

# Five-Year Follow-up Results of a Randomized Controlled Study Comparing Intramedullary Nailing with Plate Fixation of Completely Displaced Midshaft Fractures of the Clavicle in Adults

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**Background:** Surgical management of completely displaced midshaft fractures of the clavicle is becoming more frequent, although long-term follow-up with Level-I evidence is scarce. Plate fixation (PF) of comminuted fractures provides faster functional recovery than elastic stable intramedullary nailing (ESIN). The 12-month follow-up of this randomized controlled trial, published previously, found no clinical differences at that time on the group level, but subtle differences on the subgroup level indicated that the results after closed ESIN were better than those after open ESIN. The primary aim of the study reported here was to compare the long-term clinical outcomes and sequelae after open reduction with those after closed reduction and to help surgeons develop a treatment strategy of either PF or ESIN for selected patients.

**Methods:** At a median follow-up of 66 months (range, 49 to 89 months), the 123 patients in the original study were invited to an online secure survey. We used the survey results to compare the PF and ESIN treatment arms and to perform predetermined subgroup analyses of closed compared with open ESIN in relation to Disabilities of the Arm, Shoulder and Hand (DASH) score, pain assessment, and implant removal.

**Results:** The questionnaire was completed by 114 (93%) of the 123 patients. There were no differences between the 2 treatment arms with regard to the DASH score (ESIN,  $3.1 \pm 7.0$  and PF,  $3.7 \pm 7.5$ ;  $p = 0.9$ ). The 27 patients who had been treated with closed ESIN had a significantly superior DASH score compared with the 27 patients who had been treated with open ESIN (closed,  $0.7 \pm 1.4$  and open,  $5.2 \pm 8.9$ ;  $p = 0.015$ ) and compared with the patients who had been treated with PF (closed ESIN,  $0.7 \pm 1.4$  and PF,  $3.9 \pm 7.5$ ;  $p = 0.002$ ). Patients who had been treated with closed ESIN also reported fewer sequelae than patients who had been treated with open ESIN or PF.

**Conclusions:** The results of this study, combined with those of our prior 1-year follow-up of the same patients, indicate that it seems to be advantageous to perform closed ESIN. The long-term results after PF were similar to those after open ESIN, but PF resulted in faster functional recovery and fewer patients needing to have the implant removed. Therefore, if open reduction is necessary for a comminuted fracture, it seems that the advantages of the minimally invasive ESIN procedure are lost, and the surgeon should consider conversion to PF.

**Level of Evidence:** Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Fractures of the clavicle have been reported to account for 2.6% to 4% of all fractures<sup>1,2</sup>. Approximately 80% of the fractures occur in the middle third of the bone, and approximately 70% of the midshaft fractures in adults are completely displaced by 1 bone width or more<sup>3</sup>. Primary operative

treatment results in faster functional recovery and fewer nonunions than conservative treatment with a sling, but after 12 months the differences in functional outcome may not be clinically important<sup>4-8</sup>. Even though the literature does not clearly support surgery for these fractures, surgery is becoming more frequent,

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at least in Scandinavia<sup>9</sup>. Operative treatment of completely displaced midshaft fractures provides predictable results. Two randomized controlled trials comparing open reduction and plate fixation (PF) with elastic stable intramedullary nailing (ESIN) have reported that functional recovery is faster after PF than after ESIN but that the results are similar after 6 months<sup>10,11</sup>.

We previously reported the 12-month follow-up of this randomized controlled trial of completely displaced midshaft fractures of the clavicle treated with PF or ESIN at Akershus University Hospital, Lørenskog, Norway<sup>11</sup>. The main findings at 12 months were that both methods returned the patients to their preinjury functional levels but that patients with comminuted fractures who were treated with PF rather than ESIN had better early results. For those patients, scores on the QuickDASH questionnaire (an abbreviated version of the Disabilities of the Arm, Shoulder and Hand [DASH] outcome questionnaire) were better at 1 through 5 weeks postoperatively, and the DASH and Constant scores were better at 6, 12, and 26 weeks<sup>12-16</sup>. In fractures without intermediary fragments, the 2 methods showed no differences in functional outcomes at any point in time. Compared with PF, the duration of ESIN surgery was shorter ( $p < 0.001$ ), and those patients were more pleased with their cosmetic appearance ( $p < 0.05$ ). ESIN resulted in lower rates of infection and implant failure when nails no thinner than 2.5 mm were used, indicating that this was the preferred method in midshaft fractures with no comminution, whereas PF was the superior method for most patients, as 73% in this series had intermediary fragments. Post hoc subgroup analysis of patients treated with ESIN showed that closed reduction resulted in significantly better DASH scores and Constant scores than open reduction at all time points and for all outcome measures except the Constant score at 12 months. Multivariate logistic regression for hierarchical data revealed an increase in the odds of an open procedure if surgery was delayed and if the fracture was comminuted.

The purpose of the present study was to determine whether the 12-month differences between closed and open ESIN were permanent and to compare the clinical outcomes and need for removal of the implant at a median follow-up of 66 months for patients who had been treated with PF or with closed or open ESIN.

## Materials and Methods

### Study Design

This randomized controlled trial was performed at Akershus University Hospital in Norway, which has a catchment area of about 500,000 people. The inclusion and exclusion criteria were published previously<sup>11</sup>. Eligible patients were informed of nonoperative and operative treatment options. Preinjury DASH scores were recorded when patients were first seen, to obtain baseline values. After giving informed consent, the patients were randomized to treatment with either PF or ESIN. PF was performed with a 3.5-mm LCP (locking compression plate) superior precontoured clavicle plate that had locking possibilities, and ESIN was performed with a 2.0 to 3.5-mm

titanium elastic nail. Both types of implants were produced by DePuy Synthes. Randomization was accomplished with the use of sealed, opaque envelopes in blocks of 8, 10, and 12. The operating surgeon opened the sequentially correct numbered envelope after the induction of anesthesia.

The Regional Ethical Committee for research approved the study, and the study was registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT01015924).

### Statistics

The null hypothesis was that there would be no difference in DASH scores for patients treated with the 2 methods. The alternative hypothesis was that there would be a difference of 10 points, which is considered to be the minimum clinically important difference (MCID)<sup>17</sup>. The standard deviation of the DASH score was assumed to be 15 points for each method<sup>18</sup>. For a significance level of 5% and a power of 80%, 36 patients were required in each group.

Continuous variables were analyzed using parametric or nonparametric tests when appropriate, after the normality of the data was evaluated. Chi-square and Fisher exact tests were employed to compare categorical data, and the Mann-Whitney U test was used for ordinal data. Pain was assessed with an ordinal scale: no pain, mild, moderate, and severe. Due to the small numbers of patients, this was dichotomized to pain or no pain. All statistical analyses were performed using SPSS version 24 (IBM).  $P < 0.05$  was considered significant.

### Interventions

All operative procedures were performed by the on-call surgeons and with the patients under general anesthesia, to reflect the everyday environment of the hospital. For a patient to be included in the series, the operating surgeon had to have performed each procedure at least twice previously.

The operative techniques are described in the Appendix.

### Assessment of Clinical Outcomes

Because both treatment arms had the same result at the 12-month control evaluation<sup>11</sup> and had DASH scores within 2 points of their baseline DASH scores, for the sake of simplicity we chose to use the median time value for the entire group instead of the individual 5-year controls. At a median of 66 months after surgery (range, 49 to 89 months), the patients were contacted by telephone and their e-mail addresses were obtained. They were asked to fill out a secure online questionnaire, which encrypted the sensitive data directly to a secure server.

The patients were asked if the implant had been removed or if any implant-related surgery had been performed. They were also asked if they had sustained a new fracture of the clavicle or any other injury or had undergone any operation since the primary surgery that could influence the current function of the shoulder and thus the long-term clinical result. We reviewed the patients' medical records to cross-check information. Routine removal of the implant was not offered to any patient. Patients who had PF had been

advised to wait at least 12 months before having the plate removed because we thought that initial irritation caused by the plate would settle over time and thus unnecessary surgery could be avoided.

The functional outcome was assessed with the DASH score, which is patient-oriented. A score of 0 points signifies no disability and 100 points indicates complete disability. The patients were asked if they had numbness under the incision (yes or no), pain when sleeping on the affected side, pain if something hit the clavicle, and pain at rest or with movement, and if they felt that the clavicle was painful. New radiographs were not made because previous follow-ups had verified that all fractures had healed.

## Results

A total of 353 clavicle fractures in patients between 16 and 60 years old were enrolled between June 1, 2009, and Sep-

tember 30, 2012, of which 218 were completely displaced in the middle third (Fig. 1). Of the 150 eligible patients, 123 were included in the study. There were no demographic differences between the groups (Table I) and they had the same preinjury mean DASH score of 0.5, with standard deviations of 1.2 for PF and 2.1 for ESIN ( $p = 1$ ). Of the 123 patients, 114 (93%) completed the questionnaire.

## Clinical Outcome

There were no differences in DASH scores between the PF and ESIN groups at a median follow-up of 66 months (mean and standard deviation: ESIN,  $3.1 \pm 7.0$  points and PF,  $3.7 \pm 7.5$  points;  $p = 0.9$ ). This did not change when the scores were adjusted for their individual preinjury baseline data; that is, when the baseline value was subtracted from the end result (ESIN,  $2.5 \pm 6.5$  and PF,  $3.0 \pm 7.4$ ;  $p = 0.7$ ). For 6 patients (11%) who had been treated with ESIN and 5 patients (9%)

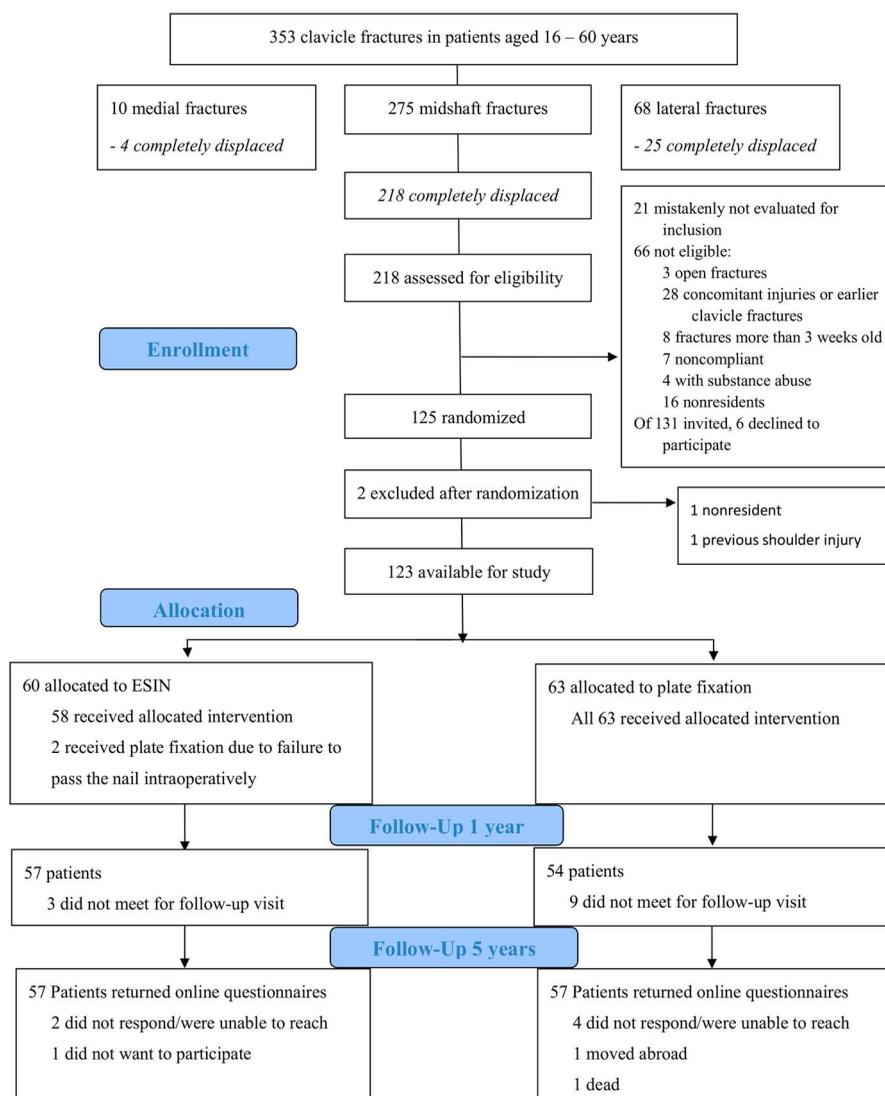


Fig. 1

Flow diagram of all patients with clavicle fractures during the study period.

TABLE I Patient Demographics and Fracture Characteristics at a Median Follow-up of 66 Months

Variable	PF (N = 60)	All ESIN (N = 54)	Open ESIN (N = 27)	Closed ESIN (N = 27)	P Values*		
					Open Compared with Closed ESIN	PF Compared with Closed ESIN	PF Compared with Open ESIN
Age at injury† (yr)	34.9 (16 to 59)	37.4 (17 to 58)	37.3 (17 to 55)	37.4 (17 to 58)	1	0.5	0.4
Time elapsed before surgery† (days)	6 (0 to 17)	5.5 (0 to 13)	6.5 (1 to 13)	4.4 (0 to 12)	<b>0.04</b>	0.07	0.8
Sex (male/female)	52/8	46/8	25/2	21/6	0.3	0.3	0.7
Mechanism of injury							
Simple fall	8 (13%)	9 (17%)	6 (22%)	3 (11%)			
Motor vehicle accident	17 (28%)	10 (19%)	5 (19%)	5 (19%)			
Sports	32 (53%)	33 (61%)	16 (59%)	17 (63%)			
Ski/snowboard/sledge	8 (13%)	11 (20%)	4 (15%)	7 (26%)			
Soccer	1 (2%)	2 (4%)	1 (4%)	1 (4%)			
Ice hockey	2 (3%)	0	0	0			
Bicycle	20 (33%)	20 (37%)	11 (41%)	9 (33%)			
Horseback riding	1 (2%)	0	0	0			
Other	3 (5%)	2 (4%)	0	2 (7%)			
Fracture characteristics							
Affecting the right side	29 (48%)	23 (43%)	13 (48%)	10 (37%)			
Intermediary fragments							
0	16 (27%)	15 (28%)	4 (15%)	11 (41%)	0.07	0.2	0.3
1	17 (28%)	13 (24%)	8 (30%)	5 (19%)	0.5	0.3	0.9
2	21 (35%)	20 (37%)	10 (37%)	10 (37%)	1	0.9	0.9
≥3	6 (10%)	6 (11%)	5 (19%)	1 (4%)	0.2	0.4	0.3
Initial vertical displacement† (bone widths)	1.6 (1 to 3)	1.6 (0† to 3)	1.6 (1 to 3)	1.5 (0† to 3)	0.9	0.3	0.6
Initial shortening† (mm)	11.4 (−5 to 39)	9.1 (−14 to 33)	10.8 (−11 to 25)	7.6 (−14 to 33)	0.3	0.1	0.6

\*There were no differences between the original randomized groups. Group differences between PF, open ESIN, and closed ESIN were tested with the t test for continuous data and with the chi-square or Fisher exact tests for categorical data. The Mann-Whitney U test was used for ordinal data. Bold type signifies a statistically significant difference. †Data are presented as the mean with the range in parentheses. ‡Angulation >30°.

treated with PF, the change from the individual baseline DASH score was >10 points. We did not detect any differences between the ESIN and PF groups with regard to shoulder pain when the patient slept on the affected side, at rest, or during

activity. Of the patients who ultimately were treated with PF, 37% felt pain when sustaining a blow to the clavicle compared with 17% of the patients who ultimately were treated with a nail ( $p = 0.02$ ) (Table II). Interestingly, 44% of patients

TABLE II Minor Sequelae at a Median Follow-up of 66 Months After PF or ESIN

	PF Compared with All ESIN			Open Compared with Closed ESIN			PF Compared with Closed ESIN*	PF Compared with Open ESIN*
	PF (N = 60)	All ESIN (N = 54)	P Values*	Open ESIN (N = 27)	Closed ESIN (N = 27)	P Values*		
Incisional numbness	30 (50%)	12 (22%)	<b>0.002</b>	10 (37%)	2 (7%)	<b>0.009</b>	<b>0.0001</b>	0.3
Pain when sleeping	23 (38%)	13 (24%)	0.1	8 (30%)	5 (19%)	0.5	0.09	0.4
Pain with a direct blow	22 (37%)	9 (17%)	<b>0.02</b>	8 (30%)	1 (4%)	<b>0.02</b>	<b>0.001</b>	0.5
Pain at rest	11 (18%)	4 (7%)	0.09	4 (15%)	0	<b>0.05</b>	<b>0.02</b>	1
Painful clavicle	8 (13%)	4 (7%)	0.3	4 (15%)	0	0.1	<b>0.05</b>	1
Pain with movement	21 (35%)	12 (22%)	0.1	9 (33%)	3 (11%)	0.1	<b>0.02</b>	0.8

\*Chi-square and Fisher exact tests. Bold type signifies a statistically significant difference.

who had the plate removed still complained of such pain, but it occurred in only 1% of patients who had ESIN with closed reduction, regardless of whether or not the implant was removed.

Numbness under the incision was persistent in 12 (22%) of the patients ultimately treated with ESIN and 30 (50%) of the patients treated with PF ( $p = 0.002$ ). When patients who had a secondary operative procedure were excluded, 33% of ESIN patients and 48% of PF patients still had hypoesthesia at a median follow-up of 66 months after the primary operation.

### Subgroup Analysis for ESIN

In the original ESIN group<sup>11</sup>, open reduction was necessary for 31 fractures and closed reduction was performed for 29. At a median follow-up of 66 months, 27 patients each had originally undergone each type of reduction. Patients who had closed ESIN had the same results at 66 months as at 12 months, and compared with the patients who had open ESIN they had a persisting, significantly better long-term functional outcome as measured by the DASH score (closed ESIN,  $0.7 \pm 1.4$  and open ESIN,  $5.2 \pm 8.9$ ;  $p = 0.015$ ).

Although there was a faster initial recovery for fractures with little comminution, there were no differences in the functional outcomes at 12 months<sup>11</sup> or at a median follow-up of 66 months in any of the subgroups of patients who had 0, 1, 2, or  $\geq 3$  intermediary fragments.

### Open Versus Closed Procedures

The DASH score was significantly different between the patients who had closed ESIN and those who had open ESIN, as already mentioned; it was also significantly different between those who had closed ESIN and those who received PF (closed ESIN,  $0.7 \pm 1.4$  and PF,  $3.9 \pm 7.5$ ;  $p = 0.002$ ). However, it did not differ significantly between patients who had open ESIN and those who had PF (open ESIN,  $5.1 \pm 9.3$  and PF,  $3.9 \pm 7.5$ ;  $p = 0.6$ ). Thus, patients who had a closed procedure had significantly better functional outcomes than those who had an open procedure. Additionally, patients who had closed ESIN reported fewer long-term sequelae than those who had an open procedure (Table II).

### Implant Removal

Pain over the implant and skin-tenting were the most common issues leading to removal of the implant (Table III). More patients in the ESIN group than in the PF group needed to have the implant removed; in addition, the majority of patients treated with ESIN had a secondary procedure, compared with one-third of patients treated with PF. ESIN performed with open reduction did not influence the need for implant removal, as the main complaint was the protruding medial end (open ESIN, 18 of 27 and closed ESIN, 19 of 27;  $p = 0.8$ ). We could not detect any difference in the DASH score between the patients in whom the implant remained in place and those whose implant had been removed (ESIN group,  $3.4 \pm 7.4$  and  $3.0 \pm 6.9$ ,  $p = 0.9$ ;

TABLE III Secondary Surgical Procedures After PF or ESIN

	Plate (N = 57)	ESIN (N = 57)	P Value*
Removal	16	37	<0.001
Local anesthesia	0	20	
General anesthesia	16	17	
Reason for removal†			
Superficial infection	0	1	
Deep infection	1	0	
Pain over implant	8	9	
Skin-tenting	11	28	
Cosmetic appearance	1	2	
Other reasons for secondary surgery‡			
Shortening of nail due to skin-tenting		10	
Implant failure	0	1	
Nonunion	0	1	
Deep infection	2	0	
Other	0	1‡	
All secondary procedures			
General anesthesia	18	21	
Local anesthesia‡	0	31§	

\*Chi-square test. †More than 1 cause per patient was possible. ‡1 nail placed outside lateral fragment was repositioned. §5 nails were shortened and later removed.

PF group,  $3.3 \pm 5.1$  and  $4.8 \pm 11.6$ ,  $p = 0.5$ ). There were no refractures.

### Discussion

At a median follow-up of 66 months, the functional outcome after operative fixation with PF or ESIN was predictable and excellent for both methods. The rates of secondary surgery with the patient under general anesthesia were similar. At 12 months, incisional numbness was present in 57% of the patients who had PF, and at 66 months it was present in 50%, indicating that a cutaneous nerve lesion that remains after 12 months is likely to be permanent.

In the predetermined subgroup analysis, we found that the inferior DASH score for patients treated with open ESIN compared with closed ESIN persisted. Although this was a statistically significant difference of 4.4 points, the difference is probably too small to be clinically important, a difference of 10 points having been reported to be the threshold for clinical importance for the DASH<sup>17</sup>. However, the difference was consistent over many years, and the DASH scores of the patients who had closed reduction had a small standard deviation of 1.4, which suggests that the findings were robust. A major ceiling effect for the DASH score in athletes has been reported<sup>19</sup>.

A ceiling effect is thought to be present when more than 15% to 20% of the patients achieve the best possible score. This makes discrimination between higher-functioning individuals difficult. Our patients reported a nearly perfect preinjury DASH score of 0.5, and 57% of the fractures were sports-related. Furthermore, 46% had a DASH score of 0 at the median follow-up of 66 months, indicating a ceiling effect. The small differences we found are below the MCID, and the results should be interpreted with caution.

The advantage of ESIN for comminuted fractures seems to lie in the closed reduction, which led to fewer long-term clinical sequelae in this study. Although ESIN is considered to be minimally invasive, open reduction was necessary in 52% of the patients in our series, as it was in 41% and 74% of patients in 2 other reported series<sup>10,20</sup>. Multivariate regression analysis in our previous publication revealed an increase in the odds of open ESIN surgery with an increase in surgical delay from the day of injury and with an increased number of intermediary fragments<sup>11</sup>. There were more patients without comminution in the closed ESIN group than in the groups that had open ESIN or PF (Table I), although the difference was not statistically significant. It is possible that the difference between the subgroups is explained by the fact that noncomminuted fractures of the clavicle are lower-energy injuries, although the mechanisms of injury were similar between the groups. However, this study was not sufficiently powered to detect differences in these small subgroups.

Implant removal was more prevalent in the ESIN group. Several Level-I studies have reported rates of implant removal of 53% to 89% for ESIN and 10% to 19% for PF, but none of those patients were followed for longer than 1 year, and in 2 of the studies the patients were offered removal of all nails<sup>4-6,8,10,21</sup>. In our study, implant removal was not recommended for any patient unless clinical symptoms were present. When removal was warranted, if the patient agreed, it was performed in the outpatient clinic under local anesthesia. With this approach, 20 of 37 patients who had ESIN had the implant removed under local anesthesia in the outpatient clinic, avoiding the extra cost, time, and risk of general anesthesia, and 17 had removal under general anesthesia. Of the 57 patients who had PF, general anesthesia was used for all 16 whose plate was removed. PF has been reported to cause less irritation when the plate is placed anteriorly, but this has not seemed to result in fewer implant removals<sup>22,23</sup>. The high rate of implant removal in the ESIN group in this study was mainly due to pain over the nail's medial entry portal, which clearly was related to a protruding nail. There is a technical aspect to this, as we observed that in most of these patients the nail had not been cut short enough during the primary procedure. The provided nail-cutter is not designed for clavicle fractures and leaves 5 to 10 mm of the nail protruding from the bone, due to the nail's oblique entry position. Therefore, the surgeon should use a different cutter or, alternatively, advance the nail farther into the bone with an impactor. A few patients had a mild degree of telescoping over intermediary fragments, and after introduction of the nail into the lateral aspect of the

clavicle some had a gap of a few millimeters in the fracture. This usually reduced by itself after a few days, resulting in increased medial protrusion. If the nail had been cut flush to the bone, many of the secondary surgeries might have been avoided.

One of the weaknesses of this investigation is that it is a single-center study, which limits the external validity of the results; another weakness is that we did not examine the patients in person. However, 21 different surgeons performed the procedures, making the results more applicable to the average surgeon. The radiographic results were reported in the previous study of this group of patients<sup>11</sup>, but the Constant score used in that study was not used in this one. Nevertheless, the DASH and Constant scores did correlate strongly for the earlier controls, and we thought that more patients would be lost to follow-up if they had to come in for an examination than if they were asked to fill out an online questionnaire. A large proportion of the patients had the implant removed, for various reasons (Table III). Almost half of the patients who had a plate removed still reported feeling pain. We probably should have asked about the degree to which implant removal alleviated their complaint, to get some sense of the benefit to the patient. Six patients reported sustaining a second shoulder injury between the 12 and 66-month follow-ups, and that might have influenced their functional outcome. However, only 1 of these patients reported a change that exceeded the MCID of 10 points from the preinjury DASH score; this suggests that a second injury would not influence the overall results.

The strengths of this study are its prospective randomized controlled design and an adequate power analysis with 93.5% follow-up. Validated patient-oriented outcome measures were used. Subgroup analyses were predetermined based on the results at 12 months and replicated those results. Of 150 eligible patients, 123 (82%) were included and 93% of these were included in the follow-up for this study.

PF provides faster rehabilitation in the first 6 months for patients with comminuted fractures, whereas ESIN provides a better cosmetic result, which might be more important to some patients<sup>10,11</sup>. Either PF or ESIN may be used for any completely displaced midshaft fracture of the clavicle, with the choice depending on which parameter is the most important to the patient.

In conclusion, we found no clinically relevant functional differences between the PF and ESIN groups at a median follow-up of 66 months. Furthermore, subgroup analyses revealed that, in contrast to closed reduction, open reduction and fixation with either PF or ESIN has similar long-term sequelae for patients, which indicates that the open reduction itself is responsible for the long-term sequelae. On the basis of this study and our previous 12-month follow-up of the same group of patients, it seems to be advantageous to perform closed ESIN, which is facilitated by early surgery and little comminution. Our results further suggest that if open reduction is necessary for patients with comminuted fractures, the advantages of the minimally invasive ESIN procedure seem to be lost.

For patients who need open reduction, the surgeon should consider PF because it has similar long-term results but a faster functional recovery and it is less likely to require later removal.

## Appendix

 A description of the operative techniques and postoperative management is available with the online version of this article as a data supplement at [jbjs.org \(http://links.lww.com/JBJSOA/A69\)](http://links.lww.com/JBJSOA/A69). ■

NOTE: This work was performed on the TSD (Tjeneste for Sensitive Data) facilities, owned by the University of Oslo, operated and developed by the TSD service group at the University of Oslo IT Department (USIT) ([tsd-drift@usit.uio.no](http://tsd-drift@usit.uio.no)).

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