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

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Primary objective:To study the Quick-DASH (Disabilities of the Arm, Shoulder, and Hand) scores, reflecting functional outcome and pain in patients who sustained a complex elbow dislocation and were treated with ORIF and/or arthroplasty and a hinged...

Ethical review	Approved WMO
Status	Completed
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON36547

Source
ToetsingOnline

Brief title
Elbow fixator

Condition

- Joint disorders

Synonym
Complex elbow dislocation, elbow dislocation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cohort study, Complex elbow dislocation, Elbow fixator, Fractuur

Outcome measures

Primary outcome

Quick-DASH (Disabilities of the Arm, Shoulder, and Hand) score

Secondary outcome

Mayo elbow performance index (MEPI)

Oxford Elbow Score

Pain level at both sides (VAS)

Range of motion at both sides

Radiographic healing of the fractures

Rate of secondary interventions

Rate of complications

Health-related quality of life (Short Form-36; SF-36)

Study description

Background summary

The elbow joint is the second most commonly dislocated joint in adults. The annual incidence of elbow dislocations is 6.1 per 100.000. Complex dislocations of the elbow are associated with fractures. The majority of elbow fractures in adults involves the radial head (30%), the olecranon process (20%), or the coronoid process (10-15%).
The fundamental goal in the management of fracture dislocation of the elbow is the restoration of the osseous-articular restraints. Therefore, the majority of these complex dislocations is treated with open reposition and internal fixation (ORIF) and/or arthroplasty. Due to ligament disruption, complex elbow dislocations are at risk of persistent instability if not treated adequately. The current postoperative management of instable elbows following ORIF and/or arthroplasty consists of primary ligament repair and/or a period of

plaster immobilization.
A period of plaster immobilization after ORIF may result in a limited range of motion of the elbow joint with subsequent stiffness and (major) disability. A hinged external elbow fixator, on the other hand, may provide enough stability to start early mobilization after surgery. This may potentially limit future disability due to restricted motion.

Study objective

Primary objective:
To study the Quick-DASH (Disabilities of the Arm, Shoulder, and Hand) scores, reflecting functional outcome and pain in patients who sustained a complex elbow dislocation and were treated with ORIF and/or arthroplasty and a hinged external fixator.

Secondary objectives:
1. To examine the Mayo elbow performance index (MEPI) in patients who were treated with ORIF and/or arthroplasty and an hinged external fixator after a complex elbow dislocation
2. To examine the Oxford Elbow Score in patients who were treated with ORIF and/or arthroplasty and an hinged external fixator after a complex elbow dislocation
3. To determine the level of pain (recorded using a Visual Analogue Scale; VAS) experienced by the patients who were treated with ORIF and/or arthroplasty and an hinged external fixator after a complex elbow dislocation
4. To determine the range of motion of the elbow joint in patients who were treated with ORIF and/or arthroplasty and an hinged external fixator after a complex elbow dislocation
5. To determine the rate of secondary interventions and other postoperative complications (i.e., reluxations, instability, heterotopic ossifications, infections, bleeding, venous thrombosis and neurological deficit) in patients who were treated with ORIF and/or arthroplasty and an hinged external fixator after a complex elbow dislocation
6. To determine the time to radiographic healing in patients who were treated with ORIF and/or arthroplasty and an hinged external fixator after a complex elbow dislocation
7. To determine the health-related quality of life (Short Form-36, SF-36) in patients who were treated with ORIF and/or arthroplasty and an hinged external fixator after a complex elbow dislocation

Study design

Multicenter cohort study

Intervention

Hinged external elbow fixator

Study burden and risks

The intervention is a standard of care treatment modality.
The clinic follow-up visits at t=2 and 6 weeks, and 3, 6, and 12 months are part of Standard of Care.
The same holds true for the X-rays at t=2 and 6 weeks, and 3, 6, and 12 months, and the pre-operative X-ray or CT-scan (for diagnosis).
Patients are asked to complete a set of questionnaires at the clinic FU visits mentioned. There are no risks involved in this.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

If any of the following criteria applies, patients will be excluded:
1. Patients with distal intra-articular humeral fractures
2. Patients with additional traumatic injuries of the affected upper limb
3. Patients who underwent repair of the collateral ligaments
4. Patients with an impaired elbow function (i.e., stiff or painful elbow or neurological disorder of the upper limb) prior to the injury
5. Retained hardware around the affected elbow
6. Likely problems, in the judgment of the investigators, with maintaining follow-up (e.g., patients with no fixed address will be excluded)
7. Insufficient comprehension of the Dutch language to understand the rehabilitation program and other treatment information in the judgment of the attending physician
Exclusion of a patient because of enrolment in another ongoing drug or surgical intervention trial will be left to the discretion of the attending surgeon, on a case-by-case basis

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-08-2009

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	27-08-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23505
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL28503.078.09
OMON	NL-OMON23505