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Lapidus Arthrodesis with a Single Lag Screw and a Locking H-Plate

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A R T I C L E I N F O

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A B S T R A C T

The aim of this pilot study was to assess if using an interfragmental lag screw and a Darco® locking H-plate for the modified Lapidus arthrodesis in the treatment of hallux abducto valgus deformity (1) would allow for earlier weight bearing than previously described and (2) would indicate whether any changes would occur radiographically with the earlier weight bearing. Twenty-one metatarsocuneiform arthrodeses, in 18 patients, were retrospectively evaluated through chart review and postoperative radiographs. Original diagnoses included painful hallux abducto valgus and osteoarthritis of the first metatarsocuneiform joint. The mean age of the patients was 48 (range, 16 to 70) years. The mean follow-up duration was 38.5 (range, 29 to 60) months. The overall radiographic osseous union rate was 90.5% (19/21 feet), although there were 2 asymptomatic nonunions. There were no cases of fixation failure, and the surgical correction was preserved on follow-up radiographs. Overall, the mean time to full weight bearing was 4.7 (range, 3 to 7.5) weeks, and it was a mean of 8 (range, 7 to 10) weeks before the patient was back to wearing comfortable shoes. The authors concluded that metatarsocuneiform arthrodesis fixated with 1 interfragmentary lag screw and a Darco® locking H-plate provides sufficient stability to allow earlier weight bearing than has been previously described with other internal fixation constructs.

Although the surgical technique was originally described by Albrecht in 1911, Lapidus popularized fusion of the first metatarsocuneiform joint (MCJ) (1, 2). As indicated by Lapidus, fusion of the MCJ was used to correct the severe hallux abducto valgus deformity secondary to metatarsus primus varus. Since the original description, various surgical approaches, fixation techniques, and indications for this procedure have been described (3–8). Despite the applicability of first MCJ arthrodesis, there are several potential complications that could develop, including first metatarsal shortening, elevation, and nonunion, which have been attributed to various factors including fixation failure, patient compliance issues, and the overall postoperative regimen (7, 9–11). In regard to fixation techniques, Kirschner wires, staples, crossed screws, plating, combinations of internal fixation, and external fixation have all been shown to be effective in stabilizing the joint (6, 8, 12–14). To optimize fusion rates, most authors recommend a postoperative course of 6 to 8 weeks of protected non-weight bearing (3, 6, 7, 12).

More recently, locking plates have been shown to provide increased rigidity and stability to osteotomies and arthrodeses in the lower extremity (15–19). However, there has only been 1 published report that describes the use of locking plates for Lapidus arthrodesis (20). This investigation was undertaken to determine whether the use of the Darco Lapidus Plating System® locking H-plate (Wright Medical Technology, Inc., Arlington, TN) can be used to achieve successful fusion of the first MCJ and enable the patient to begin weight bearing earlier in the postoperative period.

Patients and Methods

Between November 2004 and April 2007 the senior authors (C.A.C. and M.C.M.) performed 21 metatarsocuneiform (MC) fusions in 18 patients. A retrospective chart review was completed by one of the authors (CRDM), for all of the patients who had undergone MC arthrodesis. Preoperative diagnoses included painful hallux abducto valgus, metatarsus primus varus, MC instability with hypermobility, and isolated MC osteoarthritis. Only patients with MCJs fixated with a locking H-plate were included in the study, and the follow-up period had to be at least 29 months. Along with demographic variables, data describing when patients were permitted to initiate weight bearing as well as when they were transitioned to a normal shoe were also abstracted. Immediate non-weight bearing and long-term weight bearing follow-up anteroposterior (AP) and medial oblique and lateral foot radiographs were evaluated to confirm preservation of the surgical correction. It should be noted that a difference in weight bearing status between the 2 sets of radiographs does present a bias that is both clinically real and useful. The radiographic measurements were made by the same author (CRDM), in an effort to maintain consistency. The hallux valgus angle (HVA), first intermetatarsal angle (IMA), and standing lateral first metatarsal angle were measured and compared based on the method described by Sangeorzan and Hansen (5). The radiographs were also inspected for the presence of any signs of alteration of the fixation in comparison with the immediate postoperative images, fixation failure, and/or loosening of the hardware. Osseous union was determined by the radiographic

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presence of trabeculation across the MCJ on all 3 standard radiographic views and clinically determined by the presence of a painless fusion site upon both weight bearing and aggressive manipulation of the joint.

The operative intervention consisted of placing the patient supine, using intravenous sedation and monitoring anesthesia care, and using a mid-calf tourniquet combined with either lidocaine and/or bupivacaine with dilute epinephrine (1:200,000) infiltrated proximal to the surgical site, and about the first MCJ, to achieve local anesthesia and to aid hemostasis. A linear incision was made over the dorsomedial aspect of the first metatarsophalangeal joint (MTPJ), and anatomical dissection was used to systematically carry out a modified McBride bunionectomy. After completion of the bunionectomy and release of the plantar lateral soft tissue contracture of the first MTPJ, the incision was extended proximally to bisect the medial column to the level of the navicular-medial cuneiform joint. A mini-distractor was placed dorsally over the MCJ to enhance access to the joint. The MCJ was then resected with rongeurs, curettes and power burs, or planar joint resection with power instrumentation, depending on the requirements of each individual patient. The distal hole created in the metatarsal by the Kirschner wire used with the mini-distractor was typically used as the entry point for an interfragmental compression screw oriented from the dorsal aspect of the base of the first metatarsal to the plantar aspect of the medial cuneiform (Figure 1). After confirming proper placement of the interfragmental lag screw, a 4-hole locking H-plate was applied to the medial to slightly plantar-medial aspect of the MCJ (Figures 2 and 3). Four 3.5-mm locking screws were used to stabilize the plate to the medial column. On occasion, the pre-drill for the locking screws would intersect the interfragmental compression screw, thereby requiring the use of a nonlocking 3.5-mm screw in place of a locking screw. By redirecting the screw within the plate, contact with the interfragmental screw was avoided. Wounds were closed in anatomical layers, and the foot was placed in either a hard Jones compressive dressing or a posterior splint, and maintained non-weight bearing on the operated foot in the initial postoperative period. The standard postoperative course involved initial wound inspection 7 to 10 days after the surgery, at which time a posterior splint was reapplied and the patient was maintained non-weight bearing. At 3 to 4 weeks postoperatively, weight bearing was initiated in a pneumatic, immobilizing walking boot. Full weight bearing in the patient's regular shoe gear routinely began at approximately 7 weeks postoperatively.

The statistical plan entailed null hypothesis testing in an effort to answer the following question: does fixation of the Lapidus arthrodesis with the locking H-plate combined with a single interfragmental compression screw provide adequate correction and stability if weight bearing is permitted before the sixth postoperative week? In order to answer this question, the authors evaluated whether there was a difference between radiographic measurements observed in the immediate and long-term postoperative periods. Specifically, the following null hypothesis was formulated:

> If there is no difference between the immediate and long-term postoperative radiographic measurements, then there will be no statistically significant (at the 5% level) difference between the measurements.

The Student's *t* test and conventional equivalence testing was used to test the null hypothesis. Furthermore, we wanted to show that the early and long-term postoperative radiographic measurements, although not identical, were close enough to be considered clinically equivalent. Using the equivalence test, we set the delta value (i.e., the maximum difference that we considered not to make a difference) at 5% of the immediate postoperative value. To this end, we calculated the probability of clinical equivalence using confidence intervals (CIs) and the *t* distribution. The statistical analyses were performed by Jeffery S. Kane, PhD (Professional Statistical Services, Pasadena, CA).

Results

Review of the medical records revealed 22 patients who had undergone a total of 25 Lapidus procedures fixated with a locking H-plate. Of the 25 feet, 4 cases were excluded because the locking H-plate was not used in combination with an interfragmental compression screw. With these exclusions taken into consideration, there were 21 MC fusions in 18 patients who met our inclusion criteria (Table 1). The mean follow-up duration was 38.5 (range, 29 to 60) months. There were 17 (94.44%) women and 1 (5.56%) man in the case series, with a mean age of 47.9 (range, 16 to 70) years at the time of surgery. Additional procedures included plantar plate repair in 2 (11.11%) patients, tailors bunion correction in 4 (19.05%) feet, and hammertoe correction in 7 (33.33%) feet. There were no cases of hallux abducto valgus recurrence. Radiographic union was confirmed in 19 (90.5%) of 21 feet. Two (9.52%) patients developed asymptomatic nonunions, identified at 11 and 12 months postoperatively, respectively. None of the cases demonstrated fixation failure such as hardware breakage or screws backing out from either the plate or bone interface. No plates or screws have required removal. The mean time to full weight bearing was 4.7 (range, 3 to 7.5) weeks. After confirming radiographic consolidation and preservation of the fixation construct,

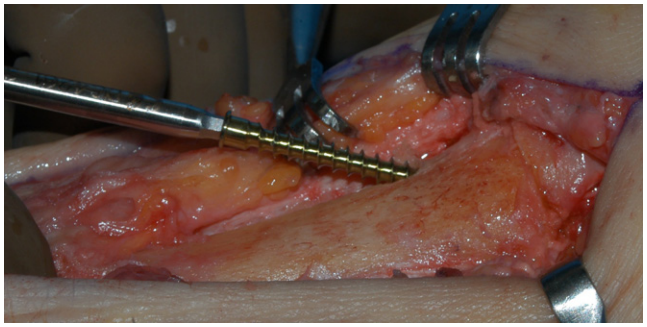

Fig. 1. One nonlocking screw was inserted across the metatarsocuneiform joint from dorsal-distal in the metatarsal to the proximal-plantar in the medial cuneiform.

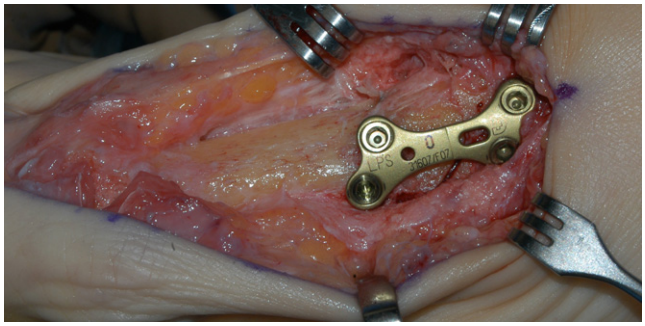

Fig. 2. After confirming adequate interfragmental screw compression, a 4-hole Darco® locking H-plate was applied to the plantar medial aspect of the joint.

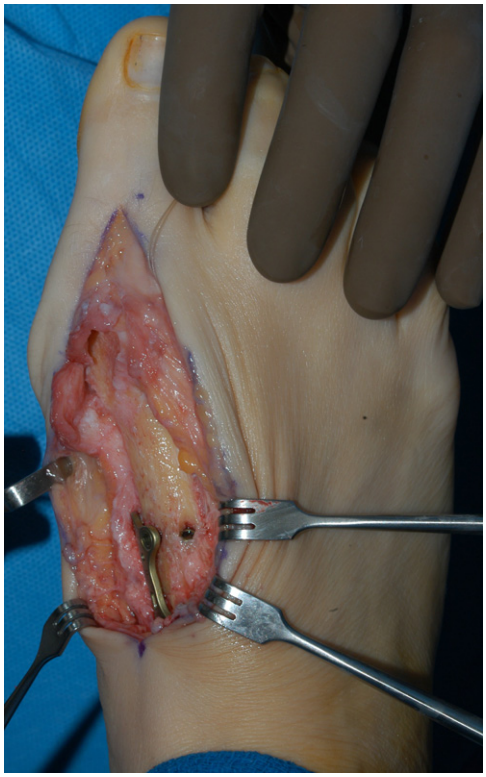

Fig. 3. Intraoperative anteroposterior view.

Table 1
Case series dataset

Variable	N	Mean ± Standard Deviation	Range
Weeks to weight bearing	20	4.73 ± 1.33	3, 8
Weeks wearing regular shoes	20	8.05 ± 0.95	7, 10
Months follow-up	20	15.75 ± 9.03	29, 60
Age at surgery	20	47.90 ± 16.68	16, 70
Weight	16	149.88 ± 33.32	108, 230
Height	16	5.36 ± 0.33	65.0, .2

Abbreviation: N, number of patients in the case series.
The sample size varied as retrospective chart review failed to ascertain the height and weight of a number of patients in the case series.

the patients were permitted to transition to a regular shoe at a mean of 8.1 (range, 7 to 10) weeks postoperatively.

Radiographic measurements confirmed preservation of the surgical correction at a minimum of 29 months postoperatively, when immediate and long-term (≥ 29 months) postoperative radiographs were compared (Figures 4 through 7). The statistical analyses (Tables 2 through 4) comparing the immediate and long-term postoperative radiographic measurements are depicted in Tables 2 through 4. The mean hallux abductus angle (HAA) on immediate postoperative radiographs was 11° (range, 4° to 19°), and the final HAA averaged 12.2° (range, 6° to 18°), and this difference was not statistically significant ($P = .152$). The mean immediate postoperative first IMA was 7.4° (range, 4° to 12°), and the final first IMA averaged 7° (range, 4° to 10°), and this difference was not statistically significant ($P = .083$). The immediate non-weight bearing

Fig. 5. Immediate postoperative lateral radiograph.

postoperative standing lateral first metatarsal angle averaged 21.1° (range, 18° to 28°), and the mean long-term weight bearing standing lateral first metatarsal angle was 19.7° (range, 14° to 24°), and this difference was statistically significant ($P = .021$). Equivalence testing revealed that the probability that the IMA, HAA, and standing lateral first metatarsal angle measurements were clinically equivalent between the immediate and long-term postoperative radiographs was 39.7%, 29.1%, and 33.5%, respectively (Tables 2 through 4).

Discussion

Common complications related to the Lapidus arthrodesis include first metatarsal shortening, fixation failure, and the development of nonunion (3, 5, 7). In an effort to enhance stabilization of MC

Fig. 4. Immediate postoperative anteroposterior radiograph.

Fig. 6. Twenty-nine months postoperative anteroposterior radiograph.

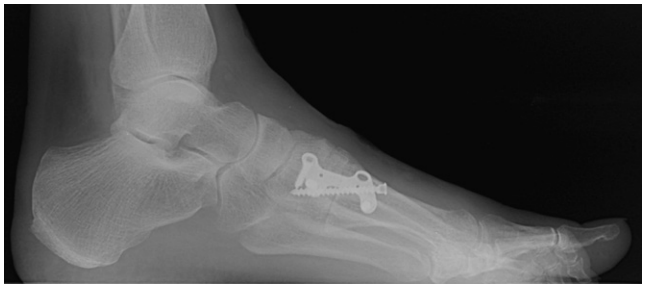

Fig. 7. Radiographic measurements confirmed preservation of the surgical correction at 29 months postoperatively. Osseous union was determined by the radiographic presence of trabeculation across the metatarsocuneiform joint.

arthrodesis, a wide range of internal and external fixation devices have been used for this procedure. External fixation for this procedure had been documented (13, 21). Anterior cervical locking plates have been used successfully in the fixation of various midfoot arthrodeses, including the talonavicular, medial naviculocunieform, metatarsocuneiform, and calcaneocuboid joints (16). Locking plate fixation has also been shown to be effective when used to fixate the proximal first metatarsal Chevron osteotomy (18), and other forefoot and rearfoot arthrodesis procedures (22–24).

Cadaveric studies have also been conducted to compare the load to failure between a locking H-plate and standard crossed screws. In one investigation (20), 10 matched pairs of cadaver feet were used, wherein 1 foot of each pair was randomly assigned to fixation with a dorsally placed Normed H titanium locking plate (Normed Medizin-Technik Vertriebs-GmbH, Tuttlingen, Germany) or 2 crossed ACE DePuy 4.0 (DePuy/Ace, Warsaw, IN) titanium cannulated screws. The specimens were loaded to failure in a 4-point bending configuration. The load to failure was 58.09 N for the locking H-plate and 140.08 N for screw fixation, and these values were statistically significantly different. The authors of that investigation concluded that screw fixation created a stronger and stiffer fixation construct in comparison with the Normed locking H-plate under conditions of sagittal plane loading, and they speculated that the reason for the observed difference could be attributed to a lack of interfragmental compression, dorsal (compression surface) of the plate, and the lack of strength within the locking H-plate group.

Table 2
Comparison and equivalence* of the immediate and 29 months postoperative intermetatarsal (IM) angles (N = 21 feet in 18 patients)

A. Paired Samples Statistics				
Variable	Mean	N	SD	Standard Error Mean
Pair 1				
Intermetatarsal angle immediate	7.60	20	1.789	.400
Intermetatarsal angle 29 months	7.00	20	2.077	.465

B. Paired Samples Correlations			
Variable	N	Correlation	*P*
Pair 1			
Postoperative IM angle immediate Postoperative IM angle at 29 months	20	.722	< .0001

C. Paired Samples *t* Test								
	Paired Differences					t	df	Significance (2-tailed)
	Mean	SD	Standard error mean	95% CI of the difference				
				Lower	Upper			
Pair 1								
IM angle immediate to IM angle 29 months	.600	1.465	.328	−.086	1.286	1.831	19	.083

* This *t* test has a *P* value of .083, which is not low enough to reject the null hypothesis. Using the equivalence test, we set the delta value (i.e., the maximum difference that is considered to not make a difference) at 5% of the immediate postoperative value: .05 × 7.6 = .38. The zone of indifference is a difference of ± .38. This zone only encompasses 39.7% of the 95% CI of the observed difference. This can be interpreted as a 39.7% probability that the 2 measurements were equivalent, which cannot be considered strong support for equivalence.

Table 3
Comparison and equivalence of the immediate and 29 months postoperative hallux valgus (HV) angles (N = 21 feet in 18 patients)

A. Paired Samples Statistics				
Variable	Mean	N	SD	Standard Error Mean
Pair 1				
HV angle immediate	10.84	19	3.962	0.909
HV angle 29 months	12.16	19	3.819	0.876

B. Paired Samples Correlations			
Variable	N	Correlation	*P*
Pair 1			
HV Angle immediate to HV angle 29 months	19	.516	.024

C. Paired Samples *t* Test								
	Paired Differences					t	df	Significance (2-tailed)
	Mean	SD	Standard error mean	95% CI of the difference				
				Lower	Upper			
Pair 1								
HV angle immediate to HV angle 29 months	1.316	3.830	.879	3.162	.530	1.497	18	.152

*This *t* test has a *P* value of .152, which is not low enough to reject the null hypothesis. Using the equivalence test, we set the delta value (i.e., the maximum difference that is considered to not make a difference) at 5% of the immediate postoperative value: .05 × 10.84 = .542. The zone of indifference is a difference of ± .542. This zone only encompasses 29.1% of the 95% CI of the observed difference. This can be interpreted as a 29.1% probability that the 2 measurements were equivalent, which cannot be considered strong support for equivalence.

In our study, the authors first applied an axial compression screw across the MC arthrodesis site, thereby creating rigid interfragmental compression, after which a 4-hole Darco® LPS locking H-plate was applied along the medial to slightly plantar-medial aspect of the MC fusion site. Applying the plate to the plantar-medial surface of the fusion enables the plate to withstand greater pullout forces (25, 26). The combination of the interfragmental compression screw, as noted by Gallentine et al, further increases friction between the osseous fragments, thereby increasing rigidity of the fixation construct, and this is even further stabilized and able to resist sagittal plane displacement with the addition of the splintage provided by the plantar-medial locking H-plate (18). Similarly, Ruch and Chang demonstrated significantly greater stability when the screw and plate were combined to achieve Lapidus fusion, in comparison with other fixation (25). In their investigation, the load to failure of the combined plate-and-screw construct was nearly twice that of the other techniques tested, including crossed screws and a medially placed 5-hole plate. Based on these in vitro investigations, the combination of an interfragmental compression screw and a plate placed as close as possible to the tension surface of the fusion site is the most rigid configuration for stabilization of the first MC fusion interface.

Moreover, this was the premise upon which the authors based their decision to allow their postoperative patients to initiate weight bearing earlier than the traditional time of 6 to 8 weeks after Lapidus arthrodesis.

It is interesting to note that various surgeons have permitted weight bearing after MC arthrodesis at different times in the postoperative phase, ranging from immediately postoperative to 10 weeks

Table 4
Comparison and equivalence* of the immediate and 29 months postoperative standing lateral first metatarsal (SLFM) angles (N = 21 feet in 18 patients)

A. Paired Samples Statistics				
Variable	Mean	N	SD	Standard Error Mean
Pair 1				
SLFM angle immediate	21.15	20	2.254	.504
SLFM angle 29 months	19.70	20	2.536	.567

B. Paired Samples Correlations			
Variable	N	Correlation	*P*
Pair 1			
SLFM angle immediate to SLFM angle 29 months	20	.423	.063

C. Paired Samples *t* Test								
	Paired differences					t	df	Significance (2-tailed)
	Mean	SD	Standard error mean	95% CI of the difference				
				Lower	Upper			
Pair 1								
SLFM angle immediate to SLFM angle 29 months	1.450	2.585	.578	.240	2.660	2.509	19	.021

* This *t* test has a *P* value of .021, which is low enough to reject the null hypothesis. Using the equivalence test, we set the delta value (i.e., the maximum difference that is considered to not make a difference) at 5% of the immediate postoperative value: .05 × 21.15 = 1.053. The zone of indifference is a difference of + or – 1.053. This zone only encompasses 33.5% of the 95% CI of the observed difference. This can be interpreted as a 33.5% probability that the 2 measurements were equivalent, which cannot be considered strong support for equivalence. Thus, by both null hypothesis and equivalence testing, it must be concluded that the later measurement is lower than the earlier measurement.

after surgery (4, 7). Lapidus permitted immediate weight bearing in a canvas or leather-soled slipper for the first month, followed by a wide shoe or sandal for the second postoperative month (4). Weight bearing patients on the fourth postoperative day in a surgical shoe combined with external skeletal fixation have also been shown to be successful (21). Catanzariti and colleagues have stated that the postoperative course is influenced by the type of fixation, whether or not bone grafting was used, and serial radiographic findings and, in their practice, patients are typically allowed to begin weight bearing between the sixth and eighth postoperative weeks (7). This timeframe appears to be consistent throughout much of the literature related to MC arthrodesis (3, 5, 6, 11, 12, 27). Furthermore, transition to regular shoes has been advocated around the tenth postoperative week, which seems to be a commonly accepted time for osseous union to be confirmed (11). In the current study, patients were initially permitted to bear weight on their operated foot at 3 weeks postoperatively. Interestingly, one of the earlier patients in our investigation disregarded our non-weight bearing instructions and began bearing weight on the operated foot at 2 weeks after the operation. Despite the patient's noncompliance with the therapeutic regimen, postoperative radiographs and the clinical examination failed to demonstrate any evidence of displacement or failure of the fixation, and the surgical alignment was not disturbed. As our experience with the case series evolved over an approximately 2-year period, we began to allow our patients to bear weight on the operated foot earlier in the postoperative period. The radiographs within our study demonstrated no significant differences in the immediate and long-term follow-up radiographic appearance of the HA and first IM angle at the operative site. A significant difference was noted in the immediate and long-term follow-up radiographic appearance of the lateral first metatarsal angle.

Use of the Student's *t* test did not demonstrate a statistically significant difference between the immediate and long-term HA angle ($P = .152$) and first IM angle ($P = .083$) measurements. However, *t* test comparison of the immediate and long-term postoperative standing lateral first metatarsal angle revealed a statistically significant difference ($P = .021$). Additionally, equivalence testing demonstrated weak support for equivalence among the immediate and long-term measurements for all 3 angles: HA angle (29.1%), first IM angle (39.7%), and the standing lateral first metatarsal angle (33.5%). In regard to the standing lateral first metatarsal angle, both the Student's *t* test and the equivalence test indicated that the immediate and long-term postoperative measurements, namely $21.2^\circ \pm 2.25^\circ$ and $19.7^\circ \pm 2.54^\circ$, respectively, differed. Although these values demonstrated a statistically significant difference, radiographically and clinically the differences were difficult to appreciate. Small differences among the angles may stem from a variety of factors including obliquity of the radiographic beam and foot positioning, human error while measuring the radiographs, and measuring angles on radiographic film and paper. Probably the most important consideration that should be accounted for is that immediate postoperative radiographs were taken non-weight bearing and the long-term radiographs were taken with the patient weight bearing.

We observed a number of complications recorded in the medical records. Two of the patients in our series developed radiographic changes suggestive of a nonunion. They were permitted to begin weight bearing at 3.5 and 4 weeks postoperatively, respectively. Despite the radiographic nonunions, first metatarsal alignment was satisfactory and there was no apparent loosening of the fixation in either case. Clinically, both patients were asymptomatic, even upon application of aggressive focal manipulation of the MCJ. The medical history in both of these patients was unremarkable except for the fact that one of them had a history of chronic cigarette smoking. A third patient stepped down on her operated foot during the fifth postoperative week secondary to a fall; however, the immediate postincident radiographs demonstrated no significant displacement or loosening of the hardware and she went on to experience an unremarkable recovery thereafter. Three other patients developed fracture blisters and eventual wound dehiscence directly over the first metatarsal, and all of these wounds healed uneventfully with localized wound care.

This pilot study is, to the best of our knowledge, the first clinical investigation to show that a locking H-plate combined with a single interfragmental compression screw is a satisfactory means of fixation for an MC arthrodesis. The results also demonstrate that the combination of a single interfragmental compression screw with a locking plate maintains correction long term, even in patients who sustain delayed or nonunion as depicted by radiographic evidence of transarthrodesis boney trabeculation. Moreover, we believe that use of locking-plate technology enabled our patients to begin weight bearing at an earlier interval in the postoperative phase, without apparently compromising the clinical outcome. Although the statistical analyses indicated that there was a statistically significant difference in the first metatarsal angle as measured on the immediate (non-weight bearing) and long-term (weight bearing) postoperative lateral radiographs, this difference did not appear to be clinically significant and the variation in the radiographic measurements was minor. Like many pilot investigations, our study conveys a number of limitations that threaten the validity or our conclusions. Namely, our findings depended completely on previous documentation that had to be interpreted by subsequent investigators, and not all of the variables that a reasonable clinician familiar with MC fusion would find interesting in regard to a successful outcome of this surgical intervention. Such variables, in our opinion, would include the severity and reducibility of the deformity, the presence or absence of subchondral

bone cysts visualized on radiographs, ankle equinus, neuropathy, or other potentially meaningful independent variables. Furthermore, we did not measure pain or foot-related quality of life, and we did not undertake a sensitivity analysis that could have explained just how robust our results were. Instead, we focused our attention on the duration of time to weight bearing and resumption of regular shoe gear, as well as the alteration of certain radiographic measurements. We also did not undertake explanatory analyses that could have explained the influence that any single variable, or multiple variables, had on the outcomes that we observed.

In summary, the authors evaluated the effectiveness of the Darco Lapidus Plating System® locking H-plate for first MC fusion in a group of patients allowed to begin weight bearing at a mean of 4.7 weeks postoperatively. Successful radiographic union developed in all but 2 patients who demonstrated asymptomatic nonunions. There were no patients who experienced failure of fixation, and surgical correction was maintained despite weight bearing patients earlier then previously described. Although there were "statistically significant" changes in the radiographic angles, these were minor, subject to error because of a number of factors, and of no clinical significance. Based on these findings, we have concluded that an MC arthrodesis fixated with 1 interfragmental compression screw and a locking H-plate is sufficient to permit weight bearing as early as 3 weeks postoperatively. The results of this preliminary investigation may be useful in the development of randomized controlled clinical trials, as well as prospective cohort studies, that focus on first MC arthrodesis.

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