Injury, Int. J. Care Injured 45S (2014) S3–S8

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

Intramedullary nail versus volar plate fixation of extra-articular distal radius fractures. Two year results of a prospective randomized trial

Gertraud Gradl [b], Nadja Mielsch [a], Martina Wendt [a], Steffi Falk [a], Thomas Mittlmeier [a], Philip Gierer [a], Georg Gradl [a,*]

[a] Department of Trauma- and Reconstructive Surgery, Surgical Clinic University of Rostock, Schillingallee 35, 18055 Rostock, Germany
[b] Department of Trauma and Reconstructive Surgery, Aachen University Medical Center, Pauwelstrasse 30, 52074 Aachen, Germany

ARTICLE INFO

Keywords:
Distal radius fractures
Locked plating
Intramedullary nailing
Complications
Functional outcome

ABSTRACT

Background: Intramedullary techniques for stabilization of displaced distal radius fractures are now available. Purported benefits include limited soft tissue dissection while affording sufficient stability to allow early wrist motion.

The primary null hypothesis of this randomized trial is that there is no significant difference with respect to functional outcome, pain and disability between patients treated with either 2.4-mm volar locking plate fixation or intramedullary nail fixation of unstable dorsally displaced extra-articular fractures of the distal radius.

Methods: We conducted a single-centre, parallel-group trial, with unrestricted randomization. Patients with dorsally displaced extra-articular distal radius fractures were randomized to receive volar locking plate ($n = 72$) fixation or intramedullary nailing ($n = 80$). The outcome was measured on the basis of the Gartland and Werley and Castaing score; the pain level; the range of wrist motion; the rate of complications; and radiographic measurements including volar tilt and ulnar variance. Clinical and radiographic assessment was performed at 8 weeks, 6 months, 1 year and 2 years after the operation.

Results: There were no significant differences between groups in terms of range of motion, grip strength or the level of pain during the entire follow-up period ($p > 0.05$). There was no significant difference between treatment groups with respect to volar tilt or ulnar variance ($p > 0.05$). There was no significant difference in the complication rate between groups ($p > 0.05$).

Conclusions: The present study supports the view that intramedullary nail fixation and volar plate fixation for the treatment of displaced extra-articular distal radius fractures have equivalent radiographic and functional outcomes.

Level of evidence: Level I therapeutic study.

Introduction

There are three broad categories of treatment for distal radial fractures: closed reduction and immobilization in a cast, percutaneous fixation with Kirschner wires and/or external fixation, and open reduction and internal fixation. While each has merits and disadvantages, there is no consensus regarding which is the best treatment option [1]. A literature review by the Cochrane Collaboration revealed a lack of robust clinical evidence to support any one intervention over another [2].

Recently, intramedullary techniques have been introduced for stabilization of displaced distal radius fractures [3–5]. The purported benefits include limited soft tissue dissection, a low profile implant with less risk of soft tissue irritation, divergent subchondral screw placement, and locked fixed-angle fixation, affording sufficient stability to allow early wrist motion [3–5].

However, the role of intramedullary stabilization of distal radius fractures remains unclear. We hypothesized that there is no significant difference in functional and radiological outcome of unstable dorsally displaced extra-articular fractures of the distal radius treated with either 2.4-mm volar locking plate fixation or intramedullary nail fixation (Targon DR).

Materials and methods

Study design

This was a single-centre prospective randomized trial.

* Corresponding author. Tel.: +49 381 4946262; fax: +49 381 4946052.
E-mail address: georg.gradl@med.uni-rostock.de (G. Gradl).

0020–1383/$ – see front matter © 2013 Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.injury.2013.10.045

Patient selection

Eligible participants were all adults aged 18 or over with dorsally displaced (>20°) extra-articular distal radius fractures (AO type A3).

All patients were recruited at one single Level I trauma centre from September 2005 to June 2008.

Institutional Review Board approval was granted before initiation of this study, and strict confidentiality guidelines were followed. All patients provided written informed consent at the time of enrolment.

Sample size

Volar tilt and range of motion data [6,7] were used to perform sample size estimate [8]. In order to detect a mean difference (and standard deviation) in volar tilt of 3 ± 5.5° and a difference of >5° in range of motion with 80% power, a sample size of 67 patients per treatment group was needed. A target of 152 enrolled patients was adopted to accommodate an assumed 10% attrition rate.

Randomization

Participants were randomly assigned following simple randomization procedures (computerized random numbers) to one of the two groups (plate fixation or intramedullary nailing). Patients were assigned sequentially numbered opaque, sealed and stapled envelopes to conceal allocation from the enrolling researcher. The researcher was not involved in patient treatment.

The treating physicians opened corresponding envelopes at the preoperative visit only after the enrolled participants completed all baseline assessments.

Treatment

According to our hospital's policies, all operations were performed as inpatient procedures in the operating room with the patient under regional or general anaesthesia.

Operative technique

Targon® DR

Fixation was performed according to manufacturer guidelines. A 4-cm skin incision was made from the tip of the radial styloid.

Care was taken to identify and gently retract the radial sensory branches that cross the compartment obliquely by using gentle, blunt longitudinal dissection as soon as the deepest dermal layer of skin had been incised.

The interval between the first and second dorsal compartments was developed subperiosteally (Fig. 1).

The fracture was manipulated and was reduced by insertion of a Kapandji wire (radial styloid) under fluoroscopic control. Using the Kapandji wire as a guide wire, the intramedullary canal was opened with a cannulated reamer, followed by broaching of the medullary cavity, using the designated profilers.

Once broaching and sizing were completed, the actual implant and insertion jig were assembled on the back table and inserted into the distal radius.

After correct placement was confirmed, four 1.8 mm drilling wires were inserted through the insertion jig and replaced by fixation screws.

Length, tilt and rotation were confirmed prior to insertion of the proximal bicortical locking screws. Final images were taken to confirm reduction and fixation of the fracture (Fig. 2). After wound closure, a simple dressing was applied.

Volar locked plating

Volar plate fixation was performed through a standard Henry approach [9] (Fig. 1). Once anatomic reduction was confirmed with fluoroscopy, fractures were temporarily fixed with a Kirschner wire inserted percutaneously through the radial styloid. Locked plating was then routinely performed. We recorded operative time, fluoroscopy time and duration of hospital stay.

Postoperative management

Patients were not immobilized and were allowed immediate forearm, wrist, and finger motion. Formal therapy was individualized.

Strenuous tasks, sports activity, and weight bearing were allowed once radiographs confirmed fracture union.

Functional assessment

Follow-up was performed at 8 weeks, 6 months, 1 year and 2 years after the operation. All patients were evaluated by an independent investigator not involved in the patients' treatment. Blinding of the investigator was not possible due to obvious differences in incision placement. Functional assessment included measurement of active range of wrist motion, using a goniometer. Grip power was measured with a dynamometer (Jamar; JA Preston Corp., Jackson, MI) at position 3, and an average of three trials. All clinical data were compared with the non-involved side.

Wrist pain was evaluated using the visual analogue scale (VAS) (VAS 0 = no pain, VAS 10 = severe pain).

Subjective and objective data were summarized in the Gartland and Werley Score (0–2 = excellent to >20 = poor) [10] and the Castaing Score (0 = perfect to >25 = very poor) which comprises wrist function and radiographic data [11].

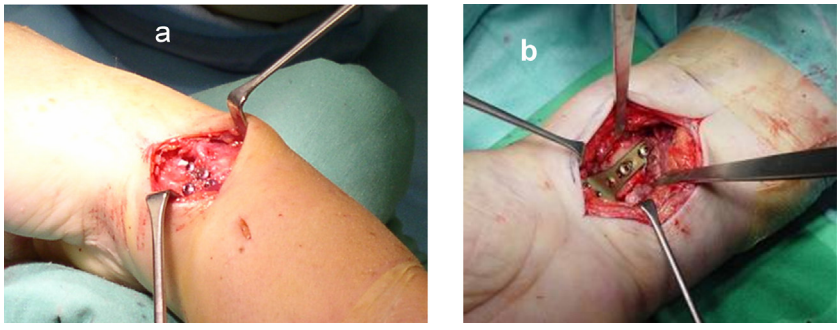

Fig. 1. Left panel: surgical approach for intramedullary nailing; Right panel: surgical approach for plate fixation.