Long Term Outcomes of Fractures of Both Bones of the Forearm

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Ethical review	Approved WMO
Status	Pending
Health condition type	Fractures
Study type	Observational invasive

Summary

ID

NL-OMON33735

Source
ToetsingOnline

Brief title
Long term outcomes both bones fractures

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
arm fracture, both bones fractures

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Both bones, Long Term, Outcome, Trauma

Outcome measures

Primary outcome

* Primary Study Question: Does depression as measured by the CESD account for a

greater portion of the variability in DASH scores than forearm arc of motion?

Secondary outcome

* Secondary Study Questions:

What are the predictors of DASH scores from among the following:

depression, motion and radiographic measures?

Study description

Background summary

Internal fixation of both bones diaphyseal forearm fractures has been associated with high union rates[1]. Healing occurs reliably after closed reduction but malunion, with resultant decreased range of motion is a rare but important complication. Stabilization with internal plate fixation restores nearly normal anatomy and motion. However, a moderate reduction in strength should be anticipated[1, 2].
The purpose of the study is to investigate long term objective and subjective patient based outcomes. Secondly, univariate and multivariate analyses will be performed to identify objective and subjective predictors of disability as measured with the Disability of Arm, Shoulder and Hand (DASH), and the clinical outcome according to the Modified Mayo Wrist Score (MMWS) [19] and the Modified Gartland and Werley Score (MGWS).

Prior to the AO era of open reduction and internal fixation, treatment of diaphyseal forearm fractures was problematic. Plates *solved* the problem of diaphyseal forearm fractures. Already in 1972, orthopaedic surgeons reported rates of union greater than 95% with ASIF compression plates[3, 4]. Multiple studies show predictable rates of healing and low complication rate of ORIF for both bones forearm fractures[3, 5-14]. Only severe compound fractures, grade IIIB and C are associated with unsatisfactory outcome[7]. Open reduction and

internal fixation is the evidence-based standard of care[1-3, 5-14].
It is a notable achievement of orthopaedic surgery that a formerly problematic injury has been transformed into one that we can repair so that the patients has very little objective impairment. It is a true success story of orthopaedics[2].
In this context, it is notable that disability after this injury does NOT correlate with impairment, at least according to Droll and coleagues[1]. They concluded that perceived disability as measured with the DASH and SF-36 questionnaires is determined by pain more than by objective physical impairment. If this finding can be confirmed in Dutch patients with even longer follow-up, it will establish definitively the substantial and largely unexplained gap between objective impairment and subjective disability[15]. This finding would establish that even the best orthopaedic treatments are not sufficient to optimize health and well-being and a more comprehensive biopsychosocial model of illness *even obvious illnesses such as fractures* is merited and worthwhile.

Study objective

The aim of this project is to assess objective impairment and arm-specific disability (DASH scores) in long-term follow-up of patients with diaphyseal fractures of both bones of the forearm treated with open reduction and plate and screw fixation, and to determine the correlation between impairment and disability.

* Primary Study Question: Does depression as measured by the CESD account for a greater portion of the variability in DASH scores than forearm arc of motion?

* Secondary Study Questions:
What are the predictors of DASH scores from among the following: depression, motion and radiographic measures?

Hypothesis: We expect that subjective factors *i.e. pain and depression as measured by CESD-NL and PCS* account for a greater portion in the variability of DASH scores than objective measures such as forearm motion and radiographic outcome.

Study design

* Study Subjects, specimens or materials
We will collect data from the AO trauma database and clinical charts of all patients that have been treated with open reduction and internal fixation for fractures of both bones of the forearm between 1974 and 1998 to allow for at least 10 years follow-up. .

* Effect and outcome variables

Classification and description of fractures of both bones of the forearm and radiological quantification of distal radial intra-articular incongruity if present (mm).

Arm function as quantified by the following scoring systems:

* The Disabilities of the Arm, Shoulder and Hand questionnaire (DASH)[18, 19] is scaled from 0 *100 point with higher scores indicating worse upper extremity-specific disability.

Radiographic follow up with standard forearm projections, Anterior-posterior (AP), Lateral (LAT) and Oblique views (OBL). Standard measurements for radial tilt, volar inclination and ulnar variance will be used.

* Methods for taking measurements
Informed consent will be obtained from all patients prior to enrollment. Only patients older than 18 years will be included.

Demographic and injury related data will be obtained from the AO-AMC trauma database and the patients* clinical charts.

The DASH questionnaire will be filled out by the patients at their long-term follow up appointment. Range of motion in the radio-ulnar deviation, pronation-supination and flexion-extension arcs will be measured with a hand held goniometer. Lastly, objective evaluation for grip strength (max of 3 attempts with dynamometer 3rd station, elbow at 90 and neutral) will be performed by authors not involved in the patient care.

Study burden and risks

Not applicable

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

We will collect data from the AO trauma database and clinical charts of all patients that have been treated with open reduction and internal fixation for fractures of both bones of the forearm between 1974 and 1998 to allow for at least 10 years follow-up

Exclusion criteria

Patients younger than 18 years.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL25786.018.08