The Journal of Foot & Ankle Surgery 000 (2022) 1–9

Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org

Original Research

One- and Two-Year Analysis of a Five-Year Prospective Multicenter Study Assessing Radiographic and Patient-Reported Outcomes Following Triplanar First Tarsometatarsal Arthrodesis With Early Weightbearing for Symptomatic Hallux Valgus

George T. Liu, DPM, FACFAS[1], Avneesh Chhabra, MD, MBA[2], Mindi J. Dayton, DPM, MHA, FACFAS[3], Paul D. Dayton, DPM, MS, FACFAS[3], William J. Duke, DPM, FACFAS[4], Daniel C. Farber, MD[5], Daniel J. Hatch, DPM, FACFAS[6], Deidre A. Kile, MS[7], Jennifer Koay, MD[8], Jody P. McAleer, DPM, FACFAS[4], Abdi Raissi, MD[9], Katherine M. Raspovic, DPM, FACFAS[1], Robert D. Santrock, MD[10], Robert P. Taylor, DPM, FACFAS[11], Michael D. VanPelt, DPM, FACFAS[1], Dane K. Wukich, MD[12]

[1] *Associate Professor, Department of Orthopaedic Surgery, University of Texas Southwestern Medical Center, Dallas, TX*
[2] *Professor of Radiology & Orthopedic Surgery, Chief of Musculoskeletal Radiology, Department of Radiology, University of Texas Southwestern Medical Center, Dallas, TX*
[3] *Foot and Ankle Center of Iowa/Midwest Bunion Center, Ankeny, IA*
[4] *Jefferson City Medical Group, Jefferson City, MO*
[5] *Associate Professor of Orthopaedic Surgery, Vice Chair for Education, University of Pennsylvania Medicine, Perelman School of Medicine, Philadelphia, PA*
[6] *Foot and Ankle Center of the Rockies, Greeley, CO*
[7] *Biostatistician, Evergreen, CO*
[8] *Associate Professor of Radiology, West Virginia University, School of Medicine, Morgantown, WV*
[9] *Desert Orthopaedic Center, Las Vegas, NV*
[10] *Orthopedic Foot & Ankle Center, Worthington, OH*
[11] *Stonebriar Foot & Ankle, Frisco, TX*
[12] *Professor, Department of Orthopaedic Surgery, University of Texas Southwestern Medical Center, Dallas, TX*

ARTICLE INFO

Level of Clinical Evidence: 4

Keywords:
bunionectomy
early weightbearing
lapidus bunionectomy
triplanar first tarsometatarsal arthrodesis

ABSTRACT

We report one- and 2-year results of a prospective, 5-year, multicenter study of radiographic, clinical, and patient-reported outcomes following triplanar first tarsometatarsal arthrodesis with early weightbearing. One-hundred and seventeen patients were included with a mean (95% confidence interval [CI]) follow-up time of 16.6 (15.5, 17.7) months. Mean (95% CI) time to weightbearing in a boot walker was 7.8 (6.6, 9.1) days, mean time to return to athletic shoes was 45.0 (43.5, 46.6) days, and mean time to return to unrestricted activity was 121.0 (114.5, 127.5) days. There was a significant improvement in radiographic measures with a mean corrective change of -18.0° (-19.6, -16.4) for hallux valgus angle, -8.3° (-8.9, -7.8) for intermetatarsal angle and -2.9 (-3.2, -2.7) for tibial sesamoid position at 12 months (n = 108). Additionally, there was a significant improvement in patient-reported outcomes (Visual Analog Scale, Manchester-Oxford Foot Questionnaire, and Patient-Reported Outcomes Measurement Information System) and changes were maintained at 12 and 24 months postoperatively. There was 1/117 (0.9%) reported recurrence of hallux valgus at 12 months. There were 16/117 (13.7%) subjects who experienced clinical complications of which 10/117 (8.5%) were related to hardware. Of the 7/117 (6.0%) who underwent reoperation, only 1/117 (0.9%) underwent surgery for a non-union. The results of the interim report of this prospective, multicenter study demonstrate favorable clinical

Financial Disclosure: G.T. Liu is a consultant for Orthofix and Gramercy Extremity Orthopedics. A. Chhabra is a consultant for Image Biopsy Labs and Icon Medical. K.M. Raspovic is a consultant for Orthofix. D.K. Wukich is a consultant for Orthofix and Wright Medical Technology and receives royalties from Arthrex.

Conflict of Interest: A. Chhabra, W.J. Duke, D.C. Farber, D.J. Hatch, J.P. McAleer, M.J. Dayton, P.D. Dayton, A. Raissi, R.D. Santrock, R.P. Taylor and J. Koay are consultants for Treace Medical Concepts, Inc. W.J. Duke, D.J. Hatch, J.P. McAleer, M.J. Dayton, P.D. Dayton and R.D. Santrock have open market stock ownership of Treace Medical Concepts, Inc. P.D. Dayton, D.J. Hatch, J.P. McAleer and R.D. Santrock receive royalties for intellectual property from the Treace Medical Concepts, Inc.

Address correspondence to: George T. Liu, DPM, FACFAS, Department of Orthopaedic Surgery, University of Texas Southwestern Medical Center, 1801 Inwood Road, Dallas, TX 75390
E-mail address: George.liu@utsouthwestern.edu (G.T. Liu).

https://doi.org/10.1053/j.jfas.2022.04.008

and radiographic improvement of the HV deformity, early return to weightbearing, low recurrence, and low rate of complications.

Hallux valgus (HV) is one of the most prevalent musculoskeletal deformities of the foot affecting approximately 23% of adults aged 18-65 years and 35.7% over 65 years (1). The deformity has been associated with functional impairment related to pain, gait abnormalities, and problems with balance (2-6). Additionally, HV deformities have also been shown to negatively impact the physical and social domains of a patients' health-related quality of life (7). Operative correction has been shown to be more effective than conservative measures in the treatment of symptomatic HV deformities (8,9).

Traditional evaluation of HV involves radiographic measures using the intermetatarsal angle (IMA), hallux valgus angle (HVA), distal metatarsal articular angle and tibial sesamoid position (TSP) interpretating HV as a 2-dimensional (2D) deformity. However, HV has been shown to be multiplanar deformity characterized by metatarsus primus varus, hallux valgus and pronation of both the first metatarsal and hallux in the frontal plane (10-13). A 3-dimensional (3D) computed tomography (CT) study of HV patients reported that approximately 87% of HV deformities involve pronation of the metatarsal in the frontal plane (14). The sesamoid position has been shown to be a radiographic indicator of frontal plane position of both the hallux and first metatarsal. One study identified that sesamoid rotation angle on short-axis magnetic resonance imaging (MRI) was a more reproducible measure for detecting axial rotation of sesamoid or pronated first metatarsal compared to the traditional radiographic parameters of lateral sesamoid displacement or TSP (15). In a cadaveric study, the TSP is shown to be influenced by the frontal plane position of the hallux through its connection of the sesamoid phalangeal ligament (16). Additionally, frontal plane position of the first metatarsal was also found to influence the position of the tibial sesamoid. Supinatory rotational correction of the first metatarsal in patients with HV was associated with reduction of the tibial sesamoid and lateral round sign of the first metatarsal head (17,18). Accordingly, incomplete correction of the frontal plane component of HV deformities evidenced by incomplete sesamoid reduction and residual first metatarsal lateral round sign have been associated with increased risk for HV recurrence (12,19,20).

The Lapidus procedure has been indicated for severe HV deformities and HV recurrence due to the ability to stabilize and correct the deformity at the first tarsometatarsal (TMT) joint (21-24). Because the first TMT joint contributes to the most motion and sustains a high level of stress in the first ray during the gait cycle, unprotected full weightbearing after first TMT joint arthrodesis is generally not recommended until 6 weeks (25-28). Achieving successful fusion rates with early weightbearing using various first TMT fixation techniques has therefore been the subject of several studies (29-34).

A novel method of instrument-assisted HV correction was developed to achieve reproducible triplanar correction for first TMT arthrodesis with biplanar plating fixation (35,36). Preliminary retrospective reports have demonstrated satisfactory radiographic correction of the triplanar deformity, early return to weightbearing, and low complication rates (37,38). The purpose of this study is to report the interim findings of a prospective, multicenter clinical trial on radiographic, clinical, and patient-reported outcomes after triplanar first TMT arthrodesis using biplanar plating system with early return to weightbearing in patients with symptomatic HV deformities.

Patients and Methods

This is a prospective, multicenter, 5-year clinical trial involving 7 US-based sites (2 academic centers and 5 subspecialty practices) with 13 foot and ankle surgeons who considered experienced users with at least 1 year of experience with the instrument-assisted triplanar first TMT arthrodesis system. From November 20, 2018 to April 30, 2021, a consecutive cohort of patients enrolled in this study underwent first TMT joint realignment multiplanar arthrodesis for symptomatic HV deformity. Institutional review board approval was obtained for each study site. An electronic data capture system was utilized by study site personnel to transfer study data from source records onto common electronic case report forms in a validated system. The validated system platform is a web-based secure electronic software application compliant with Good Clinical Practices data protection/data privacy and electronic record regulatory requirements. The data that is entered into the validated system is de-identified and only a unique subject number is used to identify a subject in the database. No data were transferred between institutions participating on this study. Inclusion criteria were symptomatic HV in patients between 14 and 58 years of age, intermetatarsal angles between 10.0° and 22.0°, and hallux valgus angles between 16.0° and 40.0°. Exclusion criteria consisted of prior HV surgery, body mass index (BMI) > 40 kg/m^2, diabetes with HbA1c ≥ 7%, evidence of peripheral neuropathy (current clinical diagnosis of peripheral neuropathy or ≤8 of 10 points with a 5.07 Semmes-Weinstein Monofilament exam), metatarsus adductus ≥ 23°, moderate to severe osteoarthritis of the first metatarsophalangeal (MTP) joint complex evidenced by radiographic signs of joint space narrowing, peripheral osteophytosis, subchondral cyst formation and absence of intersesamoid ridge (crista) or clinically positive grind test, and current use of nicotine products.

Surgical Technique and Postoperative Protocol

The detailed surgical technique has been previously published (36). A dorsal incision was placed just medial to the extensor hallucis longus tendon to access the first TMT joint. Release of the lateral capsule and suspensory ligaments of the first MTP joint is performed. After mobilizing the first TMT joint, a fulcrum device was placed into the proximal first and second metatarsal interspace and a positioner device was applied to achieve deformity correction in all 3 anatomic planes (frontal, transverse, sagittal). Fluoroscopy confirmed correction of the HV deformity and placement of the positioner device. A cutting guide was applied to the first TMT joint, and the position was verified with fluoroscopy as shown in Fig. 1. Osteotomies were performed with cut guides for en bloc resection of the articular surface of the first metatarsal base and medial cuneiform. The joint surfaces were then fenestrated with a drill bit and a compressor instrument was used to appose the joint surfaces. All patients had a biplanar plating construct consisting of 2 low-profile 4-hole titanium plates applied to the dorsal and medial aspects of the first TMT joint. The surgeon had the option of supplementing the biplanar plating construct with an additional interfragmentary screw across the first TMT joint and an intercuneiform screw from the medial to intermediate cuneiform if intercuneiform instability was concurrently identified. Patients were bandaged and placed in a splint, cast, or boot walker on the day of surgery. At the first postoperative visit (within 3 weeks of the procedure), patients were instructed to begin weightbearing as tolerated in a boot walker. Patients were allowed to transition from the boot to an athletic shoe at 6 weeks and allowed to return to full activity at 4 months, postoperatively. Representative preoperative and postoperative radiographs are shown in Fig. 2.

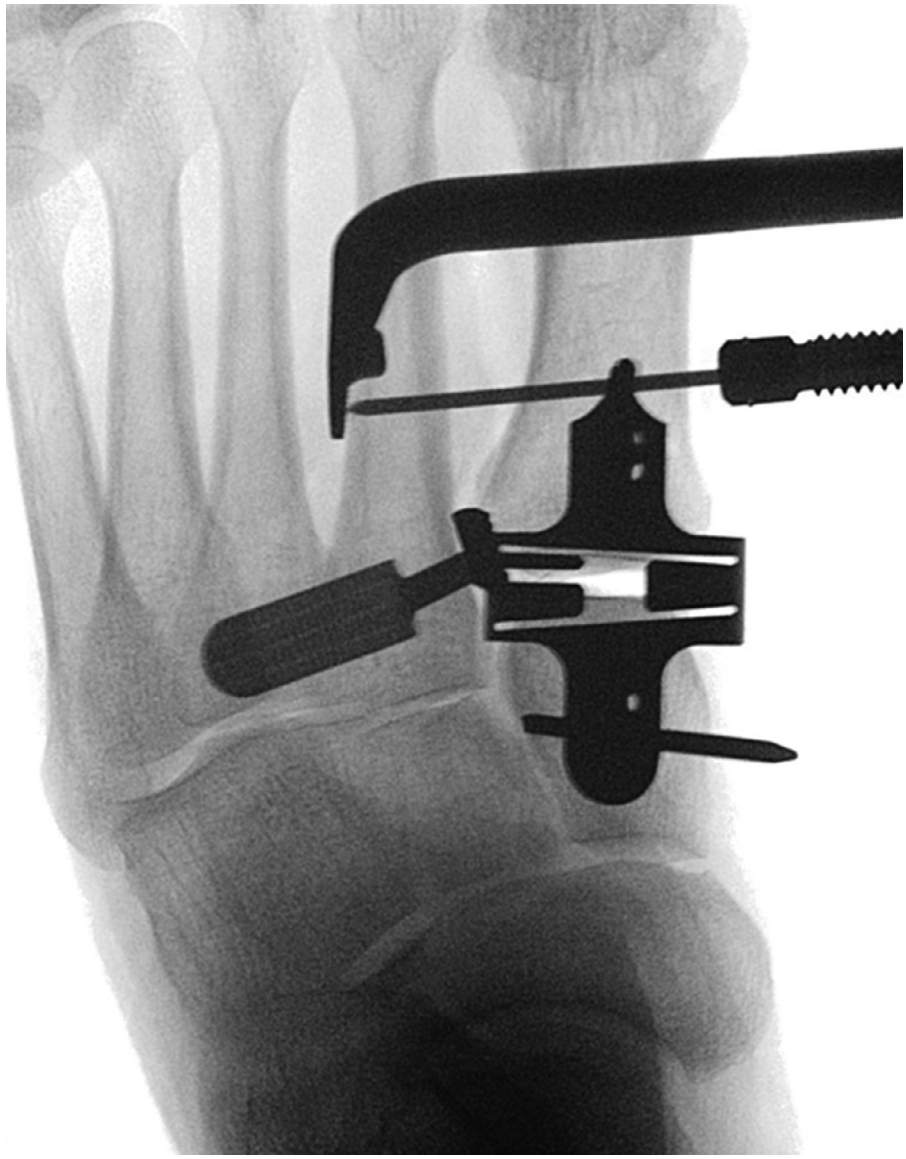

Fig. 1. Fluoroscopic imaging demonstrating use of the positioner and cut guide.

Radiographic and Clinical Outcomes

Radiographic imaging was obtained preoperatively and at 6 weeks, 6 months, 12 months, and 24 months postoperatively. Imaging included weightbearing anterior-posterior (AP), lateral, and sesamoid axial radiographs in a standardized manner with individual site-technologist training. Two independent fellowship trained experienced musculoskeletal radiologists (A.C. and J.K.) reviewed the blinded radiographic data and performed all measurements using a picture archiving and communication system (AGMednet Judi//Imaging, version 7.10). The readers participated in a one-time training session on measurements on 20 cases. All measurements were performed blinded to the clinical data or other reader's measurements, and the measurements from the 2 radiologists were averaged. The IMA was defined as the angle between the longitudinal axis of the first and second metatarsals in AP radiographs. The HVA was defined as the angle between the longitudinal axis of the first metatarsal and proximal phalanx in AP radiographs. Tibial sesamoid position was graded from 1 to 7 and defined as the position of the medial sesamoid in relation to the longitudinal axis of the first metatarsal in AP radiographs (39). Sagittal plane intermetatarsal angle was defined as the angle between the longitudinal axis of the first and second metatarsals in lateral radiographs with first metatarsal dorsiflexion defined as a positive value (40). Successful correction was defined as 2 of the following 3 criteria being met 6 weeks postoperatively: IMA $< 9.0°$, HVA $< 15.0°$, and TSP as ≤ 3. Radiographic recurrence was considered to have occurred in those patients with correction if 2 of the following 3 criteria were met at least 12 months postprocedure: IMA of $\geq 12°$, HVA $\geq 20°$, and TSP ≥ 4.

Patient-reported outcomes for the operative foot were measured by visual analog scale (VAS) (41), Manchester-Oxford Foot Questionnaire (MOxFQ) (42), and Patient-Reported Outcomes Measurement Information System (PROMIS-29) (43) before the procedure and at scheduled intervals during recovery. Visual analog scale was reported based on pain associated with the base of the hallux (bunion-related) preoperatively and at zero to 3 weeks, 6 weeks, 4 months, 6 months, 12, and 24 months postoperatively. Quality of life via MOxFQ and PROMIS-29 was

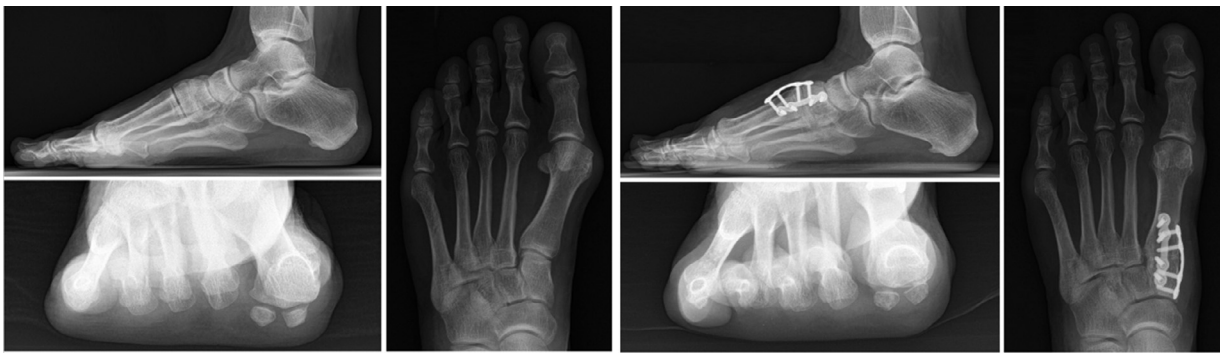

Fig. 2. Preoperative (left) and postoperative (right) radiographs illustrating the IMA correction, sagittal plane alignment and the sesamoid alignment.

Table 1
Patient demographic information

Baseline Characteristic	Category	Value
Age (years), mean (95% CI)		40.6 (38.5, 42.7)
Sex, n (%)	Male	12 (10.3%)
	Female	105 (89.7%)
BMI, mean (95% CI)		26.1 (25.2, 26.9)
Foot, n (%)	Left	56 (47.9%)
	Right	61 (52.1%)
Diabetes, n (%)	Yes	1 (0.9%)
	No	116 (99.1%)
Labor class, n (%)	Sedentary	22 (18.8%)
	Light work	41 (35.0%)
	Medium work	44 (37.6%)
	Heavy work	8 (6.8%)
	Very heavy work	2 (1.7%)

Abbreviations: CI, confidence interval; BMI, body mass index.

Table 2
Additional procedures performed with triplanar first tarsometatarsal correction

Additional Procedures	Number (%)
Lateral release (modified McBride)	113/117 (96.6%)
Stabilization screw(s) medial to intermediate cuneiform	24/117 (20.5%)
Akin osteotomy	18/117 (15.4%)
Tailors bunion	9/117 (7.7%)
Hammertoe (any)	9/117 (7.7%)
Bone graft harvest	9/117 (7.7%)
Gastrocnemius recession	7/117 (6.0%)
Compression screw at TMT	4/117 (3.4%)
Weil osteotomy	2/117 (1.7%)

Abbreviation: TMT, tarsometatarsal.

Table 3
Postoperative time to return to activity and work

Activity	n	Days, Mean (95% CI)
Weightbearing in CAM boot	117	7.8 (6.6, 9.1)
Return to athletic/running shoes	117	45.0 (43.5, 46.6)
Return to unrestricted activity	116	121.0 (114.5, 127.5)
Return to work	117	25.2 (19.3, 31.1)
Return to full work	114	54.2 (45.8, 62.5)

Abbreviations: CI, confidence interval; CAM, controlled ankle motion.

collected preoperatively, and at 6 months, 12 months, and 24 months postoperatively. Additional endpoints included pre- and postoperative transfer pain (pain beneath second or third MTP joint) as well as clinical complications defined as infection (pain, swelling, redness worse than the anticipated postoperative course requiring treatment intervention), wound dehiscence (surgical incision failing to heal during the anticipated postoperative course requiring treatment intervention), pain at implant site, neurovascular insults, implant complications, and nonunion (clinical pain at fusion site and at least one of the following: lucency at first TMT joint, hardware failure and/or loss of correction). Additionally, data were collected with respect to time (days) to return to work (or normal household activities if nonworking) and time to return to full work, while noting work classification (sedentary, light work, medium work, heavy work, very heavy work).

These interim results were limited to patients completing at least 12 months of follow-up. All statistical analyses were performed using SAS software, version 9.4 (SAS Institute Inc., Cary, NC). Continuous variables were summarized using means and 95% confidence intervals (CIs). Categorical variables were summarized using frequencies and percentages. Inferential statistics were performed on changes from baseline using a paired t-test. Confidence intervals which did not contain zero were regarded as significant at the 0.05 level.

Results

A total of 183 patients were enrolled in the clinical trial. Ten patients were identified as screening failures, ineligible for the study and dropped from the study protocol. A final 173 eligible patients underwent first TMT joint realignment multiplanar arthrodesis for symptomatic HV deformity. At time of data cut-off for the interim analysis, there were 117 patients with at least 12 months of follow-up of which 40 patients had at least 24 months of follow-up. Mean time of follow-up was 16.6 (range 11.2-29.0) months. At the time of the analysis, 9 patients dropped out of the trial (3 moved out of state, 6 were lost to follow-up during the COVID-19 pandemic). Patient demographic information is summarized in Table 1. Adjunctive procedures that were concurrently performed are shown in Table 2. Patients underwent early return to weightbearing, with a mean number of days postprocedure to boot walker, to athletic shoes, and to unrestricted activity of 7.8 (95% CI: 6.6, 9.1), 45.0 (95% CI: 43.5, 46.6), and 121.0 (95% CI: 114.5, 127.5), respectively, shown in Table 3. The patients returned to work within an average of 25.2 (95% CI: 19.3, 31.1) days and to full work within an average of 54.2 (95% CI: 45.8, 62.5) days.

Radiographic measurements were taken at baseline, 6 weeks, 6 months, 12 months, and 24 months shown in Table 4 and Fig. 3. A statistically significant improvement from baseline in radiographic measures was observed at 6 weeks postprocedure, as evidenced by confidence intervals that do not contain zero, and statistically significant improvements were maintained at 24 months as shown in Table 5. Of the 115 patients with 6-week radiographic data, 114 (99.1%) met the definition of correction. Of those corrected, 1 patient (0.9%) exhibited recurrence at 12 months. A statistically significant improvement from

Table 4
Radiographic measures at times: baseline, 6 week, 6 month, 12 months, 24 months, mean (95% CI)

Radiographic Measure	Baseline (n = 117)	6 Weeks (n = 115)	6 Months (n = 114)	12 Months (n = 108)	24 Months (n = 38)
Hallux valgus angle (HVA)	25.2° (24.0, 26.5)	8.6° (7.7, 9.5)	6.8° (5.7, 7.9)	7.1° (6.0, 8.3)	7.2° (5.2, 9.1)
Intermetatarsal angle (IMA)	13.1° (12.6,13.7)	4.0° (3.6, 4.4)	4.7° (4.3, 5.1)	4.8° (4.3, 5.2)	5.0° (4.1, 5.9)
Tibial sesamoid position (TSP)	5.2 (5.0, 5.4)	1.6 (1.4, 1.7)	2.0 (1.8, 2.2)	2.3 (2.0, 2.5)	2.1 (1.7, 2.4)
Sagittal plane intermetatarsal angle*	1.4° (1.1, 1.8)	0.6° (-0.0, 1.2)	0.3° (-0.2, 0.8)	-0.1° (-0.7, 0.4)	1.4° (-0.5, 3.3)

Abbreviation: CI, confidence interval.
* Dorsiflexion is a positive value.

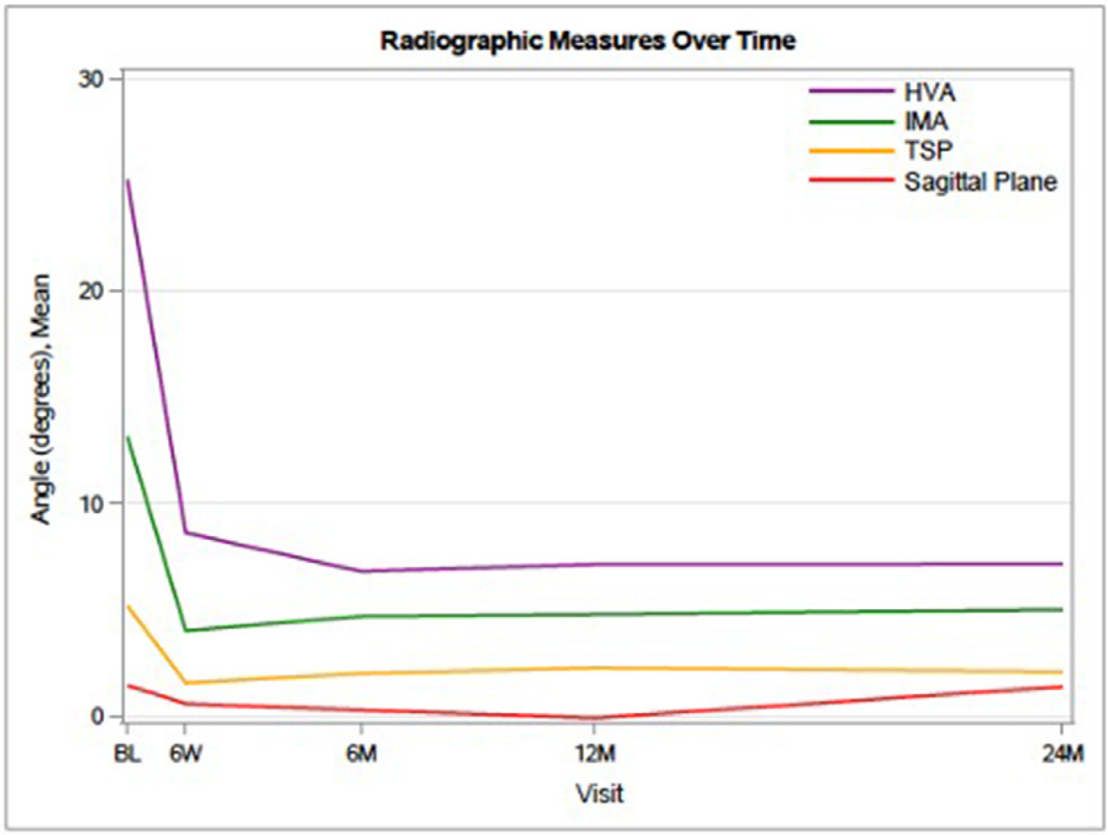

Fig. 3. Graph demonstrates decrease of radiographic measure from baseline to 6 weeks and maintained at 12 and 24 months.

baseline in patient-reported outcomes is shown in Table 6 and Fig. 4. A statistically significant improvement in all PROMIS domains was also observed at 6 and 24 months postprocedure, and all but one PROMIS domain demonstrated a statistically significant improvement over baseline at 12 months as shown in Table 7. Radiographic measures and patient-reported outcomes collected after the 6-month follow-up demonstrated continued improvement up to 24 months. Of the 89 patients without transfer pain at baseline, 2 (2.2%) reported transfer pain postprocedure. Of the 17 patients with baseline transfer pain, fifteen (88.2%) reported no transfer pain postprocedure. There were 16 (13.7%) patients who experienced clinical complications with 6 (5.1%) undergoing reoperation for removal of hardware (4 (66.7%) due to

Table 5
Change from baseline in radiographic measures, mean (95% CI)

Radiographic Measure	6 Weeks (n = 115)	6 Months (n = 114)	12 Months (n = 108)	24 Months (n = 38)
Hallux valgus angle (HVA)	−16.7° (−18.2, −15.2)	−18.4° (−20.0, −16.9)	−18.0° (−19.6, −16.4)	−18.9° (−21.6, −16.2)
Intermetatarsal angle (IMA)	−9.1° (−9.7, −8.6)	−8.5° (−9.0, −7.9)	−8.3° (−8.9, −7.8)	−8.5° (−9.4, −7.6)
Tibial sesamoid position (TSP)	−3.6 (−3.9, −3.4)	−3.2 (−3.4, −3.0)	−2.9 (−3.2, −2.7)	−3.0 (−3.4, −2.6)
Sagittal plane intermetatarsal angle*	−0.9° (−1.5, −0.3)	−1.2° (−1.7, −0.7)	−1.6° (−2.2, −1.0)	−0.4° (−2.3, 1.5)

Abbreviation: CI, confidence interval.
* Dorsiflexion is a positive value.

Table 6
Patient-reported outcomes, mean (95% CI)

Measure	Baseline	6 Months	12 Months	24 Months	Change From Baseline		
					6 Months	12 Months	24 Months
VAS pain score	n = 117	n = 114	n = 112	n = 40	n = 114	n = 112	n = 40
	4.7 (4.4, 5.0)	1.3 (1.0, 1.6)	1.0 (0.8, 1.2)	0.8 (0.6, 1.1)	−3.4 (−3.8, −3.0)	−3.7 (−4.1, −3.3)	−4.6 (−5.3, −3.9)
MOxFQ walking/standing	n = 116	n = 114	n = 113	n = 40	n = 113	n = 112	n = 40
	46.8 (42.6, 51.1)	17.8 (13.8, 21.8)	11.6 (8.4, 14.8)	6.0 (3.3, 8.6)	−29.7 (−35.0, −24.4)	−35.6 (−40.4, −30.7)	−45.8 (−52.6, −39.0)
MOxFQ pain	n = 117	n = 114	n = 113	n = 40	n = 114	n = 113	n = 40
	56.2(52.3, 60.0)	22.8 (19.3, 26.4)	19.2 (15.5, 23.0)	11.6 (8.0, 15.3)	−33.4 (−37.5, −29.3)	−36.5 (−40.8, −32.1)	−49.5 (−56.4, −42.6)
MOxFQ social interaction	n = 117	n = 114	n = 113	n = 40	n = 114	n = 113	n = 40
	45.3 (41.1, 49.5)	13.2 (9.5, 16.9)	8.7 (5.6, 11.8)	5.8 (2.3, 9.2)	−32.2 (−36.9, −27.5)	−35.8 (−40.3, −31.3)	−47.3 (−53.4, −41.3)

Abbreviations: CI, confidence interval; VAS, visual analog scale; MOxFQ, Manchester-Oxford Foot Questionnaire.

pain; 2 (33.3%) per patient request), 4 (3.4%) cases of hardware breakage that did not necessitate hardware removal, and 1 (0.9%) patient who exhibited nonunion requiring reoperation seen in Table 8.

Discussion

This interim analysis of a prospective, 5-year, multicenter study assessing radiographic and patient-reported outcomes of instrument-guided triplanar HV correction with first TMT realignment arthrodesis demonstrates favorable clinical results with anatomic correction and early return to weightbearing. Statistically significant improvements in radiographic measurements over baseline were observed at 6 weeks and maintained at 12 and 24 months. One (0.9%) patient experienced recurrence at 12 months. Shibuya et al (44) reported the importance of TSP on recurrence rate of 50% with a postoperative TSP >4 on the 7-point scale in their series of 151 patients undergoing HV correction. Okuda et al (12) reported that incomplete reduction of HV deformities with residual HVA of 15°, IMA of 8°, and TSP ≥ 5 at a mean follow-up of 3.1 months had 10-fold increased odds for HV recurrence. In this study, we report a mean (95% CI) of 8.6° (7.7, 9.5) for HVA, 4.0° (3.6, 4.4) for IMA, and 1.6 (1.4, 1.7) for TSP at the 6-week follow-up visit.

Full weightbearing without protective devices is often not recommended until 6 weeks for first TMT joint fusions (25-28). Early return to weightbearing may be beneficial to patients by reducing their dependence on ancillary non-weightbearing devices and injuries associated with their use (45). We used a biplanar plating construct with 2 low-profile 4-hole titanium plates in all cases of first TMT arthrodesis. The mean time to weightbearing in a short leg boot walker was 7.8 days.

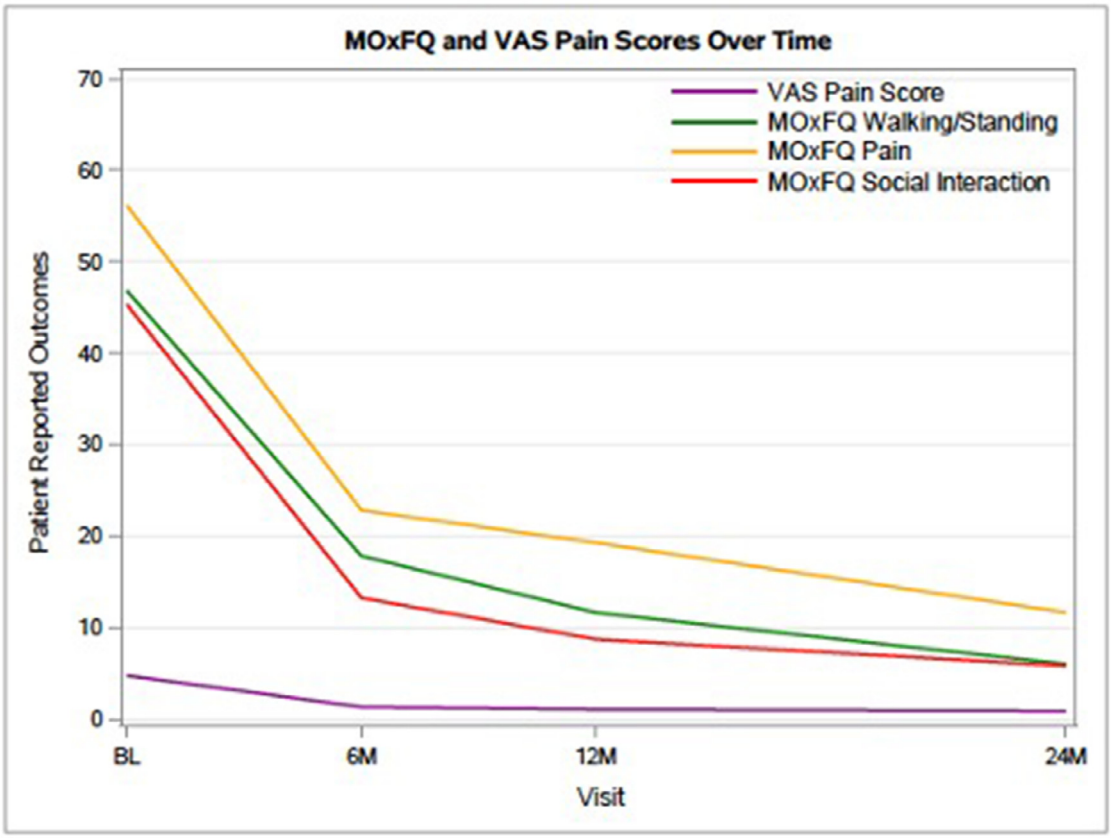

Fig. 4. Graph demonstrates improvement of measure from baseline to 6 weeks and maintained at 12 and 24 months.

Table 7
. PROMIS-29, mean (95% CI)

Measure (PROMIS Domain)	Baseline (n = 110)	6 Months (n = 109)	12 Months (n = 108)	24 Months (n = 40)	Change From Baseline		
					6 Months (n = 107)	12 Months (n = 106)	24 Months (n = 40)
Physical function	45.5 (43.9, 47.0)	51.6 (50.2, 53.0)	54.0 (52.9, 55.1)	55.9 (55.0, 56.8)	6.1 (4.1, 8.0)	8.4 (6.5, 10.2)	11.2 (8.6, 13.8)
Anxiety	47.1 (45.5, 48.6)	43.7 (42.5, 44.9)	42.9 (41.8, 44.0)	43.8 (41.9, 45.7)	−3.4 (−5.0, −1.8)	−3.9 (−5.3, −2.5)	−3.2 (−5.2, −1.1)
Depression	43.5 (42.5, 44.6)	42.6 (41.8, 43.4)	42.2 (41.4, 43.0)	41.9 (40.6, 43.1)	−1.2 (−2.3, 0.0)	−1.3 (−2.5, −0.1)	−2.4 (−4.1, −0.6)
Ability to participate in social roles/activities	53.3 (51.6, 54.9)	60.0 (58.6, 61.4)	60.6 (59.3, 62.0)	62.2 (60.6, 63.7)	6.8 (5.0, 8.7)	7.0 (5.1, 8.9)	10.4 (7.7, 13.1)
Fatigue	45.5 (43.7, 47.2)	40.9 (39.4, 42.4)	40.4 (39.1, 41.8)	41.3 (38.9, 43.7)	−4.8 (−6.6, −3.0)	−4.5 (−6.3, −2.8)	−6.2 (−9.0, −3.4)
Pain interference	56.0 (54.6, 57.4)	47.1 (45.7, 48.5)	45.2 (44.0, 46.4)	43.2 (42.1, 44.4)	−8.8 (−10.6, −7.0)	−10.6 (−12.3, −8.9)	−13.4 (−16.1, −10.7)
Sleep disturbance	47.7 (46.3, 49.1)	44.5 (43.1, 46.0)	44.6 (43.2, 46.0)	43.2 (40.8, 45.6)	−3.2 (−4.8, −1.7)	−3.1 (−4.8, −1.4)	−4.1 (−6.8, −1.4)
Pain intensity	4.5 (4.1, 4.9)	1.3 (1.0, 1.6)	1.0 (0.7, 1.3)	0.6 (0.3, 0.9)	−3.3 (−3.7, −2.8)	−3.5 (−3.9, −3.1)	−4.3 (−5.0, −3.6)

Abbreviations: PROMIS-29, Patient-Reported Outcomes Measurement Information System, profile form 29, version 2.1; CI, confidence interval.

Table 8
Clinical complications at any time up to 24 months postprocedure

Complication	Number (%)
Broken hardware (hardware not removed)*	4/117 (3.4%)
Hardware removal (per patient request)†	2/117 (1.7%)
Hardware removal (due to pain)†	4/117 (3.4%)
Nonunion†	1/117 (0.9%)
Wound complication	1/117 (0.9%)
Postoperative nerve hypersensitivity	1/117 (0.9%)
Pain	2/117 (1.7%)
Parathesias	1/117 (0.9%)

* Did not require reoperation. Patients are considered healed per protocol definition. Hardware status by patient: 1 broken screw; 1 broken dorsal plate and 2 broken screws; 1 broken medial plate and 2 broken screws; broken medial plate.

† Required reoperation.

Mean time to return to shoes and unrestricted activity was 45.0 and 121.0 days, respectively. We reported a nonunion rate of less than 1% in this interim analysis. Previous studies evaluating early weightbearing within 2 weeks following Lapidus procedure reported nonunion rates ranging between 8.0% and 9.5% (27,28).

Patient-reported outcomes have been used as a functional measure of physical and mental function after musculoskeletal surgery and have been used to measure health-related quality of life improvement after HV surgery. Patients demonstrated decrease in pain with VAS and improvements in the MOxFQ domains of Walking/Standing, Pain, and Social Interaction. PROMIS uses computer-adaptive technology to collect data in domains of physical function, pain, and depression and has shown reliability and responsiveness with reporting outcomes in foot and ankle surgery (46). There are few reports on PROMIS with treatment outcomes of HV (47,48). The interim results presented in this study indicate favorable patient response with triplanar correction at 6, 12, and 24 months with statistically significant reduction of pain and depression, and improvement of function.

Frontal plane component of HV deformity was discussed by Okuda et al (49) demonstrating that the rounded morphology of the first metatarsal head was a sign of pronation/eversion of the metatarsal. Dayton et al (50,51) demonstrated that the lateral position of the sesamoid apparatus in HV deformities was associated with first metatarsal pronation/eversion not solely lateral translation. Additionally, in a series of 35 patients who underwent HV correction with first TMT correction, Dayton et al (17) demonstrated that supinatory correction of the first metatarsal was associated with reduction of the TSP. Previous retrospective studies utilizing triplanar correction methods treating HV deformities have reported favorable outcomes with radiographic reduction, low recurrence, and low nonunion rates (37,38). The findings from this prospective study are consistent with these previous reports.

There are several notable findings in this observational clinical trial. The longitudinal data demonstrates maintenance of the IMA, HV, TSP of the HV correction from the sixth week through 24 months. While this data may support the role of triplanar correction and biplanar fixation methods with this maintenance of HV correction, we recognize that this association would be better evaluated with a comparative trial design. Second, fusion rates were comparable to the first TMT healing rates of previously published reports with early weightbearing (29,33,34). Patients in this study were allowed protected weightbearing in a boot walker within a mean of 7.8 days and exhibited a nonunion rate of less than 1% with biplanar plate fixation method. Third, TSP position correction, which has been reported as risk factor for HV recurrence, was consistently corrected to a mean of 1.7 with only undergoing a release of the lateral capsule and suspensory ligaments. While this data may suggest a role for TSP and HV recurrence, analysis with further time points will be help to support this relationship. Fourth, we reported minimal elevation of the first metatarsal in our series. The mean sagittal plane position of the first metatarsal was 0.9 degrees. Maintaining sagittal position and length of the first metatarsal supports first MTP range of motion and reestablishes the anatomy of the metatarsal parabola preventing transfer metatarsalgia. Although mean shortening of the first metatarsal was not recorded in this study, Hatch et al (52) previously reported a mean 2.4 mm of shortening and -0.2 degrees change in sagittal alignment using this instrument-assisted technique. Only 1 (1.4%) patient underwent lesser metatarsal osteotomies as part of the index procedure. Clinically, 5.1% of patients reported lesser metatarsal pain postprocedure.

We recognize several limitations of this study. This is an interim report of up to 24 months postoperative follow-up on a 5-year prospective study. Participating patients were being continuously enrolled and patients will be followed for up to 60 months for radiographic measures, recurrence, healing, complications, and patient-reported outcomes. We used standard radiographic measurements which have known degrees of error in both radiographic technique and angular measures. To control these variables, training was provided to all study sites regarding image acquisition and standard method for interpretation. Interim quality surveillance audits were also performed. The measurements were performed by 2 independent fellowship-trained experienced musculoskeletal radiologists. We recognize that there is a potential selection bias of patients in our study by excluding subjects above the age of 59 years which represents more than a third of the population afflicted with HV deformity. Additionally, some of our data was collected during the time of the COVID-19 pandemic which may have affected the return to work and return to full work reporting. Additionally, this is a single-arm study without

a control or comparison group, therefore direct comparisons on time to weightbearing, fixation constructs, and complication rates related to this specific technique are based on historic results of other procedures. Last, we recognize that the financial disclosures and conflicts of interest whether actual or potential are important considerations in identifying any source of influence or bias in a clinical trial. Several of authors were involved with the design of the instrumentation and implants in consultation with bioengineers who were funded by the sponsors of this study. Other authors served as consultants during the design and implementation of the study (A.C., M.J.D., P.D.D., W.J.D, D. C.F., D.J.H., J.K., J.P.M., A.R., R.D.S., and R.P.T.). One author served as a consultant for statistical and data analytics support (D.A.K.). All study sites received predetermined financial support for research-related activities. For example, the institutions of the following authors received institutional research support for this study (A.C., G.T.L., K.M. R., M.V.P., and D.K.W.). No study investigator received any direct compensation for participation in this study. Some of the authors receive royalties for intellectual property from the sponsoring company (P.D. D., D.J.H., J.P.M., and R.D.S.). Other authors have open market stock ownership of the sponsoring company (M.J.D., P.D.D, W.J.D, D.J.H., J.P. M., and R.D.S.). Financial disclosures are publicly available on the Centers for Medicare and Medicaid Services website at https://www.cms.gov/openpayments.

In conclusion, this is the first report on an interim analysis of a 5-year prospective, multicenter, clinical trial using an instrumentation-assisted triplanar correction system for the treatment of symptomatic HV deformities. We report statistically significant improvements in radiographic correction, low recurrence of deformity, and early return to activity with low complication rates up to a 24-month postoperative review. Additionally, we report statistical improvements in patients' health-related quality of life up to a 24-month follow-up period.

References

1. Nix S, Smith M, Vicenzino B. Prevalence of hallux valgus in the general population: a systematic review and meta-analysis. J Foot Ankle Res 2010;3:21.
2. Benvenuti F, Ferrucci L, Guralnik JM, Gangemi S, Baroni A. Foot pain and disability in older persons: an epidemiologic survey. J Am Geriatr Soc 1995;43:479.
3. Hurn SE, Vicenzino BT, Smith MD. Correlates of foot pain severity in adults with hallux valgus: a cross-sectional study. J Foot Ankle Res 2014;7:32.
4. Koski K, Luukinen H, Laippala P, Kivela SL. Physiological factors and medications as predictors of injurious falls by elderly people: a prospective population-based study. Age Ageing 1996;25:29.
5. Nix SE, Vicenzino BT, Collins NJ, Smith MD. Gait parameters associated with hallux valgus: a systematic review. J Foot Ankle Res 2013;6:9.
6. Nix SE, Vicenzino BT, Smith MD. Foot pain and functional limitation in healthy adults with hallux valgus: a cross-sectional study. BMC Musculoskelet Disord 2012;13:197.
7. Hernandez-Castillejo LE, Martinez Vizcaino V, Garrido-Miguel M, Cavero-Redondo I, Pozuelo-Carrascosa DP, Alvarez-Bueno C. Effectiveness of hallux valgus surgery on patient quality of life: a systematic review and meta-analysis. Acta Orthop 2020;91:450.
8. Klugarova J, Hood V, Bath-Hextall F, Klugar M, Mareckova J, Kelnarova Z. Effectiveness of surgery for adults with hallux valgus deformity: a systematic review. JBI Database Syst Rev Implement Rep 2017;15:1671.
9. Torkki M, Malmivaara A, Seitsalo S, Hoikka V, Laippala P, Paavolainen P. Surgery vs orthosis vs watchful waiting for hallux valgus: a randomized controlled trial. JAMA 2001;285:2474.
10. Dayton P, Feilmeier M. Comparison of tibial sesamoid position on anteroposterior and axial radiographs before and after triplane tarsal metatarsal joint arthrodesis. J Foot Ankle Surg 2017;56:1041.
11. Mortier JP, Bernard JL, Maestro M. Axial rotation of the first metatarsal head in a normal population and hallux valgus patients. Orthop Traumatol Surg Res 2012;98:677.
12. Okuda R, Kinoshita M, Yasuda T, Jotoku T, Kitano N, Shima H. Postoperative incomplete reduction of the sesamoids as a risk factor for recurrence of hallux valgus. J Bone Joint Surg Am 2009;91:1637.
13. Scranton PE Jr., Rutkowski R. Anatomic variations in the first ray: Part I. Anatomic aspects related to bunion surgery. Clin Orthop Relat Res: 1980;244:244–255.
14. Kim Y, Kim JS, Young KW, Naraghi R, Cho HK, Lee SY. A new measure of tibial sesamoid position in hallux valgus in relation to the coronal rotation of the first metatarsal in CT scans. Foot Ankle Int 2015;36:944.
15. Skweres J, Chhabra A, Hummel J, Heineman N, Dessouky R, Xi Y, Zhang L, Wukich D. Sesamoid malalignment in hallux valgus: radiographic and MRI measurements and their correlation with internal derangement findings of the first metatarsophalangeal joint. Br J Radiol 2019;92:20190038.
16. Dayton P, Feilmeier M, Kauwe M, Holmes C, McArdle A, Coleman N. Observed changes in radiographic measurements of the first ray after frontal and transverse plane rotation of the hallux: does the hallux drive the metatarsal in a bunion deformity? J Foot Ankle Surg 2014;53:584.
17. Dayton P, Kauwe M, DiDomenico L, Feilmeier M, Reimer R. Quantitative analysis of the degree of frontal rotation required to anatomically align the first metatarsal phalangeal joint during modified tarsal-metatarsal arthrodesis without capsular balancing. J Foot Ankle Surg 2016;55:220.
18. Okuda R, Yasuda T, Jotoku T, Shima H. Supination stress of the great toe for assessing intraoperative correction of hallux valgus. J Orthop Sci 2012;17:129.
19. Okuda R, Kinoshita M, Yasuda T, Jotoku T, Kitano N, Shima H. The shape of the lateral edge of the first metatarsal head as a risk factor for recurrence of hallux valgus. J Bone Joint Surg Am 2007;89:2163.
20. Shibuya N, Kyprios EM, Panchani PN, Martin LR, Thorud JC, Jupiter DC. Factors associated with early loss of hallux valgus correction. J Foot Ankle Surg 2018;57:236.
21. Coetzee JC, Resig SG, Kuskowski M, Saleh KJ. The Lapidus procedure as salvage after failed surgical treatment of hallux valgus: a prospective cohort study. J Bone Joint Surg Am 2003;85:60.
22. Ellington JK, Myerson MS, Coetzee JC, Stone RM. The use of the Lapidus procedure for recurrent hallux valgus. Foot Ankle Int 2011;32:674.
23. Lapidus PW. A quarter of a century of experience with the operative correction of the metatarsus varus primus in hallux valgus. Bull Hosp Joint Dis 1956;17:404.
24. Lapidus PW. The author's bunion operation from 1931 to 1959. Clin Orthop 1960;16:119.
25. Bednarz PA, Manoli A 2nd. Modified lapidus procedure for the treatment of hypermobile hallux valgus. Foot Ankle Int 2000;21:816.
26. Mauldin DM, Sanders M, Whitmer WW. Correction of hallux valgus with metatarsocuneiform stabilization. Foot Ankle 1990;11:59.
27. Myerson M, Allon S, McGarvey W. Metatarsocuneiform arthrodesis for management of hallux valgus and metatarsus primus varus. Foot Ankle 1992;13:107.
28. Sangeorzan BJ, Hansen ST Jr. Modified lapidus procedure for hallux valgus. Foot Ankle 1989;9:262.
29. Blitz NM, Lee T, Williams K, Barkan H, DiDimenico LA. Early weight bearing after modified lapidus arthodesis: a multicenter review of 80 cases. J Foot Ankle Surg 2010;49:357.
30. Clark HR, Veith RG, Hansen ST Jr. Adolescent bunions treated by the modified lapidus procedure. Bull Hosp Joint Dis Orthop Inst 1987;47:109.
31. Dayton P, Hatch DJ, Santrock RD, Smith B. Biomechanical characteristics of biplane multiplanar tension-side fixation for lapidus fusion. J Foot Ankle Surg 2018;57:766.
32. King CM, Richey J, Patel S, Collman DR. Modified lapidus arthrodesis with crossed screw fixation: early weightbearing in 136 patients. J Foot Ankle Surg 2015;54:69.
33. Prissel MA, Hyer CF, Grambart ST, Bussewitz BW, Brigido SA, DiDomenico LA, Lee MS, Reeves CL, Shane AM, Tucker DJ, Weinraub GM. A multicenter, retrospective study of early weightbearing for modified lapidus arthrodesis. J Foot Ankle Surg 2016;55:226.
34. Saxena A, Nguyen A, Nelsen E. Lapidus bunionectomy: early evaluation of crossed lag screws versus locking plate with plantar lag screw. J Foot Ankle Surg 2009;48:170.
35. Dayton P, Ferguson J, Hatch D, Santrock R, Scanlan S, Smith B. Comparison of the mechanical characteristics of a universal small biplane plating technique without compression screw and single anatomic plate with compression screw. J Foot Ankle Surg 2016;55:567.
36. Smith WB, Dayton P, Santrock RD, Hatch DJ. Understanding frontal plane correction in hallux valgus repair. Clin Podiatr Med Surg 2018;35:27.
37. Dayton P, Santrock R, Kauwe M, Gansen G, Harper S, Cifaldi A, Egdorf R, Eisenschink J. Progression of healing on serial radiographs following first ray arthrodesis in the foot using a biplanar plating technique without compression. J Foot Ankle Surg 2019;58:427.
38. Ray JJ, Koay J, Dayton PD, Hatch DJ, Smith B, Santrock RD. Multicenter early radiographic outcomes of triplanar tarsometatarsal arthrodesis with early weightbearing. Foot Ankle Int 2019;40:955.
39. Hardy RH, Clapham JC. Observations on hallux valgus; based on a controlled series. J Bone Joint Surg Br 1951;33-B:376.
40. Usuelli F, Palmucci M, Montrasio UA, Malerba F. Radiographic considerations of hallux valgus versus hallux rigidus. Foot Ankle Int 2011;32:782.
41. Hayes MHS, Patterson DG. Experimental development of the graphic rating method. Psychol Bull 1921;18:89.
42. Morley D, Jenkinson C, Doll H, Lavis G, Sharp R, Cooke P, Dawson J. The Manchester-Oxford Foot Questionnaire (MOXFQ): development and validation of a summary index score. Bone Joint Res 2013;2:66.
43. Cella D, Yount S, Rothrock N, Gershon R, Cook K, Reeve B, Ader D, Fries JF, Bruce B, Rose M, Group PC. The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH roadmap cooperative group during its first two years. Med Care 2007;45:S3.
44. Shibuya N, Jasper J, Peterson B, Sessions J, Jupiter DC. Relationships between first metatarsal and sesamoid positions and other clinically relevant parameters for hallux valgus surgery. J Foot Ankle Surg 2019;58:1095.
45. Manocha RHK, MacGillivray MK, Eshraghi M, Sawatzky BJ. Injuries associated with crutch use: a narrative review. PM R 2021;13:1176.
46. Hung M, Baumhauer JF, Latt LD, Saltzman CL, SooHoo NF, Hunt KJ, National Orthopaedic F; Ankle Outcomes Research N. Validation of PROMIS (R) physical function computerized adaptive tests for orthopaedic foot and ankle outcome research. Clin Orthop Relat Res 2013;471:3466.

47. MacDonald A, Houck J, Baumhauer JF. Role of patient-reported outcome measures on predicting outcome of bunion surgery. Foot Ankle Int 2020;41:133.
48. Nixon DC, McCormick JJ, Johnson JE, Klein SE. PROMIS pain interference and physical function scores correlate with the foot and ankle ability measure (FAAM) in patients with hallux valgus. Clin Orthop Relat Res 2017;475:2775.
49. Okuda R, Yasuda T, Jotoku T, Shima H. Proximal abduction-supination osteotomy of the first metatarsal for adolescent hallux valgus: a preliminary report. J Orthop Sci 2013;18:419.
50. Dayton P, Kauwe M, Feilmeier M. Clarification of the anatomic definition of the bunion deformity. J Foot Ankle Surg 2014;53:160.
51. Dayton P, Kauwe M, Kauwe JS, Feilmeier M, Hirschi J. Observed changes in first metatarsal and medial cuneiform positions after first metatarsophalangeal joint arthrodesis. J Foot Ankle Surg 2014;53:32.
52. Hatch DJ, Dayton P, DeCarbo W, McAleer JP, Ray JJ, Santrock R, Smith B. Analysis of shortening and elevation of the first ray with instrumented triplane first tarsometatarsal arthrodesis. Foot Ankle Ortho 2020;5:1.