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Radiographic and Patient-Reported Outcomes of a Low-Cost Modified Lapidus Bunion Correction Technique

Chinmay Shivaram Paranjape, MD[1], Jingru Zhang, MS[2], Trapper Lalli, MD[1], Feng-Chang Lin, PhD[2], and Joshua N. Tennant, MD, MPH[1]

Abstract

Background: The modified Lapidus (ML) is a powerful procedure for correction of hallux valgus (HV) with emerging techniques. Studies considering patient-reported outcomes, radiographic measures, complications, and implant costs are currently limited.

Methods: Retrospective cohort with prospectively collected Patient Reported Outcome Information System Physical Function (PROMIS-PF) Computerized Adaptive Test (CAT) scores, radiographic parameters (intermetatarsal angle, IMA; hallux valgus angle, HVA; and tibial sesamoid position, TSP), complications, and total operative time and implant costs were reviewed from 2014 to 2019.

Results: Seventy-three feet (68 patients) underwent bunion correction by ML with lag-screw fixation. Median age was 55.8 years (IQR 45.6, 53.9), 4 of 73 (5.5%) were male, 11 of 73 (15.1%) were smokers, and 15 of 73 (20.6%) were diabetic (median HbA1c 6.4% [IQR 6.0, 7.4], none insulin dependent, 5 of 15 with neuropathy). Complications included 6 of 73 (8.2%) wound issues resolved with topical or oral treatment, 9 of 73 (12.3%) painful or broken hardware requiring hardware removal. Two of 73 (2.7%) had persistent pain despite union. One of 73 (1.4%) was overcorrected and required first MTP arthrodesis. Of 3 nonunions (2.7%), 1 resolved with corrected hypothyroidism, 1 was asymptomatic and required no treatment, 1 had a hallux valgus recurrence and sought revision surgery elsewhere. Preoperative radiographic angles were HVA 35 degrees, IMA 14 degrees which improved at final postoperative follow up to HVA 10 degrees, IMA 6 degrees. Tibial sesamoid position improved from 6.05 $\pm$ 1.00 to 2.22 $\pm$ 1.38. Thirty-two patients had preoperative and 42 had 1-year postoperative outcomes. PROMIS-PF (51% collection rate) was 43 (IQR 37,52) preoperatively, 37 (31, 39) at 6 weeks, 46 (42, 51) at 3 months, and 49 (41, 53) at $>$360 days postoperatively. The drop in PROMIS-PF between preoperative and 6 weeks and the rise from 6 weeks to 3 months were statistically significant. Pre- and postoperative PROMIS-PF scores were not significantly different. Implant cost averaged US$146.

Discussion/Conclusion: We report low complication rates and costs with high patient postoperative functional and radiographic outcomes. PROMIS-PF decreased acutely postoperatively but recovered and maintained high levels by 3 months postoperatively.

Level of Evidence: Level IV, case series.

Keywords: bunion, Lapidus, cost, PROMIS CAT, physical function

Background and Significance

Many surgical procedures have been proposed for correction of hallux valgus (HV). One powerful means of deformity correction is the first tarsometatarsal (TMT) arthrodesis or the "Lapidus" procedure.[17] Although initially conceived by

[1]University of North Carolina System, Chapel Hill, NC, USA
[2]University of North Carolina, Chapel Hill, NC, USA

Corresponding Author:
Joshua N. Tennant, MD, MPH, University of North Carolina System, 3147 Bioinformatics, 130 Mason Farm Rd, Chapel Hill, NC 27514-3916, USA.
Email: josh_tennant@med.unc.edu

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Albrecht, Kleinberg, and Truslow,[12,18] it was first described by Paul Lapidus in 1934.[14] Although some controversy exists over indications for the procedure, most authors agree that the Lapidus procedure is a powerful means of correcting severe HV deformity with an increased intermetatarsal angle (IMA; ie, >14 degrees) and hallux valgus angle (HVA; ie, >30 degrees),[6] with concomitant first TMT arthritis or instability.[3]

Fixation of the first TMT arthrodesis has been achieved through multiple techniques. One simple method, and the authors' preferred method, is to use 3 or 4 screws placed by lag technique to achieve rigid interfragmentary compression. Although this method has shown good results in the literature, it requires familiarity and proficiency with the technique.[3,5,14] Previous authors have reported on patient-reported and radiographic outcomes following lag screw Lapidus[9] and have demonstrated radiographic correction of HV and IMA angles as well as full return of patient-reported physical function outcomes.[7,13] However, studies have not elucidated the time-dependent change in PROMIS, notably the physical function (PF) subdomain, in the early postoperative period. In today's era of cost-conscious health care, payers and policy makers strive to increase value by achieving good outcomes with low operative costs.

Our intent was to retrospectively study prospectively collected patient reported and radiographic outcomes of a crossed screw Lapidus technique and report implant costs of our technique for this procedure. We hypothesized HAV correction is achieved radiographically with high levels of patient physical function and low implant costs.

Methods

Study Design

Institutional review board approval was obtained prior to initiation of the study. We performed a retrospective review of prospectively collected radiographic data and patient-reported outcomes (PROMIS-PF CAT). We identified 117 patients who underwent Lapidus by crossed lag screw technique from January 2014 to December 2020. Inclusion criteria were patients aged 14-85 years old undergoing primary bunion correction surgery by modified Lapidus procedure. Although we did not exclude anyone on the basis of medical comorbidities during our retrospective review, patients were medically optimized for any comorbid conditions prior to being offered surgery. After applying inclusion and exclusion criteria, we identified 73 feet in 68 patients eligible for inclusion. Patients provided their written consent to proceed with review of their data.

Preoperative Visit, Intraoperative Technique, and Postoperative Rehabilitation

Patients were seen in clinic preoperatively. We routinely collect PROMIS-PF scores via a CAT survey. A concerted effort was made to collect these scores on each patient, although this was based on the singular efforts of the lead author and was not consistent, especially early in the study period. Preoperative weightbearing radiographs consisting of anteroposterior, lateral, oblique, and standing axial sesamoid views were obtained prior to surgery.

For surgical technique, patients were placed in the supine position on the operating table. A thigh tourniquet was applied and regional neuraxial anesthesia was used along with general anesthesia. Patients were then prepped and draped in a sterile fashion. A scalpel was used to perform a percutaneous lateral release of the first metatarsophalangeal (MTP) joint lateral joint capsule and adductor hallucis insertion to allow for a manual varus manipulation of 20 degrees. A dorsomedial longitudinal incision was then made medial to the EHL and centered over the first tarsometatarsal (TMT) joint. Dissection was carried down to the first TMT joint. A small osteotome was placed into the joint to initially release the first tarsometatarsal capsule, particularly the medial and plantar capsule. With the soft tissue released, the bone cut from the medial cuneiform was then performed. The cut was made in the coronal plane with the same orientation of the joint, which was probed prior to the cut with the oscillating saw, and this dorsal to plantar trajectory was then marked on the medial skin of the foot. Extreme care was taken with this trajectory to avoid final dorsiflexion or plantarflexion deformity of the first ray. The cuneiform wedge cut was determined by taking a conservative cut of 2 to 3 mm from the lateral side of the medial cuneiform articular surface, with the medial side of the cut with minimal resection from the articular surface, effecting a wedge removal in the axial plane, while leaving the sagittal position of the first ray unchanged. A threaded 3.2-mm Steinmann pin was placed in the first metatarsal to allow rotational correction, with a reduction clamp also placed between the first and second metatarsals. Correction was provisionally held with a 2.0-mm threaded Kirschner wire. The fusion site was then assessed for congruity in the provisionally fixed position; if gaps were visible, the space was filled either with autograft from a separate harvest of 2-3 cm^3 of calcaneal autograft. Two solid stainless steel 3.5-mm cortical screws (Stryker, Kalamazoo, MI) were placed across the first TMT in crossing fashion using a lag by technique. A third solid stainless steel 3.5-mm cortical screw was used to maintain the intermetatarsal correction and was placed from the first metatarsal through the second. If purchase of the first intermetatarsal screw was not excellent, a fourth screw was placed parallel and just distal to the third screw between the first and second metatarsals. Wounds were irrigated and skin was closed with 3-0 nylon sutures. Soft minimally compressive dressings were placed and the patient was placed in a postoperative shoe and made weightbearing as tolerated with crutch or walker assistance.

After surgery, patients were seen for 2-week, 6-week, and 3-month visits. Patients were encouraged to keep following up for a 6-month, 1-year, and 2-year follow-up, but

many elected not to. Radiographs were routinely obtained at the 6-week and 3-month visits (Figure 2). Patients were radiographically followed until the 1-year postoperative visit according to their choice of returning for this visit. We obtained weightbearing anteroposterior, oblique, and lateral views of the foot as well as a standing axial sesamoid view of the first ray. Patients do not routinely receive physical therapy. Patients were allowed to transition to regular wide toe box shoe-wear as tolerated, which typically occurs around the 6-week postoperative visit.

Analysis and Statistics

Descriptive summary statistics were obtained and reported. To analyze PROMIS-PF scores, we binned postoperative scores according to postoperative date (periods: preoperative, postoperative day 1-45, 45-90, 90-180, 180-360, and 360-1400). We then used analysis of variance (ANOVA) to test the difference between groups. A post hoc comparison was implemented using Tukey method to control an overall type I error under 5%.[19] *P* values were reported and noted to be significant when under this value. All calculations and data operations were performed using R studio (open source, Boston, MA).

For radiographic outcomes, 2 authors (J.N.T. and C.S.P.) performed measurements of HVA, IMA, and tibial sesamoid position (TSP) as described previously in the literature.[15] These were measured and reported on routine radiographs at preoperative and 1-year postoperative visits. Continuous variables such as HVA and IMA were reported for the difference between the 2 authors. The agreement in TSP as a categorical variable was reported in Cohen kappa. Both statistics were reported with a 95% CI.

Finally, costs were obtained from the manufacturer implant costs recorded in the charge capture at the time of surgery and reported as an average.

Results

Baseline Patient Demographics

Patients had a median age of 55.8 years (IQR 45.6-53.9), were 4 of 73 (5.5%) male, and 15 of 73 (20.6%) diabetic. Diabetic patients had a mean HbA_{1c} of 6.4% (IQR 6.0-7.4). Of our diabetic patients, 5 of 15 (33%) had documented neuropathy, and none were insulin dependent within 30 days of surgery or postoperatively. Current smokers comprised 11 of 73 (15.1%) of our patient population, although all were required to stop smoking for at least 1 month prior to surgery, as reported to the surgeon in the preoperative visit. These results are tabulated in Table 1.

PROMIS-PF Scores

A total of 35 patients (51% of the eligible cohort) had preoperative PROMIS-PF surveys. The preoperative PROMIS-PF score was a median of 43 (IQR 37-52). Postoperative PROMIS-PF data were available for a total of 42 patients (62% of the eligible cohort) for at least 1 time point. PROMIS-PF dropped significantly at the 6-week visit to 37 (n = 11, IQR 31-39, $P = .006$) but rose significantly by the 3-month visit (n = 23, median 46, IQR 42-51, $P = .008$). At time points greater than 1 year postoperatively, patients achieved a median PROMIS-PF of 49 (n = 42, IQR 41-53). There were no significant differences between initial preoperative scores and either the 3-month or the 1-year postoperative scores ($P > .05$ for all comparisons). These scores are represented graphically in Figure 1.

Table 1. Patient Demographics (Reported for 73 Feet in 68 Patients).

Demographic	Mean (IQR) or n/n (%)
Age, mean (IQR)	55.8 (45.6-53.9)
Male	4/73 (5.5)
Diabetes	15/73 (20.6)
Insulin dependent	0/15 (0)
HbA1c, %, mean (IQR)	6.4 (6.0-7.4)
Neuropathy	5/15 (33)
Smoker	11/73 (15.1)

Abbreviation: HbA_{1c}, glycated hemoglobin; IQR, interquartile range.

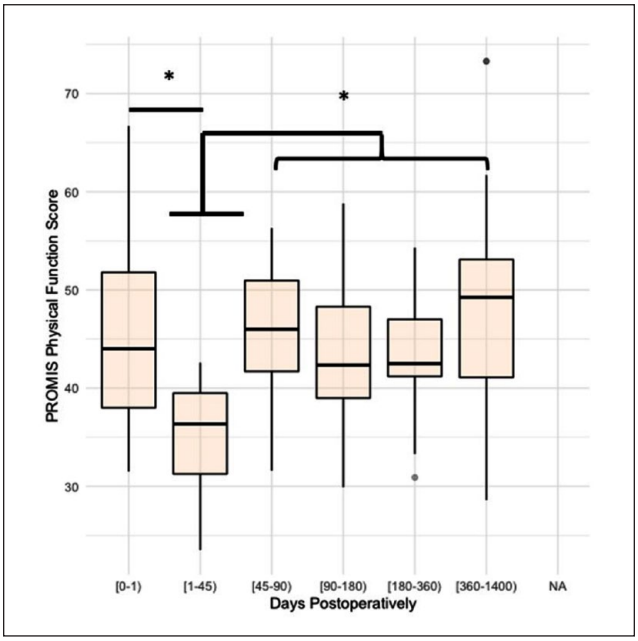

Figure 1. PROMIS-PF scores vs postoperative time in days. Preoperative scores fell in the first 45 days postoperatively ($P = .006$* for [0-1) vs [1-45)) but rose by 90 days post operatively ($P = .008$* for [1-45) vs [45-90)). These gains were maintained until final available follow-up ($P > .05$ for remaining comparisons).

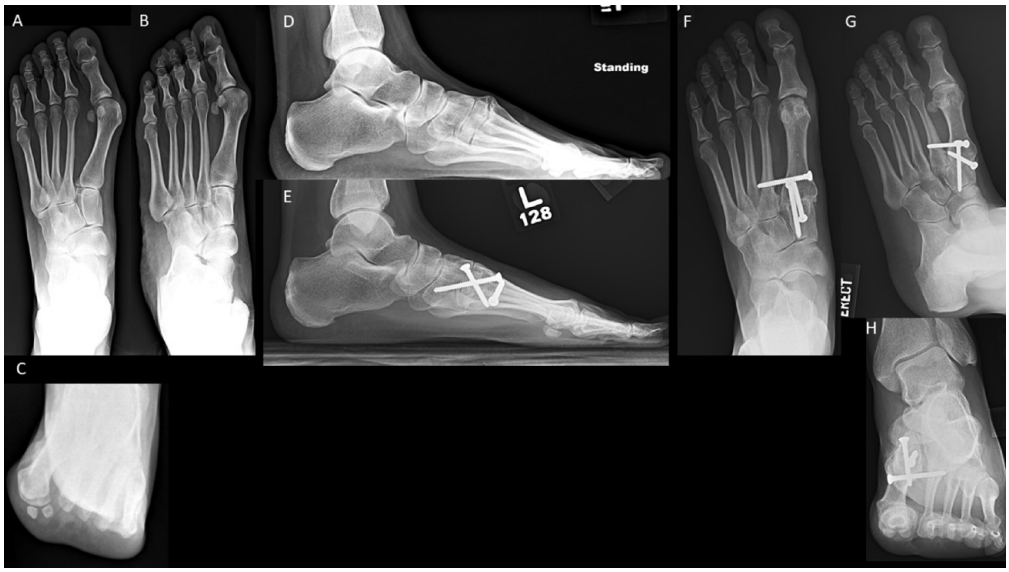

Figure 2. Representative radiographic outcome: preoperative (A) upright anteroposterior foot, (B) oblique foot, (C) sesamoid, and (D) lateral foot views shown. Final upright postoperative radiographs at 3 years and 5 months are shown as follows: (E) lateral foot, (F) anteroposterior foot, (G) oblique foot, and (H) sesamoid view are shown.

Radiographic Outcomes

Our cohort had a mode radiographic follow-up of 82 days with a median of 173 days. Preoperatively, HVA was 35 degrees (IQR 30-40 degrees), which improved to 10 degrees (IQR 5-15 degrees) at the final postoperative visit ($P < .001$). IMA improved significantly from 14 degrees (IQR 12-16 degrees) to 6 degrees (IQR 3-9 degrees) ($P < .001$). TSP was found to be 6.05 ± 1.00 preoperatively, improving to 2.22 ± 1.38 postoperatively. The agreement between the 2 authors in TSP is 0.61 (95% CI 0.70, 0.78), which falls in the range of substantial agreement justified in Landis and Koch. The authors' HVA and IMA differences are 0.019 and −0.21, respectively. Both confidence intervals cover 1, showing no difference statistically.

Complications

Wound healing issues were defined as persistent serosanguinous drainage or wound gapping requiring leaving sutures at the 2-week follow-up or requiring local wound care and antibiotics. These occurred in 6 (8.2%) of 73 patients. Hardware complication, defined as painful and broken hardware that required removal, was seen in 9 (12.3%) of 73 feet. Three total nonunions occurred (4.1%). One (1 of 73, 1.4%) resolved after correction of hypothyroidism. One was associated with a recurrence that sought revision surgery elsewhere (1.4%), and 1 was an asymptomatic nonunion that did not desire further surgery (1.4%). Hallux varus due to overcorrection was seen in 1 patient (1.4%). There were 2 painful corrected bunions without nonunion (2 of 73, 2.7%).

Costs and Operative Time

On average, we used 3 solid stainless-steel screws and 2 Kirschner wires, a saw blade, and drapes (supplies). Our average (±SD) implant costs were $146 ± 108, and our average supply costs were $322 ± 257. The average operative time was 105.8 ± 27.7 minutes.

Discussion

The modified Lapidus procedure is a valuable operative means of addressing hallux valgus and metatarsus primus deformities, especially in patients with increased IMA and HVA angles, first TMT hypermobility, and in patients with first TMT arthrosis. When Dr Lapidus first introduced the procedure, he relied on heavy chromic suture to achieve fixation.[14] Since then, many modifications have been proposed with the most conventional modification involving the use of crossed screws in the sagittal plane, parallel to one another in the anteroposterior projection.[1,3,9]

This study adds to the patient-reported outcomes literature surrounding modifications to the Lapidus procedure for correcting hallux valgus. First, we found that preoperatively, patients with hallux valgus have PROMIS-PF scores below their age- and sex-matched peers, with 50 being a normalized average value. We found that our technique led

to expected PROMIS-PF decreases by the 6-week postoperative visit, likely due to both pain and self-limitation from the surgery. PROMIS-PF scores then rose to values that were closer to the normalized average but not statistically different from the preoperative value, both at the 3-month and 1-year postoperative visits. Taken together, we feel that our data provide a glance at how patients fare in early follow-up after HV correction surgery with our technique. Preoperatively, patients function slightly below their peers with regard to physical function. As might be expected, they experience decreases in their PROMIS PF scores in the perioperative 6-week period, likely due to pain and restrictions placed on them before quickly rising to final values. Although there was not a statistically significant difference between final 1-year and 3-month values, we did note a trend toward clinically higher and closer to normal PROMIS-PF scores at the later time points. This suggests that with adequate deformity correction, there may be a functional gain over baseline at 3 months postoperatively and beyond, although our study was underpowered to detect such a difference.

We observed a complication rate similar to that previously reported.[7,13] We noted a higher rate of hardware removal than other authors. The ability to load weight on the operative foot early in the postoperative course is both appealing to patients, but also a significant aspect of recovery. Early pedal weightbearing reduces the incidence of muscular atrophy, disuse osteopenia, and facilitates rehabilitation.[11] Recent data has shown a low incidence of nonunion complications with early pedal weightbearing with crossed screw fixation modified Lapidus procedures, which further supports the practice of early protected weightbearing as shown in our study.[2,4,11]

Our interpretation of the study is limited in a few key ways. First, our study was retrospective in nature with short-term follow-up both clinically and radiographically. Our collection of postoperative PROMIS scores, only 51% of the cohort, was limited by an inconsistent collection technique that relied on collection by the senior surgeon administering the test himself. We have since improved the collection methods in our practice, with increasing support from both our department and institution. Although we offered patients a fairly standardized follow-up schedule out to 2 years, many patients elected not to follow up past the 3-month time point. We hypothesize that this could be due to a perceived good outcome, as patients who especially had undergone surgery on the contralateral side and done well with longer follow-up particularly chose to not follow up beyond 6 weeks for the second side. It is also consistent with other studies examining postoperative outcomes after triplanar hallux valgus correction.[2,4]

Our study demonstrated excellent patient-reported and radiographic outcomes with low complication rates for hallux valgus correction with a modified Lapidus tarsometatarsal fusion technique. We also showed low implant costs. Our operative costs were comparable to those reported by Hyer et al in 2008 for a similar technique.[10] Taken together with our outcomes and complication profile being comparable to studies reporting on other methods of fixation, we would advocate for a technique that delivers reliable results at a lower cost.[8,16] We do not consider our cohort study a definitive answer on the matter, but rather we advocate for further prospective randomized comparisons between our technically demanding lag screw technique and more costly locked plating system techniques for modified Lapidus triplanar bunion correction.

Ethical Approval

Ethical approval for this study was obtained from the University of North Carolina Biomedical Institutional Review Board (Study 19-2717).

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. ICMJE forms for all authors are available online.

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ORCID iDs

Chinmay Shivaram Paranjape, MD, https://orcid.org/0000-0001-6552-2975
Joshua N. Tennant, MD, MPH, https://orcid.org/0000-0002-6916-368X

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