# Prospective Multicenter Study Assessing Radiographic and Patient Outcomes Following an Instrumented Mini-Open Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing

## Introduction

Hallux valgus (HV) is a common orthopedic problem of the foot, with a prevalence in adults of approximately 25%.[1] HV is recognized as a complex three-dimensional (3D) deformity with significant contributions in the transverse, sagittal, and frontal planes.[2, 3, 4, 5, 6] Yet, surgical correction of HV has traditionally focused on the transverse and sagittal planes, with metatarsal osteotomies being the most common surgical approach. These traditional metatarsal osteotomy approaches have been associated with radiographic recurrence up to 30% to 78%, with a recent systematic review of long-term outcomes of distal osteotomies demonstrating recurrence of 10% and 64% using post-operative hallux valgus angle (HVA) of 20° and 15°, respectively.[7, 8, 9, 10] An instrumented system for achieving triplanar HV correction through first tarsometatarsal (TMT) arthrodesis was recently developed and has demonstrated positive early clinical and radiographic results with low recurrence rates.[11,12]

Recently, there has been a trend towards minimally invasive surgical (MIS) approaches for HV correction using distal first metatarsal osteotomies. Some of these MIS distal osteotomy techniques include 3D correction of the frontal-plane rotational deformity and have demonstrated positive outcomes.[13, 14] An instrumented system was recently developed for performing a mini-open triplanar 1st TMT arthrodesis and the purpose this study is to assess the clinical, radiographic, and patient-reported outcomes for HV correction performed with this system through a mini-open approach (≤4cm) with biplanar fixation to allow early return to weightbearing.

## Methods

This is a prospective, multicenter study involving 9 US-based centers and 9 surgeons. Institutional review board approval was obtained for each study site. A consecutive cohort of patients were enrolled in the study who received first TMT arthrodesis through a mini-open approach to correct their symptomatic HV. Inclusion criteria were as follows: symptomatic HV in patients between 14 to 58 years of age, IMA between 10.0-22.0°, and HVA between 16.0-40.0°. Exclusion criteria included the following: a prior history of HV surgery, previous surgeries on the operative foot involving joint fusion (other than lesser toes/digits), additional arthrodesis or concomitant procedures outside the first ray (other than intercuneiform stabilization), BMI >40 kg/m2, diabetes with HbA1c ≥7, evidence of peripheral neuropathy, symptomatic or asymptomatic flatfoot, metatarsus adductus of ≥23°, moderate to severe osteoarthritis of the first metatarsophalangeal (MTP) joint complex, and current use of nicotine products.

The surgical technique utilized was similar to a previously published study[15], with modifications to allow the procedure to be performed through a mini-open dorsal incision (≤4cm) **(Figure 1)**. The initial and final incision length was measured intraoperatively. The surgical technique utilized an over the skin bone positioner device to correct the 1st metatarsal in all three planes, a miniaturized cut guide to produce the first TMT joint cuts, and a compressor device for TMT joint apposition. A titanium biplanar locking plate construct consisting of a four-hole dorsal-lateral straight plate and a medial u-shaped plate was used to fixate the first TMT joint. The surgeon had the option of supplementing the biplanar plating with additional interfragmentary screws across the TMT joint and/or intercuneiform joint to address intercuneiform instability. All patients were instructed to begin weightbearing as tolerated in a controlled ankle motion (CAM) boot within 3 weeks of the index procedure. Patients were transitioned from the CAM boot to an athletic shoe at six weeks postoperatively and allowed to return to full activity at four months postoperatively. Representative preoperative and postoperative radiographs are shown in **Figure 2**.

Radiographic imaging was obtained preoperatively, and at 6 weeks, 4-, 6-, 12-, and 24-months postoperatively. Imaging included weightbearing anterior posterior (AP), lateral, and sesamoid axial radiographs. An independent fellowship-trained musculoskeletal radiologist (blinded) reviewed the radiographic images and performed all measurements using a picture archiving and communication system (AG Mednet Judi/Imaging, version 7.10). The radiographic measures reported in this study were IMA, HVA, tibial sesamoid position (TSP), osseous foot width, and sagittal-plane IMA (defined as the angle between the longitudinal dorsal cortex of the first and second metatarsals on lateral radiographs, with first metatarsal dorsiflexion defined as a positive value).[16] Given that there is not a standard definition of HV recurrence, and the literature commonly utilizes greater than 15 degrees and 20 degrees of postoperative HVA, we selected to report utilizing both thresholds for comparison.[5] Protocol-defined nonunion was defined as clinical pain at the TMT plus one or more of the following radiographic findings: lucency, hardware failure, or recurrence.

Patient-reported outcomes for the operative foot were measured by VAS, MOxFQ, and PROMIS-29. Visual analog scale was reported based on pain associated with the base of the big toe (bunion-related) preoperatively and at 6 weeks, 6-, 12-, and 24-months postoperatively. Quality of life via MOxFQ and PROMIS-29 was collected preoperatively and at 6-, 12-, and 24-months postoperatively. An assessment of the primary incision was assessed by the patient and observer (surgeon) utilizing the Patient and Observer Assessment Scale (POSAS: Patient and Observer Scale, Dutch Burns Foundation, Beverwijk, The Netherlands). Note that the POSAS patient and observer scales are separate questionnaires with different scales.

The forefoot (level of 1st metatarsal head), midfoot (level of 1st TMT joint), and midcalf (level of myotendinous junction of gastroc) circumference were measured utilizing a flexible tape measure preoperatively and at 6 weeks, 6-, and 12-months postoperatively. Additional endpoints included clinical complications related to the surgical procedure and/or implants, concomitant procedures, and metatarsalgia reported by the patients.

All statistical analyses were performed using SAS software, version 9.4 (SAS Institute Inc., Cary, NC). Continuous variables were summarized using means, standard deviations (SD), medians, quartiles, and 95% confidence intervals (CIs) whereas categorical variables were summarized using frequencies and percentages. Inferential statistics were performed using a paired t-test to assess mean changes from baseline. Significance was determined at the 0.05 level. Confidence intervals for proportions were derived using the Clopper-Pearson method.

## Results

One hundred and five patients were treated, of whom 75 (71.4%) had achieved their 12-month follow-up and 11 (10.5%) patients completed their 24-month follow-up. Demographic information is summarized in **Table 1**. Patients underwent an early return to weightbearing with mean (95% CI) 7.9 (6.7, 9.1) days to weightbearing in a CAM boot, 6.1 (5.9, 6.4) weeks to an athletic shoe, and 3.8 (3.5, 4.2) months to full unrestricted activity.

Eighty-four patients (80.0%) had at least one concomitant procedure. The most common adjunctive procedures were medial eminence or medial capsular ridge resection (59.0%), intercuneiform stabilization with a screw (48.6%), and Akin osteotomy (22.9%).

Significant improvements from baseline in mean radiographic measurements for HVA, IMA, and TSP were observed at six weeks and maintained through the 12-month visit whereas clinical improvements were maintained at the 24-month visit **(Table 2)**. There was a small mean (95% CI) increase in sagittal plane intermetatarsal angle (dorsiflexion) of 0.9° (0.3°, 1.6°) at 12 months. Regarding patients achieving correction (defined as 2 of 3 criteria being met at 6 weeks: IMA <9.0°, HVA <15.0°, and TSP <=3), 94.2% (98/104) achieved 6-week correction. Using recurrence definitions of postoperative HVA greater than 15° and 20°, recurrence rates were 5.5% (95% CI: 1.5%, 13.4%) and 0.0% at 12 months and 0.0% for both thresholds at 24 months, respectively **(Table 3)**. Clinically and statistically significant 12-month reductions in osseous foot width were observed with a mean (95% CI) reduction of 7.2 mm (6.3, 8.1), with clinically significant 24-month reductions of 8.6 mm (4.7, 12.4) **(Table 2)**.

There was a significant decrease from baseline in forefoot circumference at 12 months **(Table 4)**. Midfoot circumference increased with swelling at 6 week and 6 month follow-up, but returned to the baseline circumference at 12 months. Likewise, the calf circumference decreased at 6 week and 6-month follow-up but returned to baseline at the 12-month follow-up.

Significant improvements in patient-reported outcomes were also observed, with an improvement in VAS over baseline beginning at the 6-week visit and continuing through 12 months **(Table 5)**. Walking/Standing, and Pain improved over baseline and continued to improve through the 12- and 24- month visit **(Table 5)**. Similar improvements were observed across all PROMIS domains **(Table 6)**. MOxFQ domains of Social Interaction, The median (min, max) incision length was 3.5 cm (3.0, 4.0). A clinically meaningful improvement in the cosmetic appearance of the scar was observed in both the observer and patient POSAS scores through 12- and 24- months **(Table 7, Figures 3-4)**.

One (1.0%) patient in the overall treated cohort of 105 required reoperation for removal of hardware due to pain. Eleven other patients (10.5%) experienced clinical complications that did not require surgical intervention, with pain being the most reported event (n=4, 3.8%). No patient experienced symptomatic nonunion **(Table 8)**. Of the 75 patients with baseline and 12-month follow-up metatarsalgia data, only two patients (2.7%) reported metatarsalgia at 12 months **(Table 9)**. None (0%) of the 28 patients who reported baseline metatarsalgia continued to report metatarsalgia at 12 months postoperatively. Of the 47 patients who reported no metatarsalgia at baseline, only 2 (4.3%) developed metatarsalgia at 12 months.

**Figure 1** | The procedure is performed through a mini-open dorsal incision (≤4cm) dorsal incision.

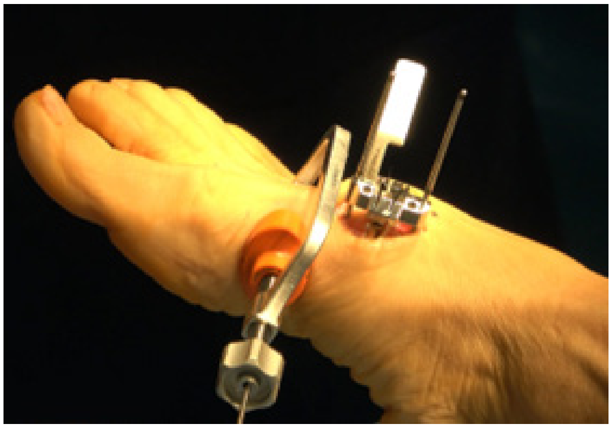

**Figure 2** | Representative preoperative (left) and 24month postoperative (right) radiographs.

**Table 1** | Demographics and Baseline Characteristics

| Baseline Characteristics | Category | Patient Population |
|---|---|---|
| **Age (years), mean (SD)** | | 41.0 (12.4) |
| **Sex, n (%)** | Male | 7 (6.7%) |
| | Female | 98 (93.3%) |
| **BMI (kg/m$^{2}$), mean (SD)** | | 25.5 (4.9) |

**Table 2 |** Radiographic measures, mean (95% confidence interval)
There are significant (p<0.01) improvements over baseline at all post-op timepoints through 12 months

| Radiographic Measure | Baseline (n=105) | 6 Week (n=104) | 6 Month (n=98) | 12 Month (n=75) | 24 Month (n=11) |
|---|---|---|---|---|---|
| **Hallux Valgus Angle (HVA)** | 26.6° (25.3, 27.8) | 6.4° (5.2, 7.6) | 6.5° (5.1, 7.8) | 7.1° (5.6, 8.6) | 5.6° (3.3, 7.8) |
| **Intermetatarsal Angle (IMA)** | 14.1° (13.5, 14.6) | 3.7° (3.2, 4.3) | 4.7° (4.0, 5.3) | 4.8° (4.1, 5.6) | 3.0° (1.6, 4.3) |
| **Tibial Sesamoid Position (TSP)** | 5.0 (4.8, 5.3) | 1.7 (1.5, 1.9) | 2.3 (2.1, 2.6) | 2.7 (2.4, 3.0) | 1.9 (1.4, 2.5) |
| **Sagittal-Plane Intermetatarsal Angle*** | 0.3° (-0.1, 0.8) | 1.8° (1.2, 2.3) | 1.3° (0.8, 1.9) | 1.4° (0.8, 2.0) | 1.1° (-1.3, 3.5) |
| **Osseous Foot Width (mm)**** | 93.4 (92.0, 94.7) | – — | 86.0 (84.6, 87.4) | 85.7 (84.2, 87.2) | 79.3 (75.6, 83.1) |

*Dorsiflextion is a positive value
**n=9 patients excluded due to x-ray format that did not allow for quantitative length measurements. Inferential statistics not performed at month 6 due to small sample size.

**Table 3** | Radiographic recurrence definition N (%) 95% confidence interval
None of the patients had recurrence using post-op HVA of >20° at 12 or 24 months.

| Visit | HVA >15° | HVA >20° |
|---|---|---|
| **12 Month** | 5.5% (4/73) (1.51, 13.44) | 0.0% (0/73) |
| **24 Month** | 0.0% (0/11) | 0.0% (0/11) |

**Table 4 |** Foot Circumerence Measurements

| Circumferential Measurements in cm, Mean (95% Confidence Interval) | | | | |
|---|---|---|---|---|
| **Swelling Measures** | **Baseline (n=105*)** | **6 Week (n=104)** | **6 Month (n=98)** | **12 Month (n=75)** |
| **Forefoot Circumference** | 20.7 (20.1, 21.3) | 20.8 (20.2, 21.5) | 20.2 (19.5, 20.8) | 19.8 (19.1, 20.5) |
| **Midfoot Circumference** | 20.2 (19.6, 20.8) | 20.9 (20.3, 21.5) | 20.5 (19.9, 21.1) | 20.2 (19.6, 20.9) |
| **Calf Circumference** | 33.4 (32.5, 34.3) | 31.5 (30.6, 32.3) | 32.4 (31.5, 33.3) | 32.9 (32.0, 33.8) |

*One subject was missing measurements for Forefoot and Midfoot

**Table 5** | Patient-reported outcomes, mean (95% confidence interval)
Significant improvements were seen over baseline in VAS and MOxFQ through 12m post-op.

| Measure | Baseline (n=105) | 6 Week (n=104) | 6 Month (n=98) | 12 Month (n=74) | 24 Month (n=11) |
|---|---|---|---|---|---|
| **VAS Pain Score** | 3.5 (3.1, 3.9) | 1.6 (1.4, 1.9) | 1.2 (0.9, 1.5) | 0.9 (0.7, 1.2) | 1.0 (0.0, 2.0) |

| Measure | Baseline (n=105) | 6 Month (n=98) | 12 Month (n=75) | 24 Month (n=11) |
|---|---|---|---|---|
| **MOxFQ (Walk/Stand)** | 41.2 (36.7, 45.8) | 17.6 (13.6, 21.7) | 8.8 (5.4, 12.1) | 7.8 (-1.6, 17.1) |
| **MOxFQ (Pain)** | 50.2 (46.6, 53.9) | 22.8 (19.0, 26.6) | 14.5 (10.9, 18.0) | 10.5 (-2.6, 23.5) |
| **MOxFQ (Social Interaction)** | 42.7 (38.7, 46.8) | 14.0 (10.5, 17.7) | 9.0 (5.9, 12.1) | 6.8 (-7.0, 20.7) |
| **MOxFQ (Index Score)** | 44.4 (40.8, 48.1) | 18.4 (14.7, 22.0) | 10.6 (7.6, 13.6) | 8.4 (-2.9, 19.6) |

**Table 6** | PROMIS
Significant improvements observed across all PROMIS domains at 6 and 12 months post-op.
Continued improvements were also observed in the 24-month subjects (n=10).

| PROMIS Domain | Baseline (n=99) | 6 Month (n=92) | 12 Month (n=70) | 24 Month (n=10) |
|---|---|---|---|---|
| **Ability to Particiate in Social Roles/Activities** | 54.1 (52.3, 56.0) | 59.3 (57.9, 60.7) | 61.5 (60.3, 62.7) | 61.5 (58.3, 64.7) |
| **Anxiety** | 48.3 (46.3, 50.2) | 44.2 (42.7, 45.8) | 43.7 (42.2, 45.1) | 44.3 (39.6, 48.9) |
| **Depression** | 44.9 (43.3, 46.4) | 43.3 (42.1, 44.5) | 43.8 (42.3, 45.3) | 42.9 (40.0, 45.8) |
| **Fatigue** | 45.8 (43.7, 47.8) | 41.9 (39.9, 43.8) | 41.2 (39.2, 43.2) | 38.9 (34.0, 43.7) |
| **Pain Intensity** | 3.9 (3.5, 4.3) | 1.3 (1.0, 1.7) | 0.9 (0.6, 1.2) | 1.1 (-0.4, 2.6) |
| **Pain Interference** | 54.1 (52.4, 55.8) | 45.6 (44.2, 47.0) | 43.6 (42.6, 44.7) | 44.6 (41.0, 48.2) |
| **Physical Function** | 45.9 (44.2, 47.5) | 52.9 (51.6, 54.3) | 55.0 (53.9, 56.0 | 55.4 (51.6, 59.1) |
| **Sleep Disturbance** | 49.1 (47.6, 50.6) | 44.9 (43.1, 46.8) | 44.3 (42.4, 46.2) | 44.4 (38.2, 50.6) |

**Figure 3** | Representative preoperative (left) and 12 month postoperative (right) incision/scar assessments.


**Figure 4** | Representative preoperative (left) and 24 month postoperative (right) incision/scar assessments.


**Table 7** | Incision length and POSAS* scar analysis (95% confidence interval)
High patient satisfaction with post-operative scar appearance.

| Incision Length (cm) | | | | |
|---|---|---|---|---|
| **Median (Min,Max)** | | | **3.5 (3.0, 4.0)** | |
| **Measure** | **4 Month (n=98)** | **6 Month (n=98)** | **12 Month (n=75)** | **24 Month (n=11)** |
| **POSAS Observer** | 14.6 (13.4, 15.9) | 12.1 (11.2, 13.1) | 10.8 (9.8, 11.8) | 7.5 (6.2, 8.7) |
| **POSAS Patient** | 22.7 (20.4, 24.9) | 18.2 (16.0, 20.4) | 13.4 (11.6, 15.2) | 8.8 (5.3, 12.4) |

**POSAS (Patient and Observer Scar Assessment Scale) – Total POSAS score can range from 6 to 60 and is calculated by summing the 6 component scores. A lower score denotes similarity to normal skin.*

**Table 8** | Complications and AEs - presented at the patient level

Limited clinical complications:
1 (1.0%) of the 105 patients required reoperation (hardware removal).
11 (10.5%) patients experienced at least one clinical complication not requiring surgical intervention.
Symptoms of 3 patients were ongoing at the time of data analysis; symptoms were pain (N=2) and malunion/stiffness (N=1).
0 (0.0%) patients experienced a protocol defined non-union.

| Complication Requiring Surgical Intervention | Number (%) n=105 | Complication Not Requiring Surgical Intervention | Number (%) n=105 |
|---|---|---|---|
| **Hardware removal due to pain** | 1 (1.0%) | **Other Pain** | 4 (3.8%) |
| | | **Infection** | 2 (1.9%) |
| | | **Malunion & Stiffness** | 1 (1.0%) |
| | | **Other AE*** | 3 (2.9%) |
| | | **Hardware Failure (HW not removed)**** | 1 (1.0%) |

* Other AEs: allergic reaction to surgical glue (1), cuneiform fracture (1), skin abrasion (1)
**Patient is considered healed per protocol definition.

**Table 9** | Metatarsalgia
Majority of patients experienced resolution of pre-op metatarsalgia.

| Metatarsaligia | | | |
|---|---|---|---|
| **Metatarsaligia at baseline** | **Metatarsaligia at 12 months n (row% (column %)** | **Metatarsaligia at 12 months n (row% (column %)** | **Row Total** |
| Yes | 0 | 28 (100.0%) (38.4%) | 28 |
| No | 2 (4.3%) (100%) | 45 (95.7%) (61.6%) | 47 |
| Column Total | 2 | 73 | |

## Discussion

This analysis of the prospective, multicenter study demonstrates favorable results of 1st TMT arthrodesis through a mini-open incision (median incision length of 3.5cm) with an early return to protected weightbearing, low radiographic recurrence, high union rates, low complication rates, and improvement in patient-reported outcomes at 12- and 24- months follow-up. When assessing the primary study endpoint, the low rate of radiographic recurrence maintained postoperatively through 12 and 24 months suggests a beneficial role of triplanar correction, including frontal plane rotation and TSP alignment, in achieving long-term correction of HV. In contrast, a recent systematic review of 2D distal osteotomy studies with five or more years follow-up, found pooled recurrence rates of 64% and 10% using the same HVA thresholds of 15° and 20°, respectively.[10] While the current study is only at 12 and 24 months follow up, our reported findings suggest the positive association between metatarsal rotational and sesamoid alignment in restoration of coronal plane anatomy of the MTP joint and maintenance of HV correction.

Reduction in foot width is another important consideration in hallux valgus correction assessment.[17] The current study demonstrated an osseus foot width reduction of approximately 8.2% and 15.1% at 12 and 24 months, respectively, as well as a decrease in forefoot circumference. Previously published distal osteotomy studies have shown an increase in midfoot width and a limited reduction in forefoot width, with reported osseous reduction of 5% and soft tissue reduction of 2%.[16,17]

The sagittal component of the HV deformity is important and changes in sagittal alignment can impact MTP range of motion, first ray loading, and transfer metatarsalgia to the lesser metatarsals. In the current study there was a small increase (mean 0.9°) in the sagittal intermetatarsal angle relative to baseline, indicating a slightly dorsiflexed 1st ray position. While the long-term clinical significance of the current findings is not yet known, only 2 of the 75 patients (2.7%) reported metatarsalgia at 12 months despite approximately 35% of patients reporting metatarsalgia preoperatively and no lesser metatarsal osteotomies (ex. Weil osteotomy) were performed. The slight dorsiflexed position of the first ray in the current study is in contrast to a recently published study of a similar instrumented 1st TMT system that was performed through an open incision approach, which demonstrated slight plantarflexion postoperatively.[7] It is hypothesized that the mini-open approach and positioner clamp utilized in the current study over the skin of the 1st metatarsal may have impacted the ability to control the sagittal position of the first ray.

The current study also demonstrated significant improvements over baseline in patient-reported outcomes (PROs), including pain on VAS and all MOxFQ domains through 12- and 24- months follow-up. This improvement in PROs is consistent with the improvements observed in the prospective, multicenter study of the open instrumented 1st TMT arthrodesis approach.[12] Further, the patients in the current study, with a median mini-open incision length of 3.5cm, also provided a favorable assessment of the cosmetic appearance of their scar utilizing the POSAS scale. Taken together, these findings indicate that positive PROs and scar cosmetic assessment can be reliably achieved with a smaller 3.5cm incision using the instrumented 1st TMT arthrodesis mini-open approach.

We recognize several limitations in this study. This is a single arm study without a control or comparison group. Radiographic measurements have known amounts of error in both radiographic technique and assessment of measurements. We attempted to control these radiographic variables by providing standardized image acquisition training and technique manuals to each site, as well as using an independent musculoskeletal radiologist to perform the measurements. Further, hallux valgus deformities were selected based on specific inclusion and exclusion criteria to try to help control the impact of confounding variables on the study results.

## Conclusion

In conclusion, this prospective, multicenter study of an instrumented system for 1st TMT correction of HV deformities through a mini-open incision demonstrated statistically significant and favorable improvements in radiographic correction, low deformity recurrence, early return to activity with low complication rates, and improvements in patient-reported outcomes.

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