Abstract: Talonavicular (TN) arthrodeses for TN arthritis have a high rate of nonunions for an essential hindfoot joint. In this case series, 12 patients underwent an isolated TN arthrodesis using a novel implant (IO FIx) by a single surgeon with a minimum 1-year follow-up (30.1 ± 14.7 months; mean ± SD). All patients (62 ± 12 years) underwent an aggressive rehabilitation protocol given the strength and compression of the implant. There were no nonunions, nor were there any patients lost to follow-up. Time to radiographic union was 9.6 ± 1.4 weeks. The Visual Analog Scale pain level decreased from 7.3 ± 0.9 preoperatively to 2.1 ± 0.7 postoperatively (P < .001). The IO FIx implant can potentially improve TN arthrodesis fusion rates and surgical outcomes.

Levels of Evidence: Therapeutic, Level IV: Case series

Keywords: talonavicular arthrodesis; fusion; nonunion; visual analog scale; SF-12

Case Series Using a Novel Implant and Accelerated Rehabilitation for Patients Undergoing an Isolated Talonavicular Arthrodesis

Gait analyses after TN arthrodesis show that hindfoot inversion is reduced by 70% and the time of heel off during the stance phase of gait increases from 45% to 83%. TN arthrodeses have favorable outcomes; however, nonunions, reported at rates between 5% and 40%, continue to be a significant issue. Fixation methods include compression screw fixation, staple fixation, locking and nonlocking plate fixation, as well as combined fixation of screws, staples, and/or plates. The higher the TN joint compression afforded by the fixation increases the likelihood of complete union. Screw fixation has the inherent benefit of generating compression across the fusion site, but is...
limited by the geometry of the TN joint and the screw trajectory angle. Jarrell et al examined the relative stiffness and strength of screw fixation versus screw and plate fixation in TN fusions.11 Screw fixation was found to decrease the medial midfoot contact area, but none of the other parameters differed between the multiple fixation constructs. Recently in a cadaveric study, Granata et al found that a dorsal locked compression plate with 1 retrograde screw was more effective at limiting the motion across the TN joint compared with the traditional construct of 2 retrograde screws.12 A complication of screw fixation is iatrogenic fracture of the medial navicular caused by a thin bone bridge. Additionally, using multiple devices for TN joint fixation may require accessory incisions, increased cost, or stretching of the singular incision, which may lead to wound complications.

The IO FIX fixation device (Extremity Medical, Parsippany, NJ), which is the primary method of fixation in this study, has a few notable advantages over traditional screw fixation. The IO FIX is composed of a post that is implanted into the navicular body to provide a secure seating surface for the head of the compression screw, which enables screw trajectories that may not be possible or are too risky with standard compression screws (Figure 1). Additionally, the device allows either fixed (via a Morse taper) or variable angle screws to be inserted depending on the surgeon preference. Last, the IO FIX minimizes soft tissue irritation by placing the edge of the post flush with the navicular surface reducing any metal prominence in an already prominent area of the foot. In this case series, we investigate the postoperative bony union and functional outcomes of 12 consecutive patients who underwent TN arthrodesis with the IO FIX device and an accelerated rehabilitation (rehab) program.

Methods and Materials

Between 2010 and 2013, 12 patients (7 females and 5 males) aged 62 ± 12 (mean ± SD) years underwent TN arthrodesis by a single surgeon (Table 1). Surgical indications comprised both posttraumatic TN arthritis (4 patients), rheumatoid arthritis (3 patients), and idiopathic TN arthritis (5 patients). Two patients reported smoking less than a pack a day, and 3 of the patients had type 2 diabetes mellitus. One patient had undergone systemic chemotherapy for cancer, which was completed over 2 years prior to TN arthrodesis. No patients were lost to follow-up, and all were evaluated at a minimum of 1 year after the surgery (30.1 ± 14.7 months). Patients were evaluated with radiographs, 10-point Visual Analog Scale (VAS) pain scale, and the Short-Form-12 (SF-12) at the preoperative visit and at a minimum of 12 months or most recent follow-up. Bony union was defined as both bridging bone on postoperative radiographs and clinical relief of preoperative pain. Computed topography (CT) scans were not used to assess union. Patients were asked to state when they thought they were placing “a fair amount of weight” on the affected leg. All patients gave informed consent to having their clinical course studied.

Operative Technique

Patients were placed in a supine position with a thigh tourniquet inflated to 250 mm Hg. A dorsal medial incision was created between the tibialis anterior and posterior tibialis tendon with exposure and lateral retraction of the tibialis anterior tendon. In all patients a single incision was utilized and no supplemental dorsal or lateral incision was used. Regularly, a Hintermann distractor or lamina spreader was used to obtain better access to the lateral TN joint. Both sides of the TN joint were visualized and the cartilage was removed using curettes, osteotomes, and a high-speed burr (under constant irrigation to prevent thermal necrosis). Also, a 2.0-mm solid drill was used to make multiple perforations on both sides of the TN joint. The reamings from the drillings were used to pack the joint to augment healing and the drill holes served to increase the surface area of the bone prepared. Care was taken to preserve the natural contour of the TN joint during the preparation for arthrodesis.

Initially, a 1.6-mm guide pin was placed into the navicular body for the post of the IO FIX. It is important to think “2 steps ahead” and use the alignment instrument to determine the
proposed position of the lag screw into the talus during this step (Figure 2). The post is then placed into the navicular after measuring, drilling, and reaming to allow a good fit into bone. In 9 patients, an 8.0-mm post was utilized to allow placement of a 5-mm lag screw. In 3 patients, who had a lower body mass index, a 6.6-mm post was placed, which accompanies a 4-mm lag screw. A 1.6-mm guide wire is then placed through the eyelet in the post and into the talus. Fluoroscopy was routinely used to make sure the position of the wire was outside of the subtalar joint and within the talar neck and body. A variable or fixed angle screw was then placed through the eyelet of the post creating compression across the TN joint along the line of the post. In terms of screw tightness, a “2 finger” technique is utilized to minimize iatrogenic navicular fracture. One case was supplemented with a percutaneous 0.062 in. Kirschner-wire (K-wire) to help with severely osteoporotic bone in a 72-year-old patient. The wound was closed in layers and no drains were used. A short leg, well-padded splint was applied and the patient was made non–weight bearing to help with swelling and wound healing (Figure 3).

**Rehab Protocol**

After the senior author’s initial success with the IO FiX device in achieving union for TN arthrodesis, a more conservative rehab protocol was accelerated based on the patient’s postoperative pain. Historically, patients after a TN arthrodesis were placed in a splint for a week postoperatively, then a non-weight bearing short leg cast for 4 to 6 weeks, and then a controlled ankle motion (CAM) boot for a remaining 4 to 6 weeks. After noticing that the short leg casts were severely degraded and worn down from weight bearing in many patients between 4 and 6 weeks postoperatively, the authors decided to change the rehab protocol. In the accelerated protocol utilized in this series, patients were placed in a CAM boot at 1 week postoperatively, if swelling and wound issues allowed. Otherwise, the CAM boot would be placed at 2 weeks postoperatively and a new splint would be applied at 1 week postoperatively and patients were told they could be weight bearing at tolerated if the pain would allow it, but only when in the CAM boot. Crutches and walker were used based on the patients’ desires ad lib.

The pre- and postoperative patient scores were compared using a t-test calculator to determine statistical significance. An α level of $P < .05$ indicated a statistically significant difference. Data are reported as mean ± standard deviation (SD).


**Table 2.**
The IO FIx Talonavicular Arthrodesis With an Accelerated Rehabilitation Protocol Significantly Decreased Patients’ Pain (Measured by Visual Analog Scale [VAS] Pain Scale) as Well as Improved the Short-Form (SF-12) Physical Component Postoperatively ($P < .001$). There Was No Significant Change in the SF-12 Mental Component Postoperatively ($P > .05$).a.

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS pain</td>
<td>7.3 ± 0.9</td>
<td>2.1 ± 0.7</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SF-12 Physical</td>
<td>27.9 ± 4.2</td>
<td>42.2 ± 3.5</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SF-12 Mental</td>
<td>50.8 ± 6.9</td>
<td>54.4 ± 3.8</td>
<td>.103</td>
</tr>
</tbody>
</table>

*aAn $\alpha$ level of $P < .05$ indicated a statistically significant difference. Data are reported as mean ± standard deviation.*

**Results**

The VAS pain level decreased from 7.3 ± 0.9 preoperatively to 2.1 ± 0.7 postoperatively ($P < .001$; Table 2). The SF-12 physical component improved from 27.9 ± 4.2 preoperatively to 42.2 ± 3.5 postoperatively ($P < .001$), while the SF-12 mental component did not change from 50.8 ± 6.9 preoperatively to 54.4 ± 3.8 postoperatively ($P > .05$).

Radiographically, there were no nonunions that occurred in the 12 patients. Radiographic union occurred at 9.6 ± 0.4 weeks (Table 2). No patients presented with enough pain to suggest nonunion-like symptoms. No patients required hardware removal or complained of prominent hardware. Three patients had a superficial wound infection that resolved with oral antibiotics for 10 days. One of these patients was a smoker and none of them were diabetic. No patients had a deep infection that required operative intervention. There were no intraoperative fractures of the navicular or talus. None of the 12 patients were lost to follow-up.

It is difficult to quantify the amount of weight bearing that occurred in the postoperative phase, but all patients used the CAM boot by 2 weeks postoperatively. Subjectively, on average, patients stated that they were placing weight on the affected side by 3.5 weeks (range 2.2-5.5 weeks). The one patient, who had the supplemental 0.062 in. K-wire placed, underwent a removal of the wire in the office setting at 4 weeks and delayed weight bearing until 6 to 7 weeks postoperatively.

**Discussion**

Use of a novel fixation device (IO Fix) for TN arthrodesis with an accelerated rehab protocol by a single surgeon significantly decreased patients’ pain (VAS) and improved their physical functional outcomes (SF-12 physical component) in a small case series ($P < .001$). These findings suggest that the IO Fix device has the potential to improve patient outcomes with a quicker return to weight bearing. We believe this implant has the possibility to improve and optimize TN arthrodesis fixation and improve historically unsatisfactory fusion rates.

All 12 of the TN arthrodesis went on to osseous union without the need for a revision procedure. Post-TN arthrodesis nonunion has been reported by Ljung et al9 in 7 of 19 feet (37%) for rheumatoid arthritis, by Chen et al7 in 1 of 16 feet for TN arthritis, by Harper and Tisdal10 in 1 of 27 feet (4%) for acquired flatfoot, and by Lombardi et al11 in 1 of 10 feet (10%) for posterior tibial tendon insufficiency. Recently, Barkatali and Sundar1 reported zero nonunions in a series of 7 TN arthrodesis for TN osteoarthritis utilizing three 5.5-mm screws.

The novel fixation device for TN arthrodesis did not significantly change the SF-12 mental component. The minimum follow-up of 1 year (30.1 ± 14.7 months) may not have been adequate to document a change in the mental component. Additionally, the mental component of the SF-12 can be affected by other comorbidities (mental health issues, social situation, etc).

Strengths of the study include the fact that no patients were lost to follow-up. Also, validated outcome measures (SF-12 and VAS scale) were used to study patient outcome. Furthermore, a single surgeon performed all of the operations to limit surgical variation.

Limitations of this study involve the retrospective design and the small number of patients. Additionally, some of the data were reported subjectively by the patients (time in CAM boot and time to weight bearing) and were subject to selection bias. Also, we utilized plain radiographs to determine osseous union without confirmation by CT scan. We chose to avoid CT scans in order to avoid increased radiation exposure to the patients as well as to minimize cost.

Furthermore, a definitive learning curve exists with the implantation of the IO Fix device, and this study did not look at the initial patients that the device was used in, but in those after it had been used by the primary surgeon for a few years. In this series, no iatrogenic fractures of the navicular occurred. However, early in the surgeon’s experience with the implant, we did experience this complication from overtightening a fixed angled Morse taper screw in an osteoporotic patient.

As we move into a new age of medicine, implant cost is becoming
more of a concern. Although this implant is more expensive than a typical cannulated screw, it is comparable in price to a locking plate, which is commonly used for a TN fusion. It is important to be mindful of implant costs when making decisions on what implants to use for surgical fixation. However, earlier time to weight bearing, satisfactory outcomes, and possibly an earlier return to work for the patient should be factored into clinical decision making along with the implant cost.

**Conclusion**

In this series of 12 patients, we show that the IO FiX device can be used safely with good clinical efficacy and surgical outcomes. The IO FiX device can potentially improve TN arthrodesis fusion rates; however, larger double-blinded studies are needed for confirmation of the findings presented in this current study.

**Authors’ Note**

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**References**