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A Comparison of Bone Union and Complication Rates for Locking vs. Non-Locking Plates in Distal Fibular Fracture: a Retrospective Study of 106 Cases.

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A Comparison of Bone Union and Complication Rates between Locking and Non-Locking Plates in Distal Fibular Fracture: Retrospective Study of 106 Cases.

Abstract:

Background: Ankle fractures represent the third most frequent fracture in elderly patients. There is a current tendency to fix long bones fractures with locking plates. However, we rarely find published accounts about the use of locking plates in distal fibula fractures, except for biomechanical ones, studying human cadaveric fibula.

Objectives: The main objective was to compare radiographic bone union rates at 6 and 12 weeks of follow up, then wound complications and hardware removal rates, and construct cost.

Study Design & Methods: We retrospectively analyzed 105 patients who underwent surgery with locking plates or non-locking plates over a two-year period, out of which 42 patients were treated with non-locking plates (VIVESTTM - Stryker[®]) and 63 with locking plates (VariAxTM - Stryker[®]). We analyzed bone union on anterior posterior and lateral X-rays of the ankle. We collected data of wound complications and hardware removal from patient records. Multiple linear regression techniques were performed after identifying dependent variables.

Results: There was no significant difference between non-locking and locking plates in the radiographic bone union rate of distal fibula, respectively at 6 and 12 post-operative weeks (85.71% vs. 81% ; $p = 0.525$ and 97.62% vs. 96.83% ; $p = 1$). No significant difference was found in the wound complication rate between the two groups (11.9% vs. 11.12% ; $p = 0.9$). No significant differences were found in the hardware removal rate, either with or without operative site's infection (respectively: 30.95% vs. 39.68% ; $p = 0.361$ and 21.42% vs. 38.09% ; $p = 0.071$). Cost efficiency is in the favor of non-locking plates.

Conclusion: Non-locking constructs are as effective as locking constructs in the treatment of displaced distal fibula fractures at a substantially lower cost. High-quality randomized controlled trials are needed in the future to verify the finding of this study.

Keywords: Ankle Fracture, Distal Fibula, Locking Plate, Bone Union

I. INTRODUCTION :

Ankle fractures are frequent in traumatology. Their incidence of 122 to 184 per 100,000 people/year (1–3), out of which 25% in elderly over 65 (4), puts them as the third most common fracture in elderly patients (3,5). Open reduction and internal fixation in displaced distal fibula fractures is considered as the treatment of choice (6). The most common surgical technique nowadays is plating (7). The advent of locking-plates has radically changed the management of long bones fractures (8–11). This innovation using fixed-angle screws offers better angular and axial stability (12,13), particularly in metaphysis and epiphysis, independently of bone mineral density (12). These Locking constructs have progressively changed our surgical practices, especially in cases of osteoporosis or comminuted fractures, instability and/or cortical fixation difficulties (13).

Several cadaveric studies biomechanically comparing locking plates (LP) and non-locking plates (NLP) have been conducted (14–20). However, few studies compared bone union in distal fibula fractures treated with Locking vs. non-locking constructs (21–24).

The primary outcome of our study was to assess radiographic bone union rates in distal fibula fractures of a NLP (VIVES™, Stryker®, Mahwah, NJ, USA) vs. a LP (VariAx™, Stryker®, Mahwah, NJ, USA) at 6 and 12 weeks of follow up. Secondary outcomes included the assessment of wound complications and hardware removal rates, in addition to a comparison of each construct's cost. Our key assumption was that Non-locking constructs are as effective as locking constructs in the treatment of displaced distal fibula fractures.

II. PATIENTS and METHODS :

1. Population:

We retrospectively reviewed a consecutive cohort of patients who underwent surgical fixation of closed malleolar fractures of the ankle between January 2012 and December 2013. We included patients above 18, with displaced isolated distal fibula, bi malleolar or tri malleolar fractures, treated surgically with either a LP or NLP, with a minimal 3 months follow-up period. Open ankle fractures, pilon or diaphyseal associated fractures and injuries treated with another type of osteosynthesis (isolated medial malleolar fracture treated with screws, fractures treated with external fixators, fractures treated with kirschner wires, fractures treated with isolated syndesmotic screws) were excluded. After excluding non-eligible patients, we

have sent a memorandum notifying concerned patients about their participation. The memo defines the purpose of the study and its execution, in addition to their right of objection and withdrawal regarding the use of their personal information (25).

Data was collected from patient charts and electronic records of the department of orthopedic surgery and traumatology of our institution. The fracture type was defined on preoperative anterior-posterior and lateral radiographs according to AO classification (26). The primary outcome was the radiographic confirmation of lateral malleolar fracture union at 6 and 12 weeks. We defined radiographic union as the disappearance of all fracture lines in the anterior posterior and lateral views. Two senior orthopedic surgeons, blinded to the aim and protocol of the study, determined separately the radiographic union of each case. In the event of disagreement, a third interpretation was performed by an independent radiologist to decide this issue. Wound complications were split into superficial or minor complications (delayed wound healing and wound secondary dehiscence) and deep or major infectious complications (27). Clinical outcomes as pain, swelling and stiffness, as well as hardware removal percentage were recorded from follow-up data. The construct costs were calculated using the prices of the sales made by the corresponding trader to our institute.

2. Operative technique :

All procedures were performed in a supine position under general or spinal anesthesia. All patients benefited from the use of a tourniquet at top of thigh and received antibiotic prophylaxis according to the institute protocol. After fracture reduction, the use of lag screws as well as the plate's thickness was left to the discretion of the operation surgeon. Then a locking or non-locking plate was placed on the lateral aspect of the fibula. Surgeons had no choice in the type of plate they would use: In 2012, there was only NLP available in our institute and as of January 2013, they were replaced with LP. The NLP used, Vives™ (Stryker®, Mahwah, NJ, USA) was a MACONOR-2 type periarticular plate characterized by its “diamond-shaped” rough deep surface and its continuous 1.8 mm thickness. The LP, VariAx™ fibula locking plate system (Stryker®, Mahwah, NJ, USA), is a low profile pre-countered periarticular plate. It is 2 mm thick proximally and 1.3 mm distally, and it possesses the SmartLock™ polyaxial locking mechanism (Figure 1). All proximal plate screws were non-Locking in both groups. All four distal plate screws were cancellous non-Locking in the NLP group and Locking in the LP group (Figures 2 and 3). Medial malleolar fractures were reduced and fixed with either cancellous screws or tension band wiring. Anterior posterior

screws were eventually used in case of a displaced posterior fragment. Medial collateral ligament suture and or syndesmotic repairing by a temporary screw have been undertaken when necessary. Drains were routinely used and wound closure techniques were common to both groups. All patients benefited from a plaster cast postoperatively and a pharmacological venous thromboembolic prophylaxis throughout 6 weeks of immobilization and non-weight bearing. Clinical and radiographic follow-up was routinely achieved at 3, 6 and 12 weeks postoperatively. Weight-bearing and rehabilitation began after 6 weeks. Further follow-up examinations were established in case of complication.

3. Statistical analysis :

Statistical analysis was performed using « R-Studio® » version 3.4.2 for Windows® (Boston, USA). Descriptive statistics were performed to summarize demographic and clinical variables and to evaluate distributional characteristics. Continuous variables were evaluated using Student and Wilcoxon tests, and were expressed with means +/- standard deviation and range. Categorical data were evaluated using Chi-square or Fisher tests, and expresses as percentages. We used simple linear analysis studying the direct relation between the variable and the primary outcome. Multiple linear regression techniques were performed after identifying dependent variables. Data was expressed as odds ratios with their ninety-five percent confidence intervals and p-values defined at 5% (statistical significance was defined at $p < 0, 05$).

III. RESULTS

A total of 198 ankle fractures were assessed between January 2012 and December 2013. After applying exclusion criteria, there was left 128 distal fibulas that underwent fixation with a lateral plate. Twenty-two patients were lost during follow-up. After inclusion, one patient expressed his opposition to the use of his personal data by a written letter. A hundred and five patients were analyzed: 42 received a NLP and 63 received a LP (Figure 4).

1. Population and surgical characteristics

The mean age of the population at surgery was fifty years [17; 84] and 60% of patients were female. Mean body mass index (BMI) was 26, 7 Kg/m² [16.4; 46.2]. The most frequent comorbidity was smoking (n= 44; 41.9%). We have found 31 dislocated ankles (29.52%) and the rate of skin blisters, before and after surgery, was 14, 29%. Referring to the AO classification for ankle fractures, type 44-B was predominant (n= 102.97, 14%) and sub-type 44-B2 or bi-malleolar was the most frequent –n= 70; 66.67%). All the population's data is detailed in table 1. No significant differences were found between groups in all variables except for the AO fracture type (p= 0.011) and sub-type 44-B (p= 0.024). The use of lag screws in conjunction with the plate was significantly higher in the NLP group (65.08% vs. 40.48%; p = 0.012).

2. Radiographic bone union rate

Bone union rate is detailed in table 2. We have not found a significant difference in bone union rate either at 6 or 12 weeks postoperatively between NLP and LP groups. Simple linear analysis of bone union at 6 and 12 weeks are exposed in table 3. Odds ratios concerning multiple linear regression analysis at 6 weeks are exposed in table 4. Multivariable analysis has not found any differences in bone union at 6 weeks after adjustment for age, gender and fracture type. However, a significant difference was found in both groups, with sub-type 44-B3 requiring longer time to bone union comparing to sub-type-B2 (OR= 0.25 [0.069 – 0.936]; p= 0.035). Concerning bone union at 12 weeks, multiple linear regression analysis have showed a statistically significant delay in bone union in case of skin blisters (OR = 0.066 [0.003; 0.762]; 0.034). Other variables were not related to bone union delay. Odds ratios concerning multiple linear regression analysis at 12 weeks are exposed in table 5.

3. Complications

Complication rates are detailed in table 6. Twelve wound complications were found the cohort, including four deep infections in NLP group and two in LP group. There was no significant difference in wound complications in the NLP group compared to the LP group (11.9 vs. 11.1; p= 0.9). This finding was similar when comparing minor and major wound complications between the study groups (respectively: 2.38 vs. 7.94; p= 0.398 and 9.52 vs. 3.17; p= 0.154). The rates of other complications were comparable (p= 0.138). There were no early revisions, except for syndesmotic screws ablation at 6 postoperative weeks. One patient

required a late arthroscopic arthrolysis in the context of ankle equinus stiffness. Multiple linear regression techniques could not be performed for complication rates.

4. Hardware removal (HR)

The overall HR rate was 36.19% (table 7) and there was no significant difference between the groups ($p= 0.361$). All four infected sites of the NLP group have benefited of HR. On the contrary, in the LP group, only one out of two plates was removed after infection. The plate left in place was of an early infection while the fracture had not healed yet. After taking HR for infection out of count, there was 9 HR (21.42%) in the NLP group and 24 HR (38.09%) in the LP group. This difference was not statistically significant ($p= 0.071$). Plate removal was performed earlier in the NLP group independently of the infection factor (respectively: 13.5 ± 2.5 vs. 17.2 ± 7.7 ; $p= 0.044$; 10.2 ± 5.43 vs. 16.5 ± 8.1 ; $p= 0.007$). Simple linear analyses of hardware removal are illustrated in table 3. The influential variables were age, fracture sub-type 44-B and wound complications. A multiple linear regression analysis concerning these variables has been performed as can be seen in table 8. It has been demonstrated that HR rates decreases with age (OR=0, 94 [0.899; 0.978]; $p=0.004$). Otherwise, it was observed that fracture sub-type 44-B3 causes 4 times as many hardware removals as sub-type 44-B2 and 8.5 times as many as sub-type 44-B1. These results were statistically significant (respectively: OR=4.075 [1.021; 17.455]; $p=0.048$ and OR=8.568 [1.478; 59.817]; $p=0.021$). In contrast, there was no difference between sub-types 44-B1 and 44-B2.

5. Constructs costs

Table 9 shows the price of each plate and different type of screws. Since they have the same price, proximal bicortical screws were not taken into account. It has been noted that a locking construct is 235.5 euros more expensive than a standard non locking construct.

IV- Discussion

When a closed and displaced distal fibula fractures occurs, it is essential to regain the length of the fibula and maintain the stability of the ankle joint. Surgical treatment is a standard practice in the young and active population which demands a quick return to their activities. In elderly patients (over 60) with unstable ankle fractures, a recent randomized clinical trial with blinded outcome assessors have showed that the use of close contact casting compared

with surgery resulted in similar functional outcomes (28). A substantial increase in the use of countered locking plates occurred in treating distal fibula fractures at our institution, whatever the age. The aim of our study was to verify the need to support such a shift in our practices. The primary outcome of our study was to assess radiographic bone union rates in distal fibula fractures of a NLP (VIVES™, Stryker®, Mahwah, NJ, USA) vs. a LP (VariAx™ Stryker®, Mahwah, NJ, USA) at 6 and 12 weeks of follow up. It has been shown that the initial assumption is confirmed since there were no difference in bone union rate either at 6 or 12 weeks postoperatively between NLP and LP groups.

Herrera-Pérez & al. have retrospectively compared locking versus non-locking one-third tubular plates for treating osteoporotic distal fibula fractures. No statistically significant difference in time to radiographic bony union was reported between the two groups (average time of 15.27 weeks [11-16] in LP group vs. 12.58 weeks [9-13] in NLP group – $p = 0.15$) (22).

Likewise, while retrospectively reviewing a consecutive cohort of 145 patients, Lyle & al. have not detected significant differences in the radiographic time to bony union among three plate groups including one locked plate (23). In another assessor blinded randomized controlled trial conducted on fifty-two patients to compare the effectiveness of LP and NLP, the intention to treat analyses of Tsukada & al. showed no difference in the radiographic bone union rate of the fibula (24).

In contrast, in a retrospective cohort of 147 patients, Huang & al. (21) have compared radiographic outcome of three types of plates. They have found that the healing time was significantly less in patients treated with a LCP distal fibula plate (20.0 ± 3.8 weeks) than in patients treated with a LCP metaphyseal plate (23.0 ± 3.4 weeks, $p < 0.0001$) and a conventional one-third tubular plate (23.1 ± 3.6 weeks, $p < 0.0001$). Otherwise, no significant difference was found between the last two plates ($p = 0.867$), although one is a locking plate. Interestingly, there is no information of the use of lag screws, which could explain the increase of time to healing in NLP group. In addition, the MIPO technique as described by Hess & al. (29) was used in the LP groups, which could have theoretically reduced the risk of periosteum damage and the loss of the fracture's hematoma.

On the one hand, some authors have reported the possibility of fixing distal fibula fractures with isolated anterior posterior lag screws, associated with a 6-weeks immobilization period, and ended up having the same results functionally and radiographically (7,30). On the other,

Takemoto & al. have demonstrated that both NLP and LP act similarly as a neutralization device when a lag screw is used to implement compression in the fracture site (31). Other cadaveric studies have been carried in the purpose of comparing conventional NLP and new LP biomechanics. No biomechanical differences have been demonstrated when comparing locking and non-locking one-third tubular plates in Weber (32) B and C distal fibula fractures (14,15,17). However, Bariteau & al. have found that locked plating is biomechanically superior, with a statistically significant stiffer fixation, to a standard one third tubular plate in comminuted Weber C ankle fractures (17). This finding is lost and both constructs are comparable when fractures are initially fixed with lag screws. It has been demonstrated that fixation with standard NLP is depending on bone mineral density (BMD) whereas the LP was independent of BMD (14,18). Distal periarticular countered plates have been proved biomechanically superior either it is non-locking in the study of Davis & al. (16) or locking in those of Zahn and Switaj (18,19). These recent biomechanical studies seems to have shown that locking countered plates provides improved fixation strength in osteoporotic bone and comminuted distal fibula fractures. Nguyentat et al. concluded to the absence of significant differences between LP and NLP during both fatigue and torque to failure testing in distal fibula fractures with no comminution and normal BMD (20).

The multivariable analysis of this study has found a statistically significant longer time to bone union in sub-type 44-B3 comparing to sub-type-B2 at 6 weeks postoperatively, independently of age, gender and construct type (locking or non-locking). Concerning bone union at 12 weeks, multiple linear regression analysis has showed a statistically significant delay in bone union in case of initial or secondary skin blisters. These findings are in line with those reported by Bhadra & al. in their meta-analysis about delayed union and nonunion of the fibula between 1950 and 2011. They found that initial fracture pattern, severity of comminution at the fracture site, degree of displacement of fracture fragments, and high-energy injury seemed to be related to the occurrence of delayed fibular union or frank nonunion (33). The distal third of the fibula was the most common site (85%) for delayed union or pseudoarthrosis in both combined tibia-fibula fractures and low-energy ankle fractures.

The overall wound complication rate for the study (11.42%) was comparable to those described in the literature (22,23,27,34,35). There was no significant difference in wound complication rates in the NLP group compared to the LP group (11.9 vs. 11.1; $p = 0.9$). Despite the fact that a majority of authors haven't demonstrated any differences in

complication rates, particularly wound complications, between Locking and non-Locking plates in the fixation of the distal third of the fibula (22–24,34,36), Scheppers (27) and Lynde (35) have found a significant higher wound complication rate in Locking plates. In addition, Moss & al. reached to a statistically higher percentage of deep infectious complication in the LP group (37).

Scheppers & al. have compared one-third tubular low profile 1mm thick NLP to High profile 2.8 mm and 3.3 mm thick LP. They have concluded to the augmentation of wound complication rates along with the thickness of the used plate (27). The Same conclusion was suggested in Moss's study, where they used LP had 1.7 and 2.8mm thick , compared to one-third tubular 1mm thick NLP (37). However, Moriarty & al. have recently demonstrated that the use of locking plates for the treatment of distal fibular fractures is not associated with an increased wound complication rate. They have used low profile periarticular LP 1.3 mm thick distally, compared to one-third tubular and reconstruction NLP, respectively 1 and 3.5 mm thick (36).

Moss & al. have found a HR rate statistically higher in the thicker LP group (37). Schepers & al. (27) reported a HR rate of 27.3% without any difference between NLP and thicker LP groups. Contrarily to the findings of our study, the latter also found that plate removal was performed 2 months earlier in the thicker LP group, without this result being statistically significant. Petruccelli & al. (34) haven't found any difference in HR rates between Locking and non-Locking constructs. Naumann & al. retrospectively reviewed a cohort of 997 patients in the purpose of determining the risk factors for hardware removal of an internal fixation following ankle fracture surgery (lateral plate and medial / anterior-posterior screws in case of a bi malleolar or tri malleolar fracture). They have revealed that male sex, age and treatment with a syndesmosis screw were associated with a lower hazard for the removal of hardware due to complaints (38). Inversely, an increase in duration of the initial operation was associated with a higher hazard of experiencing hardware removal. Our study has likewise demonstrated that HR rates decreases with age. We have also observed an increase in HR rates in sub-type 44-B3 or trans-syndesmotic tri malleolar fractures. This may be related to functional limitations, discomfort and pain linked to additional implants, particularly screws fixing medial and posterior malleoli. These results should be considered as assumptions for we need further controlled trials to ensure the reliability of such findings, especially since there was no difference between sub-types 44-B1 and 44-B2 in our statistical analyses.

It is clear that a low profile construct, whether it's Locking or non-Locking, induce a lower incidence of metal prominence, hence less wound complications and HR rates. In this study, the LP is a low profile pre-counteracted periarticular plate with a distal thickness of 1.3 mm, which is considerably thinner than other LP used in the mentioned studies, and slightly thinner than the periarticular NLP with a distal thickness of 1.8 mm. This could explain the similar outcomes in both wound complications and HR rates between locking and non-locking constructs in our study.

Financially wise, a typical counteracted locking plate construct costs \$800 more than a comparable one-third tubular plate construct in the USA. Based on a calculated estimate of 60000 locking plates used annually, Moss & al. have found that a total of \$50 million can be avoided annually (37). Our study has equally found a staggering higher price for the locking construct which is 235.5 euros more expensive than a standard non locking construct. We can easily save millions of euros on a French national scale by using non-locking constructs for non-comminuted distal fibula fractures with normal BMD.

Finally, the present retrospective study has limitations. The patients were not randomized for treatment with the two types of fixations. However the choice of the period of the study is linked to the fact that we have always used NLP for distal fibula fractures, until the end of 2012 when our department started using the LP. This was in the purpose of decreasing selection bias! The overall number of patients was relatively small. No significant differences were found between groups in all variables except for the AO fracture type. Sub-types A and C couldn't be integrated in a multiple linear regression analysis because of their small numbers. Sub-type B had to be analyzed alone, which generated a selection bias. The use of lag screws in conjunction with the plate was not comparable between groups, which constituted a confounding factor. Further studies with improved design to account for these different biases are needed.

V- Conclusion:

Locking plates are increasingly used for fractures of distal fibula and are associated with significantly augmented costs. Bone union rates appear to be similar in both locking and non-locking constructs of the distal fibula, especially in case of an associated immobilization. Locking plates are an interesting option in comminuted and/or osteoporotic fractures. The thickness of the plate appears to be correlated to the onset of wound complications. Measures to increase surgeons' awareness about cost-reduction programs are needed. High-quality randomized controlled trials are needed in the future to verify the finding of this study.

VI – Conflict of interest

The authors declare no conflict of interest. This research did not receive any specific funding from organizations in the public, commercial, or not-for-profit sectors.

TEXT WORD COUNT: 3657 (without abstract and references)

VI – References

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Figure 1 : a) lateral surface, b) length, c) medial or deep surface of the VariAx[™] plate on the left and the Vives[™] on the right

Figure 2: Anterior posterior and lateral view of a VariAx[™] plate osteosynthesis

Figure 3: Anterior posterior and lateral view of a Vives[™] plate osteosynthesis

Fig 4: Flow chart

Table 1: Population and surgical characteristics^a Pearson's Chi-squared test / ^b Welch Two Sample t-test (Student) / ^c Fisher's Exact Test

* Means +/- standard deviation and range

		Total	NLP	LP	p-value
Patients (n)		105	42	63	
Gender (%)	Male	42 (40)	18 (42,86)	24 (38,1)	0,625 ^a
	Female	63 (60)	24 (57,14)	39 (61,9)	
Age *		50,4 +/- 17,2 [17 ; 84]	51,8 +/- 18,7 [20 – 84]	49,4 +/- 16,2 [17 – 82]	0,486 ^b
BMI *		26,7 +/- 5,9 [16,4 ; 46,2]	26,1 +/- 4,5 [17,7 - 42,5]	27,1 +/- 6,6 [16,4 - 46,2]	0,347 ^b
Smoking (%)	Y	44 (41,9)	21 (50)	23 (36,5)	0,169 ^a
	N	61 (58,1)	21 (50)	40 (63,5)	
Alcohol (%)	Y	19 (18,09)	9 (21,43)	10 (15,88)	0,468 ^a
	N	86 (81,91)	33 (78,57)	53 (84,12)	
Diabetes mellitus (%)	Y	10 (9,52)	4 (9,52)	6 (9,52)	1 ^c
	N	95 (90,48)	38 (90,48)	57 (90,48)	
Peripheral arterial disease (%)	Y	2 (1,9)	0	2 (3,18)	0,515 ^c
	N	103 (98,1)	42 (100)	61 (96,82)	
Chronic renal failure (%)	Y	1 (0,95)	0	1 (1,59)	1 ^c
	N	104 (99,05)	42 (100)	62 (98,41)	
Corticosteroids (%)	Y	1 (0,95)	0	1 (1,59)	1 ^c
	N	104 (99,05)	42 (100)	62 (98,41)	
ASA score (%)	1	32 (30,47)	9 (21,42)	23 (36,5)	0,237 ^c
	2	65 (61,9)	29 (69,05)	36 (57,14)	
	3	8 (7,62)	4 (9,52)	4 (6,34)	
	4	0	0	0	
Side	Y	52 (49,52)	23 (54,8)	29 (46)	0,38 ^a
	G	53 (50,48)	19 (45,2)	34 (54)	
Dislocation (%)	Y	31 (29,52)	14 (33,33)	17 (26,98)	0,484 ^a
	N	74 (70,48)	28 (66,67)	46 (73,01)	
Skin Blisters (%)	Y	15 (14,29)	8 (19,05)	7 (11,12)	0,254 ^a
	N	90 (85,71)	34 (80,95)	56 (88,88)	
Fracture Type: AO Classification (%)	44-A1	2 (1,9)	2 (4,76)	0	0,011 ^c
	44-A2	0	0	0	
	44-A3	0	0	0	
	44-B1	17 (16,19)	2 (4,76)	15 (23,8)	
	44-B2	70 (66,67)	33 (78,57)	37 (58,73)	
	44-B3	15 (14,28)	5 (11,9)	10 (15,87)	
	44-C1	0	0	0	
	44-C2	1 (0,95)	0	1 (1,59)	
	44-C3	0	0	0	
Lag Screw (%)	Y	58 (55,24)	17 (40,48)	41 (65,08)	0,012 ^a
	N	47 (44,76)	25 (59,52)	22 (34,92)	
Operation time (min)		61,92 +/- 19,45 [35 ; 120]	60,23 +/- 16,99 [40 ; 110]	63,04 +/- 20,99 [35 ; 120]	0,452 ^b

Table 2: Radiographic bone union at 6 and 12 weeks postoperatively

No: Persistency of a visible fracture line on one or more radiographic views

Yes: complete disappearance of the fracture line on both anterior posterior and lateral views

^a Pearson's Chi-squared test / ^b Fisher's Exact Test

		Total cohort	NLP	LP	p-value
Bone union at 6 weeks	No	18 (42,86)	6 (14,29)	12 (19)	0,525 ^a
	Yes	24 (57,14)	36 (85,71)	51 (81)	
Bone union at 12 weeks	No	3 (4,76)	1 (2,38)	2 (3,17)	1 ^b
	Yes	60 (95,24)	41 (97,62)	61 (96,83)	

Table 3: Simple linear analysis of bone union at 6 and 12 weeks, and of hardware removal rate

^a Pearson's Chi-squared test / ^b Welch Two Sample t-test (Student) / ^c Fisher's Exact Test

Variables	6 weeks	12 weeks	Hardware removal
Plate (NLP/LP)	0,525 ^a	1,000 ^c	0,183 ^a
Age	0,264 ^b	0,811 ^b	< 0,001 ^b
Gender	0,916 ^a	0,811 ^a	0,622 ^a
BMI	0,249 ^b	0,763 ^b	0,776 ^b
Smoking	0,810 ^a	1,000 ^c	0,520 ^c
Alcohol	1,000 ^c	0,454 ^c	0,603 ^a
Diabetes Mellitus	1,000 ^c	1,000 ^c	0,490 ^c
Peripheral arterial disease	1,000 ^c	1,000 ^c	1,000 ^c
Chronic renal failure	1,000 ^c	1,000 ^c	1,000 ^c
Corticosteroids	1,000 ^c	1,000 ^c	1,000 ^c
ASA Score	0,242 ^c	0,645 ^c	0,093 ^c
Sub-type 44-B (B1, B2 et B3)	0,045 ^c	0,442 ^c	0,019 ^c
Skin Blisters	0,284 ^c	0,053 ^c	0,941 ^a
Lag screw	0,623 ^a	0,586 ^c	0,223 ^a
Wound complications	1,000 ^c	0,308 ^c	0,038 ^c

Table 4: multiple linear regression analysis at 6 weeks

Variables	OR [IC95%]	p-value
LP (ref = NLP)	0,899 [0,263 ; 2,939]	0,86
Age	1,016 [0,98 ; 1,054]	0,384
Male Gender (ref =female)	1,253 [0,357 ; 4,758]	0,729
AO 44-B2 (ref=44-B1)	0,743 [0,097 ; 3,819]	0,741
AO 44-B3 (ref=44-B1)	0,186 [0,022 ; 1,107]	0,082
AO 44-B1 (ref = 44-B2)	1,345 [0,262 ; 10,263]	0,74
AO 44-B3 (ref = 44-B2)	0,25 [0,069 ; 0,936]	0,035

Table 5: multiple linear regression analysis at 12 weeks

Variables	OR [IC95%]	p-value
LP (ref = NLP)	0,538 [0,021 ; 7,041]	0,644
Age	1,012 [0,927 ; 1,108]	0,788
Male Gender (ref =female)	1,736 [0,091 ; 60,099]	0,72
Skin Blisters (ref= NO)	0,066 [0,003 ; 0,762]	0,034

Table 6: General and wound complications

Wound complications: superficial or minor complications = delayed wound healing and wound secondary dehiscence / deep or major infectious complications = dehiscence after infection

Other complications: Complex regional pain syndrome (CRPS), synostosis, Deep vein thrombosis (DVT), Heparin-induced thrombocytopenia (HIT), tibialis posterior tendinopathy (TPT), post-operative ankle stiffness

^a Pearson's Chi-squared test / ^b Welch Two Sample t-test (Student)

		Total cohort	NLP	LP	p-value
Wound complications (%)		12 (11,42)	5 (11,9)	7 (11,12)	0,9 ^a
Minor (%)		6 (6,67)	1 (2,38)	5 (7,94)	0,398 ^b
Major (%)		6 (4,76)	4 (9,52)	2 (3,17)	0,154 ^b
Other complications (%)	CRPS	9 (8,57)	4 (9,52)	5 (7,93)	1 ^c
	Synostosis	5 (4,76)	3 (7,14)	2 (3,17)	
	DVT	1 (0,95)	1 (2,38)	0	
	HIT	1 (0,95)	1 (2,38)	0	
	TPT	1 (0,95)	0	1 (1,58)	
	Stiffness	1 (0,95)	1 (2,38)	0	
Total of other complications (%)		18 (17,14)	10 (23,8)	8 (12,69)	0,138 ^a
Total All Complications (%)		30 (28,57)	15 (35,7)	15 (23,8)	0,185 ^a

Table 7: Hardware removal rate

HRR: Hardware removal rate

^a Pearson's Chi-squared test / ^b Welch Two Sample t-test (Student)

* Means +/- standard deviation and range

	Total cohort	NLP	LP	p-value
General HRR (%)	38 (36,19)	13 (30,95)	25 (39,68)	0,361 ^a
Time (Month)*	14,4 +/- 7,8 [2 ; 38]	10,2 +/- 5,43 [2 ; 18]	16,5 +/- 8,1 [2 ; 38]	0,007^b
HRR Without Infection (%)	33 (31,42)	9 (21,42)	24 (38,09)	0,071 ^a
Time (Month)*	16 +/- 6,8 [8 ; 38]	13,5 +/- 2,5 [10 ; 18]	17,2 +/- 7,7 [8 ; 38]	0,044^b

Table 8: multiple linear regression analysis of hardware removal

Variables	OR [IC95%]	p-value
LP (ref = NLP)	2,238 [0,721 ; 7,538]	0,173
Age	0,94 [0,899 ; 0,978]	0,004
Gender Male (ref = Female)	0,778 [0,23 ; 2,51]	0,677
AO 44-B2 (ref=44-B1)	2,009 [0,508 ; 9,076]	0,337
AO 44-B3 (ref=44-B1)	8,568 [1,478 ; 59,817]	0,021
AO 44-B1 (ref=44-B2)	0,462 [0,104 ; 1,784]	0,28
AO 44-B3 (ref=44-B2)	4,075 [1,021 ; 17,455]	0,048
Wound Complications (ref=NO)	4,784 [0,741 ; 40,789]	0,11

Table 9: Cost evaluation

	NLP	LP	Difference
Plate cost (whatever the length)	148,5 €	168 €	19,5 €
Proximal screw cost (CORTICAL)	6 €	6€	0
Distal screw cost (CANCELLOUS vs. LOCKING)	6 €	60 €	54 €
Price of 4 distal screws within the periarticular part of the plate	24 €	240 €	216 €
Construct cost without Proximal screws	172,5 €	408 €	235,5 €