High Irritation and Removal Rates after Plate or Pin Fixation in Patients with Displaced Midshaft Clavicle Fractures

Martijn H. J. Hulsmans, MD[1]

Mark van Heijl, MD, PhD[1]

R. Marijn Houwert, MD, PhD[2]

Eric R. Hammacher, MD, PhD[3]

Sven A. G. Meylaerts, MD, PhD[4]

Michiel H. J. Verhofstad, MD, PhD[5]

Marcel G. W. Dijkgraaf, PhD[6]

Egbert J. M. M. Verleisdonk, MD, PhD[1]

[1]Department of Surgery, Diakonessenhuis Utrecht, Utrecht, The Netherlands

[2]Utrecht Traumacenter, Utrecht, Utrecht, The Netherlands

[3]Department of Surgery, St Antonius Hospital, Nieuwegein, The Netherlands

[4]Department of Surgery, Medical Center Haaglanden, The Hague, The Netherlands

[5]Trauma Research Unit Department of Surgery, Erasmus Medical Centre, University Medical Center Rotterdam, Rotterdam, The Netherlands

[6]Clinical Research Unit, Academic Medical Center Amsterdam, Amsterdam, The Netherlands

ABSTRACT

Background

Studies comparing plate with intramedullary nail fixation of displaced midshaft clavicle fractures show faster recovery in the plate group and implant-related complications in both groups after short-term followup (6 or 12 months). Knowledge of disability, complications, and removal rates beyond the first postoperative year will help surgeons in making a decision regarding optimal implant choice. However, comparative studies with followup beyond the first year or two are scarce.

Questions/purposes

We asked: (1) Does plate fixation or intramedullary nail fixation for displaced midshaft clavicle fractures result in less disability? (2) Which type of fixation, plate or intramedullary, is more frequently associated with implant-related irritation and implant removal? (3) Is plate or intramedullary fixation associated with postoperative complications beyond the first postoperative year?

Methods

Between January 2011 and August 2012, patients with displaced midshaft clavicle fractures were enrolled and randomized to plate or intramedullary fixation. A total of 58 patients with plate and 62 patients with intramedullary nails initially were enrolled. Minimum followup was 30 months (mean, 39 months; range, 30–51 months). Two patients (3%) with plate fixation and two patients (3%) with intramedullary nails were lost to followup. The QuickDASH was obtained at final followup and compared between patients who had plate fixation and those who had intramedullary nail fixation. Postoperative complications measured include infection, implant-related irritation, implant failure, nonunion, and refracture after implant removal. Indications for implant removal included implant-related irritation, implant failure, nonunion, patient's wish, or surgeon's preference.

Results

Between patients with plate versus intramedullary nail fixation, there were no differences in QuickDASH scores (plate, 1.8 ± 3.6; intramedullary nail, 1.8 ± 7.2; mean difference, -0.7; 95% CI, -2.2 to 2.04; $p = 0.95$). The proportion of patients having implant-related irritation was not different (39 of 56 [70%] versus 41 of 62 [66%]; relative risk, 1.05; 95% CI, 0.82–1.35; $p = 0.683$). Intramedullary fixation was associated with a higher likelihood of implant removal (51 of 62 [82%] versus 28 of 56 [50%]; relative risk, 1.65; 95% CI, 1.24–2.19; $p < 0.001$). Among the removed implants more plates than nails were removed after the 1-year followup (12 of 28 [43%] versus six of 51 [12%]; $p = 0.002$). There were no infections, implant breakage, nonunions, or refractures between the 1-year and final followup in either group.

Conclusions

After a mean followup of 39 months, disability scores were excellent. Major complications did not occur after the 1-year followup moment. A frequent and bothersome problem after both surgical treatments is implant-related irritation, resulting in high rates of implant removal, after 1 year. Future research could focus on analyzing risk factors for implant irritation or removal.

INTRODUCTION

During the last few decades, several studies investigating the optimal treatment of displaced midshaft clavicle fractures (DMCF) have been conducted. Sequelae rates up to 46% after nonoperative treatment were reported and advantages of surgical fixation over nonoperative treatment of these fractures include quicker rehabilitation or return to daily activities and lower nonunion rates.[4,15,20] Therefore operative treatment, especially in the young patient who relies on the upper limb for work or sports, has been advised.[7] The two most commonly used techniques for operative treatment of displaced midshaft clavicle fractures are plate fixation (PF) and intramedullary fixation (IMF) using a pin or nail.

Studies comparing these techniques showed excellent outcomes in bone healing, functionality, and low rates of major complications requiring revision surgery up to 1 year postoperatively.[1,23] One frequent and bothersome problem for patients after surgical treatment of DMCF is implant-related irritation. Reported irritation rates range from 9% to 44% after PF and 9% to 62% after IMF. It often is treated by surgical implant removal (a second operation).[1,4,6,20-23] However, comparative studies or studies regarding the development of implant-related irritation with followup beyond the first year or two are scarce.[1,4,14,19,23]

van der Meijden et al.[21] previously conducted a multicenter randomized controlled trial comparing these operative techniques and confirmed the aforementioned low disability scores, low major complication rates, implant-related irritation, and implant removal occur frequently after 6 or 12 months. However, that study did not focus on implant-related irritation, the severity of the subjective implant-related irritation was not classified, and patients were followed only until a maximum of 12 months. We extended the followup because we expected these implants to still cause irritation and to be removed after the 1-year followup. This also might influence the disability scores.

Therefore, the current study provides additional followup on the same patients reported in the previous study [21]. We asked: (1) Does plate fixation or intramedullary nail fixation for DMCF result in less disability? (2) Which type of fixation, plate or intramedullary (IM) nail, is associated with implant-related irritation and implant removal? (3) Is plate or IM nail fixation associated with postoperative complications beyond the first postoperative year?

PATIENTS AND METHODS

We prospectively investigated the population of a previously published multicenter randomized controlled trial.[21] The original trial compared PF (n = 58 patients) with IMF (n = 62 patients) for displaced midshaft clavicle fractures and included patients from January 2011 until August 2012. Surgeons participating in this study had extensive experience (> 20 procedures) with each surgical technique. Outcomes were the DASH and Constant-Murley scores and complications at 2, 6, 12, 24, and 52 weeks.[21]

For the current study, patients were contacted between January and March 2015, resulting in a minimum followup of 30 months (mean, 39 months; range, 30–51 months). An independent researcher (RL) performed the followup and conducted all outcome parameters with a telephone survey. Medical files were double-checked for any complications that the patient may not have

mentioned. Patient inclusion, randomization, surgical technique, and postoperative management were explained in detail in the previous study.[21]

Data were analyzed according to the intention-to-treat principle. Fifty-eight patients were randomized to PF (27 [47%] simple fractures and 31 [53%] wedge or complex fractures) and 62 to IMF (24 [39%] simple fractures and 38 [61%] wedge or complex fractures). The mean age of the patients in the PF group was 38 years (SD, 14.6 years) and 53 (91%) men participated. The mean age of patients in the IMF group was 40 years (SD, 13.2 years) and 60 (97%) men participated. The endpoints for this study were disability (QuickDASH), varying degrees of implant-related irritation and implant removal for any reason, and complications that occurred beyond the first postoperative year.

One hundred sixteen patients (97%) were contacted in 2015 and four patients (3%) were lost to followup. Two patients in the PF group were already lost to followup 1 year after surgery. The other two, both in the IMF group, had died from cancer. Because they had no complications and their implants had been removed on request before their 1-year followup, data regarding implant-related complications were included for analysis. The mean followup was 39 months (range, 30-51 months).

Outcome Measures

Disability

The first section of the survey included the *QuickDASH questionnaire, which* is a short, validated, reliable patient-oriented outcome measure for assessing upper extremity disability. Higher scores represent greater disability and lower scores indicate a better functioning extremity (range, 100-0).[3,9]

Implant-related Irritation

The second section of the survey addressed patient-reported implant-related problems, implant removal, and whether surgical consideration was attributable to implant-related irritation. Patients who had other causes of irritation such as infection or nonunion were excluded from this analysis. Patients were asked a series of binary (yes or no) questions that focused on the subsequent actions after these implant-related problems (eg, implant removal). They were asked if the implant was removed, if so, was it attributable to implant-related irritation; and if not, did they experience any kind of implant-related irritation and were they considering removal or was surgery not performed because of fears. The questions were based on extensive clinical experience and designed for easy use in outpatient clinical settings. A schematic representation of the questions is shown in the flowchart (Figure 1).

Complications

The last section of the survey addressed complications, interventions needed to treat these complications, and implant removal for the period between 1-year and the final followup. The same definitions for complications and revisions were used as in the original trial.[21] Minor complications included infection (superficial or deep) and implant-related irritation. Complications requiring revision surgery were considered major and included implant failure, nonunion, and refracture after implant removal. A painful or unpleasant sensation in the affected clavicle in cold environments was considered cold intolerance. In both groups indications for implant

removal included implant-related irritation, implant failure, nonunion, patient's wish, or surgeon's preference to prevent future complications.

Statistical Analysis

Postoperative outcome scores are presented as mean ± SD and were compared using Student's t-test for continuous variables (QuickDASH score). Categorical data are presented as absolute numbers (percentage) and were compared using Pearson's chi square test or the Fisher's exact test in case of low cell frequencies. To compare the QuickDASH score in 2015 with the DASH scores obtained during previous followups, the 11 QuickDASH questions were derived from the total DASH scores. SPSS software (Version 20.0; IBM, Armonk, NY, USA) was used for data analysis. Significance was established at a p value less than 0.05.

RESULTS

Disability

At final followup at 39 months, there were no differences in QuickDASH scores (plate, 1.8 ± 3.6; IM nail, 1.8 ± 7.2; mean difference, -0.7; 95% CI, -2.2 to 2.04; p = 0.945) (Table I). At earlier times of 1.5, 6, and 12 months, disability scores were not significantly different (Figure 2). Three months postoperatively there was a significant difference in disability scores in favor of the PF group (plate, 5.1 ± 7.2; IM nail, 9.4 ± 11.6; mean difference, -4.3; 95% CI, -7.9 to -0.6; p = 0.023).

Implant-related Irritation

Although the proportion of patients having implant-related irritation was not different (plate, 39 of 56 [70%]; IM nail, 41 of 62 [66%]; relative risk, 1.05; 95% CI, 0.8–1.4; p = 0.683), IMF was associated with a higher likelihood of implant removal (51 of 62 [82%] versus 28 of 56 [50%]; relative risk, 1.65; 95% CI, 1.2–2.2; p < 0.001) (Table II). The reasons for implant removal did not differ between the PF and the IMF groups (p = 0.551). All 28 plates were removed with the patients receiving general anesthesia; 13 IM nails were removed with the patients receiving local anesthesia and 38 were removed with the patients receiving general anesthesia.

A subanalysis of gender-specific implant removal rates showed no difference (male, 74 of 111 [67%] versus female, five of seven [71%]; relative risk, 0.93; 95% CI, 0.6–1.5; p = 1.000).

Complications

There were no infections, implant failures, nonunions, or refractures between the 1-year and the final followup in either group. Beyond the first postoperative year PF was associated with more implant-related irritation compared with IMF (28 of 56 [50%] versus eight of 60 [13%]; relative risk, 3.9; 95% CI, 1.9–7.8; p < 0.00) (Table III). Among the removed implants more plates than IM nails were removed after the 1 year followup (12 of 28 [43%] versus six of 51 [12%]; p = 0.002). Cold intolerance was not different between treatment groups (plate, 10 of 56 [18%]; IM nail, 10 of 60 [17%]; relative risk, 1.07; 95% CI, 0.5–2.4; p = 0.865).

DISCUSSION

In studies comparing PF with IMF for displaced midshaft clavicle fractures, the majority of complications after 1 year are implant-related.[1,23] van der Meijden et al.[21] previously reported on this group of patients, and found that until 6 months the PF group experienced less disability than the IMF group. They also reported low rates of major complications requiring revision surgery, although implant-related irritation occurred frequently within 1 year and often could be treated with implant removal.[21] However, that study did not focus on the implant-related irritation, the severity of the subjective implant-related irritation was not classified, and patients were followed only until a maximum of 12 months. Therefore, we compared outcome and implant-related irritation after a mean followup of 39 months in the original cohort of the randomized controlled trial[21] comparing PF versus IMF for displaced midshaft clavicle fractures.

This study had numerous limitations. First, implant-related irritation is a subjective measurement as is the decision to remove an implant. By classifying the severity of the implant-related irritation and standardizing the questions, we tried to score irritation as consistent as possible. In the future we think this classification could be helpful by applying consistent indications to make a decision regarding implant removal. Second, a multicenter study in which multiple surgeons participate may lead to variable and possibly unpredictable results. However, surgical techniques, postoperative rehabilitation, followup, and indications for revision surgery were standardized to ensure uniformity regarding these issues across the participating hospitals. Third, one could question the accuracy of the answers conducted via telephone. However, verbally conducted QuickDASH scores replicate clinically relevant scores of the written QuickDASH and have good test-retest performance.[12] Fourth, the QuickDASH score is not specifically designed for patients with a displaced midshaft clavicle fracture. Nevertheless, it often is used as one of the tools to measure function.[1, 4,18-20] Fifth, because patients experience and recall symptoms differently, we know this study could be susceptible to recall bias. By asking patients the same (standardized) questions and ensuring they were not aware of the study hypothesis, we think the recall bias is low. Finally, the standardized flowchart (Figure 1) we used to classify the severity of the subjective implant-related irritation is not validated. By focusing on the subsequent actions the patient is willing to take, we believe it is useful to inform patients correctly regarding postoperative irritation or removal rates.

In contrast to results of van der Meijden et al.[21], who reported faster recovery during the first 6 months after PF, no differences were observed in disability (QuickDASH scores) between PF and IMF after a mean followup of 39 months. Interpreting these disability scores, one may conclude PF could be favorable for early rehabilitation protocols or return to sports. However, there was no difference between the two groups 39 months postoperatively.

Biomechanical studies also showed PF provided a more rigid construct, especially in rotational stability, compared with IMF.[5,17] As these biomechanical studies reported on time-0 testing, not taking biologic influences into account, we can relate only to the short-term predictions and these findings probably could not be used for advice regarding return to sports.[5,17]

In the current study, QuickDASH scores improved marginally after 1 year, and were comparable to previously reported data after long-term followup.[10,14,16] Results of one study indicated that shoulder

disability scores reached a steady state 1 year postoperatively [19]. After 1 year, the improvement in shoulder disability scores of patients treated surgically was less than 10 and 8 points, which are the minimal numbers for a clinically important difference for the DASH and QuickDASH, respectively.[8,13,19]

Implant-related irritation is a troubling, subjective endpoint because symptoms likely are governed by a multitude of variables including patient pain perception, bone quality, thickness of the overlying soft tissue, and possibly the surgeon's experience. These patient- and surgeon-specific variables may explain the wide variation in irritation rates reported by others (9%-64%).[1,4,6,20,22,23] Some surgeons consider irritation as discomfort coexisting with the treatment rather than a complication. For this reason, we did not aim to quantify irritation but rather focused on the actions needed to treat the irritation based on intensity per the patient's perspective.

Our study showed high implant-related irritation and removal rates, especially in the IMF group. This could be explained by the relatively high amount of wedge and complex fractures (61%). We believe these fractures are prone to intra- or postoperative shortening of the clavicle causing the pin to migrate and irritate; IMF therefore is probably less suitable for these type of fractures.

Naimark et al.[14] reported patient-reported outcomes after PF of midshaft clavicle fractures and also completed an implant-related outcome survey in 73 patients. They reported a substantially lower overall plate removal rate compared with the rate in our study (15% versus 50%). The lower response rate they reported (66% versus 97%) could be an explanation for this. Patients doing poorly or pursuing implant removal elsewhere may be less likely to respond to the questionnaires. Another 12% of their patients expressed a strong desire to have the plate removed[14], which is comparable to the 11% in this study.

van der Meijden et al.[21] reported a total of three infections and six major complications, although none of these developed after the 1 year followup. An explanation for the low major complication rates, like implant failure, could be that in half of the patients (16 in the PF group and 45 in the IMF group) the implant had been removed before the 1-year followup.[21] Only a few studies have analyzed complications with followup beyond the first year after surgical treatment of displaced midshaft clavicle fractures.[2,10,11,14] Comparable to the current study, they reported low rates of infection, failure, and nonunion. Therefore, it may be concluded that implant-related irritation is the most frequent complication and seems to be the most frequent reason that necessitated implant removal.[2,10,11,14]

At final followup implants were removed more often after IMF in our patients. However, after the first year of followup, more implant removals were done in the PF group compared with the IMF group. Although implant removal with patients receiving local anesthesia seems to be an advantage of IMF, several patients preferred general anesthesia owing to fear of the surgical procedure with local anesthesia. An explanation for the higher percentage of irritation and implant removal in the PF group between the 1-year and the final followup could be that a large proportion of the implants in the IMF group had been removed within the first year postoperatively. In other words a larger proportion of plates was still in situ after one year, which potentially could cause irritation.

After a mean followup of 39 months, shoulder function was excellent and only marginally improved after 1 year for patients with PF and IMF of displaced midshaft clavicle fractures. Major complications

did not occur after the 1-year followup. A frequent and bothersome problem after both surgical treatments is implant-related irritation, resulting in high rates of implant removal, and also after a period of one year. Clinical followup therefore should be extended beyond the first postoperative year. Future research could focus on using standardized questions to classify the severity of the subjective implant-related irritation. Analyzing risk factors, like fracture classification, for implant irritation or removal could be another subject to focus on in the search for the optimal implant choice.

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Figure I. A schematic representation of the questions regarding implant-related irritation and removal is shown. Patients who had other causes of irritation such as infection or nonunion should be disregarded.

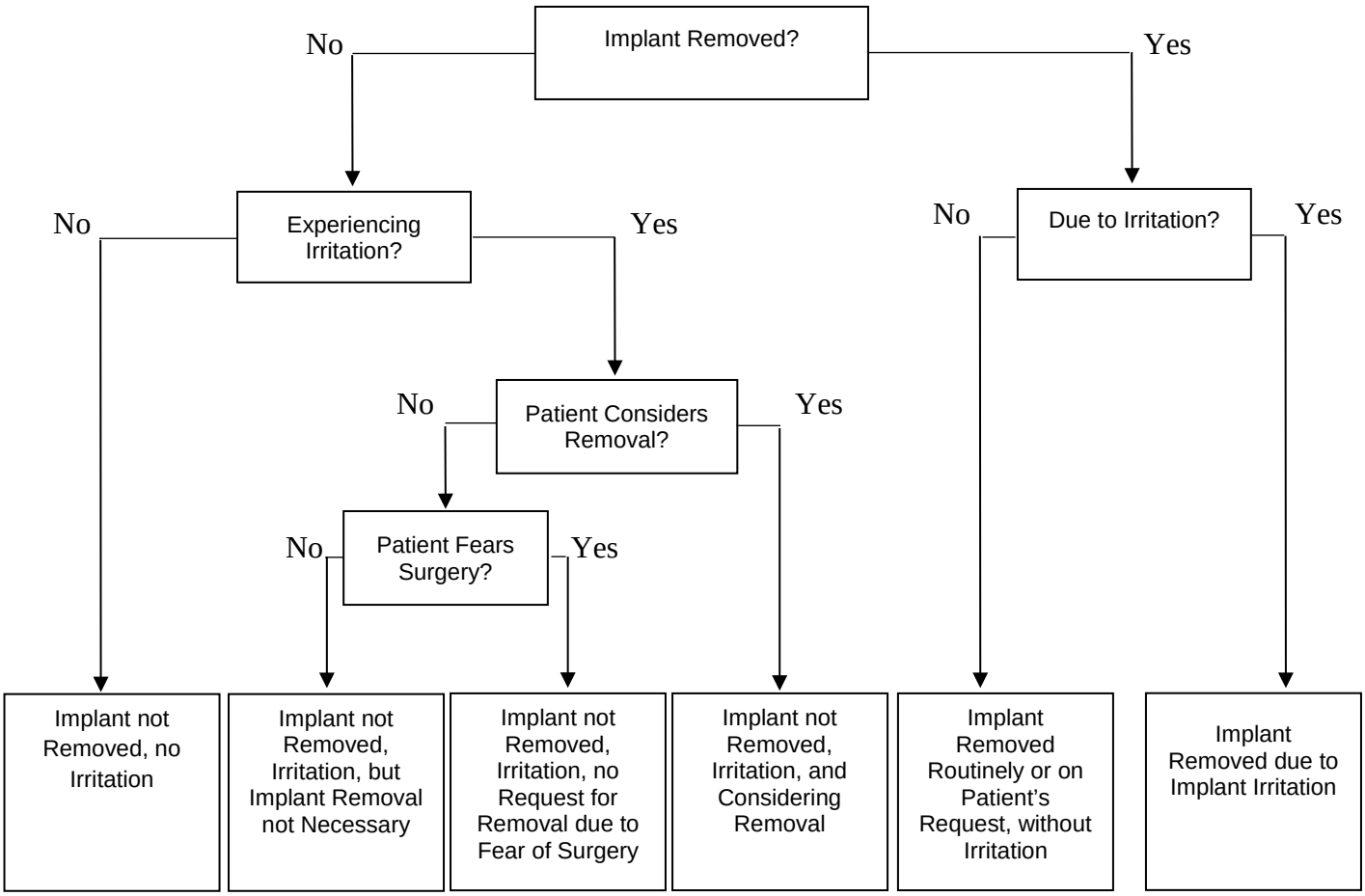

Figure II. The graph shows a comparison of the postoperative QuickDASH scores at 11.2, 3, 6, 12 and 39 months.

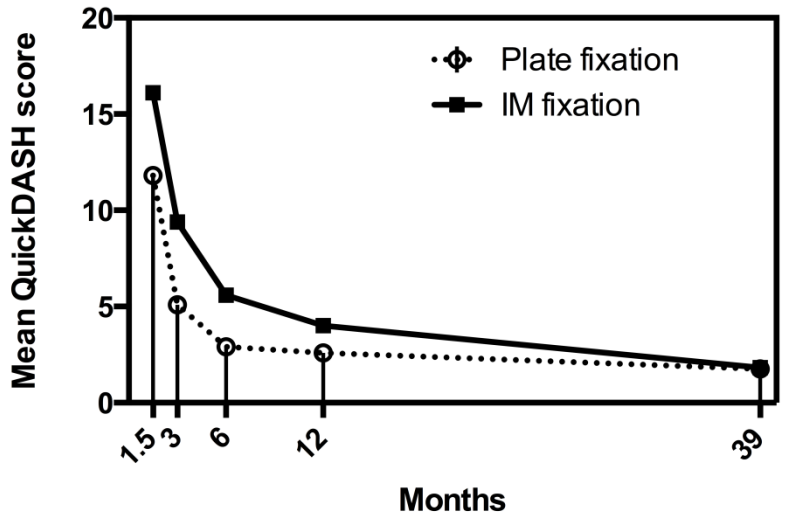

Table I. QuickDASH scores after plate or IM nail fixation of displaced midshaft clavicle fractures

Follow-up moment	Plate Fixation (N = 56)†	Intramedullary Fixation (N = 62)‡	Mean difference, (95% CI)	*P* value
	Mean (SD)	**Mean (SD)**		
1.5 month	11.8 (12.1)	16.1 (14.0)	-4.3 (-9.2, 0.5)	0.080
3 months	5.1 (7.2)	9.4 (11.6)	-4.3 (-7.9, 0.6)	0.023
6 months	2.9 (5.1)	5.6 (9.9)	-2.7 (-5.8, 0.4)	0.092
12 months	2.6 (5.2)	4.0 (9.8)	-1.4 (-4.4, 1.6)	0.347
39 months	1.8 (3.6)	1.8 (7.2)	-0.7 (-2.2, 2.0)	0.945

†Two patients lost to follow-up.

‡2 patients died; included because implants were already removed on patients' request before the 1 year follow-up moment.

Table II. Classification of implant related problems based on results of questionnaire (Followup = 39 months)

Classification	**Plate Fixation (N = 56)†**	**Intramedullary Fixation (N = 62)‡**	**Relative risk, (95% CI)**	***P* value**
Implant related irritation	39 (70%)	41 (66%)	1.05 (0.8, 1.4)	0.683
Implant removed	28 (50%)	51 (82%)	0.61 (0.5, 0.8)	*<0.001**
Reason removed				0.551
Due to implant-related irritation	21 (75%)	35 (69%)	1.09 (0.8, 1.5)	
Patient's wish or surgeon's preference	7 (25%)	16 (31%)	0.80 (0.4, 1.7)	
Status not removed				0.939
No irritation	10 (36%)	5 (45%)	0.79 (0.4, 1.8)	
Experiencing irritation, but implant removal not necessary	8 (29%)	3 (27%)	1.05 (0.3, 3.2)	

Experiencing irritation, but no request for removal due to fear for reoperation	4 (14%)	1 (9%)	1.5 (0.2, 12.5)
Experiencing irritation, considering removal	6 (21%)	2 (18%)	1.2 (0.3, 5.0)

*Numbers are cumulative over the first post-operative year and beyond.

* *P* value < .05 is statistically significant

†Two patients lost to follow-up.

‡2 patients died; included because implants were already removed on patients' request before the 1 year follow-up moment.

Table III. Postoperative complications beyond the first postoperative year

Complications	**Treatment**	**Plate fixation (n = 56)†**	**Intramedullary fixation (n = 60)‡**	**Relative risk (95% CI)**	***P* value**
Superficial infection	Antibiotics	0	0	-	-
Deep infection	Surgical drainage	0	0	-	-
Implant-related irritation					< 0.001*
Yes	Observation	18 (32%)	5 (8%)	3.86 (1.5-9.7)	
	Implant shortening^	0	1 (2%)	0.98 (0.9-1.0)	
	Implant removal, local anesthesia	0	1 (2%)	0.98 (0.9-1.0)	
	Implant removal, general anesthesia	10 (18%)	1 (2%)	10.71 (1.4-81.0)	

No**		28 (50%)	52 (87%)	0.57 (0.4-0.8)	
Implant failure	Major revision	0	0	-	-
Nonunion	Major revision	0	0	-	-
Refracture after removal	Major revision	0	0	-	-
Cold intolerance		10 (18%)	10 (17%)	1.05 (0.5-2.4)	0.865

IM = intramedullary; †two patients lost to followup; ‡two patients died, and are not included for analysis; *****significant with $p < 0.05$; ^partial removal of the protruding end of the titanium elastic nail with patient under local anesthesia, only the broken tip was removed; **includes16 plates and 45 nails removed before the 1-year followup moment.