable results regarding

ROM and patient-reported outcome scores. [3, 16-20] The variability in reported results may have been a function of the shortcomings of retrospective analysis. Because most of the studies on this topic have been small and retrospective, had inconsistent surgical indications, had substantial loss to follow up, and used inconsistent approaches to measurement outcomes, those studies are difficult to evaluate. Therefore, we aimed to assess patients with complex elbow dislocations who were treated with a hinged external elbow fixator and early mobilization, prospectively and in a consistent fashion in terms of (1) functional outcome; (2) ROM; and (3) fixator-related adverse events.

This study had some limitations. First, the sample size was small in relation to the number of participating centers, but reasonable given that complex elbow dislocations with residual instability after fracture treatment are an uncommon problem. To the best of our knowledge, this is the first prospective study of this size with a highly structured follow up design regarding complex elbow dislocations. The sample size did not allow analysis of a possible effect of fracture types on the patient-reported and clinical outcome measures. Second, because inter- and intraobserver reliability of testing elbow stability is unknown, the decision to use external hinged fixation was and will remain arbitrary. Likewise, some Mason Type II or III fractures are treated with radial head prostheses, whereas others are treated with open reduction and internal fixation or a nonoperative approach. With the medial collateral ligament disrupted after most elbow dislocations, the radial head acts as the primary buttress against valgus stress. One can imagine the importance of stable fracture fixation or radial head replacement on elbow stability in these patients. It is not unlikely that the heterogeneous approach to radial head fractures could have contributed to a difference in outcomes among our patients. A similar discussion accounts for fractures of the coronoid process.

Third, one year of follow up might not have been long enough to know the final patient reported outcome measures and ROM, because the trends of the *Quick*DASH, Oxford Elbow Score, MEPI, and ROM all suggested additional improvement at 1 year. However, the role of osteoarthritis on the long-term outcome remains unknown.

Finally, the different hospitals and surgeons in the current study, rather than the experience of one surgeon, might have been a source of multiple confounding factors, but this emphasizes the generalizability of our results.

Our series show very little disability after external fixator treatment of complex elbow fracture-dislocations. At 2 years, the median *Quick*DASH score of 7 is consistently lower than Quick-DASH scores reported in previous articles on similar types of injuries treated with a hinged fixator (P_{25}-P_{75}, 15-28 points) [17, 20, 33, 34] or treated with ligament repair (P_{25}-P_{75}, 15–28 points). [34-37] The slight disability is paralleled by high scores on the additional patient-reported functional outcome measures. In the current study, most patients reported the maximum score (100 points) for the MEPI. MEPI scores in previous studies of patients with complex elbow injuries range between 75

and 93. [3, 4, 20, 33, 37, 38] The flexion-extension arc result was better than expected. The 118° flexion-extension arc in our patients was in line with those reported for patients treated with ligament repair (P_{25}-P_{75}, 112°-117°) [34-37], but consistently higher than for patients treated with a hinged external fixator (P_{25}-P_{75}, 93°-99°). [3, 20, 38, 39] The latter could be because of the mean time to fixator placement. The most important differences in treatment between the current and previous studies were the use of early active mobilization, no collateral ligaments were reconstructed, and the short interval between trauma and surgery. However although it is likely that a combination of these factors played a role, their individual merit could not be extracted from current data.

Delay in treatment could be an important explanation for the superior results in our study. The mean time to fixator placement in previous studies [3, 20, 38, 39] was between 26 days and 2 months versus 6 days in the current study. Although our study was not designed to define the window of opportunity for surgery, its results emphasize the importance of early reestablishment of a concentric and stable joint, which allows early movement. This is in concordance with Ruch and Triepel [17] who reported flexion-extension arcs of 120° and 84° in patients who underwent early versus delayed treatment with a hinged external fixator, respectively.

The fixator-related complication rate was relatively high in our study. The most frequent complication (five patients), which always resulted in fixator replacement, was joint incongruency. All other complications (pin tract infection, pin tract fractures, and redislocation) also have been reported by others and at similar rates. [8, 39, 40] All surgeons had applied hinged external elbow fixators and attended a compulsory technique-oriented hands-on course before this study. Nevertheless, the most logical explanation for the high complication rate is underexposure of the surgeons to the procedure. This fuels the debate whether hinged elbow fixators should be used only by experienced surgeons. One patient reported moderate instability when evaluating the MEPI (this is the same patient who was treated with a lateral collateral ligament repair). No true recurrent dislocation was seen during the complete follow up in any of the patients. This suggests that surgical repair of the collateral ligaments is not indicated as a standard procedure for adequate healing of the injured collateral ligaments. From experience with ligamentous injuries to the knee and ankle, it is known that ligaments have the ability to heal and to form a scar-like neoligament. Nevertheless, few data are available supporting a nonoperative approach to ligamentous injuries after complex dislocations of the elbow. [16, 33, 34, 41]

This study confirmed that the hinged external elbow fixator provides enough stability to start early mobilization in patients with closed reduction or open treatment after an acute complex elbow dislocation with residual instability. This was reflected in good functional outcome scores and only slight disability despite a relatively high complication rate.

ACKNOWLEDGEMENTS

We thank the Oxford and Isis Outcomes, part of Isis Innovation Limited, for their kind support. We also thank Kiran C. Mahabier (research physician; Trauma Research Unit Department of Surgery, Erasmus MC, Rotterdam, The Netherlands) and Harold Goei, Gerben De Reus, and Liza Van Loon (medical students; Trauma Research Unit Department of Surgery, Erasmus MC, Rotterdam, The Netherlands) for assistance in data collection.

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PART IV

General discussion, summary, and appendices

General discussion

10

DISCUSSION

The treatment of traumatic elbow dislocations is challenged by the joint's complex anatomy and the fact that the elbow is prone to develop post-traumatic stiffness. Immobilization is known as an important risk factor for contracture of the elbow after dislocation. Therefore, the keystone in the treatment of elbow dislocations is to find a balance between two seemingly conflicting principles; to treat instability on one hand whilst preventing stiffness on the other hand.

Stability of the elbow is highly dependent on the integrity and congruency of the joint and its ligaments. As joint capsule and ligaments are known to be disrupted, following a simple elbow dislocation, post-reduction stability is mainly dependent of bony articulations and dynamic stabilizers. [1-3] Earlier experience with injuries to the medial collateral ligament of the knee and lateral collateral ligaments of the ankle learned us that ligaments have the ability to heal to form a scar-like neo-ligament with properties that restore functional stability. [4-6] A small randomized controlled trial confirmed that the same holds true for ligaments of the elbow. The authors demonstrated that surgical repair of torn ligaments in patients with simple traumatic elbow dislocations did not improve joint stability and long-term functional outcome compared to a non-operative approach. [7] Another study demonstrated that if healing tissue was not loaded, regeneration resulted in unstructured scar tissue. Moreover, they found that functional load on healing ligaments cause collagen fibers to heal in a longitudinal direction which optimized the mechanical properties. [8] Equally important is the fact that movement of any synovial joint is essential for the flow of synovial fluid, which plays an important role in the maintenance of articular cartilage. [9] It has been demonstrated, it has been demonstrated that immobilization of a joint may result in pressure necrosis of the cartilage. [10] The concept of early mobilization following an elbow dislocation was discussed in a systematic review which encompassed only one small RCT (n=50) with multiple methodological issues comparing early mobilization with immobilization. The conclusion of the review was that early mobilization led to less extension deficit on the short term with no evidence of benefit at one year. [11, 12] Nevertheless, most surgeons still tend to treat patients with simple elbow dislocations with plaster immobilization, possibly initiated to avoid recurrent dislocations. [13] To answer the question regarding optimal treatment of patients with simple traumatic elbow dislocation, we performed a randomized controlled trial (**Chapter 5)** that compared early mobilization with three weeks of plaster immobilization. *Quick*-DASH scores and range of motion at one year did not differ between the two groups but at six weeks both *Quick*-DASH scores and the arc of flexion and extension were significantly better in the early mobilization group. No recurrent dislocations were observed in both groups and patients treated with early

mobilization returned to work eight days sooner. In conclusion, simple elbow dislocations should be treated with early mobilization. The fear for recurrent dislocations after early mobilization of these type of injuries seems unjustified.

Due to extensive ligamentous injury, bony articulations are the main stabilizers after simple traumatic elbow dislocations. [1-3] As these osseous constraints are compromised in complex elbow dislocations these injuries are often instable post-reduction. [14] In general, plaster immobilization or a hinged brace cannot adequately treat gross elbow instability and redislocation or subluxation during immobilization is common. [1] All protocols that focus on complex elbow dislocations share the common opinion that restoration of the osseous stabilizers should receive top priority. [14-22] Less unanimous are the protocol attitudes regarding the treatment of injured collateral ligaments. Some argue that anatomic and stable repair of all associated fractures will convert the injury into a simple elbow dislocation (one without fractures). [23, 24] Nonetheless, most protocols advise ligamentous repair if instability persists following anatomical reconstruction and stable fixation of the associated fractures. Most protocols focus mainly on the LCL, but some authors even advocate standard repair of the MCL, requiring an additional medial approach [21, 24-26]. They stress the role of the MCL as the primary stabilizer against valgus stress, but ignore the self-healing ability of the ligaments. [25-28] Moreover, the actual role of the MCL in the clinical situation may have been overrated by biomechanical studies. Most cadaver studies possibly undervalue the merit of dynamic stabilizers in the conscious patient. [29, 30] The compressive load that these muscles apply over the joint contributes importantly contributes to stability. [1, 31-34] A recent biomechanical study proved that active extension and flexion adequately stabilized the joint in LCL and MCL deficient elbows. [35] Moreover, one could discuss the frequency of valgus forces during normal daily activities. Valgus stress occurs mainly in high demand patients and throwing athletes. [36-38] An additional argument against ligament repair is provided by a study that demonstrated that most collateral ligament injuries are mid-substance tears which can even be accompanied by proximal or distal detachment of the ligaments (76%). [39] These tears often have two frayed ends like a torn rope making it impossible to anatomically repair them without over-shortening the ligament. Overly tightened or malpositioned ligaments are likely to induce forces beyond the isometric point which may contribute to stiffness or instability with concomitant discongruency of the joint rather than treat it. [40-42]

Alternatives for ligament repair include operative transfixation of the ulnohumeral joint or hinged external fixation. [43] Plaster immobilization is not advised as it is not uncommon for an unstable elbow to re-dislocate in a cast. Moreover, immobilization is associated with stiffness, as was described before. Transfixation of the ulnohumeral joint by cross-pinning equally impedes mobilization, but also damages the articular surface of the ulnohumeral joint and should be reserved for older, infirm patients. [37]

A hinged external elbow fixator theoretically stabilizes the joint while allowing ligaments and fractures to heal, without impeding early mobilization. A novel prospective case series aimed to evaluate the role of early mobilization with a hinged external fixator in the treatment of complex elbow dislocations (**Chapter 9**). The conclusion was that a hinged external elbow fixator provides enough stability to start early mobilization. Patients reported good functional outcome scores and all patients except one had stable elbows after one year. On the other hand, there was a relatively high rate of fixator-related complications, most of which were fixator malalignments. This was most likely due to underexposure of the participating surgeons to this technically demanding procedure. Even in experienced hands the mounting of an external fixator while maintaining a concentric joint is a challenge. [43, 44] Another explanation could be that the minority of the patients with a fracture of the coronoid process were treated with ORIF (18%). There is an increasing understanding of the role of the anteromedial facet of the coronoid process. It serves as an insertion site for the AMCL, the primary constraint against valgus stress. [38, 45, 46] Moreover, it plays a role in varus stability as it protrudes from the proximal ulnar metaphysis medially thereby lengthening the articular surface. [47, 48] It is not unthinkable that, due to unawareness of their existence and unfamiliarity with the relevance of this structure, neglected fractures to the anteromedial facet, importantly influenced the high rate of malalignments. In more than one way this study fueled the debate whether patients with complex elbow instability are better off in the hands of dedicated surgeons. Centralizing these complex type of injuries towards expert clinics will increase the surgeons' understanding and experience. Tailor made treatment strategies, combined with adequate counseling and follow up are the cornerstones in improving functional outcome and quality of life of patients with such a challenging injury.

FUTURE PERSPECTIVES

This thesis answered some questions regarding the treatment of both simple and complex elbow dislocations, but gave rise to many others.

A follow up period of one year might have been too short for arthritic changes to occur. In order to evaluate long-term sequelae of both simple and complex elbow dislocations both prospective studies should be supplemented with a long-term follow up study.

Moreover, patients with similar levels of elbow impairment often reported varying disability. It would be interesting to examine the correlation between perceived disability by the patients and the objective physical impairment after elbow dislocations. What determines impairment more: pain, elbow function, injury to the dominant

side, employment, socio-psychological problems, range of motion, etc, etc? A better understanding of this relationship may be valuable in counseling patients with elbow dislocations and might even result in treatment strategies that improve outcome.

The differences in reported disability could also be explained by subtle residual elbow instability which can be overlooked easily in physical examination. The conduction of a study in which patients from both prospective elbow studies undergo dynamic radiographs during valgus- and varusstress could elucidate this hypothesis.

Furthermore, it would be interesting to compare functional outcome in patients from the complex elbow dislocation study (no ligamentous reconstruction; **chapter 9**) with patients from a surgeon who always reconstructs (lateral) collateral ligaments in a case control study. The most prevalent type of complex dislocation that would make the most homogeneous population are patients with a dislocation accompanied by fractures of the radial head and coronoid process ("Terrible triad injury"). It would not provide us the answers we would acquire with a randomized trial, but such a study is easier to conduct and would definitely bring us a step closer to the definite answer to the question "do I use an external fixator or do I reconstruct the ligaments in my patient with a complex elbow dislocation?"

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I. Summary
II. Samenvatting

11

I. SUMMARY

Chapter 1 is the introduction of this thesis. The elbow is the second most common major joint to dislocate after the shoulder in the adult population. Its primary stabilizers are the articulation between the proximal ulna and the distal humerus, the anterior bundle of the medial collateral ligament (against valgus stress) and the lateral collateral ligament complex (against varus stress). Dislocations are traditionally classified by the presence (complex dislocations) or absence (simple dislocations) of associated fractures and by the direction of the displacement of the forearm relative to the humerus. There is a paucity in evidence concerning the optimal aftertreatment in terms of whether to immobilize or not, for both simple and complex elbow dislocations. Also the necessity of surgical repair of all injured ligaments, as well as the role of a hinged external fixator in the treatment of complex elbow dislocations, remains subject of debate.

Chapter 2 aimed to assess population-based trends in the incidence of upper extremity injuries in the Dutch population between 1986 and 2008, and to give a detailed overview of the associated health care costs. The overall age-adjusted incidence of upper extremity injuries increased from 970 to 1,098 per 100,000 persons (13%) in the period 1986–2008. The highest incidence was seen in young persons and elderly women. Total annual costs for all injuries were 290 million euro, of which 190 million euro were paid for injuries sustained by women. Wrist fractures were the most expensive injuries (83 million euro) due to high incidence, whereas upper arm fractures were the most expensive injuries per case (4,440 euro). Major cost peaks were observed for fractures in elderly women due to high incidence and costs per patient.

Chapter 3 aimed to examine the recent long-term population-based incidence trend of elbow dislocations in the adult Dutch population between 1986 and 2008 and to give a detailed overview of the associated health care costs in 2007. The mean incidence rate over time was 5.6 per 100,000 person years. The total costs for elbow dislocations were € 1.63 million per year. The majority of these costs were accounted for by the female population (€ 1.14 million versus € 0.49 million by males). The average costs per case were € 2,555.

Chapter 4 and 5 describe the protocol and results of a randomized clinical trial comparing early mobilization and plaster immobilization in patients with a simple traumatic elbow dislocation. One hundred patients were randomized to early mobilization (immediate motion exercises; n=48) or three weeks plaster immobilization (n=52). Follow up was one year. *Quick*-DASH scores at one year were 4.0 [95% CI 0.9-7.1] points in the early mobilization group versus 4.2 [95% CI 1.2-7.2] in the plaster

immobilization group. At six weeks early mobilized patients reported less disability (*Quick*-DASH 12 [95% CI 9-15] points versus 19 [95% CI 16-22]; p<0.05) and had a larger arc of flexion and extension (121° [95% CI 115-127] versus 102° [95% CI 96-108]; p<0.05). There were no recurrent dislocations and patients returned to work eight days sooner after early mobilization (10 versus 18 days; p=0.020). In conclusion, patients should be treated with early mobilization following closed reduction of simple elbow dislocations. Patients recover faster and return to work earlier. The fear for recurrent instability seems unjustified.

Chapter 6 assessed and compared the total costs (direct health care costs and indirect costs due to loss of production) after early mobilization versus plaster immobilization in patients with a simple elbow dislocation. Also, it aimed to evaluate cost-effectiveness. Data of the randomized clinical trial described in **chapter 5** was used. There were no significant differences in health-related quality of life measured with the EQ-5D, SF-36 PCS, and SF-36 MCS between the two groups throughout the 1-year follow up. Mean total costs per patient were €3,624 in the early mobilization group versus €7,072 in the plaster group (p=0.094). Shorter work absenteeism in the early mobilization group (10 versus 18 days; p=0.027) did not lead to significantly lower costs for productivity loss (€1,719 in the early mobilization group versus €4,589; p=0.120). In conclusion, plaster immobilization has inferior results at almost double the costs. From a clinical as well as a socio-economic point of view, early mobilization should be the treatment of choice for a simple elbow dislocation.

Chapter 7 aimed to investigate the reliability, the validity and responsiveness of the Dutch version of the Oxford Elbow Score (OES) in adult patients with non-surgically treated simple elbow dislocations. Data of the randomized clinical trial described in **chapter 5** was used. The OES demonstrated adequate internal consistency (Cronbach α, 0.92). The construct- and longitudinal validity was supported by a high degree of correctly hypothesized correlations with other PROMs. The anchor- and distribution based minimal clinically important difference (MCID) values for the OES total score were 8.2 and 11.9 points, respectively. There were no floor effects and the OES was the latest PROM to demonstrate a ceiling effect. In conclusion, the Dutch version of the OES is a reliable, valid and responsive instrument for evaluating elbow related quality of life. Even in non-operatively treated patients.

Chapter 8 and 9 describe the protocol and results of a prospective multicenter case series which evaluated the use of a hinged elbow fixator in the treatment of complex elbow dislocations in terms of functional outcome, range of motion and fixator-related adverse events. The median Quick-DASH score was 6.8 points after one year. The me-

dian VAS score for pain was 0.5, the MEPI was 100 points and the OES was 90 points. The median flexion-extension and pronation-supination arcs were 118 and 160 degrees, respectively. One patient reported recurrent instability. Ten patients (37%) experienced fixator-related complications of whom seven patients (26%) required secondary surgery. In conclusion, hinged external fixation provides enough stability to start early mobilization after an acute complex elbow dislocation with residual instability after fracture treatment. This is reflected in good functional outcome scores and only slight disability despite a relatively high complication rate.

CONCLUSIONS

Chapter 2

* The overall incidence of upper extremity injury in the Netherlands increased by 13% in the period 1986–2008.
* A substantial share of total costs (€ 290 million) was accounted for by females with upper extremity fractures (42%) and especially women with wrist fractures (21%).

Chapter 3

* The mean incidence rate of elbow dislocations in the Netherlands between 1986 and 2008 is 5.6 per 100,000 person years.
* The total costs for elbow dislocations were € 1.63 million per year.
* Costs per case (€ 2,555) approximate those of elbow fractures (€ 3,297).

Chapter 4 and 5

* Early active mobilization is a safe and effective treatment in simple traumatic elbow dislocation. Patients recovered faster and returned to work earlier. The fear for recurrent dislocation seems unjustified.

Chapter 6

* Plaster immobilization has inferior results at almost double costs, and should therefore be abandoned in patients with simple elbow dislocations.
* Altering treatment protocols in the Netherlands could reduce care costs with at least 3.2 Million Euro each year.

Chapter 7

* The Dutch version of the OES is a reliable, valid and responsive instrument for evaluating elbow related quality of life, also in non-operatively treated patients.

Chapter 8 and 9

* A hinged external elbow fixator provides enough stability to start early mobilization after an acute complex elbow dislocation.
* Fixator malalignment is a frequently observed complication.

II. SAMENVATTING

Hoofdstuk 1 is de introductie van dit proefschrift. De elleboog is op de schouder na, het meest frequent geluxeerde grote gewricht. De primaire stabilisatoren zijn de articulatie tussen de proximale ulna en de distale humerus, the anterieure streng van het mediale collaterale ligament (tegen valgus stress) en het laterale collaterale ligamentaire complex (tegen varus stress). Van oudsher worden ellebooglu xaties ingedeeld naar de aan- (complexe luxaties) of afwezigheid (eenvoudige luxaties) van fracturen en naar de richting van de verplaatsing van de onderarm ten opzichte van de humerus. Er is weinig bekend over de optimale nabehandeling met betrekking tot het wel of niet immobiliseren van simpele dan wel complexe ellebooglu xaties. Met betrekking tot complexe ellebooglu xaties is het nog onduidelijk of het al dan niet herstellen van geruptureerde collaterale ligamenten nodig is en wat de rol van de dynamische fixateur in de behandeling kan zijn.

Hoofdstuk 2 had als doel om een overzicht te geven van de lange termijn trends in incidentie en geassocieerde zorgkosten van letsels van de bovenste extremiteit in de Nederlandse bevolking tussen 1986 en 2008. De incidentie van letsels aan de bovenste extremiteit is in deze periode van 970 naar 1098 per 100.000 persoonsjaren gestegen (13%). De hoogste incidentiecijfers werden gezien bij jongeren en oudere vrouwen. De totale zorgkosten voor alle letsels gecombineerd bedroegen 290 miljoen euro, waarvan 190 miljoen euro bij vrouwen. Polsfracturen zijn het duurst (83 miljoen euro) vanwege de hoge incidentie. Humerusfracturen hebben de hoogste kosten per patiënt (4440 euro). Een hoge piek in kosten werd gezien bij oudere vrouwen welke met name werden veroorzaakt door een combinatie van de hoge incidentie en de hoge kosten per patiënt.

Hoofdstuk 3 geeft een overzicht van de lange termijn trends in incidentie en geassocieerde zorgkosten van traumatische ellebooglu xaties in de Nederlandse bevolking tussen 1986 en 2008. De gemiddelde incidentie was 5,6 per 100.000 persoonsjaren. De gemiddelde directe kosten voor ellebooglu xaties bedroegen € 1,63 miljoen per jaar. Vrouwen waren verantwoordelijk voor het grootste gedeelte van deze kosten (€ 1,14 miljoen versus € 0,49 miljoen). De kosten per luxatie bedroegen € 2.555.

Hoofdstuk 4 en 5 beschrijven het protocol en de resultaten van een gerandomiseerde klinische studie welke, bij patiënten met een eenvoudige ellebooglu xatie, vroege mobilisatie vergelijkt met gipsimmobilisatie. Honderd patiënten werden gerandomiseerd tussen vroege mobilisatie (direct oefenen; n=48) of drie weken gips immobilisatie (n=52). De follow up periode was een jaar. De *Quick*-DASH scores na een jaar waren 4,0 [95% CI 0,9-7,1] punten in de vroege mobilisatie groep tegenover 4,2 [95% CI 1,2-

7,2] in de met gips behandelde groep. Echter, na zes weken rapporteerden de vroeg gemobiliseerde patiënten wel minder beperkingen (*Quick*-DASH 12 [95% CI 9-15] punten versus 19 [95% CI 16-22]; p<0,05). Ook was de boog van flexie en extensie in deze groep groter (121° [95% CI 115-127] versus 102° [95% CI 96-108]; p<0,05). Er werden geen re-luxaties gezien en patiënten waren acht dagen eerder aan het werk na vroege mobilisatie (10 versus 18 dagen). Patiënten met een simpele traumatische ellebooglu xatie kunnen veilig vroegtijdig gemobiliseerd worden. Patiënten herstellen sneller en zijn eerder in staat hun werkzaamheden te hervatten. Zorgen over een kans op reluxaties lijken ongegrond.

Hoofdstuk 6 beschrijft de totale kosten (directe zorgkosten en indirecte kosten veroorzaakt door werkverzuim) na vroege mobilisatie en vergelijkt deze met de kosten voor gipsimmobilisatie in patiënten met een eenvoudige ellebooglu xatie. Ook had deze studie als doel om de kosten-effectiviteit te bepalen. Hiertoe is gebruik gemaakt van de data van de gerandomiseerde studie die in **hoofdstuk 5** is beschreven. Gedurende de gehele follow up van een jaar was er geen verschil in gezondheids-gerelateerde kwaliteit van leven (gemeten met de EQ-5D, SF-36 PCS, en SF-36 MCS) tussen de twee groepen. De mediane totale kosten per patiënt waren €3.624 in de vroege mobilisatie groep versus €7.072 in gips groep (p=0,094). Korter werkverzuim in de vroege mobilisatiegroep (10 versus 18 dagen; p=0,027) heeft niet geleid tot lagere kosten voor werkverzuim (€1.719 in de vroege mobilisatie groep versus €4.589; p=0,120). Concluderend geeft gipsimmobilisatie inferieure resultaten terwijl de kosten bijna twee maal zo hoog zijn. Zowel vanuit klinisch oogpunt alsook vanuit een sociaaleconomisch perspectief, zou vroege mobilisatie de behandeling van keuze moeten zijn bij patiënten met een eenvoudige ellebooglu xatie.

Hoofdstuk 7 had als doel om de betrouwbaarheid, validiteit en bruikbaarheid van de Nederlandse versie van de Oxford Elbow Score (OES) te onderzoeken bij patiënten met een eenvoudige ellebooglu xatie. Hiertoe is gebruik gemaakt van de data van de gerandomiseerde studie die in **hoofdstuk 5** is beschreven. De OES liet adequate betrouwbaarheid zien (Cronbach alpha 0,92). De construct- en longitudinale validiteit werden bevestigd door een hoog aantal juist voorspelde correlaties met de andere meetinstrumenten. Het minimaal klinisch relevant verschil (MCID) was 8,2 punten middels de ankermethode en 11,9 punten middels de distributie-gebaseerde methode. Er waren geen vloereffecten en de OES bereikte als laatste meetinstrument het plafondeffect. Concluderend is de Nederlandse versie van de OES een betrouwbaar, valide en bruikbaar instrument om de elleboog-gerelateerde kwaliteit van leven te meten.

Hoofdstuk 8 en 9 beschrijven het protocol en de resultaten van een prospectieve multicenter case series naar het gebruik van een dynamische fixateur in de behandeling van complexe traumatische ellebooglуxaties. Met name werden functionele uitkomst, range of motion en fixateur gerelateerde complicaties bestudeerd. De mediane *Quick*-DASH score bedroeg 6,8 punten na een jaar. De mediane VAS (pijn) bedroeg 0,5 op een schaal van nul tot tien, de MEPI was 100 punten en de OES 90 punten. De mediane boog van flexie en extensie was 118 graden de boog van pro- en supinatie was 160 graden. Slechts een persoon rapporteerde instabiliteit. Complicaties deden zich bij 10 patiënten (37%) voor, hiervan moesten er zeven (26%) opnieuw geopereerd worden. Een externe fixateur biedt voldoende stabiliteit om vroeg te mobiliseren na een complexe traumatische ellebooglуxatie die persisterend instabiel is. Dit resulteerde in goede functionele uitkomsten en beperkte rest-invaliditeit. Wel deden zich relatief veel complicaties voor.

CONCLUSIES

Hoofdstuk 2

* De incidentie van letsel aan de bovenste extremiteit in Nederland is tussen 1986 en 2008 met 13% gestegen.
* Het merendeel van de totale kosten (€290 miljoen) werd bepaald door vrouwen met een fractuur (42%), met name door vrouwen met een polsfractuur (21%).

Hoofdstuk 3

* De gemiddelde incidentie van traumatische ellebooglуxaties in Nederland tussen 1986 en 2008 bedroeg 5,6 per 100.000 persoonsjaren.
* De totale kosten voor ellebooglуxaties bedroegen € 1,63 miljoen per Jaar.
* De kosten per luxatie (€ 2.555) benaderen de kosten voor elleboogfracturen (€ 3.297).

Hoofdstuk 4 and 5

* Patiënten met een simpele traumatische ellebooglуxatie dienen vroeg gemobiliseerd te worden. Ze herstellen sneller en zijn eerder weer aan het werk. De zorgen over een kans op reluxaties lijken ongegrond.

Hoofdstuk 6

* Gipsimmobilisatie geeft inferieure resultaten terwijl de kosten bijna tweemaal zo hoog zijn en dient derhalve verlaten te worden in de behandeling van patiënten met een eenvoudige ellebooglуxatie.

* Het wijzigen van behandelprotocollen in Nederland zou op jaarbasis 3,2 miljoen euro kunnen besparen.

Hoofdstuk 7

* De Nederlandse versie van de OES is een betrouwbaar, valide en bruikbaar instrument om de elleboog-gerelateerde kwaliteit van leven te meten. Zelfs in patiënten met een non-operatief behandeld ellebooglетsel.

Hoofdstuk 8 en 9

* Een externe fixateur biedt voldoende stabiliteit om vroeg te mobiliseren na een complexe ellebooglуxatie die persisterend instabiel is.
* Een verkeerd geplaatste fixateur is de meest voorkomende complicatie.

Appendices

I. Contributing authors
II. Dankwoord
III. PhD portfolio
IV. Curriculum vitae

12

I. CONTRIBUTING AUTHORS

Ed F. van Beeck
Department of Public Health, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands

Roelf S. Breederveld
Department of Surgery, Red Cross Hospital, Beverwijk, The Netherlands

Maarten W.G.A. Bronkhorst
Department of Surgery, Bronovo Hospital, The Hague, The Netherlands

Johan G.H. van den Brand
Department of Surgery, Medical Center Alkmaar, Alkmaar, The Netherlands

Boudewijn J. Dwars
Department of Surgery, Slotervaart Hospital, Amsterdam, The Netherlands

Denise Eygendaal
Department of Orthopaedic Surgery, Upper Limb Unit, Amphia Hospital, Breda, The Netherlands

J. Carel Goslings
Trauma Unit, Department of Surgery, Academic Medical Center, Amsterdam, The Netherlands

Jeroen de Haan
Department of Surgery, Westfriesgasthuis, Hoorn, The Netherlands

Dennis den Hartog
Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Dep. of Surgery, Rotterdam, The Netherlands

Robert Haverlag
Department of Surgery, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands

Esther M.M. Van Lieshout
Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Dep. of Surgery, Rotterdam, The Netherlands

Frits M. van der Linden
Department of Surgery, Groene Hart Hospital, Gouda, The Netherlands

Sven A.G. Meylaerts
Department of Surgery, Medical Center Haaglanden, The Hague, The Netherlands

Hub G.W.M. van der Meulen
Department of Surgery, Haga Hospital, The Hague, The Netherlands

Jan-Willem R. Mulder
Department of Surgery, Zaans Medical Center, Zaandam, The Netherlands

Martien J.M. Panneman
Consumer & Safety Institute, Amsterdam, The Netherlands

Peter Patka
Department of Emergency Medicine, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands

Suzanne Polinder
Department of Public Health, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands

Kees J. Ponsen
Trauma Unit, Department of Surgery, Academic Medical Center, Amsterdam, The Netherlands

Steven J. Rhemrev
Department of Surgery, Medical Center Haaglanden, The Hague, The Netherlands

W. Herbert Roerdink
Department of Surgery, Deventer Hospital, Deventer, The Netherlands

Gert R. Roukema
Department of Surgery, Maasstad Hospital, Rotterdam, The Netherlands

Niels W.L. Schep
Trauma Unit, Department of Surgery, Academic Medical Center, Amsterdam, The Netherlands

Inger B. Schipper
Department of Trauma Surgery, Leiden University Medical Center, Leiden The Netherlands

Michel A. Schouten
Department of Surgery, Hospital Rivierenland, Tiel, The Netherlands

Jan Bernard Sintenie
Department of Surgery, Elkerliek Hospital, Helmond, The Netherlands

Senail Sivro
Department of Surgery, Flevo Hospital, Almere, The Netherlands

Wim E. Tuinebreijer
Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Dep. of Surgery, Rotterdam, The Netherlands

Michiel H.J. Verhofstad
Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Dep. of Surgery, Rotterdam, The Netherlands

Egbert J.M.M. Verleisdonk
Department of Surgery, Diakonessenhuis, Utrecht, The Netherlands

Mark R. de Vries
Department of Surgery, Reinier de Graaf Groep, Delft, The Netherlands

Jos P.A.M. Vroemen
Department of Surgery, Amphia Hospital, Breda, The Netherlands

Marco Waleboer
Department of Surgery, Admiraal de Ruyter Hospital, Goes, The Netherlands

W. Jaap Willems
Department of Orthopaedic Surgery, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands

Philip Wittich
Department of Surgery, St. Antonius Ziekenhuis, Nieuwegein, The Netherlands

II. DANKWOORD

Er is een aantal mensen dat ik graag bij naam wil noemen, omdat zij nóg meer dan anderen hebben bijgedragen aan het behalen van de finishlijn.

Alle lokale hoofdonderzoekers, arts-assistenten en polidames van de deelnemende klinieken, bedankt voor jullie inzet, flexibiliteit en geduld.

Prof. dr. Patka, toen u na een jaar onderzoek de helft van de stukken uit de hypothetische inhoudsopgave van mijn conceptproefschrift schrapte, omdat er geen lijn in zat, zonk de moed me in de schoenen. Achteraf had u natuurlijk gelijk. Veel beter zo. **Prof. dr. Verhofstad**, even was ik nerveus dat er een tweede correctieronde van de boven genoemde inhoudsopgave zou gaan plaatsvinden, toen u de troon overnam. Dit bleek ongegrond. Dank voor uw beider helikopter-view, scherpe commentaren en waardevolle aanvullingen.

Dennis, toen ik destijds gedesillusioneerd uit de sollicitatie ronde voor de opleiding kwam en bij jullie aanklopte voor hulp bij het oppoetsen van mijn CV, haalde jij mij binnen, ondanks dat je wist dat mijn hart in de kliniek lag. Dank voor dat vertrouwen en de kans die jullie me hiermee boden. Ook bedankt voor de pep(er in m'n reet) talks.

Niels, van alle 50.000 kilometers die ik gereden heb om mijn data te verzamelen, werden de kilometers naar het AMC het meest beloond. Hoe vol je spreekuur ook was, je maakte altijd even tijd om bij te praten, mijn vragen te beantwoorden en om te pronken met casuïstiek en postoperatieve foto's. Dank voor je enthousiasme.

Esther, hoe jij altijd meer dagen in een week, meer uren in een dag en minuten in een uur weet te proppen is me een raadsel. Je was de afgelopen jaren afwisselend de wind, de zeilen en de roerganger die dit schip tussen de klippen door manoeuvreerde. Zonder jou was dit volstrekt onmogelijk geweest.

Ruben, dank voor dat ene telefoontje.

Ted, Kees, Wouter, Annemarie, Boudewijn, Akkie, Nike, Wibo en dr. Boelhouwer, bedankt voor drie prachtige jaren waarin voor mij bevestigd is dat er echt geen mooier vak bestaat dan het onze.

Koen. **Könes**, dierbare vriend en "lotgenoot", bedankt voor heel erg veel. Laten we hier snel een chouffe'je op drinken. Misschien mag **Freek** wel mee…

Died en Sieb, mijn besten vanaf het begin. Laten we in godsnaam vaker bomen om gaan duwen en zo nu en dan bier drinken.

Moes, mijn geweldige moeder. Ik heb een oneindige bewondering voor hoe je het in je eentje geklaard hebt en klaart. Je bent mijn held en voorbeeld. **Heleen en Coen**, mijn twee mallotige nestgenoten en allerbeste vrienden. Er verandert veel in onze drie levens. Goed om te zien dat jullie lekker jezelf blijven. **Paul en Britt**, keep up the good work.

Tellie, jij bent mijn thuis en het leven is beter met jou. **Schimp** (werktitel!), je bent zó welkom, je hebt (nog) geen idee.

III. PHD PORTFOLIO

Name PhD student: Gijs I.T. Iordens
Erasmus MC Department: Trauma Research Unit, Department of Surgery

PhD period: 2010 – 2015
Promotor(s): Prof.dr. M.H.J. Verhofstad, Prof.dr. P. Patka
Supervisor: Dr. D. den Hartog
Dr. N.W.L. Schep

1. PhD training	Year	Workload (ECTS)
General courses		
- Biomedical English Writing and Communication	2011	4
- ICH-GCP	2013	1
- OTC Course: Principles of Clinical Research	2011	1.5
Specific courses (e.g. Research school, Medical Training)		
- LISA (Lowlands Institute of surgical and applied Anatomy)	2012 – 2015	2
- CASH (Cursorisch onderwijs Aios heelkunde)	2012 – 2015	2
Seminars and workshops		
- Department research meetings	2010 – 2012	3
- Advanced Elbow Course	2011	1
Presentations		
- National conferences	2011	4
- National conferences	2012	2
- International conferences	2012	2
- National conferences	2013	4
- International conferences	2013	2
- National conferences	2014	4
- International conferences	2014	5

2. Teaching	Year	Workload (ECTS)
Lecturing		
- Teaching nurses in training	2010 – 2015	0.5
- Onderwijs aan co-assistenten	2012 – 2015	0.5
Supervising practicals and excursions, Tutoring		
- Examination of Basic Life Support for medical students	2011, 2012	0.5
Supervising Master's theses		
- Supervising medical students	2011	4
Other		
- Department journal club	2010 – 2015	1

IV. CURRICULUM VITAE

Gijsbert ("maar we noemen hem Gijs") Ioan Timon Iordens werd 26 april 1981 in Amsterdam geboren. Na zijn eindexamen op het Sint Vitus College in Bussum besloot hij het meeloten voor de opleiding geneeskunde een jaar uit te stellen. Hij monsterde aan op de "Swan Fan Makkum" een schip dat de basis bleek van een jaar vol avonturen. In 2001 startte Gijs zijn studie geneeskunde aan de Erasmus Universiteit Rotterdam. Hij zette zijn jaren als student luister bij door lid te worden van het Rotterdamsch Studenten Corps van waaruit hij enkele jaren lang deel uit maakte van het illustere medisch studententeam "Les Forgerons". Dit team introduceerde hem via het werk op de spoedeisende hulp en de OK van het Ikazia ziekenhuis met de gang van zaken in het ziekenhuis en binnen de chirurgie in het bijzonder.

Zijn interesse voor de heelkunde was gewekt. In 2005 vertrok hij naar Ghana waar hij in het St. Patrick's Hospital in Offinso (met uroloog dr. J.G. de Wall) een klinische stage liep. Het jaar er op was Boston de bestemming voor een wetenschappelijk avontuur aan de Hand and Upper Extremity Service in het Massachusetts General Hospital (dr. D. Ring). Na een keuze co-schap op de trauma-unit van het Johannes General Hospital (Johannesburg, Zuid-Afrika) en zijn afstuderen in 2009 solliciteerde hij voor een ANIOS plek heelkunde in het MCRZ (huidig Maasstadziekenhuis).

Na ander half jaar als chirurgisch assistent gewerkt te hebben solliciteerde hij in 2010 bij de Trauma Research Unit van het Erasmus MC (TRUE). Hier heeft hij zich gefocust op letsels van de bovenste extremiteit en later specifiek op ellebooglуxaties. Hieruit zou uiteindelijk de voltooiing van dit proefschrift voort vloeien. Op 1 juli 2012 is Gijs gestart met zijn opleiding tot chirurg in het Ikazia ziekenhuis (Opleider: dr. P.T. den Hoed). Na drie onvergetelijke jaren aldaar heeft hij vanaf 1 oktober 2015 de opleiding voortgezet in het Erasmus MC (Opleider: dr. B.P.L. Wijnhoven)

Traumatic Elbow Dislocations

Gijs I.T. Jordens