Original Article

Modified Lapidus procedure with a single screw and staple: A comparative analysis

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Abstract

Objective: The primary objective of the study is to review the fusion rate associated with a single screw and staple construct in Lapidus bunionectomy, and to compare the complication rates, fusion outcomes, and radiographic results with those of other common fixation methods.

Methods: Eighty-four bunionectomies met study criteria; in 24 cases, a single screw and staple construct was used, while 28 used a screw and locking plate, and 32 used two crossing screws. Although group matching was attempted, a greater body mass index was observed in the screw and locking plate group (p = 0.006).

Results: The minimum follow-up was 12 months (mean, 31.4 months), and the primary outcome was fusion rate. Union rates were achieved in 95.8% for the single screw and staple fixation (23/24), 92.8% for the screw and locking plate (26/28), and 93.8% for crossing screws (30/32) without a statistically significant difference (p = 0.474). The single screw and staple group achieved significantly (p = 0.012) earlier radiographic and clinical union, at 11.7 (+ 1.86) weeks, compared to crossing screw (13.2 + 2.39 weeks) and screw and locking plate (13.5 + 1.69 weeks) groups. There were no significant differences in final first intermetatarsal angle (p = 0.403), hallux valgus angle (p = 0.153), or complication rates (p = 0.386) among the fixation methods.

Conclusion: Our study shows that a single screw and staple construct is a viable option for Lapidus bunionectomy, demonstrating faster union time and maintained deformity correction with an acceptable complication rate. However, further research is required to validate the advantages and disadvantages of specific surgical implants.

Level of evidence III; Retrospective Case-control Study.

Keywords: Hallux valgus; Fracture fixation, internal; Bone screws; Bone nails.

Introduction

Hallux valgus is one of the most common pathologies encountered by a foot and ankle specialist. After failure of conservative treatments, deformity correction can be accomplished by a variety of techniques. One conventional procedure is the first tarsometatarsal joint (TMTJ) arthrodesis^(1,2). This method has become increasingly popular over the past century, following its expansion by Paul Lapidus in 1934⁽¹⁻³⁾. Now eponymous with Dr. Lapidus, the TMTJ fusion (or Lapidus procedure) has progressed considerably from

its original description⁽⁴⁾. The modern discourse regarding Lapidus bunionectomy has focused on minimal bony resection, anatomic reduction in all planes, robust internal fixation, and early mobilization^(4,5).

Recent evidence has noted lower recurrence rates and similar fusion rates with tri-planar correction. There are numerous radiographic parameters reported to determine correction and potentially limit long-term recurrence⁽³⁻⁵⁾. However, accurate and sustained correction may be independent of the type of fixation and secondary to intraoperative technique

Study performed at Scripps Healthcare, San Diego, CA, USA.

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How to cite this article: Sakkab R, Liew V,
Porto-Kujanpaa SED, Diaz RM, Michael L.
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and staple: A comparative analysis.

J Foot Ankle. 2025;19(2):e1890.

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and anatomic reduction⁽⁵⁻⁷⁾. Regardless, the release of novel orthopedic instrumentation and implants for Lapidus bunionectomies has continued at a steady pace^(8,9).

Historically, there have been a plethora of fixation constructs for first TMTJ arthrodesis^(1,3,6-8). The most common fixation method in the literature appears to be crossing screw fixation^(7,10,11). Other techniques have been described, including Kirschner wire augmentation(12), various plating(13), endosseous fixation⁽¹⁴⁾, and staples⁽¹⁵⁾. The senior authors' technique involves the hybrid use of a screw and staple. Biomechanical studies have emphasized the ability of nitinol staples to apply and maintain compression across a first TMTJ fusion site⁽¹⁶⁾. To our knowledge, a single screw and staple construct has not been evaluated in the literature. The primary objective of the study is to review the fusion rate associated with a single screw and staple construct in Lapidus bunionectomy, and to compare the complication rates, fusion outcomes, and radiographic results with those of other common fixation methods.

Methods

This study was approved by the Institutional Review Board. Patient data was de-identified and retrospectively reviewed. A total of 445 first TMTJ arthrodesis procedures were identified at our regional healthcare system from April 2016 to April 2023.

Inclusion criteria consisted of patients submitted to their first TMTJ arthrodesis for hallux valgus, with a minimum clinical follow-up of 12 months and radiographic follow-up of at least six months. For all surgeons, a Lapidus was

considered primarily if a patient had an intermetatarsal angle (IMA) greater than 13 degrees and any subjective evidence of medial column instability. Exclusion criteria included patients younger than 18 years of age, those undergoing lower extremity reconstructive surgery, or patients undergoing midfoot or rearfoot bony procedures at the time of their Lapidus bunionectomy. Implant type(s) were determined by operative notes and plain film radiographs. Central metatarsal osteotomy was performed sparingly but completed for long second rays based on the metatarsal parabola. And proximal phalanx osteotomy was completed if there was residual deformity at the hallux after modified Lapidus.

One author routinely utilizes a single screw and staple construct for Lapidus bunionectomies. The senior author's cases, which include either a dorsomedial locking plate or crossing screws, were used for comparison. Operative technique was otherwise similar for both. This included a standard dorsomedial approach. A soft tissue lateral release followed by meticulous joint preparation with rasp, curettage, and 2.0 mm drill bit fenestration. Deformity reduction was completed manually, with the assistance of a Weber clamp in all cases. The hardware used for the former's cases included a cannulated 4.0 mm headless compression screw positioned in a "beam" fashion to capture the plantar medial cuneiform, and a nitinol staple, placed medially if dissection allowed, typically 15 mm by 15 mm (Figures 1 and 2). The latter utilized a cannulated 3.5 mm compression screw and 5-hole locking plate placed dorsomedially with 2.5 mm screws or a crossing screw construct with two 3.7 mm solid-headed compression screws (Figure 3).





Figure 1. Anteroposterior and lateral views of a standard single screw and staple construct.

A chart review was conducted by researchers not involved in the index surgery and blinded to patient outcomes. Demographic data, including patient comorbidities based on the International Classification of Diseases (ICD-9), were recorded and are presented in Table 1. Radiographic parameters were calculated as described by Lamm et al.⁽¹⁷⁾, both preoperatively and at the latest radiographic follow-up.

Intermetatarsal angle of 1-2 metatarsals, hallux valgus angle (HVA), and the lateral axis of talar neck and first metatarsal (Meary's angle) were collected via an electronic picture archiving communication system (Intellispace Enterprise, Philips, Amsterdam, Netherlands). Union was defined as osseous bridging of at least three cortices in addition to an absence of clinical symptomatology. Complications were recorded and



Figure 2. Anteroposterior and lateral views of the standard crossing screw construct.

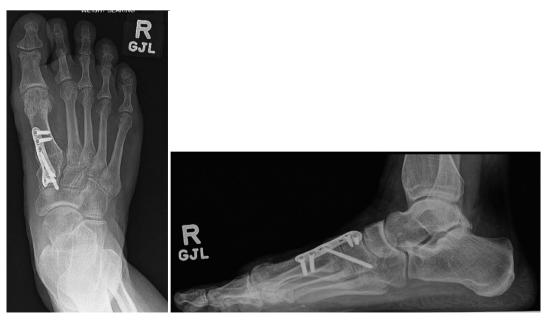


Figure 3. Anteroposterior and lateral views of the screw and locking plate construct.

deemed major if they required a return to the operating room and/or persisted for more than three months. Complications were considered minor if they were resolved with conservative care within three months. The chart review was conducted by co-investigators not involved in patient care. A radiographic review was performed while the clinician was blinded to the clinical outcome.

Postoperative protocol

All patients were placed in a non-weight-bearing splint for two weeks postoperatively. Afterward, all patients were placed in a controlled ankle motion boot and continued non-weight-bearing for four weeks. At which point they progressed to weight-bearing in a controlled ankle motion boot for 2-4 weeks, followed by a return to regular shoe gear.

Statistics

Normality tests were completed using the Shapiro-Wilk test. Only age was found to be normally distributed; therefore, analysis of variance was used to compare ages. Nominal variables were compared using the Chi-squared test. Kruskal-Wallis tests were used for nonparametric quantitative data as three fixation types were compared. The Wilcoxon test was used to compare pre- and postoperative radiographic measurements within groups. The Alpha error was set at 5%, and results lower were deemed significant. A power calculation was performed, and a sample size of 220 patients was estimated for 80% statistical power. However, the final sample size was 84 cases. Statistical analysis was completed using SPSS version 26.0 (IBM Corporation, Armonk, NY).

Results

Seventy-five patients, involving 84 feet, met the inclusion criteria for analysis. Twenty-four Lapidus bunionectomies were completed with a screw and a staple construct. One of these was completed with two screws and one staple. Twenty-eight cases were completed with a lag screw and locking plate, and 32 cases were completed with two crossing screws.

Among the groups, there were no significant differences in age, laterality, tobacco use, vitamin D, or diabetes mellitus. The lag screw and locking plate group had a significantly greater body mass index (BMI) (p = 0.006). Comparison of demographic features is seen in Table 1. Overall, the median age was 58 (SD + 14.2, range: 19-78). Mean follow-up was 31.4 months (SD + 4.13). Mean BMI was 27.4 (SD + 5.7, range: 18.5 - 45.6). Female patients comprised 89.7% of the patients, and left feet were 56.7% of cases. Regardless of implant specifics, all radiographic parameters showed significant improvement from preoperative measurements to the latest follow-up (p < 0.001). Union was achieved in 11.7 weeks (SD + 1.86) in the single screw and staple group, 13.2 weeks (SD + 2.39) in the crossing screw group, and 13.5 weeks (SD + 1.69) in the screw and locking plate group. The difference between the single screw and staple group and the others was statistically significant (p = 0.012), but not between the crossing screw and locking plate groups (p = 0.485).

The union rate was 95.8% for the single screw and staple group (23/24), 92.8% for the screw and locking plate group (26/28), and 93.8% for the crossing screws group (30/32) (Table 2). Seven superficial wounds occurred, three each in the locking plate and crossing screw groups, and one in the

Table 1. Patient demographics and risk factors among groups.

Variable	Screw and staple (n = 24)	Crossing screws (n = 32)	Screw and locking plate (n = 28)	p-value
Mean age (± SD)	58.4 (± 11.5)	51.1 (± 16.9)	57.2 (± 11.2)	0.210
BMI (± SD)	26.1 (± 4.6)	25.5 (± 4.4)	30.8 (± 6.5)	0.006*
Female (%)	19 (79.2%)	28 (87.5%)	25 (89.3%)	0.148
Laterality, right (%)	14 (58.3%)	14 (43.75%)	12 (42.9%)	0.315
Current tobacco use (%)	1 (4.2%)	0	0	0.191
Former tobacco (%)	0	4 (12.5%)	3 (10.7%)	
Diabetes mellitus	1 (4.2%)	1 (3.1%)	1 (3.6%)	0.910
Follow up, months (± SD)	31.4 (± 4.27)	30.7 (± 3.95)	32.1 (± 4.30)	0.414

BMI: Body mass index; SD: Standard deviation. *Statistically significant.

Table 2. Comparison of outcomes and complications among groups.

		Screw and staple (n = 24)	Crossing screws (n = 32)	Screw and locking plate (n = 28)	p-value
Complications	Minor	1 (4.2%)	3 (9.4%)	3 (10.7%)	0.386
	Major	2 (8.3%)	2 (6.3%)	3 (10.7%)	0.474
Adjunctive procedures	2 nd metatarsal Weil osteotomy	3 (12.5%)	4 (12.5%)	2 (7.1%)	1.0
	Akin osteotomy	4 (16.6%)	4 (12.5%)	2 (7.1%)	1.0
Fusion rate (nonunions)		95.8% (1)	93.8% (2)	92.9% (2)	0.474
Time to union (weeks, mean)		11.7*	13.2	13.5	0.012

*Statistically significant.

single screw and staple group. One hardware removal was required in the locking plate and crossing screw groups. All-cause complication rate was 17.9%, with nonunions accounting for 33.3% (5/15) overall and 71.4% (5/7) of major complications. Three of the five nonunions were symptomatic. Two underwent revision arthrodesis, one each in the locking plate and crossing screw groups. Preoperative HVA was significantly greater in the single screw and staple group (p = 0.004). Otherwise, all pre- and postoperative radiographic measurements did not show significant differences among groups, as demonstrated in Table 3 (p > 0.15).

Discussion

Several studies have compared fixation methods in Lapidus arthrodesis^(13,14,18-21). Barp et al.⁽¹⁸⁾ reviewed 147 Lapidus procedures with either crossing solid screws, locking plates with a separate compression screw, or locking plates with an integrated compression screw. They found a 7.3% lower risk of nonunion with the integrated locking system (p = 0.0056), and a 12.1% greater risk of hardware removal, which was not statistically significant (p = 0.963). The groups were matched, although no radiographic parameters were reported. In a recent review, Heifner et al.⁽²¹⁾ found no significant differences between crossing screw and plate constructs. This study did not focus on union rates, which are notoriously difficult across graft wedges. Other studies have also emphasized higher union rates with a screw and plate construct^(19,20).

On the other hand, results of staple fixation for hallux valgus correction have been infrequent. Mallette et al.⁽¹⁵⁾ in 2014 demonstrated their results using a two-staple construct for Lapidus bunionectomies. They had a 44% overall complication rate out of their 36 cases. Painful hardware accounted for half of these complications. This has not been the experience of the senior author, and painful hardware is found in 7.5% of patients postoperatively. Postoperatively, one hardware removal was required (5.3%) compared to 22.8% of cases reported by Mallette et al.⁽¹⁵⁾. It remains unclear whether dorsal versus medial staple orientation across the TMTJ impacts symptomatic prominence. In our study, staples were placed as medially as possible, given the soft tissue constraints, and no association was found between the type of fixation and complications (p = 0.386).

An advantage of staple fixation is the greater residual bone volume for additional fixation. This can play a role when there is limited space for an intermetatarsal (IM) or intercuneiform screw. An additional screw in this instance is common to

increase rigidity or address intercuneiform instability^(22,23). A suture button device could also be used, with a lower risk of cutting through screw threads compared to a staple⁽¹⁵⁾. In our study, one patient received an IM screw in the single screw and staple group, three in the crossing screw group, and none in the locking plate group. Previous reports have demonstrated the increased rigidity with a transverse screw^(4,22-24). This intercuneiform or IM screw may also provide more confidence in early weight-bearing. Also, neither of the senior authors routinely deploys a transverse screw. Rather, if there is a minor intraoperative loss in correction after hardware placement, transverse fixation is then applied between the cuneiforms or the first and second metatarsal bases. Naturally, the method of fixation is dependent on the surgeon's preference and experience.

The one difference across our treatment groups was BMI (p = 0.006). The mean BMI for the locking group was 4.7and 5.3 greater than the single screw and staple and crossing screw groups, respectively. Whether this is clinically relevant remains to be seen. Some data have shown no discrepancies in union rates between similar variances in BMI⁽⁷⁾. It is assumed that surgeons select more robust hardware for patients with higher BMI. Therefore, the difference in BMI may be due to surgeon selection and is a potential source of bias. Contemporary literature has supported the use of a compression screw and locking plate for overweight patients due to the increased biomechanical strength^(4,5,7,24). However, Aiyer et al. (23) demonstrated the significant contact area and contact force of staple fixation across the first TMTJ. They found that the contact force and area with a single staple were greater than with a crossing screw or claw plate (p < 0.05). And while the single staple also performed similarly to a crossing screw in plantar gapping (p < 0.01), the crossing screw was the superior construct compared to four-point bending at all levels of displacement (p < 0.001). The authors consider the continuous interfragmentary compression afforded by the properties of nitinol as a reason for the quicker time to union in the staple group. Unfortunately, a precise biomechanical measurement of the stiffness, contact area, and peak loads of the single screw and staple construct was not determined. In vitro biomechanical testing is certainly needed in addition to this clinical report.

Other limitations of our study are those intrinsic to a retrospective review with a small sample size. Follow-up was short and likely inadequate to evaluate the latent loss of deformity correction. Patients with concomitant midfoot or rearfoot procedures were excluded to curb heterogeneity.

Table 3. Radiographic comparison among groups.

		Screw and staple (n = 24)	Crossing screws (n = 32)	Screw and locking plate (n = 28)	p-value
IMA (degrees)	Preoperative	13.55 (±2.2)	13.48 (±4.0)	15.1 (±4.5)	0.411
	Postoperative	7.1 (±1.4)	6.7 (±2.6)	7.9 (±3.6)	0.403
HVA (degrees)	Preoperative	38.0 (±9.9)	27.6 (±9.7)	30.3 (±10.8)	0.004*
	Postoperative	18.8 (±4.4)	15.0 (±7.6)	13.8 (±9.0)	0.153

IMA: Intermetatarsal angle; HVA: Hallux valgus angle. *Statistically significant.

Inclusion of such cases would have bolstered the sample size. All operative techniques were biased to the surgeon's preference. Preferences go beyond hardware and include methods of joint preparation and reduction. However, cases were consecutive and techniques did not change over time. Furthermore, fixation constructs varied evenly for each surgeon. The cases were reviewed by researchers who were not involved in the surgical cases and were blinded to patient outcome. Additionally, computed tomography was not routinely used to assess union. A case was defined as union only if both radiographic parameters were met and the patient remained asymptomatic. True pseudoarthrosis rate may be greater than reported, albeit asymptomatic. Radiographic measurements are susceptible to detection bias. All measurements were standardized and calculated on the same system, with researchers blinded to the clinical outcome.

Lastly, an increasingly important issue in healthcare is value-based care⁽²⁵⁾. The present data demonstrates equivalent outcomes and complications for crossing screws as screw and staple. This is despite a standard fully threaded screw being less expensive than a nitinol staple⁽²⁶⁾. Future cost-

benefit analyses should be conducted to justify the higher prices of implants. One factor that needs to be considered is operating room time and efficiency.

Conclusion

Our study shows that a single screw and staple construct is a viable option for Lapidus bunionectomy. The single screw and staple group achieved combined radiographic and clinical union at 11.7 weeks, compared to 13.2 and 13.5 weeks in the crossing screw and locking plate groups, respectively (p = 0.012). The single screw and staple group also maintained deformity correction with an acceptable overall complication rate. The union rate across all fixation groups was 94.05%, which is comparable to the contemporary literature(7,11,27). Further research is required to validate the advantages and disadvantages of specific surgical implants.

Acknowledgements

The authors would like to thank Donald R. Green and Benjamin D. Cullen for their assistance with the research process.

Authors' contributions: Each author contributed individually and significantly to the development of this article: RS *(https://orcid.org/0000-0003-4488-7347) conceived and planned the activities that led to the study, interpreted the results of the study, writing, participated in the review process approved the final version; VL*interpreted the results of the study, participated in the review process, writing, and approved the final version; SD *interpreted the results of the study, participated in the review process, writing, and approved the final version; MC *performed the surgeries, review and approved the final version; RD *performed the surgeries, review and approved the final version. All authors read and approved the final manuscript. *ORCID (Open Researcher and Contributor ID)

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