CHAPTER **4**

EFFECT OF EARLY WEIGHTBEARING AFTER MODIFIED LAPIDUS ARTHRODESIS: A Retrospective Study

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INTRODUCTION

The modified Lapidus arthrodesis is a powerful procedure for the correction of hallux valgus. The procedure was first introduced in the 1930s and even Lapidus himself employed an early weightbearing protocol (1-3). The standard traditional long postoperative non-weightbearing course as well as the previously reported high nonunion rate has deterred many surgeons from utilizing the procedure (4-8). Standard postoperative protocols following a modified Lapidus arthrodesis typically consist of non-weightbearing until boney consolidation occurs, usually around 6 to 8 weeks. In theory, if guidelines that allow early weightbearing can be developed with similar results compared to standard, then perhaps the modified Lapidus arthrodesis procedure can be more easily used by patients and surgeons when it is warranted.

A retrospective single-center investigation of 44 feet in 41 patients who underwent a modified Lapidus arthrodesis by 2 different surgeons, involving a similar fixation technique but different postoperative protocols was conducted. Group 1 was the traditional group who were non-weightbearing for at least 8 weeks in a short leg cast or CAM walker, and group 2 were the early weightbearing group (EWB) who were patients who were allowed early postoperative weightbearing in a CAM walker or short leg cast (Figure 1).

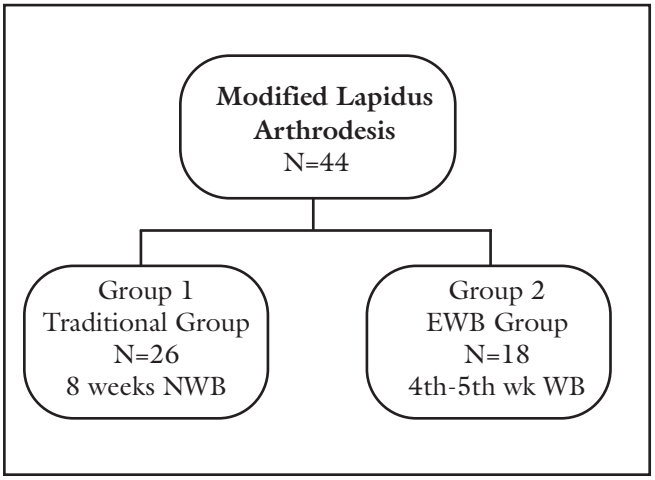

Figure 1. Retrospective single-center investigation.

The purpose of our study was to determine if an early weightbearing protocol following a modified Lapidus arthrodesis could be used without compromising correction, increasing time to radiographic healing, or decreasing the rate of osseous union. If this is possible, then perhaps this procedure will be utilized more often. Investigators analyzed charts, medical databases, and preoperative/postoperative radiographs from surgical patients of two of the authors (DPM and TCN) at one facility (Kaiser Permanente) for all patients who underwent a modified Lapidus arthrodesis from January 2009 to December 2011. Our study objectives were to determine if maintenance of surgical correction was obtained by evaluating radiographic angles with preoperative weightbearing radiographs in comparison with postoperative radiographs and determine the time as well as the rate that it will take to achieve radiographic fusion. Angles of interest were: first intermetatarsal angle (IMA), Seiberg index, and first-second metatarsal head elevation. If an early weightbearing protocol can be performed without any compromise in radiographic fusion and surgical correction then the protocol can be more easily accepted and utilized by podiatric surgeons following a modified Lapidus arthrodesis.

PATIENTS AND METHODS

A retrospective comparative cohort study was performed on consecutive patients who had modified Lapidus arthrodesis performed between January 2009 and December 2011. Electronic databases, radiographs, and medical charts were reviewed. The study was reviewed and approved by our institutional review board (protocol # 6169). The average follow-up period was 8.5 months (range 3 to 36 months). Cohort included only modified Lapidus with or without procedures of the first ray fixated with solid cortical or cancellous screws. Any patient who had concomitant procedures performed where excluded from our study. This

would decrease variables and allow for a more homogenous study. All patients in both groups must have followed the non-weightbearing or early weightbearing protocol, otherwise they were excluded from the study. Medical comorbidities such as diabetes, obesity, osteoporosis, and active smoking were not excluded. We had a total subject number of 123 feet, with 85 in the control group and 38 in the EWB group. After inclusion and exclusion criteria were met, we had a total of 44 feet in 41 patients (3 bilateral procedures).

Age, sex, smoking history, body mass index, date when postoperative weightbearing protocol began and time to radiographic union were collected. Serial radiographs were taken in order to determine when osseous fusion was achieved. This allowed extraction of radiographs and medical record data retrospectively via the electronic medical records provided at Kaiser institution. The first IMA was assessed using the preoperative weightbearing radiographs, first postoperative weightbearing radiographs, and final 3 months postoperative weightbearing radiographs, to evaluate for maintenance of surgical correction. The Seiberg index and first-second metatarsal head elevatus was assessed at the first postoperative weightbearing and final post-operative weightbearing radiographs (at the third month).

Radiographic measurements and fusion of the first metatarsocuneiform joint were assessed by a single author (ION) who did not participate in any of the surgeries or patient care. Radiographic measurements were made with digital imaging system (Stentor iSite Picture Archive and Communications system [PACS], Philips Healthcare, Amsterdam, The Netherlands) with company-provided measuring tools or with plain film radiographs and a tractograph. Fusion was determined by noting trabeculation across the first metatarsocuneiform joint space without any evidence of sclerosis, lucency, or widening of the joint space on plain film lateral and dorsoplantar radiographs (5). Medical charts were also reviewed for any clinical signs of pain, motion, and/or swelling at the surgical site.

SURGICAL PROCEDURE

Surgical procedure for all patients consisted of a modified Lapidus arthrodesis with crossed screw technique (9). A third screw was inserted from medial to intermediate cuneiform in the EWB group if transverse plane instability existed. All cases were under general anesthesia with use of a thigh tourniquet. No bilateral procedures were performed at the same time. Below are the specific details in regard to the two surgeons' surgical technique.

Technique of TCN

A curvilinear incision was made from the first metatarso-cuneiform joint to the medial first metatarsal head prominence. A lateral release was performed with adductor tendon release. A transverse capsulotomy was performed at the first metatarsocuneiform joint to minimize on periosteal stripping. Using osteotomes and curettes, joint preparation was then performed. A laminar spreader was used to distract the joint. Fenestration through the subchondral plate was performed with a 1.5 drill bit. Planning using a sagittal or power rasp was performed to close down the intermetatarsal angle. The first metatarsal was plantarflexed and translated inferiorly. The first metatarsocuneiform joint arthrodesis was temporarily fixated with a 0.062 Kirschner wire (K-wire). Good position was confirmed with fluoroscopy. A 4 mm oval burr was used to create a countersink hole for the first screw at about the proximal mid shaft of the first metatarsal. Using standard AO lag technique, a 4.0 mm solid cortical screw is placed from distal to proximal with the screw orientation being almost perpendicular to the fusion site. The second screw was placed from the dorsolateral medial cuneiform to the first metatarsal base, typically without lag technique. The foot was then stressed under fluoroscopy to check for transverse instability and a third screw was placed, when indicated, from the medial to intermediate cuneiform. This placement avoids the necessity for screw removal. A 1.5 cm linear capsulotomy was made at the dorsomedial prominence. The bunion prominence was resected. All sharp edges were smoothed with a power rasp.

Surgical Technique of DPM

A dorsal linear incision was made from the medial cuneiform to the proximal phalanx medial to the extensor hallucis tendon approximately 10 centimeters in length. A lateral release was performed with adductor tendon release. A dorsal linear capsulotomy was performed at the first metatarsocuneiform joint. A Mini A-O distractor was used with 2.4 mm guide wires and all the cartilage is removed from within the joint utilizing curettes and osteotomes with care to keep the subchondral bone plate intact. A 0.062 K-wire was then used to fenestrate the joint surface. The distractor was then removed leaving the guide wires in place to help with placement in the sagittal plane. The first metatarsocuneiform joint is then marked with a marking pen to prevent any rotation in the frontal plane during the surgery. The hallux was then dorsiflexed on the metatarsal to prevent any dorsiflexion of the metatarsal during reciprocal planning. After reciprocal planning, the guide pins and

marking pen marks are used to make sure the first metatarsal was in the correct position and fixated with guide pins and checked under fluoroscopy. The lateral compression screw was put in first utilizing A-O lag technique from proximal dorsal lateral to distal plantar lateral. The medial screw was put in second for rotational forces from distal dorsal central to proximal plantar medial. The dorsal medial bump was resected and the screw position and intermetatarsal angle were checked under fluoroscopy prior to closing.

Postoperative Protocol

Postoperative protocol consisted of non-weightbearing in a short leg cast or tall CAM walker for at least 8 weeks or until boney consolidation was complete in all 26 patients in the traditional group. The EWB group was allowed immediate postoperative heel weightbearing for balance transfer, and then advanced to weightbearing as tolerated in a CAM walker. Patients were allowed to weight bear as tolerable around the fourth or fifth week postoperatively (Table 1).

STATISTICAL METHODS

Standard descriptive statistics with 95% confidence intervals (95% CIs) were calculated for all measures using Student's t test when comparing groups of continuous variables, the chi-square test if the data were categorical, and the use of Fisher's exact test if the data did not meet the criteria of chi-square testing. Statistical analyses were performed by Donna Agan, EdD with the use of SPSS Version 12.0.

RESULTS

A total of 44 feet in 41 patients met the inclusion criteria and were included in the analyses. Baseline patient characteristics between the traditional group versus the EWB group were compared (Table 2). The two groups had comparable baseline patient characteristics and we found no statistical differences in demographic variables, tobacco use, or severity of initial deformity. We did find a statistical difference in the body mass index (BMI) between the two groups (traditional group BMI = 24.04 and the EWB group BMI = 29.60; $P = 0.003$). None of the patients were lost to follow-up. There was no statistical difference in complications between the two groups. All patients in the EWB group initiated an early weightbearing protocol immediately postoperative with heel weight-bearing for balance transfer and then advanced to weightbearing as tolerated in a CAM walker at a mean time of 4.7 weeks.

A 2-sided Student's t test found that there was no statistically significant difference radiographically in regard to the first intermetatarsal angle and elevatus measurements (Table 3). *P* values and 95% CIs for Seiberg's index, first metatarsal head elevatus, and intermetatarsal angle were 0.806 (95% CI -0.57, 0.73), 0.994 (95% CI -0.85, 0.86), and 0.483 (95% CI -0.71, 0.34), respectively.

We had a total of 5 complications in the traditional group and 3 complications in the EWB group. In the traditional group, 1 patient had fibular sesamoiditis 4 months postoperatively, which was relieved by kenalog injection. This same patient had complaints of painful

Table 1

POSTOPERATIVE PROTOCOL*

Postoperative Office Visit	**Group 1: Trad. Group** *Strict NWB 8 weeks minimum*	**Group 2: EWB Group** *Early WB mean of 4.7 wks*
3-5 days	Posterior Splint replaced NWB	Posterior Splint replaced *Heel WB for balance and transfer allowed immediate post op.*
2 Weeks	Suture removal, CAM Walker or SLC NWB	Suture removal, CAM walker or SLC Continue heel WB
4th-5th week	NWB Cam Walker or SLC	WBAT in CAM walker or SLC
5th-6th week	NWB	WBAT in CAM Walker
8th week	Gradual WB with SLC if radiographic healing noted. If not completely fused, continue NWB until 11th week evaluation	Transition to motion control running shoes

**Radiographs taken at each office visit to assess healing*

Table 2

BASELINE PATIENT CHARACTERISTICS

Variable	Group 1: Trad.	Group 2: EWB	P
Age, years	39.81	47.61	0.089
Sex	22F:4M	14F:4M	0.697
Surgical side, R:L	13R:13L	12R:6L	0.272
Tobacco use	4/22	1/18	0.634
BMI	24.04	29.60	0.003
B/L	2/26	4/18	0.208
Complication Rate	5/26	3/18	1.00
Mean Preop IMA	16.54	16.39	0.812

IMA = intermetatarsal angle; BMI =body mass index

Table 3

RADIOGRAPHIC COMPARISON

	Group 1: Trad. (n= 26)	Group 2: EWB (n=18)	P (95% CI)
Mean Change IMA, deg	0.039	0.222	0.483 (-0.71, 0.34)
Mean Change Seiberg, mm	0.296	0.217	0.806 (-0.57, 0.73)
Mean Change Elevatus, mm	-0.007	-0.011	0.994 (-0.85, 0.86)

Table 4

MEAN OF RADIOGRAPHIC VALUES

		IMA, Deg		SI, mm		1st-2ndMH	
Trad. Grp	16.54	7.96	8.00	-0.092	0.204	3.404	3.396
EWB Grp	16.39	6.94	7.17	1.056	1.272	3.683	3.672

hardware that was removed 5 months postoperatively. The other 3 complications in the traditional group were delayed unions. In the EWB group, 1 patient had medial dorsal cutaneous nerve neuritis 2 months postoperatively, which was relieved by cortisone and marcaine injection. Another patient complained of painful hardware 6 months postoperatively and the hardware was removed. The third complication in the EWB group was asymptomatic incomplete union.

Radiographic time to fusion had no statistical difference in both traditional and EWB groups. Furthermore, there was no difference in union time when we included the 3 delayed unions in our analysis, which eventually fused (Table 5). Our union rate was 100% (26/26) for the traditional group and 94% (17/18) for the EWB group. We defined a delayed union as any case that took longer than 3 months to achieve osseous union. Our traditional group had a total of three delayed unions that eventually fused. Two of the patients were smokers and took 4 months to heal. One patient took 8 months to heal with use of bone stimulator after 3 months without radiographic evidence of fusion. We defined nonunion of at least 9 months of failure to achieve osseous healing across the arthrodesis site. We had one asymptomatic incomplete union in the early weightbearing group. Radiographically, the first metatarsocuneiform joint was well-aligned and clinically there was no pain, motion, or swelling at the site. There was a small plantar gap noted at the joint 4 months postoperatively, however physiologically the fusion site was asymptomatic thus no surgical or conservative treatment was performed (Figure 2). We classified this particular fusion as an asymptomatic incomplete union because of the clinical and radiographic characteristics. A CT scan would be able to better assess the level of union in this particular case. This gives us a 94% complete union rate in our EWB group.

Table 5

RADIOGRAPHIC FUSION TIME

	Group 1: Trad. N=23; N=26	Group 2: EWB N=17	P
Fusion (Days)	62.42	55.41	0.077
Total Cases Fusion (Days)	73.77	55.41	0.078

DISCUSSION

The modified Lapidus arthrodesis is a procedure that allows powerful correction for moderate to severe hallux abducto valgus. However, one of the major drawbacks for patients and surgeons is the long postoperative course of non-weightbearing. Early weightbearing has been a topic of discussion for many years. However, there are only a few studies that have evaluated the use of early weightbearing for the modified Lapidus procedure who have shown that early weightbearing after a modified Lapidus arthrodesis can be utilized with comparable results to standard (10-12). Basile et al performed a retrospective study on 41 patients in which immediate weightbearing following a modified Lapidus arthrodesis with the use of 2 screws and a neutralization K-wire. They found no significant radiographic changes between the immediate and final 6-month postoperative radiographs in regard to first IMA, first to second metatarsal head elevation, or in Seiberg index within the groups. There were no nonunions or malunions in either group (10). Blitz et al performed a multicenter retrospective review of 80 feet in 76 patients who underwent a Lapidus arthrodesis with an early weightbearing protocol at approximately 2 weeks into their postoperative course. All 80 feet proceeded to successful union (100%) with a mean time of 44.5 days to union. No cases of pathological first ray elevatus were encountered (11).

No study to our knowledge has evaluated an actual early weightbearing protocol and when it can be implemented. If the modified Lapidus arthrodesis can be employed with early postoperative weightbearing without loss of correction, metatarus primus elevatus, or delayed fusion, then perhaps the use of the procedure will be employed more often when indicated. Current techniques with rigid internal fixation and meticulous joint surface preparation have reduced the previously documented high 10-20% nonunion rate in the modified Lapidus arthrodesis (4). Our study shows there was no statistically significant difference found between our control and cohort study in regard to maintenance of surgical correction, and pathological first ray elevatus. Our EWB group did have one asymptomatic incomplete union. However an electrical bone stimulator was not used because the patient was clinically free of any signs of nonunion, such

Figure 2A. Anteroposterior view of asymptomatic incomplete union at the first metatarsocuneiform joint.

Figure 2B. Lateral view.

as pain, swelling, or motion at the site. Incomplete union with pseudoarthrosis is sometimes an incidental radiographic finding in which patients have a normal physical examination (5). Further imaging studies such as a CT scan would better assess these types of cases.

We believe that the early weightbearing protocol can be initiated with similar success rates compared to a considerably longer non-weightbearing postoperative protocol. However, patient profile is important to consider. Patients should be excluded from an early weightbearing protocol if they have comorbidities such as diabetes, peripheral vascular disease, current smokers, metabolic bone diseases, and osteoporosis. We had a total of 5 patients who were smokers in our cohort. Two of those patients had delayed unions. Another interesting finding in our study was that the body mass index was actually statistically higher in the EWB group. Body mass index has been one of the independent risk factors noted to delay healing in an arthrodesis. We did not exclude a high BMI from initiating an early weightbearing protocol. No study to our knowledge specifically includes body mass in regards to an early weightbearing protocol. Perhaps obesity is therefore not a direct limitation for potential failure and/or delayed union due to increased force. This provokes the question of, what BMI should the cut off be? Future studies should include body mass index and investigate what the body mass index cutoff should be when initiating an early weight-bearing protocol.

Although the two surgeons used similar fixation techniques, their fixation choice was different between the two groups. The EWB group was fixated with solid 4.0 mm fully threaded cortical screws. The traditional group was fixated using solid 4.0 mm partially threaded and fully threaded cancellous screws. The 4.0 mm fully threaded cortical screws (Synthes Foot Modular Set) have a core diameter of 2.9 mm, which is larger than the (1.9 mm) 2.0 mm core diameter in the 4.0 mm cancellous screws. This perhaps can add increase stability and ability to withstand a heavier load at the fusion site, thus allowing an earlier weightbearing protocol to be enforced. However cancellous screws have a larger thread pattern, therefore in cancellous bone, the pullout strength will be stronger.

We did have some limitations in our study. First, it is a retrospective study with a small sample size. If we had a larger population size, then perhaps a statistical significance could have been more easily detected. Second, our time to follow-up varied with an average of 8.5 (range 3-36) months. Our radiographic measurements of angles were compared at the 3-month mark due to some cases who did not have films 6 months postoperatively. Since this is a retrospective study, we could not alter these factors. A minimum of at least 6 months would have been more ideal for determining maintenance of surgical correction. This same principal applies to our follow-up in chart review. If we had a longer follow-up, then perhaps we could see if there were any long term changes noted or any further complications. Fourth, the determination of union was inherently subjective. The radiographic evaluation and fusion were determined by one author (ION) who was not involved in the care of the patient, but determining fusion based solely on plain film radiographs can be an inherent limitation in some cases.

CONCLUSION

The modified Lapidus arthrodesis is a powerful procedure to utilize in hallux abducto valgus deformity. There is a substantive history in this procedure in regard to union rates and non-weight bearing protocol (13-17). However, since rigid internal fixation as well as meticulous surgical technique have been employed, the cumbersome long postoperative non-weightbearing protocol might not be necessary. Our study shows that there are similar success rates with utilizing an early weightbearing protocol compared to standard for this procedure. Care must be taken in picking the correct patient to initiate an early weightbearing protocol, and caution is advised on those with other medical comorbidities. Our results in this pilot study can be used in the development of future prospective cohort studies with a larger population size, which investigate the effects of an early weightbearing postoperative protocol after a modified Lapidus procedure.

Acknowledgment. The authors appreciate the time and dedication of Donna Agan EdD., biostatistician at Scripps Mercy Hospital, San Diego, California.

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