A PROSPECTIVE, RANDOMIZED, CONTROLLED TRIAL COMPARING EARLY-WEIGHTBEARING VS. NON-WEIGHTBEARING FOLLOWING MODIFIED LAPIIDUS ARTHRODESIS - INTERMEDIATE RESULTS

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A Prospective, Randomized, Controlled Trial Comparing Early-Weightbearing vs. Non-Weightbearing Following Modified Lapidus Arthrodesis - Intermediate Results

All disclosures are in the Final AOFAS Mobile App

- The potential conflicts of interest with this presentation are:
  - John G Anderson MD\(^1\) – Consultant: Stryker, Biomet, BESPA
  - Donald R Bohay MD\(^1\) – Consultant: Stryker, Biomet, BESPA
  - John D Maskill MD\(^1\) - None
  - Matthew Beuchel MD\(^2\) - None
  - C. Luke Rust MD\(^3\) - None
  - Jessica Hooper MD\(^4\) - None
  - Rebecca Wakeman MS-4\(^4\) - None
  - Michelle A Padley BS\(^1\) – None
  - Lindsey Rich PA\(^1\) – None

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First tarsometatarsal (TMT) arthrodesis (modified Lapidus arthrodesis) is an accepted method of correcting varying degrees of hallux valgus with or without associated first ray insufficiency. Improved techniques (such as screw fixation) have led to more reliable outcomes and a lower incidence of non-union. These developments have helped bring Lapidus arthrodesis into more widespread use.

Concerning post-operative course, surgeons have historically followed a cautious postoperative regimen permitting either non-weight bearing or conservative heel touchdown ambulation. These restrictions are in place for approximately six to eight weeks until bone consolidation is confirmed radiographically. More recently, an alternative approach to post-operative management has been advocated in which patients are allowed to begin progressive weight bearing as tolerated beginning at two weeks after surgery. The goals of this updated protocol are to improve compliance and enhance patient mobility.
The purpose of this study is to report intermediate outcomes in patients who have undergone modified Lapidus arthrodesis and were randomized to an early weight bearing protocol at two weeks post-operatively, or to the six to eight week non-weight bearing course.
33 patients: 29 female, 4 male
Mean age 54.29 years (range 20-75)
10/33 had previous surgical correction of midfoot deformity
  • 3/10 ipsilateral (non-fusion)
  • 7/10 contralateral modified lapidus
Mean length of failed conservative treatment 4.7 years
Social Factors
  • 13/33 had current or past tobacco history
    ○ 3/13 current/previous smokers experienced non-/delayed union
Medical Co-morbidities
  • Mean BMI 27.58 (+/- 5.61)
    ○ 1/16 Morbidly obese BMI 40+
Following tourniquet application and sterile preparation, a dorsal longitudinal incision was performed, and the TMT joint was identified. Care was taken in order to protect the superficial peroneal nerve. Following removal of remaining articular cartilage the joint spaces were prepared for fusion by perforating with a 2.0 drill. The joint is manually manipulated into position, held in place by K-wires. The positioning was then confirmed to be in good position with fluoroscopy. The fusion is then fixated by crossed screws, placed in the lag fashion. X rays were ordered, demonstrating optimal positioning of hardware and fusion. The tourniquet was then released. Incision is closed in a layered fashion, and sterile dressings were applied, with a bulky Jones-style splint.

<table>
<thead>
<tr>
<th>Concomitant Procedures</th>
<th>25/33 Patients</th>
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<tbody>
<tr>
<td>Gastrocnemius Recession</td>
<td>25/33 Patients</td>
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<tr>
<td>Modified McBride</td>
<td>24/33 Patients</td>
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<tr>
<td>1-2 Intercuniform Fusion</td>
<td>25/33 Patients</td>
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<tr>
<td>1-2 Intermetarsal Fusion</td>
<td>19/33 Patients</td>
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<tr>
<td>2nd Metatarsal Shortening Osteotomy</td>
<td>16/33 Patients</td>
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</tbody>
</table>
Weightbearing Instructions

- All patients were non-weightbearing until 2 week post-operative visit. At that point, patients were randomized to either early weightbearing or control weightbearing groups.
  - Early Weightbearing patients were instructed to heel touch weight bear only for the first week, and then follow the progressive weightbearing protocol:
    - With their heel only, begin weightbearing at 50lbs. Every 4 days, increase weight on the operative foot at 25lb increments. Patients could anticipate to be full-weightbearing at the end of two weeks.
  - Control Weightbearing patients were instructed to remain strictly non-weightbearing until the 6–8 week post-operative visit.

- At the 6-8 week post-operative visit, both groups were fitted with a fixed ankle support boot.
  - Early Weightbearing patients could now walk on their forefoot, and could wean out of the boot as tolerated (minimum of 4 weeks)
  - Control Weightbearing patients were instructed to follow the progressive weightbearing protocol above, bearing weight on their whole foot.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Visit 1 Pre-op (within 90 days)</th>
<th>Visit 2 operative</th>
<th>Visit 3 2 weeks</th>
<th>Visit 4 6 weeks</th>
<th>Visit 5 3 month</th>
<th>Visit 6 6 month</th>
<th>Visit 7 1 year</th>
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<tbody>
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<td>Patient Satisfactory Survey</td>
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Results: Post-Operative Swelling

2 Weeks Post-Op

6 Months Post-Op

1 Year Post-Op

EWB Group
Control Group

0 2 4 6 8 10 12 14
None Mild Moderate

0 2 4 6 8 10 12
None Mild Moderate

0 2 4 6 8 10
None Mild Moderate
Both Non-Union patients were treated with bone stimulators and successful revision after one year follow-up.

Uninterpretable patient was found to be delayed after CT following one year follow-up, treated with bone stimulator.

- **Fusion Rates:**
  - Control Group: 100%
  - EWB Group: 85%
  - For the completed study, it will be assumed that the control group will achieve 90% fusion and that the early bearing group will achieve 70% fusion, with alpha = 0.05 and beta = 0.20, we will be able to detect a statistically significant effect with 59 subjects in each group, using the chi-square test.

\[ p = 0.093 \]

(not significant, 0.005 p value required for this intermediate sample)

* Both Non-Union patients were treated with bone stimulators and successful revision after one year follow-up.

** Uninterpretable patient was found to be delayed after CT following one year follow-up, treated with bone stimulator.
Results: Radiographic

Pre-Operative  8 Weeks Post-Op  6 Months Post-Op  12 Months Post-Op
Conclusion

- Swelling appears to be reduced in the early weight bearing group. In addition, the VAS pain score shows a larger decrease post-surgery for the early weight bearing group. While this study is not yet complete, it appears that the early weight bearing course does not increase adverse events and may improve post-operative recovery.

- Patients have reported that they are able to get back to normal activities more quickly in the early weightbearing group.

- Further enrollment and follow-up are needed.

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