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Outcomes of triple arthrodesis with IOFIX type fixation: A prospective study

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ABSTRACT

Background: The aim of this study was to evaluate the patient reported outcome measures (PROMS), radiological outcome and complications when performing a triple arthrodesis using the IOFIX system for the talonavicular and calcaneocuboid joints.
Methods: Data was collected prospectively. Twenty-nine consecutive patients were reviewed 1 year post-operative. Outcomes analysed were rate of fusion, American Orthopaedic Foot and Ankle Society (AOFAS) score, Visual Analogue Scale (VAS), patient satisfaction and complications.
Results: Complete fusion was achieved in 90 %. The mean preoperative AOFAS score improved from 42 (95 % confidence interval: 22–43) to 75 (95 % confidence interval 67–82) postoperative and the mean VAS improved from 6.5 (95 % confidence interval 4.9–8.6) to 4 (95 % confidence interval 3.1–4.9), $p < 0.001$. There was an early complication rate of 13 %. After 1 year 86 % were satisfied and there was a complication rate of 3 %.
Conclusions: This study suggests that the IOFIX system offers a reliable and performant alternative technique for patients undergoing a triple arthrodesis.
Level of evidence: Level II, prospective cohort study

1. Introduction

Triple arthrodesis is often employed to address severe deformities or chronic conditions such as arthritis, flatfoot deformity, or post-traumatic complications. The procedure involves fusion of the subtalar (ST), the talonavicular (TN) and the calcaneocuboid (CC) joint. By fusing these joints, the aim is a stable and realigned foot, with alleviation of pain, improved function and prevention of further deformity progression [1–3]. A triple arthrodesis is a powerful tool as it allows correction in the sagittal, coronal, and axial planes. A successful arthrodesis relies on the meticulous preparation of the joint surfaces and a stable compression [3]. Traditionally Ki-wires, Steinmann pins, plates, screws, staples, external fixation or a combination have been utilized for fixation during this procedure. Each of these fixation devices has its own benefits and drawbacks and can be technically demanding. For example, screws can cause eccentric compression, staples are less biomechanically stable, and plates can be prominent [4]. The choice of fixation method depends on various factors including surgeon's preference, patient's condition and severity of the deformity [5,6]. However, the limitations of conventional fixation methods have paved the way for the use of IOFIX [7].

The IOFIX, an intra-osseous fixation device, is a fixed-angle device composed of a post and a lag screw (Extremity Medical, New Jersey, USA) [7]. The post is inserted parallel to the joint surface and a partially threaded lag screw can be passed through its eyelet at a 60° angle across the arthrodesis site after preparation of the joint surface. The lag screw provides a uniform compression across the joint through the morse tapered eyelet. Another advantage is the lower risk of soft tissue irritation and hardware prominence, as the

Abbreviations: PROMS, patient reported outcome measures; IOFIX, Intra Osseous FIXation; AOFAS, American Orthopaedic Foot and Ankle Society; VAS, Visual Analogue Scale; ST, subtalar; TN, talonavicular; CC, calcaneocuboid; IRB, institutional review board

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entire construct is embedded in the bone, with consequently less requirement for metalwork removal. Additionally, for the IOFIX device less soft tissue and periosteal damage is required during joint surface preparation and implantation compared to plate and screw fixation [8].

Current studies have reported the results of the IOFIX system in first metatarsophalangeal joint arthrodesis, ankle arthrodesis or in solitary TN fusions [4,9–12]. The purpose of this prospective study was to evaluate for the first time the outcomes of the IOFIX type of fixation of the TN and CC joint, as part of a triple arthrodesis surgery. The primary outcome parameter was union rate, secondary outcome parameters were AOFAS score, VAS score, patient reported satisfaction and complications. Our hypothesis was that the IOFIX device will be a valuable fixation alternative when performing a triple arthrodesis.

2. Materials and methods

A prospective review was carried out of 29 consecutive patients who had a primary triple fusion with the IOFIX device between 2015 and 2020. Patients were included, conform our study protocol, when they had a symptomatic triple joint arthritis regardless of their age. Exclusion criteria were revision surgery and fusion of additional joints. Patients were consented for the study and data were merged in a pseudo-anonymized computer database. The triple joint fixations were performed by two experienced foot and ankle surgeons in a University Hospital (GM and SW). The study was approved by the institutional review board (IRB) prior to research (S56535).

The direct lateral / sinus tarsi approach was used to prepare the ST and CC joint and for the TN a medial approach. The joint surfaces were prepared by denuding them from cartilage and subchondral bone with osteotomes and curettes. If necessary, holes were drilled with a small drill to increase bleeding. The ST joint was fixed in the corrected position with one (or two) Acutrak Headless Compression screws 6/7 and the TN and CC joint were fixed by the IOFIX device using the standard described surgical technique [13]. Intraoperative fluoroscopy was used to confirm satisfactory alignment, implant placement and the quality of fixation.

The postoperative protocol was standard for every patient: 6 weeks below the knee cast non-weightbearing and 6 weeks casting with weightbearing. If fusion had been achieved after the 12-week period of immobilisation the patients were allowed to mobilise as tolerated. In the case fusion was not achieved at this follow-up appointment, the casting period was lengthened and/or an orthotic lace up boot was applied until union was confirmed radiological and clinical.

All patients were reviewed at a 2-week, 6-week, 3-month, 6-month and 1-year follow-up. Union rates were evaluated at 3-month follow-up and later if necessary. Satisfactory fusion was determined both clinically and radiographically. Clinical fusion was defined as lack of pain while weightbearing and lack of tenderness on palpation or stressing of the joints. Radiological fusion was affirmed if trabeculae were visible in at least 3 out of 4 cortices across the joints on standing anteroposterior and lateral radiographs. AOFAS scores were assessed preoperative, at 6 months and after 1 year [14]. VAS scores and patient satisfaction scores were encircled by the patient on a 100mm-scale with a score from 0 to 10 [15]. Complications were noted during each visit by the surgeon on a paper form.

The statistical analysis was performed with the use of SPSS version 28.0.1.1 (IBM SPSS Statistics, Chicago, USA). The variable data are presented as mean, range and 95 % confidence interval (95 % CI). The linear mixed model was used to compare the preoperative and postoperative AOFAS scores and VAS scores. A p-value of 0.001 was used for statistical significance level determination.

3. Results

Fusion of the TN and CC joint was achieved at the 3-months follow-up for twenty-six patients (Fig. 1). Three patients developed a delayed union, of which two were smokers and one patient was known with ethyl abuse and diabetes mellitus. Union was achieved after one extra month of weightbearing below the knee synthetic cast for the two first patients (Fig. 2). An additional 7 months of orthotic lace up boots was necessary for the patient with diabetes until union was achieved. There was a significant improvement of the mean preoperative AOFAS score from 42 (95 % confidence interval: 22–43) to 75 (95 % confidence interval 67–82) postoperatively, $p < 0.001$. The mean VAS score preoperative was 6.5 (95 % confidence interval 4.9–8.6), which improved significant to 4 (95 % confidence interval 3.1–4.9) postoperatively, $p < 0.001$. On a questionary scale of ten, the final operative result at the 1-year follow-up was satisfactory for 25 (86 %) of the patients. The patients with unsatisfactory results (14 %) were one with progression of rheumatoid arthritis for which a naviculocuneiform arthrodesis was planned, one with tibiotalar complaints after a crush trauma for which a total ankle prothesis was planned, one who was still rehabilitating of a contralateral total ankle prothesis and total hip prothesis and one patient suffered from tendinous complaints (Table 1). Peroperative complications were reported in three (10 %) patients, consisting of an unsatisfactory fixation and supplementary fixation with staples or k-wires was needed (Fig. 3). At the 1-year follow-up there was a reported complication in only one (3 %) of the patients, which was hyperesthesia in the innervation area of the sural nerve.

4. Discussion

We studied the fixation of the TN and CC joint as part of a triple arthrodesis procedure with use of the IOFIX device. The most important findings of this prospective study were a union rate of 90 %, and a significant improvement in preoperative AOFAS scores and VAS scores compared to postoperative. At the 1-year follow-up 86 % of the patients were satisfied with the end-result and there was a complication rate of 3 %. Peroperative complications were reported in 10 %.

Union was achieved in 26 (90 %) of the patients, which is slightly better compared to alternative fixation techniques in literature. A recent retrospective study of Maier et al. mentioned a non-union rate of 11 % for an isolated triple arthrodesis [16]. In one of the largest published series of triple arthrodesis, Pell et al. reported however a union rate of 98 % [17]. Another retrospective radiographic review of 157 cases has revealed otherwise a non-union rate of 30 % [18] and a study of De Groot et al. even a non-union rate of 41 % [19]. It was already stated by Meyer et al. in 1996 that the most common complication of triple arthrodesis is a non-union with reported rates of 40 % [5]. As mentioned in our material and methods it is important to keep in mind to combine the radiographic and clinical findings for the evaluation of union. A study about triple arthrodesis in the paediatric population has demonstrated that good clinical results can be achieved despite the lack of radiographic union [20]. In our study three of the patients developed a delayed union, which have healed after an additional immobilisation period without surgical revision. They all had important comorbidities of which 2 of them were smokers.

The IOFIX device is believed to achieve a high union rate as it provides a more uniform compression across a broader surface area and it reinforces the bony bridge for the lag screw through the eyelet of the X-post. For ankle arthrodesis this was shown in a biomechanical study were there was a better force distribution across the joint surface for the IOFIX compared to single screw fixation [21] and for isolated TN arthrodesis even a fusion rate of 100 % was reported in a

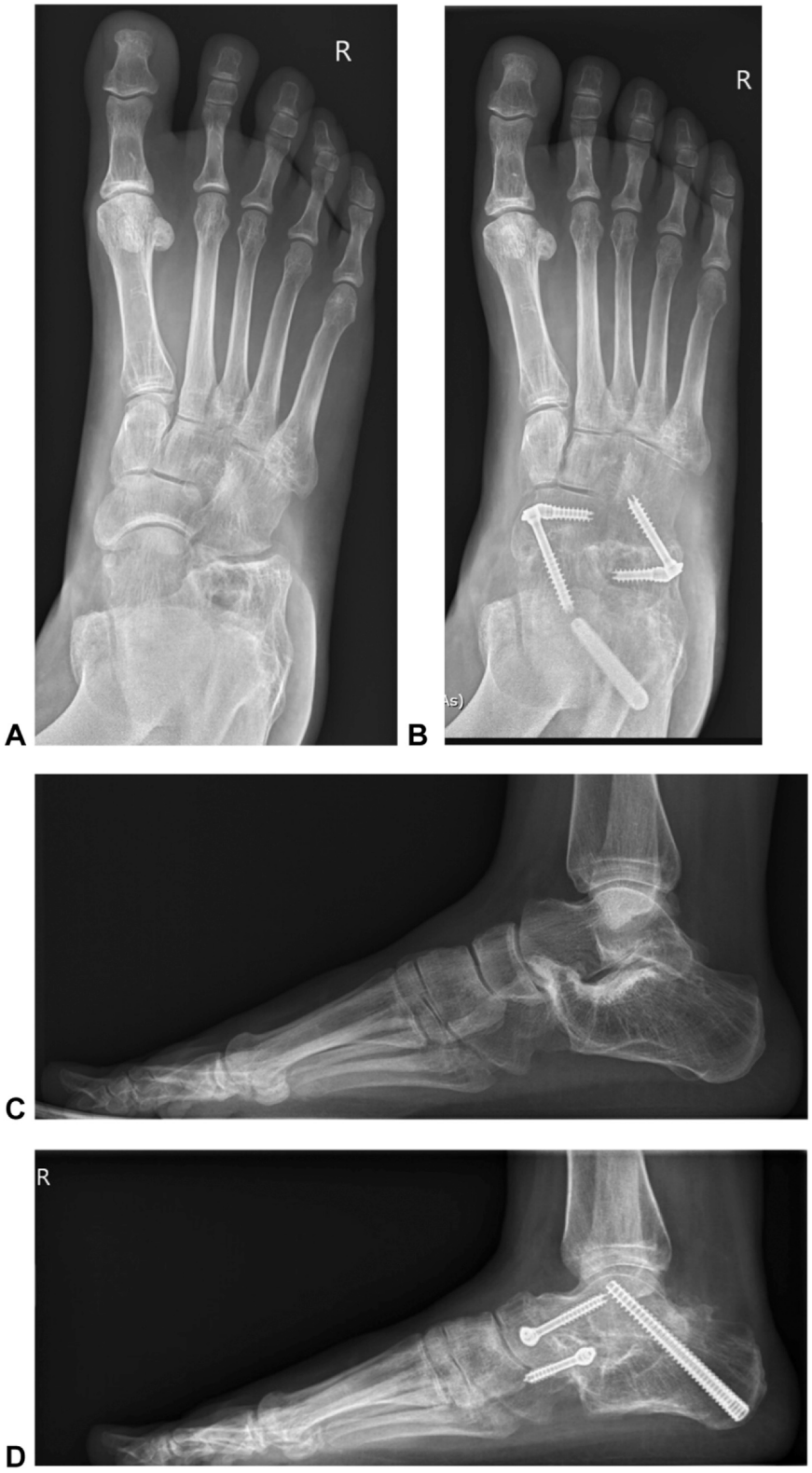

Fig. 1. A and C: Preoperative anteroposterior and lateral view of a right foot in a patient with triple arthritis. **B and D:** Postoperative anteroposterior and lateral view of the same foot with union of the TN and CC joint at 3 months follow-up.

case series [22]. In the shadow of the excellent fusion rates of this implant, there may be some reluctance by some foot- and ankle surgeons to use it because of its learning curve, need for intraoperative fluoroscopy and its relative cost compared to older fixation techniques.

The mean postoperative AOFAS-score was 75 which was also generally better than reported in literature, ranging from 61 to 74 [16,17,23–25]. When we reviewed our data 8 patients had a postoperative AOFAS score less than 75. Of these patients, one patient had Charcot Marie Tooth, three had inflammatory arthritis, one had a

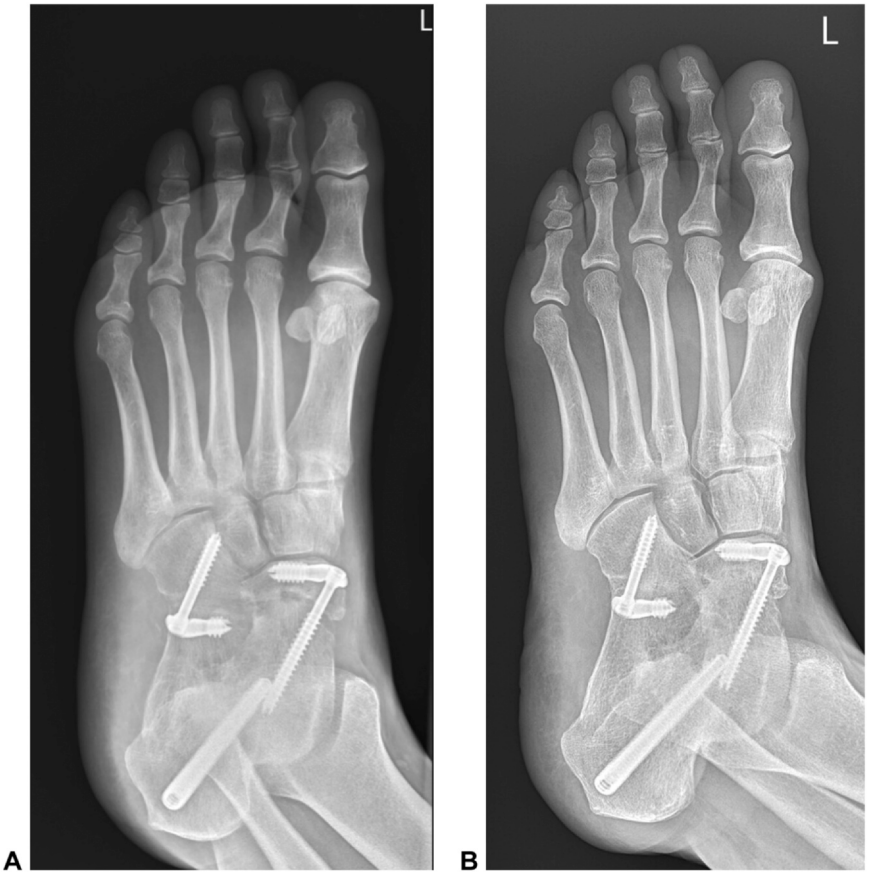

Fig. 2. A: Oblique view of a patient with delayed union of the TN joint at 3 months follow-up. **B:** Oblique view of the same patient with radiographic union after one extra month of cast immobilisation.

Table 1
Radiological outcomes and PROMS.

Outcome	Preoperative	Postoperative	p-Value
Fusion (%)	N/A	26 (90)	N/A
AOFAS score (95 % CI)	42 (22–43)	75 (67–82)	< 0.001
VAS score (95 % CI)	6.5 (4.9–8.6)	4 (3.1–4.9)	< 0.001
Patient satisfaction score (%)	N/A	25 (86)	N/A

depression after her third suicidal attempt, one patient was still in rehabilitation of a contralateral total hip and total ankle replacement, another patient had persistent pain of tendinopathy and the last patient had hyperesthesia in the sural nerve area. Smith et al. showed that patients with inflammatory arthritis had clearly lower physical component outcomes [26]. The mean VAS score had improved to 4 postoperatively, which was similar to the reported VAS-score of 4.5 of a recent study by Maier et al. [16], but higher compared to the VAS-score of 3 shown by Gobbo et al. [23]. Patients with a notable high VAS score were the patients with inflammatory arthritis, the patient with sural nerve hyperesthesia and the patient with tendinopathy. In our group of patients 86 % claimed to be satisfied with the postoperative result after 1 year, which is also comparable to results in literature ranging from 53 % to 95 % [5,19,23,26,27]. The four patients with remarkably low satisfaction scores matched the patients with lower AOFAS- and VAS-scores.

It is worth nothing that residual pain is a common cause of patient dissatisfaction when arthrodesis is performed [28]. Despite observing a consolidation rate of 90 % and at 1 year postoperatively even 100 % there is still a median VAS-score of 4. This finding implicates the need to inform the patient preoperative that the surgery will not necessarily lead to complete elimination of pain.

Per-operative complications were reported in three of the patients, were additional fixation with k-wires in one patients and staples in 2 patients, was necessary because of very poor bone quality. The first patient was a smoker and a chronic corticoid user, the second had diabetes and rheumatoid arthritis and the third patient was diagnosed with diabetes and osteoporosis. All three patients achieved union clinically and radiographically at the 3-months follow-up. At the 1-year follow-up there remained only a complication in one patient, for which no events were reported in the operative note.

Limitations of this study are the lack of a case control group, its relative short duration of follow-up. The cases weren't single surgeon, but the cases were performed by two experienced surgeons in the same hospital who maintain the same principles and followed the same training for this procedure. Our study presented the early results of a novel device for the fixation of the TN and CC joint as part of a triple arthrodesis and only for a few cases there was the need for extra fixation device to provide improved stability.

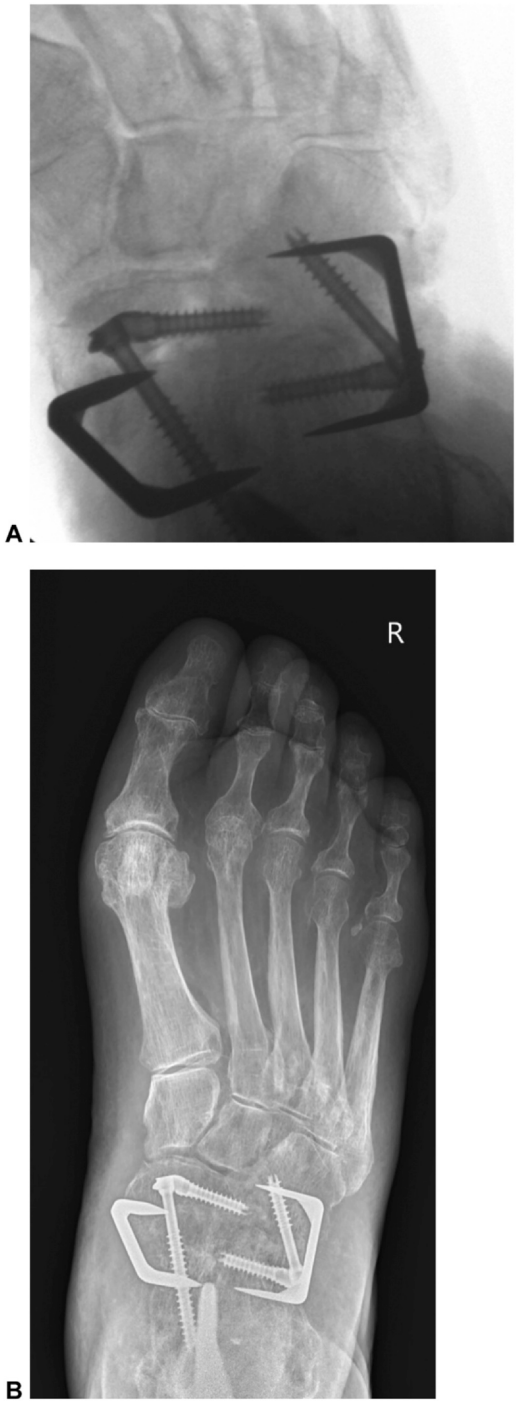

Fig. 3. A: Perioperative imaging of a patient with diabetes and rheumatoid arthritis for which supplementary fixation with staples was necessary due to unsatisfactory fixation because of poor bone quality. **B:** Postoperative anteroposterior view of the same patient with radiographic union at 3 months follow-up.

5. Conclusion

Regarding outcomes of fusion of the TN and CC joint with the IOFIX device, as part of a triple arthrodesis, there was an excellent union rate, and a significant improvement in AOFAS- and VAS-scores. Overall, there was a good satisfaction rate and a low complication rate for this novel fixation method. The combination of these outcomes makes the IOFIX system a valuable and preferable fixation technique for triple arthrodesis.

Ethical approval

The study was in accordance with institutional rules for ethical review and approved under number S56535. Data was completely deidentified.

Author contribution

LL: data curation, conceptualization, formal analysis, investigation, methodology, software, visualization, writing original draft, validation. TD: data curation, methodology, writing original draft, validation. GM: supervision, validation, writing review & editing.

Informed consent

All patients signed informed consent to participate in the study with anonymization of their data.

Declaration of Competing Interest

GM has a financial conflict of interest as a paid consultant of Extremity Medical.

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