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

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Characteristics

• 57 patients:
  • 52 female, 7 male
  • Mean age 55.82 years (range 20-75)
  • 18/57 had previous surgical correction of midfoot deformity
    • 3/18 ipsilateral (non-fusion)
    • 15/18 contralateral bunion correction procedure
  • Mean length of failed conservative treatment 5.41 years
Procedure
- A dorsal longitudinal incision was performed, and the TMT joint was identified. Care was taken 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.

<table>
<thead>
<tr>
<th>Concomitant Procedures</th>
<th>42/57 Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrocnemius Recession</td>
<td></td>
</tr>
<tr>
<td>Modified McBride</td>
<td>44/57 Patients</td>
</tr>
<tr>
<td>1-2 Intercuniform Fusion</td>
<td>45/57 Patients</td>
</tr>
<tr>
<td>1-2 Intermetatarsal Fusion</td>
<td>50/57 Patients</td>
</tr>
<tr>
<td>2nd Metatarsal Shortening Osteotomy</td>
<td>25/57 Patients</td>
</tr>
</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:
    o 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.

Results: Post-Operative Swelling

![2 Weeks Post-Op](chart1)

![1 Year Post-Op](chart2)
6 Weeks
- (33/40) EWB 82.5% swelling
- (16/17) SOC 94.1% swelling  not (quite) significant:  p = .085

3 Months
- (28/40) EWB 70% swelling
- (12/17) SOC 70.6% swelling not significant:  p = .927

6 Months
- (16/40) EWB 40% swelling
- (8/17) SOC 47.1% swelling  not significant:  p = .701

12 Months
- (9/40) EWB 22.5% swelling
- (3/17) SOC 17.6% swelling  not significant:  p = .435

Results: Union Status

![Union Status at 12 Months](image)

Fusion Rates:
- Control Group: 100%
- EWB Group: 92.5%

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.

Results: Union Rates

6 Months
- EWB: 38/40 (2 delayed)
- Control: 17/17
  - p = .415
- Tobacco History:
  - nonsmokers: 36/36 fused
  - C&F*: 2/19 delayed
  - not (quite) significant:  p = .106
- BMI: p = .840
- Age at Surgery: p = .286

12 months
- EWB: 37/40
  - Uninterpretable patient was found to be delayed after CT following one year follow-up, treated with bone stimulator
  - Control: 17/17
    - p = .495
  - Tobacco History:
    - nonsmokers: 36/36 fused
    - C&F:3/19 delayed
    - (1 current, 2 former) p = .076
- BMI: p = .945
- Age at Surgery: p = .841
### VAS Scores
- Early-Weightbearing: 4.00 – 1.45
- Standard of Care: 3.29 – 1.74
  
  not significant  \( p = .589 \)

### Time to Full Weightbearing
- EWB (40 patients): 48.83 days avg (sd 12.366)
- SOC (17 patients): 89.18 days avg (sd 13.961)
  
  significant  \( p = .000 \)

### SF-36 Scoring Dimensions

<table>
<thead>
<tr>
<th>Group</th>
<th>6 Weeks</th>
<th>3 Months</th>
<th>6 Months</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Function</td>
<td>( .274 )</td>
<td>( .842 )</td>
<td>( .710 )</td>
<td>( .399 )</td>
</tr>
<tr>
<td>Emotional</td>
<td>( .053 )</td>
<td>( .436 )</td>
<td>( .231 )</td>
<td>( .541 )</td>
</tr>
<tr>
<td>Mental Health (A)</td>
<td>( .103 )</td>
<td>( .407 )</td>
<td>( .296 )</td>
<td>( .264 )</td>
</tr>
<tr>
<td>Physical Function</td>
<td><strong>.003</strong></td>
<td>( .863 )</td>
<td>( .416 )</td>
<td>( .419 )</td>
</tr>
<tr>
<td>Mental Health (B)</td>
<td>( .036 )</td>
<td>( .570 )</td>
<td>( .292 )</td>
<td>( .378 )</td>
</tr>
<tr>
<td>Total</td>
<td><strong>.005</strong></td>
<td>( .725 )</td>
<td>( .332 )</td>
<td>( .432 )</td>
</tr>
</tbody>
</table>

### Research Report: Midfoot Reconstruction for Primary Atraumatic Arthritis: Analysis of Outcomes
- 6 Weeks
  - No significant:  \( p = .087 \)
    - (2/40) EWB
    - (0/17) SOC
  - 3 Months (EWB 5 – SOC 1)
    - not significant:  \( p = .414 \)
    - (5/40) EWB
    - (1/17) SOC
  - 6 Months (EWB 13 – SOC 2)
    - not significant:  \( p = .141 \)
    - (13/40) EWB
    - (2/17) SOC
  - 12 Months (EWB 12 – SOC 2)
    - not significant:  \( p = .134 \)
    - (12/40) EWB
    - (2/17) SOC

### Patient Satisfaction
- Early Weightbearing
  - 35/40 would do the procedure again.
    - 5/40 (no, unsure, not answered)
  - 29/40 were satisfied with the outcome
    - 11/40 (no, unsure, not answered)
  - 34/40 were happy with their assigned WB group
    - 6/40 (no, unsure, not answered)
- Standard of Care
  - 16/17 would do the procedure again.
    - 1/17 (unsure)
  - 15/17 were satisfied with the outcome
Conclusions

- There is no statistically significant difference in fusion rates or VAS pain scores.
- We noted significant differences in the number of days to full-weightbearing, as well as physical function scores at that 6-7 week visit.
- 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.
- One of the difficulties of this study was the popularity of early weightbearing for patients. 9 patients withdrew at the 2 week visit after they were randomized to control.

References:


