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Open Ankle Arthrodesis: A Retrospective Analysis Comparing Different Fixation Methods

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ABSTRACT

A wide variation of surgical options, complications, and union rates are reported in the treatment of end-stage ankle arthritis. However, open ankle arthrodesis remains the golden standard for ankle arthritis. The purpose of this study was to evaluate the union rate and complication rate as well as identify potential risk factors for different methods of fixation in patients with end-stage ankle arthritis of different etiology. In total, 42 ankles of 41 patients with ankle osteoarthritis were included for this single-center retrospective study. The mean age was 50 years (range 22-75 years). Twenty patients were treated with screw-fixation, 14 with plate(s) and 8 with intramedullary nail. The results of this study showed an overall union rate of 97.6% (41 of the 42 operated ankles) and an overall complication rate of 21.4% (9 events). The mean follow-up time was 16 months (range 2.5-83.0 months). Complications consisted of 1 nonunion, 4 deep infections, 2 cases of wound dehiscence, 1 delayed union and 1 malalignment of the ankle joint. The plate-fixation group demonstrated significantly higher infections when compared with screw and intramedullary nail fixation (p = .017). There were no other significant variables for incidence of complications between patients in the uncomplicated and complicated group. This study achieved good clinical results for different methods of fixation in open ankle arthrodesis. In specific, the use of intramedullary nail provides excellent results for end-stage ankle arthritis with high union rate and a low complication rate.

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End-stage ankle arthritis (EAA) is a common joint-disease resulting in severe pain and dysfunction due to degenerative changes of the ankle joint (1). The prevalence of symptomatic and radiographic ankle osteoarthritis in a cohort with subjects aged over 50 years was identified as 3.4% (2), leading to annual costs of approximately $370 million per year (3). With a contribution of 78% in all cases, posttraumatic osteoarthritis is the most frequent cause for EAA (4).

Ankle arthrodesis is traditionally the surgical treatment of choice for patients in which conservative treatment or joint preserving (distraction arthroplasty) surgery has failed (5,6). For the United States of America, the total number of foot and ankle arthrodesis was 56.877 in 2006 (7). The main goal in ankle arthrodesis is solid fusion of the tibiotalar joint aiming for a painless, plantigrade, and stable foot. However, ankle arthrodesis is associated with several serious complications. The most frequent complication is nonunion of the ankle joint. Currently, a standardized definition for the (non)union-rate is lacking (8). However, a commonly used definition for ankle fusion is outlined as trabecular bridging between the tibia and the talus with a painless and stable ankle joint (9-12). Other frequent postoperative complications in ankle arthrodesis are malunion, infection, aseptic loosening, malalignment, wound complications, and nerve injury that can lead up to 50% of cases in total (10,13-15).

Previous literature has indicated several risk factors for complications following foot and ankle arthrodesis, including nonunion. For example, smoking, diabetes, alcohol use, and preoperative varus ankle alignment are known risk factors (16,17).

Up till now, more than 40 different operation techniques have been developed (18). In recent years, there has been an increasing interest in arthroscopic ankle arthrodesis (AAA) and total ankle replacement (TAR) as alternative treatment options for EAA. Particularly in ankles without severe deformity, these techniques seem to offer a good alternative for open ankle arthrodesis (OAA) (19). However, despite these advantages for AAA and TAR in the treatment of ankle osteoarthritis, similar union rates and increased reoperation rates were found when these methods were compared with OAA (20,21). Therefore, in patients with moderate to severe deformity of the ankle, OAA remains the gold standard as this allows for better visualization for malalignment correction (22,23). Yet,

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OAA can be executed in various procedures. Currently, there are several approaches and fixation methods to provide solid fusion of the ankle joint. For example, the ankle arthrodesis can be performed through an anterior, medial, posterior, transfibular, or combined approach (24). Internal fixation techniques consist of screws, plates or intramedullary nails to provide good joint alignment and stabile fixation (25). Additionally, in patients with severe hindfoot/ankle deformities, the decision can be made to fuse the tibiotalar and subtalar joint (also known as tibiotalocalcaneal arthrodesis) (26).

In conclusion, there are many variations to perform an ankle arthrodesis. Therefore, evidence for a golden standard in OAA is still lacking in current literature. One of the causes is that previous literature has mainly been restricted to limited comparisons of these numerous approaches and fixation methods. Additionally, the favored method of surgery often depends on the surgical skills of the operator, the amount of joint deformity, patient demographics, and potential risk factors. As a result, recent literature displays a wide variation in reported union rates and complication rates for OAA. Therefore, we were interested in determining the union rate and complication rate for several procedures of OAA in our Academic Hospital. We hypothesized that these were superior than previous literature. The primary aim of this study was to examine the union rate and complication rate of patients that underwent OAA for EAA. Our secondary outcome was to assess the effect of different variables on the overall complication rate for identification of potential risk factors. We undertook a retrospective cohort study to compare the outcomes in patients who had undergone different methods of fixation for OAA.

Patients and Methods

Study Characteristics

This study was executed using The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (27). The procedures of this study were approved by the internal research administration department of the Amsterdam UMC, a large academic hospital in the Netherlands. By using the operation code for ankle arthrodesis, patients with severe ankle arthritis who have been operated in the Amsterdam UMC between December 2011 and April 2020 were retrospectively identified for inclusion in this study. Written informed consent for participation in the study was obtained from all patients. Data abstraction from the medical records was realized by 2 different raters (S.v. d.H. and D.P.). Discrepancies between the raters were resolved through discussion and rating by a third rater (T.S), after which consensus was reached.

Inclusion and Exclusion Criteria

Patients were included in this study if they were older than 18 years and have been operated with OAA. Exclusion criteria consisted of: (1) Patients with primary osteoarthritis as indication for surgery, (2) patients with primary hindfoot nail for fragility fractures, (3) patients with isolated tibiofibular arthrodesis (chronic syndesmotic injury), and (4) patients with a follow-up time of <2 months.

Clinical and Radiological Assessment

The following patient characteristics were extracted from the records: age, gender, location of surgery, body mass index (BMI), tobacco use, medical history including: diabetes mellitus and type of fracture. The type of fracture was divided into open or closed fractures and open fractures were classified according the Gustilo-Anderson classification (28). Clinical characteristics consisted of etiology, surgical approach, method of fixation, joint involvement, usage of graft, union rate and time to union, radiographic examination, reoperation rates, incidence of complications associated with surgery and side events. Joint involvement was defined as pure tibiotalar arthrodesis or the combination of tibiotalar and subtalar arthrodesis (tibiotalocalcaneal arthrodesis). The "overall complication rate" included nonunion, superficial and deep infections, wound dehiscence, delayed union and malalignment of the ankle joint. Postoperative wound infections (POWI) were classified into superficial or deep surgical site infections, using the Centers for Disease Prevention and Control (CDC) criteria (29). Wound dehiscence was defined as partial or total separation of previously approximated wound edges, due to a failure of proper wound healing (30). Wound dehiscence was also scored as one of the CDC criteria for POWI. However, in the absence of other signs of infection, it was scored as separate complication. Delayed union was defined as radiographic evidence of incomplete fusion 6 months after surgery (31,32). In similar way, nonunion was defined as incomplete fusion 12 months after surgery. The radiographs of patients were reviewed by a single trauma surgeon. Anterior-posterior and lateral X-ray views were used to assess union of the ankle joint. The optimal position of arthrodesis of the ankle was defined as neutral flexion, slight (zero to 5 degrees) valgus angulation, and approximately 5 to 10 degrees of external rotation (33). Ankles that deviated from this were considered malaligned. By using the predefined criteria in the registration for our outcomes, which are mentioned above, possible bias in the collection of clinical and radiological data was limited.

Surgical Techniques

All surgical procedures were performed by six trained foot and ankle surgeons. Two surgeons performed 93 percent of the procedures. Standard operative techniques were used according to each surgeon's preference. Surgery was carried out under general or regional anesthesia. For the transfibular approach, access to the ankle was gained through a 10 cm longitudinal incision over the middle part of the fibula, slightly curving anterior below the lateral malleolus (Fig.). The anterior and posterior talofibular ligaments were divided, while carefully protecting the peroneal tendons and sural nerve. The fibula was osteotomized approximately 4 to 5 cm proximal of the syndesmosis. The distal part of the fibula was prepared by hemisection in the frontal plane, with the lateral half being harvested as onlay strut graft and the medial half for additional autogenous bone grafting (34).

As for the anterior approach, a longitudinal incision lateral to the tibialis anterior tendon was used. Subsequently, joint surfaces were prepared and apposed in similar way as mentioned above. In some cases, a small accessory medial incision was made in addition to the primary incision for medial joint preparation or to remove screws from a previous surgery. In a few patients the soft tissue conditions of the ankle were very poor. Mostly due to previous surgeries of the ankle or primary bone loss (eg, open fractures) leading up to significant instability of the ankle joint. In those cases a medial, posterior or combined approach was performed.

Fixation of the ankle joint was either done by screws, plate(s) or intramedullary hindfoot nail. This decision was made based on the type of fracture, soft tissue condition and patient characteristics. As for screw-fixation, generally a 3-screw construct was performed. For plate-fixation, a single locking compression plate was used in 12 patients and double plate-fixation was used in 2 patients. In case of nail-fixation, an intramedullary hindfoot nail was inserted through the plantar surface with distal fixation in the calcaneus and proximal fixation in the tibia in standard technique.

Postoperatively, patients wore a cast for 2 to 4 weeks. Patients were kept non-weightbearing for 4-6 weeks postoperatively or until initial radiographic consolidation was visualized. Thereafter, a walking boot was used for another 6 weeks. Follow-up continued until there was radiographic and clinical union.

Statistical Analysis

Data management and analysis were performed using IBM SPSS Statistics for Microsoft Windows Version 26.0 (SPSS Inc. Released 2016, SPSS for Macintosh, Version 26.0. Chicago, SPSS Inc.). Baseline characteristics were displayed as frequencies for categoric variables and means with lower and upper limits for continuous variables. The Fisher's exact test was used to compare categorical variables. Independent t tests and one-way ANOVA were used to analyze the relationship between normally distributed variables (age and BMI). A planned multivariate analysis for post hoc analysis was not possible due to a low amount of events (less than the required 5%-10% for each variable). In this study, "events" were defined as the incidence of surgical complications during follow-up. Statistical significance was defined at the 5% ($p \leq .05$) level.

Results

Baseline Characteristics

Between December 2011 and April 2020, 42 ankle arthrodeses were performed in 41 patients with ankle osteoarthritis. In total, the cohort consisted of 29 males (69%) and 13 females (31%) with a mean age of 50 years (range 22-75 years). Twenty-two surgeries were right sided (52.4%) and 20 were left sided (47.6%) with 1 patient having undergone bilateral procedures. The average BMI was 28 kg/m^2 (range 19.1-45.0 kg/m^2). Fourteen patients (33.3%) were active smokers and 9 patients (21.4%) had a history of tobacco use. Six patients had diabetes mellitus (14.3%). Twelve fractures (28.6%) were classified as open but not all of them were clinically classified according the Gustilo-Anderson classification. The operation indication was subdivided into 3 groups: (1) Primary arthrodesis due to ankle- or pilon fractures (7.1%), (2) Secondary arthrodesis due to ankle- or pilon fractures (69%), (3) Arthrodesis due to Charcot arthritis (9.5%), and (4) Arthrodesis due to avascular necrosis of the talus with subsequent posttraumatic ankle arthritis (14.3%). Six

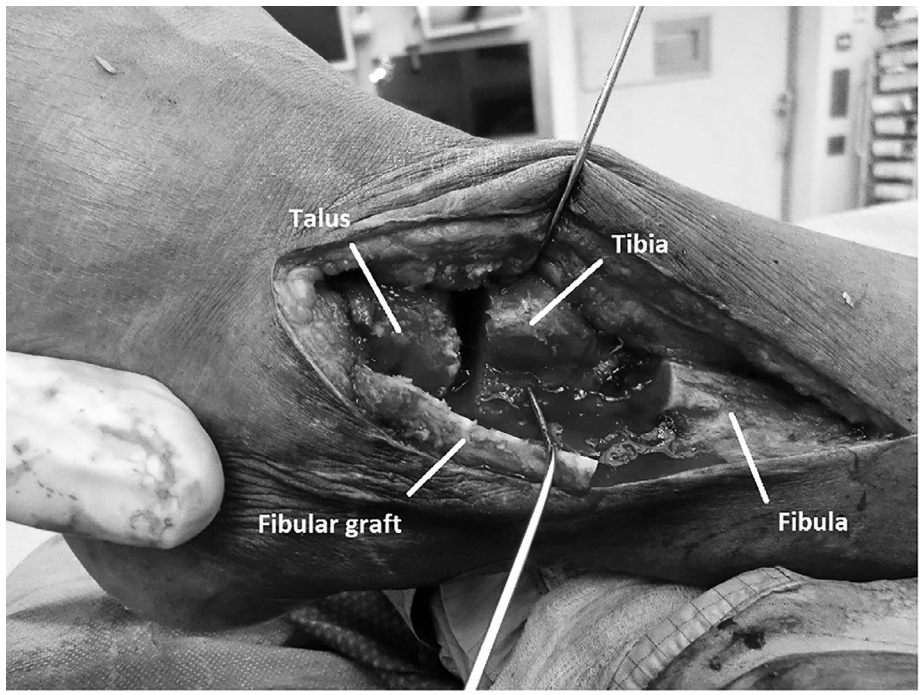

Fig. Intraoperative image illustrating the tibiotalar joint using a transfibular approach.

patients were referred from other hospitals for revision arthrodesis (14.3%). Usage of additional grafting was reported in 35 ankles (83.3%). The mean follow-up time consisted of 16 months (range 2.5-83.0 months). Comparison of baseline characteristics and clinical outcomes between patients with uncomplicated and complicated ankle arthrodesis are summarized in Table 1.

Union and Complications

In this study, union was achieved in 41 of the 42 arthrodeses (97.6%). Nonunion developed in one ankle that successfully united following revision surgery. The incidence of overall complications was 21.4%, with 9 events in 42 arthrodeses (Table 2). There were no superficial wound infections. There were 4 deep wound infections (9.5%), with 1 infection leading to a nonunion. Subsequently, these patients were treated with secondary surgery for debridement of the site of infection and antibiotics. One patient had delayed union of the ankle joint which was successfully fused after 8 months. Besides a history of smoking, no other potential risk factors could be identified for this patient. There were 2 patients with wound dehiscence, without other symptoms that met the criteria of POWI, which were successfully treated by negative pressure therapy. One patient had a malalignment of the ankle joint. After careful consideration of the risks, this patient was satisfied with his surgical outcome and declined from further corrective surgery. There were no significant variables for incidence of complications between patients in the uncomplicated and complicated group (Table 1). Thirty-one ankles were operated by the same surgeon (T.S.). The overall complication rate between surgeons was not significant (p = .822).

Method of Fixation

In this study, fixation was performed with screws in 20 ankles (47.6%), with plate(s) in 14 ankles (33.3%) and with intramedullary hindfoot nail in 8 ankles (19%). Subgroup analysis for different methods of fixation regarding the overall complication rate is summarized in Table 3. There were no significant differences for the variables age (p = .100), gender (p = .382), side of operation (p = .921), BMI (p = .409), history of tobacco use (p = .128), diabetes (p = .145), and type of fracture (p = .495) between different groups of fixation. In this study, there were 5 patients (35.7%) with a complication in the plate-fixation group, 3 patients (15%) in the screw-fixation group and no patients (0%) in the intramedullary nail group (p = .112). Subanalysis showed a significant difference of incidence

Table 1
Baseline characteristics compared for uncomplicated and complicated groups (N = 42 ankles in 41 patients)

	Uncomplicated (n = 34) (%)	Complicated (n = 8) (%)	*p* Value
Demographics			
Gender, male: female	24:10 (71:29)	5:3 (63:38)	.686
Age (yr.), mean ± SD	48.7 ± 13.3	56.4 ± 13.2	.148
Side (Left: Right)	16:18 (47:53)	4:4 (50:50)	>.99
BMI (kg/m^2), mean ± SD	28.5 ± 5.4	26.0 ± 3.6	.232
Active or history of smoking	17 (50)	6 (75)	.258
Diabetes	6 (18)	0 (0)	.576
Open fracture	9 (27)	3 (38)	.420
Etiology			.824
Primary ankle- or pilon*	2 (6)	1 (13)	
Secondary ankle- or pilon*	23 (68)	6 (75)	
Charcot	4 (12)	0 (0)	
Talar AVN	5 (15)	1 (13)	
Revision arthrodesis	4 (12)	2 (25)	.319
Usage of graft	30 (89)	5 (63)	.597
Surgical approach			.497
Anterior	4 (12)	2 (25)	
Transfibular	22 (65)	3 (38)	
Medial	1 (3)	0 (0)	
Posterior	2 (6)	1 (13)	
Combined	5 (15)	1 (13)	
Other	0 (0)	1 (13)	
Method of fixation			.112
Screw	17 (50)	3 (38)	
Plate	9 (27)	5 (63)	
Hindfoot nail	8 (24)	0 (0)	
Joint fixation			>.99
Tibiotalar	22 (65)	5 (63)	
Tibiotalar and subtalar	12 (35)	3 (38)	

Abbreviation: AVN, avascular necrosis.
* Ankle- or pilon fracture.

Table 2
Complications (N = 9 events in 8 patients)

Patient	Type of Complication	BMI	Age	Type of Fracture	DM	Tobacco Use	Graft	Fixation	Indication	Joint	Revision
Arthrodesis											
1	Infection + nonunion	28.7	72	Closed	-	Former smoker	+	Plate	AVN	TTC	-
2	Infection	24.2	49	Open	-	-	-	Plate	Ankle- or pilon*	TTC	+
3	Infection	22.8	65	Closed	-	Former smoker	N/A	Plate	Ankle- or pilon*	TTC	+
4	Infection	26.8	29	Open	-	-	+	Plate	Ankle- or pilon*	Tibiotalar	-
5	Delayed union	25.7	59	Closed	-	Former smoker	+	Screw	Ankle- or pilon*	Tibiotalar	-
6	Malalignment	33.3	54	Open	-	Active smoker	+	Screw	Ankle- or pilon*	Tibiotalar	-
7	Wound dehiscence	22.3	58	N/A	-	Former smoker	+	Screw	Ankle- or pilon*	Tibiotalar	-
8	Wound dehiscence	24.5	65	Closed	-	Active smoker	+	Plate	Ankle- or pilon*	Tibiotalar	-

Abbreviations: AVN, avascular necrosis; TTC, tibiotalocalcaneal; N/A, not available.
* Ankle- or pilon fracture.

Table 3
Incidence of complications for method of fixation (N = 42 ankles in 41 patients)

Fixation Method (N = no. Ankles), [%] Complications	Screw (n = 20)	Plate (n = 14)	Nail (n = 8)	*p* Value
Nonunion	0 [0]	1 [7.1]	0 [0]	.524
Infection	0 [0]	4 [28.6]	0 [0]	.017*
Wound dehiscence	1 [5]	1 [7.1]	0 [0]	>.99
Delayed union	1 [5]	0 [0]	0 [0]	>.99
Malalignment	1 [5]	0 [0]	0 [0]	>.99
Overall	3 [1]	6 [35.7]	0 [0]	.112

* Statistically significant difference by the Fisher's exact test.

in infections between the fixation groups (p = .017), where 4 patients had an infectious complication when plate fixation was used (28.6%) and zero infections in the groups were screw- or intramedullary nail fixation was used (0%).

Side Events

In addition to the surgery-related complications, the following side events were observed in this study. One patient developed postoperative deep venous thrombosis and was treated with anticoagulants. One patient developed Takotsubo-cardiomyopathy during hospitalization and was transferred to the department of cardiology, whereas the patient was treated with conservative treatment options. Both patients achieved successful ankle arthrodesis.

Reoperation Rate

During follow-up, 4 patients developed clinical complaints of adjacent joint-arthritis which were radiological confirmed. During the observation period, the reoperation rate after ankle arthrodesis was 23.8% (10 ankles). The following reoperation indications were observed; (1) deep infection requiring debridement (5 ankles), (2) hardware removal due to failure (1 ankle), (3) hardware removal due to discomfort (3 ankles), and (4) one case of adjacent joint arthritis leading up to additional subtalar arthrodesis several years after primary ankle surgery. One case of infection was pre-existent and was therefore not included for the overall complication rate.

Discussion

Ankle arthrodesis remains a challenging procedure with numerous surgical techniques and different outcomes described in previous literature (35,36). This single-center retrospective study was set out with the aim of assessing the union rate, complication rate and identifying potential risk factors for open ankle arthrodesis in patients with EAA. The results of this study showed an overall union rate of 97.6% (41 of the 42 operated ankles) and a complication rate of 21.4% (9 events) over an average of 16 months follow-up.

Since the ankle arthrodesis was first described by Sir Albert in 1878 (37), union rates from 60% up to 100% are reported in previous literature (38,39). However, due to surgical advancements and innovations in OAA the union rate has been improved over the last years. For instance, Yasui et al (22) published a systematic review that investigated the union rate in OAA (n = 112) and AAA (n = 124). They found an average union rate of 89% following OAA. In addition, Mok et al (40) found similar union rates in their study including more recently reported series (n = 187). Our union rate of 97.6% is largely comparable with these studies. Only 1 nonunion occurred in the present study. In this case, the patient had a history of tobacco use and avascular necrosis of the talus.

In the present study, there was an overall complication rate of 21.4% (9 events) including nonunion, infections, wound dehiscence, delayed union and malalignment of the ankle joint. Recently, Park et al (20) published a study that showed an overall complication rate ranging from 6.7% to 47.1% in 7 included studies (n = 158). In another study, the complication rate was 20% were OAA (n = 138) was compared with AAA (n = 148) (41). However, these data must be interpreted with caution since implant failure and subtalar joint arthritis were not included as complications in our study, as it was in the study of Park et al (20). The "complication rate" is a term frequently used in the literature, but to date there is no clear definition about the complications that can be included for this term. For this reason, infection is a more specifically used surgical outcome in ankle arthrodesis. Hess et al (42) reported a low infection rate of 8.6% in their systematic review of 32 studies (n = 874). Likewise, to our study, they used a transfibular approach for tibiotalar and tibiotalocalcaneal arthrodesis. An infection rate of 9.5% in our study is similar to those with Hess et al (42). Interestingly, all infections occurred in the plate-fixation group. This result may be explained by the fact that plate-fixation needs more extensive dissection of the surgical area. In this study, the infected ankles were caused due to infections of *Staphylococcus aureus* (n = 2), *Pseudomonas aeruginosa* (n = 1), and *Aggregatibacter aphrophilus* with Bacteroides uniformis (n = 1).

The reoperation rate is often used for comparison of OAA, AAA, and TAR. For example, Veljkovic et al (43) reported a reoperation rate of 23.9% for TAR (n = 88), 2% for AAA (n = 50), and 7% for OAA (n= 100) in their study. However, they only included patients with nondeformed EAA and did not included hardware removal in their definition for reoperation. In the present study, the reoperation rate after ankle arthrodesis was 23.8% (10 ankles) including hardware removal. Similarly, Chalayon et al (17) reported a 19% reoperation rate in 520 uncomplicated open ankle fusions.

Debate continues about the best strategies for the management of fixating the ankle joint. Traditionally, it has been argued that screw-fixation is the more preferred procedure due to the easy usage and respectable union rates (44). In the last decade, several studies have shown good union rates for screw-fixation, ranging from 91% to 100% (12,45-47). On the other hand, some authors state that plate-fixation has superior stability and stiffness when compared to screw-fixation

(48). A recent systematic review reported a 97.6% union rate after ankle arthrodesis with plate-fixation (n = 164) (49). Also, Coetzee et al (50) achieved a 98% union rate for plate-fixation in a large retrospective cohort study (n = 100). As a result, previous literature has mostly compared screw-fixation with plate-fixation for outcomes in OAA. A recent study compared the outcome of ankle arthrodesis for cannulated screws (n = 12) and anterior fusion plate (n = 12) (51). The authors found no significant differences between the groups. Mitchell et al (52) reported lower nonunion rates when an anterior plate (7.7%) was supplemented to a compression screw construct (15.4%). Still, these results were not found significant. Hence, a superior method of fixation remains indistinct. The present study shows that intramedullary nail fixation achieved a lower complication rate when compared with screws and plates (p = .112). However, there are a limited number of published journal reports regarding comparative studies between intramedullary nail-fixation and fixation with screw or plate. Mainly because intramedullary nail-fixation is traditionally preserved as salvage procedure for cases after failed TAR or severe ankle and hindfoot deformities (53,54). Yet, with the improvements and innovations in prosthetics the indications for nail-fixation have expanded to include neuropathic conditions, club foot, and degenerative joint disease of both tibiotalar and subtalar joints (55). A biomechanical study of Berend et al (56) demonstrated that fixation with intramedullary nail was significantly stiffer than crossed screws in all bending and torsional directions. These data must be interpreted with caution because comparison between these fixation methods is challenging due to the heterogenous study cohorts. Based on the results of this study and previous literature, a golden standard for surgical technique in OAA is still lacking. Therefore, patient-specific factors seem to have an essential role in decision making for care and treatment in OAA. In 1994, Frey et al (38) identified several risk factors in their study. The authors reported that type of fracture, evidence of avascular necrosis, infection, major medical problems, and open injuries were associated with nonunion of the ankle joint. They also stated that age, surgical technique, and history of subtalar or triple arthrodesis were not associated with nonunion. More recently, Thevendran et al (57) performed a literature review on risk factors for nonunion following foot or ankle arthrodesis. In contrast to Frey et al (38), they only found fair evidence for smoking, diabetes and soft tissue injury as risk factors for nonunion. In this study, there were no significant differences in numerous factors when compared between complicated and uncomplicated groups. This is surprisingly since smoking, diabetes and type of fracture were included in our study. It is difficult to draw strong conclusion about potential risk factors in OAA based on the present study and previous literature. Largely, since most studies have relatively small sample sizes and consist of retrospective clinical cohort studies instead of randomized clinical trials.

The present study has some limitations which should be taken in account during interpretation of the results. This study was a single-center retrospective investigation without randomization. A planned multivariate analysis was not possible due to a low number of events. Therefore, our statistical results could not be corrected for possible confounding factors. Last, there was the potential for selection bias since some patients had multiple operation indications. For these patients, the most applicable etiology for the patient was chosen by 2 independent raters.

In conclusion, this study achieved good clinical results for different methods of fixation in OAA. In specific, the use of intramedullary nail provides excellent results for EAA with high union rates and a low complication rate. Overall, this study stipulates a good overview about different surgical techniques and various factors for the treatment of ankle osteoarthritis. We have provided further evidence of union rates and complication rates. However, large randomized controlled trials are needed to provide more definitive evidence for decision-making in the treatment of EAA.

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