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Original article

Reconstruction plates for midshaft clavicular fractures: A retrospective cohort study

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ABSTRACT

Background: For the fixation of displaced midshaft clavicular fractures different plates are available, each with its specific pros and cons. The ideal plating choice for this lesion remains subject to ongoing discussion. Reconstruction plates are cheap and easily bendable, but their strength and stability have been questioned. The aim of this study was to evaluate the failure rate of reconstruction plates in the fixation of clavicular fractures.
Materials and methods: A multicenter, retrospective cohort study of all consecutive patients with a displaced, midshaft clavicular fracture (Robinson type 2a/2b) treated with a 3.5-mm reconstruction plate between 2006 and 2013 were evaluated. The primary outcome measure was reoperation rate due to implant failure. Secondary outcome measures were nonunion, symptomatic malunion and elective plate removal.
Results: One hundred and eleven patients were analyzed. During a median follow-up of 8 months, 14 patients (12.6%) had implant failure, of which 7 (6.3%) required a reoperation. Three nonunions (2.7%) and no symptomatic malunions occurred. Plate removal was indicated in 37.8% of patients because of implant irritation.
Discussion: The incidence of reoperation due to implant failure following clavicular plate fixation with a reconstruction plate is 6.3%. Although comparison with other plate types is difficult since rates in literature vary greatly, reoperation rates in other plates are reported around 2–3%, suggesting that reconstruction plates have a higher incidence of implant failure warranting reoperation. Therefore, especially in patients with known risk factors for complications (e.g. smoking, osteoporosis, comminuted fractures), a stronger plate than a reconstruction plate should be considered.
Level of evidence: Level IV. Retrospective study.

1. Introduction

In the past decade, operative treatment of dislocated midshaft clavicular fractures has become more common. The evidence in favor of operative treatment still grows, as recent studies show lower nonunion and symptomatic malunion rates and earlier return to work compared with conservative treatment [1–4]. With the development of the more advanced anatomically preshaped plates, the discussion is shifting from indications for operation towards the choice of implant for the midshaft clavicle [5–7].

Reconstruction plates, available in a locking and non-locking design, are frequently used for the fixation of clavicular fractures. Originally designed for pelvic fixation, reconstruction plates have a lower profile than standard compression plates with a concentrated mass around the screw holes. These characteristics reduce plate stiffness, facilitating easy contouring in all planes to fit the anatomic shape of the clavicle [6]. However, implant failure such as bending or breaking of the plate has been reported and subsequently the strength of reconstruction plates for the fixation of clavicular fractures was questioned [2,8].

Alternatives for reconstruction plates include limited contact–dynamic compression plates (LC-DCP) and small fragment locking compression plates (LCP), which are both straight and

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strong but are difficult to fit well onto the clavicle. More recently, anatomically preshaped locking plates were introduced to fit the s-shaped clavicle without having to bend the plate. These plates supposedly provide more biomechanical stability and reduce the incidence of implant failure and plate irritation, but conclusive data is lacking. Also, they are more expensive compared with other plates such as the reconstruction plate [5].

These disadvantages of other plate types cause the cheap and easily applied reconstruction plate to remain popular for fixating clavicular fractures, but clinical evidence on implant failure rates is limited. This lack of data warrants clinical evaluation of the use of reconstruction plates for displaced midshaft clavicular fractures. Therefore, the primary aim of this study was to investigate the incidence of implant failure (i.e. plate breaking, bending and screw loosening) that necessitates reoperation. Secondary outcome measures were nonunion, symptomatic malunion and elective plate removal.

2. Patients and methods

This study describes a retrospective cohort of all consecutive patients with a displaced midshaft clavicular fracture treated with a 3.5-mm reconstruction plate between 2006 and 2013 in two non-university teaching hospitals in The Netherlands, including one level 1 trauma center. Data was presented according to the guidelines for reporting observational studies as formulated in the "Strengthening the reporting of observational studies in epidemiology" (STROBE) Statement [9].

Patients were identified using the procedure-code for open reduction and internal plate fixation of clavicular fractures. Patients were included for analysis if they met the following inclusion criteria:

- fully displaced, midshaft clavicular fracture (fracture type Robinson 2a/2b) [10] and;
- 3.5 mm reconstruction plate fixation.

In both hospitals, indications for operative fixation of an acute fracture were: More than one shaft width of dislocation, $\geq$ 2 cm shortening, compromised skin, open fractures, neurovascular injury, or a combination of these reasons. Patients were excluded if:

- follow-up was shorter than two months or;
- indication for surgery was nonunion or malunion of a previous fracture.

2.1. Surgical technique, rehabilitation and follow-up

All operations were performed or supervised by a certified orthopedic trauma surgeon, according to the AO-principles and under fluoroscopic guidance. Patients were operated under general anesthesia. Standard prophylactic antibiotics were administered. After reduction, fixation was done with lag screws and a neutralization plate or with a bridging technique. The plates were contoured by the surgeon to fit the shape of the clavicle and were positioned on either the superior or anterior-inferior surface of the bone. Plate fixation was locking or non-locking, with a minimum of three bicortical screws in both the proximal and distal end. All locking plates were made of titanium, whereas the non-locking plates were made of steel.

Postoperative treatment consisted of active non-weight bearing motion exercises of the shoulder throughout the first six weeks. After satisfactory radiographic control at six weeks postoperatively, patients were allowed to start weight bearing motion exercises. Further clinical and radiological evaluation was done on indication.

2.2. Data

Medical records and diagnostic imaging were reviewed to obtain patient characteristics, fracture type according to the Robinson classification [10], mode of fixation (locking or non-locking) and postoperative complications. The quality of fracture reduction was judged on the intra- and postoperative X-rays as "anatomical" or "non-anatomical". In the latter, a gap or step-off of 2 mm or more was present after reduction of the fracture. Bridge plating of severely comminuted fractures was also defined as non-anatomical.

The primary outcome parameter was defined as reoperation due to, or in the presence of plate breaking, plate bending or screw loosening. Overall implant failure also included asymptomatic patients. In all patients, at time of inclusion at least a year had passed since surgery. Secondary outcome parameters including nonunion, malunion, and plate removal were obtained from digital records. Nonunion was defined as no bony bridging after nine months in the presence of pain and/or impaired function.

2.3. Statistical analysis

Data were analyzed using SPSS version 20.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were calculated for all variables, including frequency counts for categorical variables and median with range for continuous variables. Differences between groups were evaluated with the Fisher's exact test for categorical variables and with the Mann Whitney *U* test for continuous variables. Statistical significance was assumed if two-sided *P*-values were below 0.05.

3. Results

One hundred and thirty-five consecutive patients received plate fixation of a clavicular fracture during the study period, of whom 123 patients met the inclusion criteria. Twelve patients were excluded because indication for surgery was nonunion or malunion ($n = 9$) or follow-up was shorter than two months ($n = 3$). The remaining 111 patients with 111 midshaft clavicular fractures were included for analysis.

3.1. Patient demographics and baseline characteristics

The median age was 41 years and most patients were male (Table 1). Surgery was performed after a median of 9.0 days (range 0–47 days). Seven patients had surgery more than three weeks after injury because the initially preferred conservative treatment was too painful or fracture dislocation increased.

Forty-six fractures (41.4%) were fixated with a non-locking reconstruction plate and 65 with a locking reconstruction plate. Most plates were positioned superiorly (83.8%). Anatomical reduction was accomplished in 90.1% of cases. Median time of follow-up was 8.0 months (range 2–54 months). All patients with a short time of follow-up had been discharged from further check-up because they were doing well at that point.

3.2. Primary outcome: reoperation due to implant failure

Reoperation due to implant failure was indicated in 7 patients (6.3%). Reasons for reoperation were plate breakage in five cases, screw loosening with nonunion in one case, and breakout of the plate in one case. In three patients with a broken plate, there was previous plate bending ($n = 2$), or nonunion ($n = 1$) (Table 2). There