**Operative treatment of dislocated midshaft clavicle fractures; Plate Or intramedullary Pin fixation? A randomized controlled trial.**

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**Abstract**

*Background*

Over the past decades **the operative treatment of displaced midshaft clavicle fractures (DMCF) has increased.** The aim of this study was to compare short and midterm results of open reduction and plate fixation (PF) and intramedullary nailing IMN for DMCF.

*Methods*

A multicenter randomized controlled trial was performed in four different hospitals. A total of 120 patients, age 18 – 65, were included and treated with either PF ($n$ = 58) or IMN ($n$ = 62). Pre- and postoperative shoulder function scores and complications were documented up until 1 year postoperatively. Statistical significance was set at $p < 0.05$.

*Results*

There were no significant differences noted between the two surgical interventions for both the DASH and Constant-Murley score at 6 months postoperatively (3.0 and 99.2 for the plate group and 5.6 and 95.5 for the IM group). Until 6 months after surgery, the PF group experienced less disability than the IMN group as indicated by the area under the curve of the DASH score for this time period ($p$ = 0.02).

The mean numbers of complications per patient, irrespective of severity level, was similar in both groups (PF: 0.67, IMN: 0.74; $p$=0.65). The vast majority of complications were implant related. There was only one recorded nonunion which occurred in the PF group and there were 2 implant failures in the IMN group.

*Conclusion*

Patients in the PF group recovered faster than the patients in the IMN group, but groups were similar at **six months postoperatively and** final follow-up. The rate of complications requiring revision surgery was, low yet implant related complications occurred frequently and could often be treated by implant removal.

## Introduction

**Over the past decades, a shift in the treatment of displaced midshaft clavicle fractures (DMCF) towards operative treatment was observed.** Rationale for operative fixation of displaced fractures includes reported higher nonunion rates and increased functional deficits following nonoperative treatment of DMCF.[1-5] Two of the most commonly used techniques for operative treatment are open reduction and internal plate fixation (PF) and intramedullary nail (IMN) fixation.[6] The optimal **fixation method** for these types of fractures remains a topic of debate.

Plate fixation provides immediate rigid fixation, including rotational stability, which is favorable for early rehabilitation protocols and is technically less demanding.[7,8] Intramedullary fixation is in general less invasive, good cosmetic results are reported and in addition, the hardware is less prominent.[4] Despite proposed benefits, each technique also has its drawbacks. Infection, hypertrophic scarring and hardware irritation and even hardware failure are reported following plate fixation.[9] Intramedullary nails often require routine removal to prevent hardware migration and prior to this, implant related irritation may occur.[10]

So far, prospective randomized data favoring either technique on which surgical decision making can be based are rare.[6,11] The purpose of this multicenter, randomized controlled trial was to report the functional results and complication rates of patients aged 18-65 with a DMCF who were randomized to either open reduction and Plate fixation Or intramedullary Pin fixation (POP-trial).[12] The null hypothesis was that PF would provide faster functional recovery than IMN fixation.

## Material and Methods

*Study Design*

The POP-study, registered in the Dutch Trial Register (NTR 2438), was performed in accordance with the Declaration of Helsinki[13] and approved by the local Medical Ethics Committee (registration number V.10.365/R-10.18D/mg). From January 2011 until August 2012, 120 consecutive patients with DCMF were included in this prospective trial in four participating hospitals. Displacement was defined as at least one shaft width **distance** on any radiograph between fracture parts, regardless of fracture shortening.

*Power Analysis and Randomization*

The sample size of 60 patients per group, was based on an assumed clinically relevant difference in the Disabilities of Arm Shoulder and Hand (DASH) score of six points in relationship to the score of a healthy population and previously reported scores following conservative treatment of DCMF.[1,14] Due to extensiveness, a more detailed rationale can be found in the study protocol.[12]

Patients were recruited in the emergency departments and handed study information if they met the inclusion criteria (Table 1). Follow up was scheduled within a week from trauma for study inclusion after obtaining informed consent. Fractures were classified according to the Orthopaedic Trauma Association classification for clavicle fractures.

Randomization to either PF or IMN fixation was performed by central computerized block randomization in the doctor's office. **Analysis after treatment** took place according to the intention-to-treat principle. Block sizes varied between 2 to 8 patients **with the two operative techniques equally presented in each block.** Additionally, the randomization procedure was stratified by participating center.[12]

*Operative Technique; Plate Fixation*

One single dosage of prophylactic antibiotics was administered preoperatively. Patients were **placed** in beach chair position and prepped in standard fashion. A longitudinal incision

parallel to the clavicle**, length of which depended on the fractured segment,** was made and the fracture was identified. Following fracture reduction, a plate (DePuy Synthes BV, Amersfoort, The Netherlands) was positioned on the anterosuperior surface of the clavicle and fixated using (non-)locking screws. Plate types were used according to surgical preference. A minimum of 3 bicortical screws was placed on each side of the fracture to ensure rigid fixation. If interfragmentary compression was possible, lag screws were placed first. Only in fractures with severe comminution, a bridging plate was used.[12]

*Operative Technique; Intramedullary Fixation*

Following similar antibiotic administration to plate fixation, patients were positioned in the supine position on a radiolucent table. Just lateral to the sternoclavicular joint a small incision was made and the anterior cortex was opened using a pointed reamer. A titanium elastic nail (TEN, DePuy Synthes BV, Amersfoort, The Netherlands or Stryker BV, Waardenburg, The Netherlands) was inserted from the medial side under fluoroscopic control. Fractures were reduced closed under image intensification with percutaneous clamps or, if closed reduction failed, in an open fashion using an additional small incision over the fracture site, **parallel to the clavicle. The length of the incision was variable at the discretion of the treating surgeon.** After complete introduction in the lateral fragment and compression of the fracture, the nail was cut at the introduction point.[12]

*Postoperative rehabilitation and Follow Up*

Regardless of the type of operative fixation, patients were given a sling for comfort yet they were encouraged to start active, non-weight bearing, mobilization as soon as pain permitted. Weight bearing was permitted after (radiographic) fracture consolidation was achieved **as observed by bridging bone or callus formation.**

All patients were followed up in the outpatient clinic at 2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery by the treating surgeon and an independent researcher (F.J.G.W. or

M.J.H.). Follow up included clinical and radiological assessment. **Self-administered** outcome scores were always completed prior to the actual follow up appointment.

*Study endpoints*

The DASH score after 6 months was considered the primary endpoint.[12,14,15] It allows for subjective disability rating and consists of a 30-item disability scale ranging from 0 (no disability) to 100 (complete disability).[14] Additionally, DASH scores were obtained at 6 weeks, 3 months and 1 year after surgery and the subjective shoulder function over the period between 6 and 6 months after the operation was assessed as derived from these measurements.

Secondary outcome measures included the Constant-Murley (CM) and SF-36 questionnaires,[16,17] and a 10-point Likert scale for satisfaction with the cosmetic result (0 = very unsatisfied, 10 = very satisfied). The CM score assesses shoulder pain, motion, strength and function and was determined in concordance with the DASH score. Of the maximum score of 100 points, 35 points are made up by patients' self-assessment and 65 points result from objective assessment.[16] The SF-36 questionnaire, completed pre-operatively and at 6 months and 1 year after surgery, measures health related quality of life and consists of 36 items covering 8 health related domains. Responses are summed and then transformed into a scale from 0 (poor health) to 100 (good health) for each domain.[17]

Recorded intraoperative data included time of surgery, conversion, performance of open reduction in case of IMN fixation and neurovascular complications. Complications were classified similar to strategies used in recently published systematic reviews,[9,10] including infection (superficial or deep), neurovascular problems (transient brachial plexus syndrome, hematoma, desensitized skin), implant related problems (soft tissue irritation, breakage, failure), bone-healing problems (nonunion, malunion) and, finally, refracture after implant removal.

The definition of a superficial infection was redness, swelling and/or purulent discharge of the wound. In case the infection required debridement or implant removal it was considered a deep infection. Brachial plexus lesions were defined as paresthesia of the arm, and/or

weakness of the little and **ring** fingers. Lesions were considered transient if spontaneous recovery occurred within a 6 month period. Soft tissue irritation was defined as irritation due to a palpable presence of the implant. Lack of radiographic healing with clinical evidence of pain and motion at the fracture site 6 months after surgery was considered nonunion. Lastly, fracture union in a shortened, angulated, or displaced position on X-ray with clinical symptoms was considered malunion.

*Statistical analysis*

Data were analyzed **by** the intention-to-treat principle. Baseline characteristics and postoperative outcome scores were compared using either a Student's T test or Mann-Whitney U test for continuous variables (baseline: BMI, age, SF-36 domain scores; intraoperative: days between fracture and surgery, duration of surgery; endpoints: DASH and CM scores at six months (between study arms and between converters and non-converters within study arms), DASH and CM scores during the six months of follow-up, SF-36 subscores difference-from-baseline scores) and a Pearson's Chi-square was used for categorical parameters. Interpolation of missing values of the shoulder scores proved to be most in concordance with the complete case approach and was therefore used as imputation method for missing follow up data. To study when differences in shoulder scores between the PF and the IMN group emerged during the first half year, a general linear random effects model was run.

Bivariate correlations between continuous variables were tested using Pearson or Spearman's rho. The complication rates of both interventions at one year after surgery were compared using a Poisson regression. The IBM SPSS Statistics version 20.0 was used for data analysis. Significance was established at a $p$-value of $<0.05$.

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## Results

*Baseline and intraoperative findings*

Of the 369 patients with a DMCF a total of 120 were enrolled in this study: 58 for PF and 62 for IMN fixation (Figure 1). There were no significant differences between groups at baseline apart from the plate group being less vital (64.5 versus 72.6; *p*=0.03) (Table 2). At one year after surgery there was a loss to follow up of 3 patients (3%), all in the plate group. These patients did not show up at final follow up, the reason of which was unknown.

In the IMN fixation group, 46 fractures (74%) were reduced in an open fashion **(CME 1)**. One patient (2%) in the plate group and 6 (10%) patients in the IMN fixation group underwent an intra-operative crossover and were further **analyzed** according to the intention to treat analysis (Table 3). There was no association between conversion and outcome at 6 months (*p*=0.42 in the IMN group; plate group not tested, because of just a single converter). In addition, in the IMN group, there was no association between time from fracture to surgery and the rate of open reduction (*p*=0.97); in turn, there was no association between open reduction and outcome (*p*=1.0).

*Primary and secondary outcomes*

Both the mean DASH score and mean CM score at 6 months postoperatively did not significantly differ between both groups (Figure 2 A-B, **CME 2**). Until 6 months after surgery, the PF group experienced less disability than the IMN group as indicated by the area under the curve (AUC) of the DASH score (*p*= 0.02, Figure 2A). At 1 year after surgery there was no difference between groups in terms of cosmetic satisfaction (*p*=0.67).

At 6 months, bodily pain (*p*=0.02) and vitality (*p*=0.03) scores of the SF-36 subscales were more improved since baseline in the PF group. Additionally, at 12 months the vitality change since baseline was still higher (*p*=0.02) in the PF group (Table 4).

*Complications*

In the PF group, 29 of 54 patients (54%) had a total of 36 complications (Table 5, **CME 3**). In the IMN fixation group 39 of 61 patients (64%) endured a total of 43 complications. The mean numbers of complications per patient, irrespective of severity level, was similar in both groups (PF: 0.67, IMN: 0.74; $p$=0.65). In the IMN group, irritation occurred on the medial side in 31 patients and laterally in 2 patients (1 patient in this group was converted to PF and suffered irritation from the plate).

In the PF group, 5 additional patients had their plates removed at their explicit request following fracture union. Also, 2 patients in the IMN group had the IM device routinely removed under local anesthesia and 10 under general anesthesia to prevent future migration of the implant according to the treating surgeon's practice.

## Discussion

There were no significant differences noted between the two surgical interventions for the primary study end parameter, the DASH score at 6 months postoperatively. **However, this present study shows that plate fixation results in a faster improvement in DASH score during the first 6 months after surgery.** Complications were mainly implant related and in total similar among groups **(CME 4)**. The IMN group endured slightly fewer complications requiring major revision.

The DASH and CM scores at final follow up were comparable to previously reported values for plate[1,5,18] and IM fixation.[4,18,19] We further assessed the level of physical functioning between 6 weeks and 6 months and demonstrated better subjective functioning in favor of PF.

In general the frequency of postoperative complications is similar between interventions. Medial protrusion of TENs was, however, a considerable problem similar to previous studies.[20,21] Since the medial end of the TEN cannot be locked, secondary shortening or rotation of the clavicle could result in protrusion of the TEN. Possible solutions for medial protrusion lie in endcaps which can be placed over the medial end of the TEN.[20] **In addition, we performed antegrade intramedullary fixation. Perhaps retrograde IMF and other implants, which are less prominent, may prevent the extent of (medial) protrusion.[26,27]** Lateral protrusion only occurred in case of accidental intraoperative penetration of the lateral cortex. In addition, the study protocol did not include routine IMN removal following fracture union. The interhospital and intersurgeon variation of participating centers in dealing with implant removal also grossly explains the high number of implant irritation in the IMN group. Furthermore, it illustrates that IM implants should be removed in routine fashion after fracture union to avoid irritation, preferably under local anesthesia.

For both interventions, the recording of symptoms of implant irritation were strictly applied, yet this does not form a valid explanation for the high number of plate irritations encountered, especially when comparing to previously reported data.[1,5] Plate placement on the anterior-

inferior aspect of the clavicle may be a solution to reduce implant irritation yet this may influence the strength of the repair construct.[22] The previously appreciated and biomechanically confirmed risk of re-fracture following plate removal was also illustrated in this study.[9,23] It stresses the importance of leaving plate and screw constructs *in situ* as long as possible and to caution patients in their rehabilitation following removal.

Reported surgical procedure lengths for both techniques were similar to previous values.[19,24] However, the number of open reductions in the IMN fixation group is remarkable when considering that one of the advocated advantages of this antegrade technique is closed reduction. A clear explanation for this high rate of open reduction could not be found. All conversions from IMN fixation to PF considered fractures located in the lateral part of the midshaft. Even when using the smallest diameter nails, the lateral fragment of the clavicle could not be entered. This raises the question of the suitability of these fracture types for antegrade IM fixation. In turn, the high rate of open reduction may explain the agreement between intervention groups in terms of cosmetic satisfaction. The one crossover in the plate group was the result of a communication error.

Recent study results indicate that patients reach a steady state in shoulder function 1 year after surgery.[25] Present study showed similar levels of functioning at 6 months and 1 year after surgery.

The strengths of this study include prospective randomization, power calculation and the report of both objective and subjective outcomes scores with sufficient follow up. In addition, care has been taken throughout the follow up process to note encountered complications and describe these in detail. However, several encountered limitations need also to be addressed. The first limitation is inherent to the study's multi-center and thus multi-surgeon design. This may lead to variations in and possibly unpredictable results. We believe, however, that this reflects daily clinical practice in average hospitals and results are therefore representative. Secondly, due to the differences in surgical techniques, both patients and treating surgeons could not be blinded. In addition, all pre- and postoperative data were collected by two investigators (F.J.W. and M.J.H.) who were not blinded either. The usage of

a self-administered outcome score which was always completed prior to the actual follow up appointment, however, limited possible investigator related bias.

Further, collecting DASH baseline scores was not planned in the original study protocol, disabling correction for remaining differences among study groups after randomization. In contrast, SF-36 scores were collected at baseline and showed that the PF group was less vital than the IMN fixation group. The higher gain in vitality scores in the plate group at 6 and 12 months may have resulted from regression-to-the-mean and should be interpreted with caution. The greater improvement in bodily pain scores between baseline and month 6 after surgery should be assessed with the same caution, for in a secondary analysis of the SF-36 subscales scores at 6 month and 12 months without correction for baseline, no significant differences between study groups were observed. We suggest suspending judgment concerning possible differences in bodily pain and vitality. Further study is needed here.

**Adherence to the intention-to-treat principle led to one major revision in the IMN group due to a failed plate fixation after intra-operative conversion. The influence on final outcome scores, however, was minimal and therefore the principle was strictly adhered to for final data presentation.**

Finally, study inclusion was not discussed with 44 potential participants because the attending surgeons did not have the required experience with either procedure as stated in the study protocol. Characteristics of these excluded patients, such as age and fracture pattern, proved to be similar to those of the included patients on retrospective comparison.

In conclusion, both procedures show satisfying functional results but patients after PF display a faster recovery the first 6 months after surgery. In turn, the rate of major complications in the PF group tends to be slightly higher than the IMN group. In both groups, the main complication concerns implant related irritation. **Future research should focus on determining which fixation type is appropriate for which fracture type.**

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**Figure 1.** Flowchart of inclusion for the POP-trial (Plate Or Pin trial for fixation of displaced midshaft clavicle fractures.

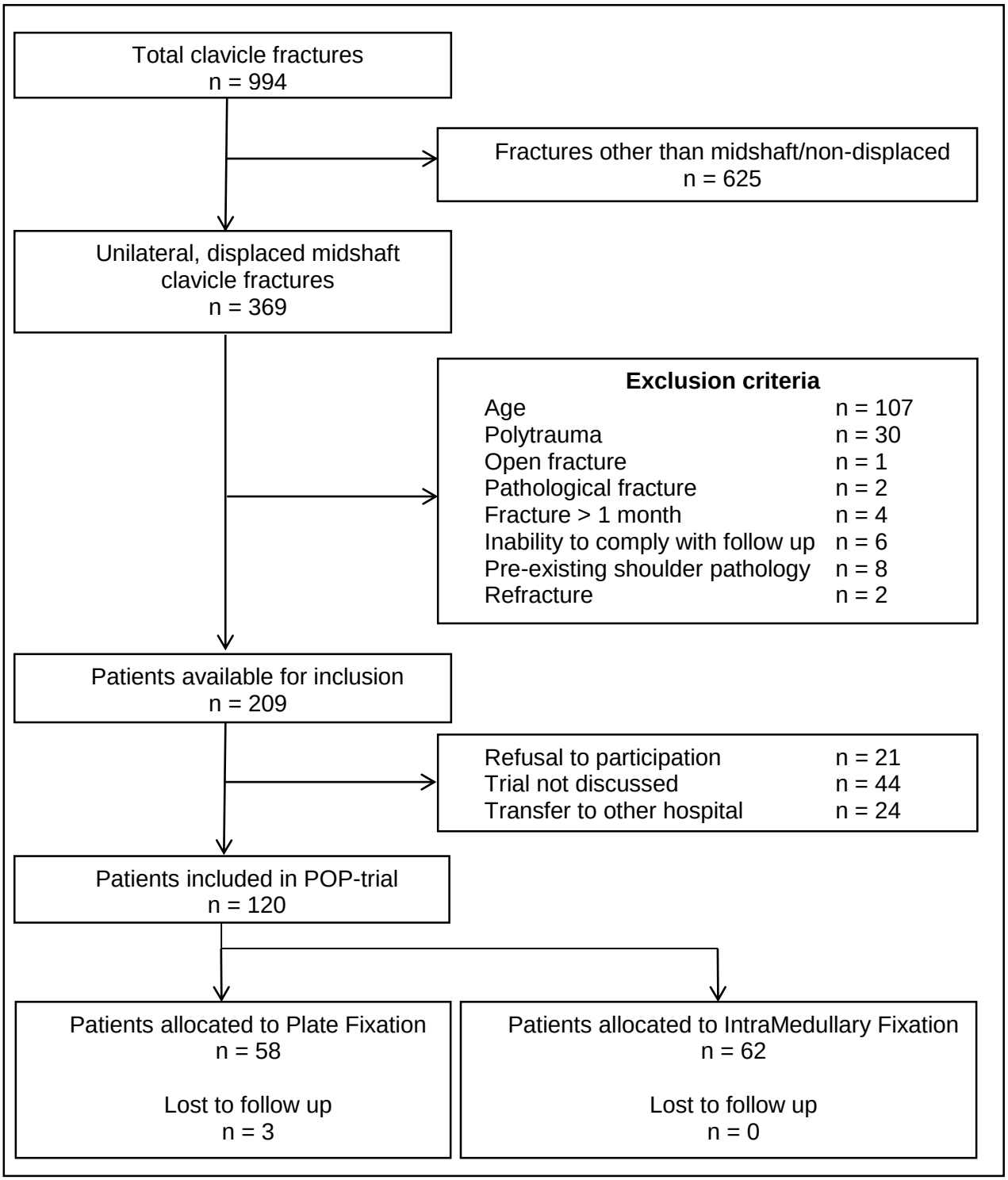

**Figure 2.** Graph displaying postoperative DASH (A) and Constant-Murley scores (B) at 6, 12, 24 and 52 weeks after surgery respectively.
SEM = Standard Error of the Mean
The DASH scores for PF were 10.8 (SEM 1.4), 4.63 (SEM 1.0), 3.0 (SEM 0.8) and 2.4 (SEM 0.6) and for IMN fixation 15.1 (SEM 1.7), 8.5 (SEM 1.4), 5.6 (SEM 1.3) and 3.9 (SEM 1.1).
The Constant-Murley scores for PF were 91.9 (SEM 1.4), 96.3 (SEM 1.0), 99.2 (SEM 0.4) and 96.0 (SEM 0.8) and for IMN fixation 84.1 (SEM 2.0), 91.1 (SEM 1.8), 95.5 (SEM 1.5) and 91.3 (SEM 1.5).
2A also displays the Area Under the Curve for the postoperative period of 6 weeks through 6 months. **(CME 3)**

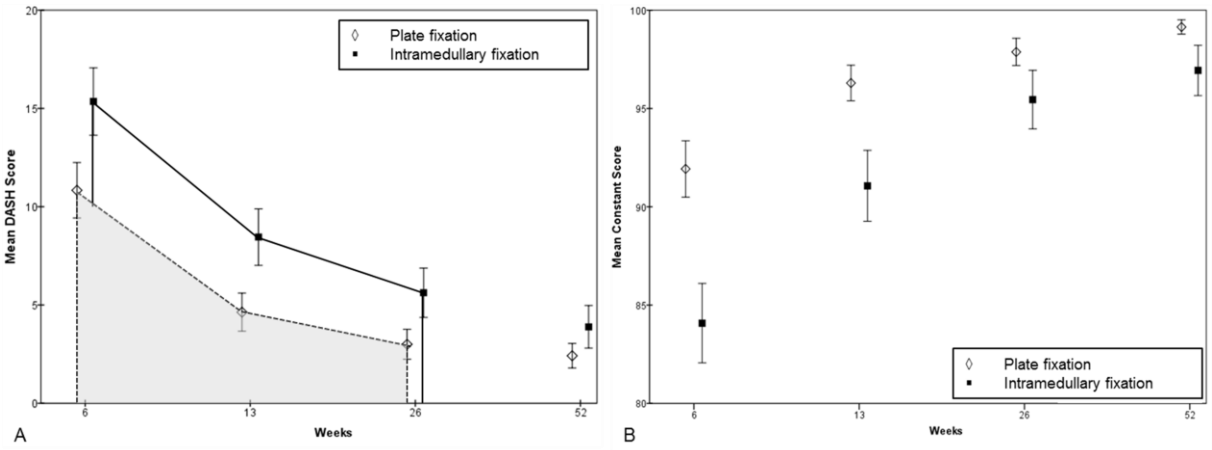

**Table 1**. Study eligibility criteria

| **Inclusion criteria** | **Exclusion criteria** |
|---|---|
| Unilateral, dislocated midshaft clavicle fracture | Polytrauma patients |
| Age 18 - 65 years old | Open fractures |
| No pre-existing shoulder pathology on affected side | Pathological fractures |
| No medical contra-indications to general anaesthesia | Fractures > 1 month old |
| Ability to provide informed consent | Neurovascular disorders |
| Ability to comply to follow up | Moderate to severe head injury at time of trauma (GCS < 12) |

GCS = Glasgow Coma Scale

**Table 2**. Baseline characteristics per group.

| **Preoperative data** | | **Plate fixation (n = 58)** | **Intramedullary fixation (n = 62)** | **p-values** |
|---|---|---|---|---|
| Age (years; mean ±SD) | | 38,4 (14,6) | 39,6 (13,2) | 0.64 |
| Gender (N, %) | Male | 53 (92%) | 60 (97%) | 0.21 |
| | Female | 5 (8%) | 2 (3%) | |
| Ethnicity (N, %) | Caucasian | 57 (98%) | 61 (98%) | 0.37 |
| BMI (kg/m2; mean ± SD) | | 24,7 (3,5) | 24,2 (3,0) | 0.36 |
| Smokers (N, %) | Yes | 19 (33%) | 20 (32%) | 0.90 |
| | No | 38 (67%) | 42 (68%) | |
| Alcohol/drugs (N, %) | Yes | 7 (12%) | 7 (11%) | 0.89 |
| | No | 51 (88%) | 55 (89%) | |
| Dominance (N, %) | Right | 50 (86%) | 55 (89%) | 0.68 |
| | Left | 8 (14%) | 7 (11%) | |
| Sports activities (N, %) | No | 17 (29%) | 20 (32%) | 0.73 |
| | Yes | 41 (71%) | 42 (68%) | |
| Fracture side (N, %) | Right | 30 (52%) | 29 (47%) | 0.59 |
| | Left | 28 (48%) | 33 (53%) | |
| Trauma mechanism (N, %) | Traffic accident | 28 (48%) | 25 (40%) | 0.17 |
| | Sports | 18 (31%) | 29 (47%) | |
| | Fall from stance/height/other | 12 (21%) | 8 (13%) | |

| | | | | |
|---|---|---|---|---|
| Fracture Classification (N, %)* | Simple | 27 (47%) | 24 (39%) | 0.58 |
| | Wedge | 29 (50%) | 34 (55%) | |
| | Complex/Comminuted | 2 (3%) | 4 (7%) | |
| SF-36 score (mean ± SD) | Physical functioning | 54,2 (± 22,5) | 55,9 (± 22,3) | 0.68 |
| | Role-physical functioning | 20,6 (± 38,1) | 21,7 (± 34,3) | 0.87 |
| | Bodily pain | 36,9 (± 19,1 | 41,9 (± 22,9) | 0.20 |
| | General health perception | 80,7 (± 19,3) | 86 (± 16,1) | 0.16 |
| | Energy/Fatigue (Vitality) | 64,5 (± 19,3) | 72,6 (± 20,5) | 0,03* |
| | Social Functioning | 67,8 (± 30,2) | 75,4 (± 24,7) | 0.24 |
| | Role-emotional functioning | 78,6 (± 38,4) | 83,1 (± 35,3) | 0.51 |
| | Mental Health | 80,9 (± 15,7) | 79,4 (± 16,1) | 0.61 |

SD = Standard Deviation. BMI = Body Mass Index (kg/m2)

*Fracture Classification according to Orthopaedic Trauma Association

**Table 3.** Intra-operative findings per procedure

| **Parameter** | **Plate fixation (n = 58)** | **Intramedullary fixation (n = 62)** |
|---|---|---|
| Time of surgery in minutes (mean, ± SD) | 54,0 (16,6) | 43,1 (23,9) |
| Conversion (N, %) | 1 (2%) | 6 (10%) |
| Open fracture reduction (N, %) | 58 (100%) | 46 (74%) |
| Neurovascular damage (N, %) | 0 | 0 |
| Incomplete reduction (N, %) | 0 | 1 (2%) |
| Lateral cortical perforation (N, %) | n/a | 1 (2%) |

SD = Standard Deviation. n/a = not applicable

**Table 4**. Mean improvement in SF-36 subscale scores compared to preoperatively.

| | | **Plate fixation** | **Intramedullary fixation** | |
|---|---|---|---|---|
| **6 months after surgery compared to preoperative** | | ***n = 47*** | ***n = 58*** | ***p-value*** |
| SF-36 score (mean ± SD) | Physical functioning | 44,1 (± 23,4) | 35,0 (± 26,2) | 0.07 |
| | Role-physical functioning | 72,3 (± 41,2) | 63,8 (± 49,4 | 0.35 |
| | Bodily pain | 55,9 (± 23,8) | 42,5 (± 33,6) | 0,02* |
| | General health perception | 2,4 (± 22,0) | 2,3 (± 16,9) | 0.22 |
| | Energy/Fatigue (Vitality) | 15,6 (± 25,4) | 4,7 (± 26,3) | 0,03* |
| | Social Functioning | 27,7 (± 30,6) | 17,7 (± 27,5) | 0.08 |
| | Role-emotional functioning | 15,2 (± 42,6) | 5,2 (± 46,6) | 0.26 |
| | Mental Health | 4,3 (± 20,3) | 3,4 (± 21,2) | 0.82 |
| **1 year after surgery compared to preoperative** | | ***n = 53*** | ***n = 59*** | |
| SF-36 score (mean ± SD) | Physical functioning | 43,0 (± 22,7) | 39,5 (± 22,9) | 0.42 |
| | Role-physical functioning | 76,9 (± 39,8) | 68,2 (± 45,7) | 0.29 |
| | Bodily pain | 58,5 (± 19,3) | 48,0 (± 28,4) | 0.07 |
| | General health perception | 4,8 (± 19,6 | 0,4 (± (26,2) | 0.13 |
| | Energy/Fatigue (Vitality) | 15,7 (± 22,1) | 4,6 (± 26,8) | 0,02* |
| | Social Functioning | 27,1 (± 33,9) | 19,9 (± 27,2) | 0.36 |
| | Role-emotional functioning | 12,2 (± 40,7) | 8,5 (± 48,2) | 0.67 |
| | Mental Health | 4,9 (± 17,5) | 5,6 (± 22,1) | 1 |

Missing values were excluded. SD = Standard Deviation.

*=$p$<0.05

**Table 5**. Postoperative complications after Plate fixation (*n* = 58) and Intramedullary (IM) fixation (*n* = 62).

| **Complication** | **Resolvement** | | | **Plate Fixation** | **Intramedullary fixation** |
|---|---|---|---|---|---|
| Infection | Superficial | *Antibiotics* | | 3 (5%) | 0 |
| | Deep | *Surgical drainage* | | 0 | 0 |
| Desensitized skin, haematoma | | *Self-limiting* | | 5 (8%) | 6 (10%) |
| Transient neuralpraxia | | *Self-limiting* | | 0 | 1 (2%) |
| Irritation due to implant protrusion | | *Wait-and-see* | | 13 (22%) | 1 (2%) |
| | | *Minor revision** | | n/a | 10 (14%) |
| | | *Hardware removal* | *Local Anaesthesia* | n/a | 8 (13%) |
| | | | *General Anaesthesia* | 11 (19%) | 25 (40%) |
| Implant breakage | | *Major revision*** | | 1 (2%) | 0 |
| Implant failure | | *Major revision* | | 0 | 2 (3%) |
| Nonunion | | *Major revision* | | 1 (2%) | 0 |
| Malunion | | *Major revision* | | 0 | 0 |
| Refracture after implant removal | | *Major revision* | | 2 (3%) | 0 |

* The minor implant revisions, which were performed under local anesthesia, included partial removal of the protruding end of an implant.

All 10 patients underwent total implant removal due to persistent irritation after minor revision. Since it involves a similar complication type, it is counted only once when summing the total number of complications per study group.