

Protocol Registration Receipt
05/28/2014

Volar Locking Plate Versus External Fixator/Cast Fixation for the Treatment of Distal Radius Fractures

This study has been completed.

Sponsor:	Mackay Base Hospital
Collaborators:	James Cook University, Queensland, Australia
Information provided by (Responsible Party):	Dr. Herwig Drobetz, Mackay Base Hospital
ClinicalTrials.gov Identifier:	NCT00809861

► Purpose

Aim: Osteosynthesis with locking plate/screws has become increasingly popular in recent years. It is the only treatment option which allows immediate postoperative immobilization. However, compared to conservative treatment or treatment with external fixators, locking plates are very expensive and the operation can be very challenging, even for experienced surgeons. The long-term results of all treatment modalities are equal, which has been shown in numerous studies. However, there are no evidence based studies published yet which look at short-term outcomes. The investigators do feel but do not know that patients who do not need postoperative immobilization return to work significantly earlier or are independent faster than patients whose wrists are immobilized for up to 6 weeks. If that is the case, then the higher costs and risks of the operation are justified, if not, then we have to re-evaluate our indications for using locking distal radius plates distal radius Methods: Group 1: Treatment of distal radius fractures with either volar or dorsal locking plates. No fixation postoperatively, immediate ROM (range of motion) exercises and usage of the wrist in activities of daily life (ADL) allowed.

Radiological and clinical controls 2 weeks, 6 weeks and 12 weeks postoperatively. Endpoints are time to return to work / return to independency (in older people), ROM; Grip strength (with Jamar Dynamometer).

Outcome scores are DASH (Disability of Arm, Shoulder and Hand Score) and PRWE (Patient related wrist evaluation).

Group 2 Treatment of distal radius fractures with either an external fixator +/- K-wires or with K-wires and forearm

cast or by cast alone. Main issue is that the wrist is immobilized for a period of 6 weeks. Radiological and clinical controls 2 weeks, 6 weeks and 12 weeks postoperatively. Endpoints are time to return to work / return to independency (in older people), ROM; Grip strength (with Jamar Dynamometer). Outcome scores are DASH and PRWE. Both plating and external fixation / cast fixation are standard and accepted treatment modalities for distal radius fractures. A power analysis indicated that a total sample size of 52 patients randomized equally (1:1) to each treatment arm without any blocking or stratification would provide 80 % statistical power ($\alpha = .05$, $\beta = .20$) to detect a 20% difference in mean DASH and PRWE scores.

Condition	Intervention	Phase
Distal Radius Fractures	Procedure/Surgery: volar locking plating Procedure/Surgery: external immobilisation	N/A

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Efficacy Study

Official Title: Volar Locking Plate Versus External Fixator/Cast Fixation for the Treatment of Distal Radius Fractures. A Randomised Controlled Prospective Study

Further study details as provided by Dr. Herwig Drobetz, Mackay Base Hospital:

Primary Outcome Measure:

- 20% difference in DASH scores [Time Frame: twelve weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- return to work [Time Frame: twelve weeks] [Designated as safety issue: No]

Enrollment: 52

Study Start Date: August 2008

Study Completion Date: December 2013

Primary Completion Date: December 2013

Arms	Assigned Interventions
Active Comparator: 1 volar locking plating of distal radius fractures	Procedure/Surgery: volar locking plating open reduction and internal fixation
Active Comparator: 2	Procedure/Surgery: external immobilisation closed reduction and external fixation

Eligibility

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Both

Inclusion Criteria:

- distal radius fracture
- age > 18

Exclusion Criteria:

- intellectual or mental impairment
- < 18 years of age

Contacts and Locations

Locations

Australia, Queensland

Mackay Base Hospital

Mackay, Queensland, Australia, 4740

Investigators

Principal Investigator: Herwig Drobetz, MD

Mackay Base Hospital

More Information

Responsible Party: Dr. Herwig Drobetz, Director Orthopaedics, Mackay Base Hospital

Study ID Numbers: DCDRS00407

Health Authority: Australia: Human Research Ethics Committee