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ORIGINAL STUDY

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Arthrodesis of the first metatarsophalangeal joint using an intraosseous fixation device

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The complication rate for an arthrodesis of the first metatarsophalangeal joint remains high. To improve results, we used a complete intraosseous fixation device (IOFIX) with proposed biomechanical advantages. Our hypothesis is that this technique has at least an equal union rate and less hardware irritation compared to other techniques. Seventy procedures were performed in 55 patients. Average follow-up was 24.5 months. All patients returned to follow-up after 6 weeks and were evaluated for union. Fifty-nine feet (84%) completed full follow-up. Union occurred in 62 of 70 feet (88.5%). Eight feet had nonunion at 1 year follow-up. Average time to fusion was 51 days. Three of 59 feet had malunion. No hardware removal was necessary. In conclusion, an MTP1 arthrodesis using IOFIX provides consistent and good functional outcomes. Due to the low-profile design, no hardware removal was necessary. However, union rates seem slightly lower compared to other techniques.

Keywords: first metatarsophalangeal joint arthrodesis; MTP1 arthrodesis; IOFIX; intraosseous fixation device.

INTRODUCTION

An arthrodesis of the first metatarsophalangeal joint (MTP1) is a frequently performed procedure. It is considered the gold standard in the operative treatment of a hallux rigidus and severe hallux valgus. Some less frequent indications are: neuromuscular disorders, avascular necrosis, correction of the rheumatoid forefoot and salvage of failed surgery *(1-3)*.

The operative technique was first described by Clutton in 1894 *(4)*. Since then, more than 100 different techniques have been proposed in literature, including Kirschner wires, Steinman pins, external fixation, wire suture, staples, compression screws and a dorsal plate with or without compression screw *(4-8)*. Numerous studies have been published comparing these techniques, but none has yet proven its superiority, therefore no consensus exists about the gold standard *(9)*.

The nonunion rate has commonly been reported as approximately 10%, ranging from 0-40%. Other possible complications are malunion, infection, hardware failure and symptomatic irritation due to hardware prominence *(5-9)*. Roukis et al. conducted a systematic review of the results

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after MTP1 arthrodesis, including only modern osteosynthesis techniques i.e. 1 or 2 compression screws, dorsal plate with or without compression screw or staples *(9)*. They reviewed 37 studies with a total of 2818 procedures. The average nonunion rate was 5.4%, which is half of the commonly reported 10%. Malunion and hardware removal occurred in respectively 6.1% and 8.5%. So, the overall complication rate remains high, summing up to 20% in total. To improve these results, new osteosynthesis techniques are being developed to improve stability and compression, which are essential for an arthrodesis. Furthermore, the implant should be low-profile to prevent irritation by hardware and the subsequent need for removal.

To accommodate these features, a novel concept was created: the IO-Fix system (Extremity Medical™, Parsippany, NJ, USA). It comprises a 6.6mm X-post and a 4.0mm lag screw (different lengths are possible). The X-post is a cancellous screw placed in the first metatarsal head parallel to the fusion surface to act biomechanically as an intra-osseous washer. The lag screw is then passed through the eyelet of the X-post, bridging the fusion site. As the lag screw is tightened, it engages the X-post's morse taper and locks into place, thereby reinforcing the cortical bone bridge, as a fracture of this cortical bone bridge leads to loss of compression. The goal of this construct is to create a more uniform and higher peak compression over the fusion site *(10)*. The intraosseous design should limit hardware prominence and therefore reduce the need for hardware removal.

This technique is used in our institution since 2011. The aim of this paper is to describe the operative technique and to retrospectively analyse the results. Our primary end-points are union rate and the need for hardware removal. Secondary end-points are per-operative stability and the possible need for additional fixation, malunion, time to union and other possible complications. Our hypothesis is that this technique has at least an equal union rate compared to other techniques and results in less soft tissue irritation.

MATERIALS AND METHODS

This is a level IV retrospective case series. It was approved by the institutional's ethical committee under number S62324. All patients who underwent a MTP1 fusion with IOFIX device were selected from the archived records of operations at XXX, from December 2011 until January 2015. In total, 70 procedures were identified in 55 patients. We decided not to exclude any patients, because we wanted to be able to detect and report each possible problem associated with the use of this relatively new technique. After informed consent, all data were retrieved from the archived electronical medical files and digital radiographs.

The patient demographics are listed in Table I. The average age was 62 years (range 36.2-78.3 years). Thirty-seven of the 55 patients were female. Seven feet had previous hallux surgery and two feet had pseudarthrosis after failed MTP1 arthrodesis. All patients had failed conservative treatment consisting of nonsteroidal anti-inflammatory drugs, shoe adjustments, insoles and activity modification. Additional surgical procedures on the lesser toes consisted of PIP-arthroplasty and/or extensor tenotomy for hammer- or clawtoes in 35 feet.

The operations were carried out by an experienced orthopaedic surgeon. A dorso-medial curvilinear incision was made over the MTP1 joint. The capsule was incised longitudinally and subperiosteally released from the dorso-medial aspect of the first metatarsal head and from the base of the first phalanx. The articular cartilage was denuded using a rongeur to create concentric concave-convex surfaces, until viable, bleeding cancellous bone was visible. If necessary, an additional lateral release was performed.

Next, the hallux was positioned in the desired alignment, with neutral rotation. The sagittal alignment was checked by using a metal tray to simulate load-bearing. Ideally, the amount of dorsiflexion is the one which allows the tip of the hallux to touch the ground and which allows the patient to wear shoes with the desired heel-height. In males, heal clearance was between 1.5 and 2 cm. In females, it was usually higher, between 2 and 3 cm. A physiological valgus position was aimed for,

Table I. — Patient demographics (HV = hallux valgus ; HR = hallux rigidus ; RA = rheumatoid arthritis)

Age		62.0 year (range 36.2-78.3)
Gender	Male (# feet)	18 (21)
	Female (# feet)	37 (49)
Topology	Bilateral	30
	Right	25
	Left	15
Indications	Severe HV (previous surgery)	32 (4)
	Severe HR (previous surgery)	19 (1)
	HR + HV	16
	Failed MTP1 arthrodesis	2
	RA without HV or HR	1
	+ RA	20
Follow-up	Average	24.5 months (range 1.5-87)
	>12m	59
	<12m	11
Reasons loss to FU	Nonrelated serious medical condition (deceased)	5 (3)
	Appointment cancelled because asymptomatic	4
	Bilateral foot sugery	2

avoiding any contact between the hallux and the second toe.

The next step was placement of the IOFIX device. A guidewire for the X-post was inserted into the metatarsal head, parallel to the joint and 7-9 mm from the joint line. The orientation is of extra importance because the IOFIX has a fixed angle of 60° and the X-post placement therefore determines the lag screw trajectory. After drilling, reaming and measuring, the X-post of appropriate length was inserted until flush with the cortex. Through the eyelet of the X-post, a guidewire was then drilled using an aiming device from medial proximal to lateral distal across the MTP joint. After drilling and measuring, the tapered lag screw was inserted under “two finger” pressure until tactile compression was felt. Fluoroscopic control was used and was subjectively graded (good, acceptable or insufficient). The diameter of the X-post was 6.6mm, the diameter of the lag screw was 4.0mm. The stability of the construct was assessed (unstable, moderate, good or very good) and if necessary, additional fixation was carried out.

Postoperative care consisted of a cork splint and weight bearing was restricted. The splint was removed after 2 weeks and the patients received a cast shoe for another 4 weeks in which weight bearing was allowed. After 6 weeks, fusion was assessed both clinically and radiographically. If fusion was achieved, patients were allowed to bear weight in an adequate shoe with a stiff sole. Another clinical evaluation was carried out at 3 months and again at 1 year, with an additional radiographic evaluation.

The average follow-up was 24.5 months (range 1.5-87 months). All patients returned after 6 weeks and were evaluated radiographically. Eleven patients were lost to follow up after 1 year. The causes of loss to follow-up are listed in Table I. Four feet were lost because patients were completely asymptomatic and cancelled their 1 year appointment, whereas 5 other patients cancelled due to serious non-related medical conditions.

As union status was our primary end-point and every patient returned for follow-up at 6 weeks, we decided to include all patients. Every patient was evaluated for peroperative stability, position of

IOFIX, peroperative complications, union status and time to fusion. Regarding hardware irritation, clinical outome and postoperative complications, only the 59 feet who completed FU were reported.

Radiographic evaluation consisted of weight bearing antero-posterior (AP), lateral and ¾ endorotation views. Fusion was considered successful when 70% or more of the articular surface showed bridging trabeculae across the fusion site on all 3 views. Union was considered delayed when it took more than 3 months, although there is no clear definition according to literature. The intermetatarsal angle (IMA) and hallux valgus angle (HVA) on AP view and dorsiflexion angle (DFA) on sagittal view were measured using the technique described by Miller *(1)*. Malunion is defined as the healing of an arthrodesis in a suboptimal position with residual deformity that is substantial enough to produce clinical symptoms *(11)*. Generally, surgeons aim for an HVA of 10-15° and a DFA of 15-25°, but no range of values is reported in literature regarding malunion as this is patient specific. And thus, malunion is assessed clinically, rather than radiographically. It was considered as a malunion if there was symptomatic contact between the hallux with the shoe/second toe or when the patient couldn't wear normal shoes *(11)*. Further clinical evaluation consisted of assessment of motion and/or pain over the MTP joint, infection and irritation due to screw prominence.

The variable data is presented as mean and range. We used the Wilcoxon signed rank test to compare the HVA, IMA and DFA preoperatively with 6 weeks postoperatively and 6 weeks with 1 year postoperatively. A p-value of less than 0.05 was considered significant.

RESULTS

Peroperatively, there was a good to very good stability after IOFIX placement in 60 procedures. Stability was moderate and unstable in respectively 6 and 4 cases (Table II). Additional fixation consisted of 6 staples, 4 Herbert crossing screws (HCS) and one IOFIX. All but one fused within 6 weeks. In case #49, stability remained poor and this lead to valgus malunion and was revised after 2 years with a plate and locking screw. A good to very good position of the IOFIX system was noted in 50 feet and an acceptable position in 10 feet. There was an insufficient placement in 10 feet, of which six were within the first 18 procedures.

Table II. — Cases with moderate or unstable fixation (HCS = Herbert crossing screw)

Case	Stability	Position of IOFIX	Extra fixation	Stability after extra fixation	Time-fusion (d)	Complication
6	moderate	good	Staple	good	39	/
7	moderate	Insufficient: x-post diameter 4.6mm	Staple	good	34	/
15	moderate	insufficient: not enough purchase in cortex	Staple	good	46	/
19	moderate	Insufficient: lag screw too short, no purchase in cortex	HCS 32	moderate	46	/
22	unstable	very good	HCS 36	good	32	/
29	unstable	good	IOFIX	good	41	/
49	unstable	Acceptable: lag screw too short but good purchase in cortex	staple	poor	70	Malunion Infection
53	unstable	Insufficient: no purchase in cortex	HCS	very good	41	/
68	moderate	good	Staple	good	38	/
70	moderate	Insufficient: lag screw too short, no purchase in cortex	HCS + Staple	Good	39	/

Radiological union occurred in 62 of 70 feet (88.5%) (Figure 1). Eight feet (11.5%) had pseudarthrosis (Figure 2). The individual cases and their possible risk factors are listed in table III. Four patients had mild symptoms that could be effectively treated conservatively. The others were asymptomatic.

Average time to fusion was 51.0 days (range 32-190). Fifty-three feet (75%) fused within 6 weeks. Three feet (5%) had a delayed union, ranging from 120 to 190 days.

The average HVA and DFA at 6 weeks were 13.5° (-6.4°-51.2°) and 26.6° (10.1°-45.2°) respectively, which was statistically significant different compared to preoperatively. There was no statistical difference between 6 weeks and 1 year postoperatively.

Fifty-one out of 59 cases (86.4%) who completed follow-up had good clinical outcome with pain-free ambulation in a normal shoe. As stated above, 4 patients with a radiographic non-union were symptomatic. One patient had mild pain due to hardware irritation. No hardware removal was necessary. One patient had a valgus malunion with severe symptoms and required revision surgery. There was one hyperextension malunion and one varus malunion, both with mild symptoms and they were treated conservatively. Other complications were 2 superficial wound infections with good clinical evolution after oral antibiotics and one

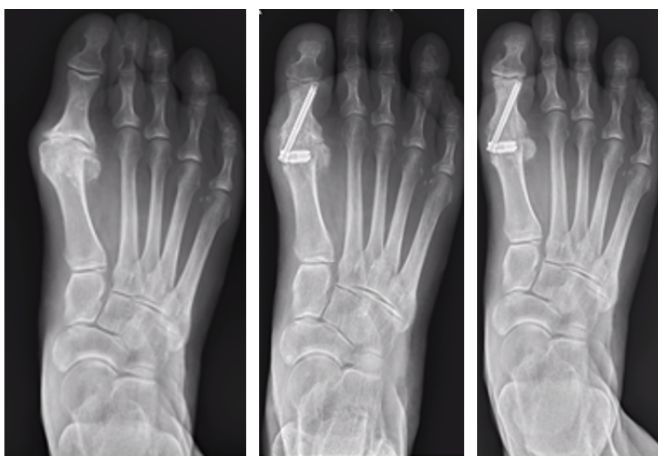

Figure 1. — Antero-posterior radiographs of the food showing fusion at 6 weeks (left= pe-op; middle= 6w post-op; right= 12m post op)

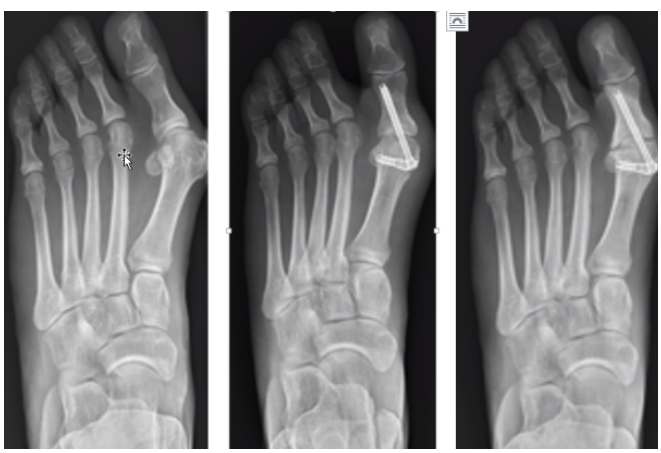

Figure 2. — Antero-posterior radiographs of the food showing nonunion of #50 (left= pe-op; middle= 6w post-op; right= 12m post op).

stress fracture of MT1 which consolidated with conservative treatment.

DISCUSSION

No technique for an MTP1 arthrodesis has yet been able to prove its superiority over others in a reproductive manner and thus, there is no consensus about the gold standard. Several authors have investigated the biomechanical properties of different techniques. Curtis et al. found that a 3.5mm cortical interfragmentary lag screw was significantly more stable than a 5-hole tubular dorsal plate *(12)*. Buranosky et al. found a dorsal vitallium six-hole plate with a 2.7mm cortical lag screw to produce more stability than two 2.7mm crossed cortical lag screws *(13)*. Neufeld et al. compared 2 crossed 4mm screws, one third tubular plate with 0.062 K-wire and 2 compression staples with 0.062 K-wire *(14)*. The screw construct showed a tendency for higher stiffness and load to 1mm displacement, although not statistically significant. Politi et al. found a dorsal miniplate with a 3.5mm cortical lag screw to produce more than twice the resistance against micromotion compared to one 3.5mm cortical lag screw, which was more stable than the dorsal miniplate alone or 2 crossed K-wires *(15)*.

In conclusion, the most stable constructs according to these studies are 2 crossed 4mm screws and a dorsal plate with an additional lag screw, but these haven't yet been compared to each other. All these studies focused on stability and rigidity of the construct by applying a plantar force over the joint and measuring the load to 1 and 2mm of displacement and load to failure. However, excessive implant rigidity does not necessarily encourage bone consolidation and what is more essential is a fixation device that generates moderate uniform compression and adequate stability *(16, 17)*.

To accommodate these features, the IOFIX device was developed. Parker et al. compared the Io-fix system with a single AO 6.5mm lag screw for an ankle arthrodesis in a human cadaveric biomechanical study *(10)*. They found that the IOFIX produced a significantly higher force and created a higher average contact area, thus generating a more uniform compression. They recognized that usually more than one lag screw is used to fuse the ankle joint, but nonetheless they were able to define the influence of the x-post, the characteristic feature of the construct.

Roth et al. found that a plantar plate for a metatarsocuneiform fusion provided significantly more stability, compared to IOFIX in a biomechanical cadaveric *(18)*. However, the plate was placed on the tension side, whereas the IOFIX was placed on the compression side. Secondly, they used the IOFIX as a fully intramedullary device, whereas the lag screw should have good purchase in the cortex to create compression and stability. Therefore, in our opinion, no definite conclusions can be made of this study, especially as a plantar plate is not feasible for an MTP1 arthrodesis.

The disadvantage of these cadaveric biomechanical studies is that the healing biological response of the bone is not taken into account. Our subjects, as in most studies, were not allowed to bear weight for the first 2 weeks and received a protective cast shoe for another 4 weeks. In this period, bony trabeculae bridge the fusion site, thereby changing the biomechanical properties of the construct. Perhaps if a less stiff construct is used, but one that generates more and uniform compression across the arthrodesis site, the joint fuses faster or more frequent with better results. Therefore, clinical studies are necessary.

We found an overall union rate of 88.5%. Eight patients had a non-union. In 4 cases, the risk factors were patient-related (smoking, obesity, DM and atherosclerotic disease). In two cases the risk factor was implant-related (insufficient placement of the IOFIX). The rate of insufficient placement in the non-union group (2/8 = 25%) seems higher than in the union group (8/62 = 13%).

We recognize that in 10 out of 70 procedures some additional stabilisation was necessary, but in practice this could be remedied simply with the use of one additional staple or lag screw leading to an uneventful healing in 9 out of 10 cases. This is partly due to the learning curve, as 6 of these cases were within the first 18 procedures. Furhtermore, in our professional opinion and expertise, not a single osteosynthesis device will be able to always achieve a fully stable construct in cases of poor bone quality.

When comparing our results with the systematic review of Roukis et al. *(9)*, our nonunion rate is higher than the average of 5.4% they reported. A possible explanation is the high heterogeneity between included papers regarding important variables that could affect outcome, such as inclusion criteria, joint preparation and postoperative rehabilitation. For example, multiple studies excluded previously failed surgery or co-morbidities like smoking and diabetes. Roukis et al. recognized this shortcoming and also stated that the methodological quality of the studies was generally poor, with only 1 level II and 10 level III studies.

Regarding other outcomes, our average time to fusion was 13 days lower (51.0 vs 64.3), no hardware removal was necessary (0% vs 8.5%) and our malunion rate was lower (4.2% vs 6.1%). However, these complications were not consistently reported in the included studies and thus may be biased.

More clinical series were published after this review. Mohammed et al. reported a nonunion rate of 9% in 23 feet using 2 crossed compression screws 6. They also included salvage procedures. Migues et al. reported a nonunion rate of 10% in 101 feet using one endomedullary screw *(8)*. Screw removal was necessary in 4 feet. Doty et al. used a dorsal hybrid locking plate with a plantar neutralization screw and reported a non-union rate of 2% in a prospective case series of 51 feet *(7)*. This is substantially lower than in our case series. However, their patients were not allowed to bear weight on the first ray for 12 weeks. No revision surgery or removal of hardware was necessary. This is in contrast with the series of Wanivenhaus et al. in which 20% of the 41 feet treated with a screw and dorsal plate, needed implant removal *(19)*. Their union rate was 95%.

Hyer et al. compared 2 crossed screws using 4.0 mm partially threated cannulated screws or 2.7 mm Herbert crossing screws (14 feet) with a 5-hole titanium plate (31 feet) in a retrospective study 20. They reported a non-union rate of 10% and 7%, respectively. They found no statistic significant difference between the groups, except for a higher cost for the plate (374$ vs 603$).

Three retrospective case series with respectively 12, 21 and 54 cases, have already been reported using the IOFIX (table IV) *(21-23)*. The union rate in our series seems slightly lower (11.5% vs 4-9%). However, this may be due to differences in patient population as they only included primary cases. Secondly, only Singhal et al reported co-morbidities. As mentioned previously, the risk factors for nonunion in our series were patient-related in 4 out of 8 cases. In general, other complications were comparable, with confirmation of little hardware irritation. The added value of this study is that it is the largest case series reported so far and enhances our knowledge and expertise of the IOFIX device.

Our study had several limitations. The first limitation is that 11 feet were lost to follow-up at 1 year (Table I). However, 4 patients cancelled their appointment because they were asymptomatic and 5 patient cancelled because of serious medical conditions, so this loss of follow up seems unlikely to cause any bias.

Another limitation is that this is a retrospective case series, with its well-known disadvantages. For this reason, we couldn't report PROM's or VAS scores to improve clinical evaluation.

Third, this study lacks a control group to allow for better evaluation of differences between techniques.

CONCLUSION

The IOFIX system is a low profile device for MTP1 arthrodesis that generates uniform compression across the fusion site. Due to the low profile design, no hardware removal was necessary. Our union rate was 88.5%. This is slightly lower compared to other techniques, reporting rates ranging from 90-98%. In our opinion, this is partly due to the learning curve of this new procedure. We may be able to eliminate some of these factors with our growing expertise and thus improve the results. A prospective case series is currently being conducted in our institution.

In general, further research is needed to determine the gold standard for treatment of MTP1 arthrodesis. Therefore, prospective randomized trials are needed, comparing the most frequently used techniques that offer the best biomechanical properties.

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