



Construct failure after open reduction and plate fixation of displaced midshaft clavicular fractures



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ABSTRACT

Introduction: Worldwide, implants mostly used for fixation of displaced midshaft clavicular fractures (DMCF) are the easily to bend reconstruction plate and the stiffer small fragment locking compression plate. Construct failure rates after plate fixation of DMCF are reported around 5 percent. Possible risk factors for construct failure are implant type and fracture type. However, little is known about the influence of fracture fixation method on construct failure. The aim of this study was to assess construct failure in plate fixation of DMCF and to identify possible risk factors.

Methods: All consecutive patients treated in a level 1 trauma centre with open reduction and fixation of DMCF using a 3.5-mm reconstruction plate or 3.5-mm small fragment locking compression plate between 2007 and 2015 were evaluated. Potential risk factors for construct failure were analysed using univariate analysis.

Results: Two hundred and fifty-nine patients were analysed. Fifty DMCF (19%) were fixated with a reconstruction plate and 209 (81%) with a small fragment locking compression plate. Construct failure was seen in 18 patients (6.9%), including 5 broken plates and 13 with screw loosening. Eight percent of all reconstruction plates broke in contrast to 0.5 percent of all small fragment locking compression plates ($p = 0.001$). All broken implants were used as a bridging plate. Loosening of screws was seen in older patients and when the plate was fixated with less than three bicortical screws on one side of the fracture ($p = 0.002$).

Conclusions: Overall construct failure after open reduction and plate fixation of DMCF occurred in 6.9 percent. Risk factors for plate breakage were the use of a reconstruction plate and a bridging method for fracture fixation. Risk factors for screw loosening were an increasing patient age and plate fixation with less than three bicortical screws on one side of the fracture.

Recommendations: Based on the results of this study our recommendation is to use a small fragment locking compression plate for open reduction and internal fixation of DMCF. The surgeon should always strive to fixate the plate on both sides of the fracture with at least three bicortical screws.

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Introduction

Clavicular fractures cover about 5 to 10% of all fractures. The majority of these fractures are located in the middle third of the clavicle and are displaced [1,2]. In the last decade several prospective randomised controlled trials showed better functional outcomes after open reduction and internal fixation for displaced midshaft clavicular fractures resulting in a shift towards operative

treatment in clinical practice [3,4]. Additionally, non-union rates seem to be lower after operative treatment (0–3%) than conservative treatment (21%) [4,5].

However, reoperation rates for implant removal due to implant irritation vary from 29 to 38% [6,7]. Recent retrospective cohort studies show construct failure rates from 1.2 up till 12.6%, including breaking or bending of plate and screw loosening [3,4,6–9].

The implants mostly used can be divided in nails and plates. Plates can be subdivided in reconstruction plates and small fragment locking compression plates. Reconstruction plates, available in locking compression and non-locking compression design, have a lower profile with a concentrated mass around the screw holes which reduces the plate stiffness. Small fragment

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locking compression plates, available in a straight and anatomically preshaped design, are stronger and therefore much more difficult to bend.

Recent retrospective cohort studies show plate failure rates between 6.3% (3.5-mm reconstruction plate) [7] and 8.5% (2.7-mm reconstruction plate) [10] when a reconstruction plate is used for the fixation of displaced clavicular fractures.

Gilde et al. [10] discourage the use of reconstruction plates because of the higher rate of plate failure in comparison to the stiffer dynamic compression plate.

In the available scientific literature, little is known about the factors that influence the risk of construct failure after plate fixation of midshaft clavicular fractures.

The primary aim of this study was to give a description of construct failure after plate fixation of midshaft clavicular fractures. The secondary aim of this study was to identify possible risk factors for construct failure including patient characteristics, fracture type, implant type and fracture fixation method.

Methods

Population

This study defines a retrospective cohort of all consecutive patients with a fresh midshaft clavicular fracture treated with open reduction and internal fixation using a 3.5-mm reconstruction plate (locking compression design) or 3.5-mm preshaped or non-preshaped small fragment locking compression plate in the period between January 1, 2007 and December 31, 2015. It was conducted in a non-university teaching level 1 trauma centre in the Netherlands.

Indications used for operative treatment were more than one shaft width of dislocation, ≥ 2 cm shortening, compromised skin, open fracture, polytrauma, neurovascular injury or non-union.

Patients were excluded from this analysis (1) in case of a new fracture (or reoperation) in a previously healed clavicle fracture, (2) when follow up was shorter than three months or (3) in case of delay in surgery of more than sixty days after injury.

Treatment and follow-up

All patients were operated under general anaesthesia and in beach chair or supine position. Standard prophylactic antibiotics were administered. All operations were performed or supervised by a certified orthopaedic trauma surgeon and assisted by fluoroscopy. All implants were made of titanium-aluminium-niobium (TAN; manufacturer Synthes, Bettlach, CH) and applied as neutralization, compression or bridging plate, according to the AO-principles [11].

Patients were seen at the outpatient clinic at least two weeks, six weeks (with radiographic control) and three months (with radiographic control) after surgery. Follow up was continued until complete consolidation of the fracture. Postoperative treatment consisted of a non-weight bearing regime with active shoulder exercises up to 90° abduction/anteflexion throughout the first six weeks. After six weeks patients were allowed to start permissive weight bearing.

Data

All patients and their characteristics were collected by performing a search in the hospital Electronic Medical Record database using the procedure code for plate fixation of clavicular fractures. Preoperative radiographs (in two different angles) were reviewed to obtain fracture type according to the Robinson classification [12]. Operation reports, intra- and postoperative

Table 1

Patient characteristics.

Total	259
Gender ^a	
Male	213 (82.2)
Female	46 (17.8)
Age (years) ^b	39 (13–73)
Robinson fracture type ^a	
2A	7 (2.7)
2B1	113 (43.6)
2B2	136 (52.5)
unknown	3 (1.2)
Days until operation ^b	6 (0–60)

^a Number (percentage).

^b Median (range).

radiographs (in two different angles) were reviewed to obtain implant type, fracture fixation method (neutralization, compression, bridging), number and type of screws (uni- versus bicortical, cortex versus locked head) on both side of the fracture.

Statistical analysis

Descriptive analyses were performed for all variables. Differences between the patient groups with or without plate breakage or screw loosening were calculated with the Pearson's chi-squared test for categorical data and the Mann-Whitney *U* test for continuous data. Differences were considered to be statistical significant at a two-sided *p*-value < 0.05 . Data were analysed using the Statistical Package for the Social Sciences (SPSS) version 23.0 (SPSS, Chicago, Illinois, USA).

Results

In total 259 patients were included in this study. The vast majority of patients were male (82%) and the median patient age was 39 years [Table 1]. All plates were placed superior or superior-anterior on to the clavicle. The median time between injury and operation was 6 days. Fifty clavicular fractures (19%) were fixated using a reconstruction plate and 209 (81%) with a small fragment locking compression plate, both straight and anatomically preshaped. Median time of follow-up was 7 months (range 3–61 months).

Construct failure was seen in 18 patients (6.9%), including 5 broken plates and 13 patients suffering from screw loosening [Table 2]. All 18 patients with construct failure were re-operated, of which 2 patients were re-operated twice due to recurrent construct failure. The median time between operation and

Table 2

Primary outcomes.

Total	259
Construct failure ^a	18 (6.9)
Breaking of plate	5 (1.9)
Loosening of screws	13 (5.0)
Patients with ≥ 1 reoperation ^a	137 (52.9)
Total reoperations	149
Indication for reoperation ^a	
Plate irritation (removal)	124 (47.9)
Construct failure	18 (6.9)
Non-union	3 (1.2)
Deep infection (gentamicin beads)	2 (0.8)
Construct failure after re-fixation	2 (0.8)
Days until construct failure ^b	37 (15–579)

^a Number (percentage).

^b Median (range).

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