**Evidence Table**

Clinical Area: Subtalar arthroereisis for flexible flatfoot  

**Study Type:** Case series.  
**Study Aim:** To determine the functional outcomes and radiographic results of adult patients with flatfeet deformities treated with reconstructive foot and ankle surgery that included a subtalar arthroereisis with MBA sinus tarsi implant.

**Outcomes**  
- **Primary:** Radiographic correction of the deformity.

**Design**
- **Number of subjects:** N=23 patients (28 flatfeet corrected).
- **Description of study population:** The study included adult patients with flexible flatfoot deformities who were surgically treated without hindfoot osteotomy or fusion and with arthroereisis using MBA sinus tarsi implant. Their age ranged from 28 to 74 years with a mean of 51 years, and two thirds were women. A total of 13 feet in 9 adults were congenital flatfeet, and 15 feet in 14 adults were acquired.
- **Inclusion criteria:** Age >18 years and failure of nonoperative measures to relieve the pain and restriction of activity due to the flatfeet deformity.
- **Exclusion criteria:** Infection, rigid flatfoot, radiographic evidence of arthritis of the subtalar and transverse tarsal joints, and previous successful hindfoot fusions.
- **Consecutive patients:** probably. The authors included the patients he treated between February 1998 and April 2003.
- **Intervention:** All patients included in the study underwent surgical reconstruction of the flatfeet under regional or general anesthesia. After correction of the deformity, a 3-cm incision was made in the skin over the sinus tarsi, the underlying tissue and fascia were dissected and the deep fascia incised to allow entry to the sinus tarsi. A guide pin was then inserted across the sinus tarsi, a cannulated sizer placed on the pin and advanced until the tip adjoined the medial margin of the sinus tarsi. The range of motion of the subtalar joint was assessed and more sizers were introduced till the desired motion was achieved. The sizers were removed and a trial implant was placed over the pin, advanced in the sinus tarsi, and positioned with a screw driver. The appropriate position of the implant was assessed by intraoperative radiography. After the position and motion were confirmed, the trial implant was removed and the actual one placed on the guidewire and advanced into position with the screwdriver. When physical and radiologic examinations confirmed that the implant was seated properly, the guide pin was removed and the incision closed. Dressing and plaster splints were then applied. Unless not indicated patients were weight bearing 2 weeks after the procedure.
- **Source of outcome data:** Patients were followed up with radiography, the American Orthopedic Foot and ankle society (AOFAS) Hindfoot scale, and patient assessment questionnaire.
- **Length of follow-up:** This ranged from 7-76 months with a mean of 44 months.  
- **Completeness of follow-up:** 100% for at least one year after surgery.
Validity

- *Is the study type appropriate for the question(s) being asked?* No, a randomized controlled study would be more appropriate.
- *Were patients similar with respect to baseline characteristics?* 46% of the flat feet were congenital and the rest acquired.
- *Was the intervention and other aspects of patient care similar for all patients (or for all patients in a defined subgroup)?* Yes.
- *Was the process of observation likely to affect the outcome?* Not for the objective outcomes.
- *Did an objective observer assess outcomes and were outcome measurements consistent?* The study was conducted by one surgeon in a single center.
- *Was follow-up duration appropriate?* Probably.

Conclusions regarding validity of methods:

The study was a case series with no comparison or control group, and potential selection and observation bias. It however had the advantage of having defined inclusion/exclusion criteria, and outcomes.

Results:

<table>
<thead>
<tr>
<th></th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiographic correction</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>In 3 parameters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AOFAS Hindfoot Scale scores</td>
<td>52</td>
<td>87</td>
<td>&lt;0.00001</td>
</tr>
<tr>
<td>Questionnaire (in scores)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Walking distance*</td>
<td>3.1</td>
<td>3.5</td>
<td>0.076</td>
</tr>
<tr>
<td>Ability to walk**</td>
<td>2.6</td>
<td>1.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Pain†</td>
<td>3.2</td>
<td>1.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Activity level††</td>
<td>2.7</td>
<td>1.6</td>
<td>0.00024</td>
</tr>
<tr>
<td>Footwear limitations‡‡</td>
<td>2.2</td>
<td>1.9</td>
<td>0.0065</td>
</tr>
<tr>
<td>Average overall satisfaction‡‡</td>
<td>8.3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 0= bedridden, 1= bed to chair, 2= household, 3= community, 4= long distance, and 5= active athlete
** 0=no difficulty, 1= some difficulty, 2= extreme difficulty
†1=no pain, 2=mild pain, 3=moderate pain, 4=severe pain.
†† 1=no limitation, 2=limited recreational/normal daily, 3=limited recreational/daily, 4=severe limitations
‡=fashionable, 2=comfortable, 3=modified shoes or braces
‡‡78% said they would have the surgery again, 18% would not, and 4% were not sure.

Complications

- MBA removed due to postoperative pain 11*/28 (30%)
- Chronic postoperative pain 11/26** (42%)

* 9 removed ≥8 months after the procedure, 1 at 7 months and 1 at 5 month
  Three patients (3 feet) had persistent sinus tarsi pain after the implant was removed.
** Feet without subtalar joint pathology
Authors’ Conclusions:

The authors concluded that reconstructive foot surgery that included a subtalar arthroereisis with the MBA sinus tarsi implant resulted in favorable clinical outcomes and patient satisfaction.

Reviewer’s Conclusions:

The study was a small case series with no control or comparison group, and potential selection and observation bias. It had defined inclusion criteria and outcomes, and a reasonable follow-up duration. Overall the results show improvement in the correction of the flatfeet deformity as observed radiographically, and in the pain experienced by the patients and their activity level, however observed improvement in walking distance was not significant. The procedure was associated with a high complication rate where 42% had chronic postoperative pain and 30% had their implant removed because of the pain.