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

M.A. Meeuwis[1], A.F. Pull ter Gunne[1], M.H.J. Verhofstad[2], F.H.W.M. van der Heijden[1]

[1]Dept. of Surgery, St. Elisabeth Hospital, P.O. Box 90151, 5000 LC, Tilburg, The Netherlands
[2]Dept. of Surgery-Traumatology, Erasmus MC, University Medical Center Rotterdam, P.O. Box 2040, 3000 CA Rotterdam, The Netherlands

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Summary

[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.

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 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 degrees 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 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 construct failure was 37 days. The most common indication for re-operation was plate removal after fracture healing due to implant irritation in (n=124; 48%). Other indications for re-operation were non-union (n=3) and deep wound infection (n=2).

Breaking of plate (n=5)

Postoperative, 4 out of 50 reconstruction plates [figure 1] and 1 out of 208 small fragment locking compression plates broke (8% *versus* 0.5%; p = 0.001; OR = 18; 95% CI: 2 - 166) [table 3]. In all 5 cases (6.2%) the plate was used to bridge the fracture. Following a neutralization or compression fracture fixation method no plate breakage occurred. This overall difference was statistically highly significant (6.2% *versus* 0% *versus* 0%; p = 0.006). Age, gender, fracture type according to Robinson's classification, the amount of bicortical screws on either side of the fracture and the proportion of locked head screws did not differ significantly between the group in which plate breakage occurred and the group in which it did not.

Four out of 20 reconstruction plates (20%) broke when a bridging method was used for fracture fixation. The working length of the implant as reflected by the median number of unused plate holes in the fracture zone tended to be shorter when the plate broke, however this difference was not statistically significant (0.5 *versus* 2 holes without screws; $p = 0.185$).

Loosening of screws (n=13)

In 8 out of 13 patients (62%) the loosening of screws occurred on the medial side of the fracture [figure 2]. Loosening of screws after plate fixation was related to a higher patient age at time of surgery (50 versus 38 years; $p = 0.007$) [table 4]. Furthermore, loosening of screws was more frequently seen when the plate was fixated with less than three bicortical screws on either side of the fracture (46% versus 14%; $p = 0.002$; OR = 5.4; 95% CI: 1.7 – 16.9). Gender, fracture type according to Robinson's classification, implant type, fracture fixation method and proportion of locked head screws was not found to be different.

Discussion

The purpose of this study was to perform a retrospective study describing construct failure after plate fixation of midshaft clavicular fractures. Further analyses were performed to identify possible risk factors.

In total 259 patients were included in this study. The overall construct failure rate after open reduction and plate fixation of midshaft clavicular fractures was 6.9%. The reoperation rate was considerable (53%), but in the vast majority (n = 124, 48%) the plate was removed due to implant irritation after bone healing.

In our study the reconstruction plate was more likely to break than the stiffer small fragment locking compression plate (8% versus 0.5%; $p = 0.001$; OR = 18; 95% CI: 2 - 166). Furthermore, loosening of screws after plate fixation was seen more often in older patients (50 versus 38 years; $p = 0.007$) and when the plate was fixated with less than three bicortical screws on one side of the fracture (46% versus 14%; $p = 0.002$; OR = 5.4; 95% CI: 1.7 – 16.9).

The construct failure rate of 6.9% in this study lies within the range of 1.2 to 12.6% described in the literature [3, 4, 6-9]. However, our reoperation rate of 53% is considerably higher than the 29 to 38% described in the literature [6, 7]. A prospective multicentre clinical cohort study performed by Vos *et al* [13] showed that up to 70% of patients treated with plate fixation for a clavicular fracture had moderate to extreme pain during activities before implant removal. The pain during activities, as well as rest pain, paraesthesia, loss of strength and stiffness dropped significantly after implant removal. That study supports the clinical observation that prominence of clavicular plates is an important cause for local shoulder complaints and removal is effective. However, such plate removal should not be regarded to as a failure, but as the second part of a staged surgical procedure and should be discussed with the patient as such.

In our study population the reconstruction plate was more likely to break than the stiffer small fragment locking compression plate. The available literature also suggests that the reduced stiffness of the reconstruction plate seems to be accountable for less biomechanical stability than provided by other plates [10, 14, 15]. Eight percent of all reconstruction plates broke in our study, which is comparable with the 8.5 to 12.6% described in several other clinical studies [7, 10, 16]. However, in our study all broken reconstruction plates were used as a fracture bridging implant. No breakage was seen when the reconstruction plate was used to neutralize or compress the fracture. This shows that a single 3.5-mm reconstruction plate is only strong enough to neutralize the forces on the clavicle after anatomical reduction and interfragmentory compression, or to function as a tension band if applied superior onto an oblique or transverse fracture. Yet, to be able to achieve absolute stability an anatomical reduction needs to be obtained which restores structural continuity. In case of a multifragmentary clavicular fracture this can be difficult, or even impossible without additional iatrogenic injury to the vascularization of the bony fragments. A less rigid, bridging construct using the plate as an internal splint to the fracture appears to be more attractive from a biological perspective.

The AO principles regarding bridge plating [11, 17] recommend to leave at least two or three plate holes without screws in the fracture zone to avoid stress concentration and plate failure. In our small group of twenty reconstruction plates used as a bridging plate, the median number of plate holes without screws in the fracture zone tended to be lower when the plate broke. However, this difference was not statistically significant due to low numbers.

Loosening of screws after plate fixation was seen more often in older patients. This can most likely be explained by a decrease in the “screw holding capacity of the bone” (e.g. due to osteopenia or -porosis) resulting in a lower pull-out resistance of screws against bending and axial loads. To achieve a higher pull-out resistance, locked head screws can be used instead of non-angular stable cortex screws. Surprisingly, in our study there seems to be a tendency for a higher proportion of locked head screws used when screw loosening occurs (0.67 versus 0.47; $p = 0.070$). Perhaps, locked head screw were more likely to be used in older patients with a lower screw holding capacity of the bone, when the number of screws that could be placed on either side of the fracture was limited, or when malalignment between the bone axis and plate lead to unicortical screw placement.

In our study, loosening of screws did indeed occur more often when the plate was fixated with less than three bicortical screws on one side of the fracture. This endorses the AO recommendation to fixate the plate with at least three bicortical screws in each main fragment on either side of the fracture [11, 17] and that proper bicortical placement of locked head screws is important as well.

This study has its limitations. Due to the retrospective data collection only patient characteristics that were automatically or routinely documented in the EMR could be used in this study. Therefore, patient comorbidities, the use of tobacco, bone mineral density and other factors that possibly influence the pure construct stability and speed of bone healing could not be taken into account. The only available data for the assessment of fracture fixation method were the operation reports and postoperative radiographs. As a result, not all aspects that might influence the quality of the construct could be evaluated. For example, the degree and number of times the plate is bent before it is applied, is a factor that influences its ability to withstand forces without breaking. Such data were absent, but favour the use of anatomical preshaped plates in general. Likewise, any malalignment between the bone axis and plate, resulting in eccentric plate positioning and possible unicortical screw placement at the far end of the plate, has a potential negative effect on stability. In our study this aspect could not be evaluated properly as a risk factor for construct failure by using just the available postoperative radiographs. An overestimation of screws being correctly placed bicortical is therefore likely. Consequently, the importance of placing at least three bicortical screws on either side of the fracture zone could be overestimated. Only routine postoperative computed tomography scans could have given the information to address this question. Finally, because of the low number of events in this retrospective cohort study it was not appropriate to perform multivariate logistic regression analysis. Therefore, interaction between risk factors could not be evaluated.

Although scientific evidence supports plate osteosynthesis of midshaft clavicular fractures, scientific data on the minimal technical requirements are absent. The recommended surgical technique has an empirical base. To our knowledge no clinical study on the technical aspects related to construct failure has been published yet. Our retrospective cohort study is the first that provides such data, with risk factors that might attribute to construct failure after plate fixation of midshaft clavicular fractures.

This study confirms and strengthens the outcomes of previous biomechanical studies and AO principles on this subject. Therefore, in our opinion, it is questionable whether a prospective randomized controlled trial comparing the different plates used in this study, fixation methods or type and number of screws as risk factors for construct failure is needed or desirable.

Probably, the biggest gain lies in reducing the high re-operation rate due to implant irritation. For example, a new technique of dual mini-fragment (2.7 mm) plating appears to provide a comparable biomechanical stability with excellent clinical outcomes and a potential decrease in secondary surgery due to implant prominence [18]. Prospective clinical studies are desirable to determine the differences in non-union, construct failure, functional outcomes and secondary surgery between single conventional and dual mini-fragment plating.

Conclusions

In this study construct failure after open reduction and plate fixation of midshaft clavicular fractures occurred in 6.9% (18 out of 259 patients). Plate breakage occurred in 5 patients (1.9%) and loosening of screws in 13 patients (5.0%). The median number of days between plate fixation and construct failure was 37.

Risk factors for plate breakage were the use of a reconstruction plate and bridge plating. Risk factors for loosening of screws were an increasing patient age and plate fixation with less than three bicortical screws on one side of the fracture.

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 midshaft clavicular fractures. Additionally, the surgeon should always strive to fixate the plate on both side of the fracture with at least three bicortical screws.

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Figure 1. Broken reconstruction plate.

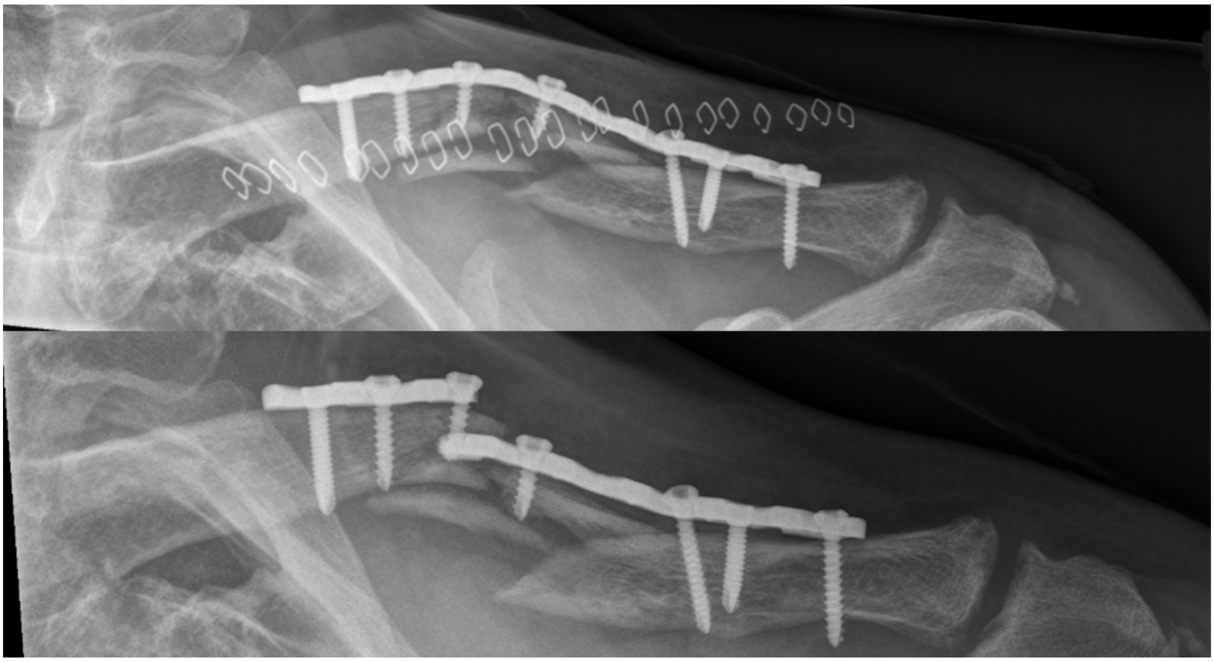

Figure 2. Loosening of screws.

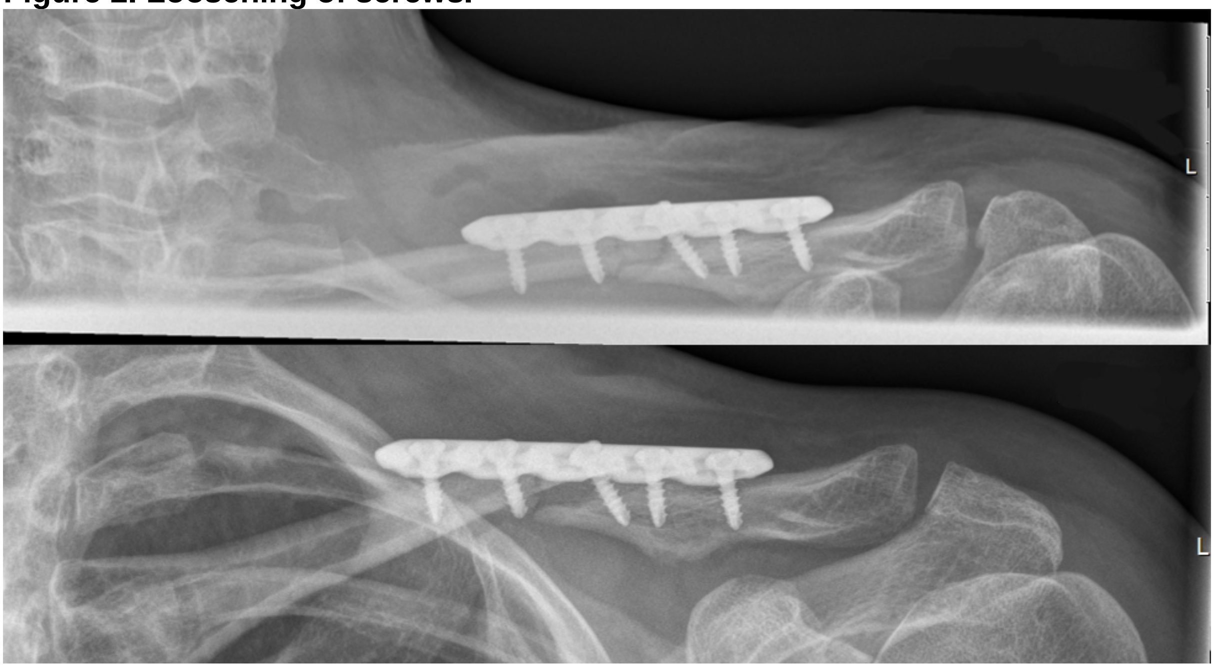

Table 1. Patient characteristics

Total	259
Gender[1]	
Male	213 (82.2)
Female	46 (17.8)
Age (years)[2]	39 (13-73)
Robinson fracture type[1]	
2A	7 (2.7)
2B1	113 (43.6)
2B2	136 (52.5)
unknown	3 (1.2)
Days until operation[2]	6 (0-60)

[1]number (percentage)
[2]median (range)

Table 2. Primary outcomes

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

[1]number (percentage)
[2]median (range)

Table 3. Breaking of plate

		Breaking of plate			
	All operations (n=259)	Yes (*n* = 5)	No (*n* = 254)	Odds ratio^{+}	*p*-value
Age[1]	39 (22-50)	46 (33-58)	39 (22-50)		0.258^{++}
Gender[2]	213 (82.2)	5 (100.0)	208 (81.9)		0.294^{+++}
Robinson fracture type[2]					
2A	7 (2.7)	0 (0.0)	7 (2.8)		0.966^{+++}
2B1	113 (43.6)	2 (40.0)	111 (43.7)		
2B2	136 (52.5)	3 (60.0)	133 (52.4)		
Unknown	2 (1.2)	0 (0.0)	3 (1.2)		
Implant type[2]					
Reconstruction plate	50 (19.3)	4 (80.0)	46 (18.1)	18 (2 – 166)	0.001^{+++}
Locking compression plate	209 (80.7)	1 (20.0)	208 (81.9)	reference	
Method of fracture fixation[2]					
Neutralization	54 (20.8)	0 (0.0)	54 (21.3)		0.006^{+++}
Compression	119 (46.9)	0 (0.0)	119 (46.9)		
Bridging	86 (33.2)	5 (100.0)	81 (31.9)		
Plate fixation with <3 bicortical screws on 1 side of the fracture[2]					
Yes	40 (15.4)	1 (20.0)	39 (15.4)	1.4 (0.2 – 12.7)	0.776^{+++}
No	219 (84.6)	4 (80.0)	215 (84.6)	reference	
Ratio: LHS / total number of screws	0.50 (0.0-0.67)	0.67 (0.5-0.86)	0.47 (0.0-0.67)		0.075^{++}

Data are shown as [1] median (P25 – P75) or [2] number (percentage). LHS = Locking head screw
$^{+}$ Univariate Logistic Regression, $^{++}$ Mann-Whitney U test, $^{+++}$ Pearson Chi-Squared test

Table 4. Loosening of screws

		Loosening of screws			
	All operations (*n*=259)	Yes (*n* = 13)	No (*n* = 246)	Odds ratio^{+}	*p*-value
Age[1]	39 (22-50)	50 (42-60)	38 (22-49)		0.007^{++}
Gender[2]	213 (82.2)	11 (84.6)	202 (82.1)		0.793^{+++}
Robinson fracture type[2]					
2A	7 (2.7)	0 (0.0)	7 (2.8)		0.136^{+++}
2B1	113 (43.6)	6 (46.2)	107 (43.5)		
2B2	136 (52.5)	6 (46.2)	130 (52.8)		
Unknown	2 (1.2)	1 (7.7)	2 (0.8)		
Implant type[2]					
Reconstruction plate	50 (19.3)	1 (7.7)	49 (19.9)	0.3 (0.0 – 2.6)	0.276^{+++}
Locking compression plate	209 (80.7)	12 (92.3)	197 (80.1)	reference	
Method of fracture fixation[2]					
Neutralization	54 (20.8)	5 (38.5)	49 (19.9)		0.253^{+++}
Compression	119 (46.9)	4 (30.8)	115 (46.7)		
Bridging	86 (33.2)	4 (30.8)	82 (33.3)		
Plate fixation with <3 bicortical screws on 1 side of the fracture[2]					
Yes	40 (15.4)	6 (46.2)	34 (13.8)	5.4 (1.7 – 16.9)	0.002^{+++}
No	219 (84.6)	7 (53.8)	212 (86.2)	reference	
Ratio: LHS / total number of screws	0.50 (0.0-0.67)	0.67 (0.33-0.92)	0.47 (0.0-0.67)		0.070^{++}

Data are shown as [1] median (P25 – P75) or [2] number (percentage). LHS = Locking head screw
$^{+}$ Univariate Logistic Regression, $^{++}$ Mann-Whitney U test, $^{+++}$ Pearson Chi-Squared test