**Abstract:** Background. Tibiototalocalcaneal (TTC) arthrodesis is a common treatment option for hindfoot arthritis and deformity. Loss of compression over time with statically locked nails may contribute to nonunion. A novel retrograde intramedullary nail with an internal pseudoelastic component has recently been used to provide sustained dynamic compression (SDC). The purpose of this study was to compare fusion rates and time to union between the SDC and nondynamized (ND) nails. Methods. All patients who underwent TTC arthrodesis with an intramedullary nail at a single institution from 2013 to 2017 and who had at least 1 year of follow-up were included in this study. Baseline patient and operative characteristics were collected and compared between the sustained SDC and ND nail groups. The rate of successful fusion, time to union, and complications were compared between the groups. Results. The SDC cohort had a significantly faster time to union by 3.9 months ($P = .049$). The SDC cohort had a higher fusion rate (78.0%) compared with the ND nail cohort (75.0%), although this was not statistically significant ($P = .75$). The SDC nail was used significantly ($P < .05$) more often in patients with known risk factors for nonunion, including female sex, smoking, revision surgery, prior trauma, and patients requiring 3D cage implants for significant bone loss. There were no differences between the groups in terms of complications. Conclusion. The SDC nail has been shown to achieve successful arthrodesis in a population at high risk for nonunion, using less hardware, and at a faster rate than ND nails.

**Level of Evidence:** Level III: Retrospective, comparative study

**Keywords:** tibiotalocalcaneal arthrodesis; pseudoelastic intramedullary nail; hindfoot arthritis; hindfoot deformity; nonunion
Introduction

Tibiotalocalcaneal (TTC) arthrodesis is a salvage procedure reserved for patients with severe hindfoot deformity, Charcot arthropathy, talar osteonecrosis, posttraumatic arthritis, and failed ankle arthroplasty. The goal is to obtain a painless, stable plantigrade foot for effective ambulation. Successful fusion across the tibiotalar and subtalar joint depends on primary bone healing because of the absence of surrounding periosteum. As such, TTC fusion using intramedullary nails has been successful because of the ability to provide a load-sharing, rigid construct under compression preventing motion across the fusion sites.

The results of TTC arthrodesis are mixed, likely because of multiple variables in play, including primary bone versus femoral head allograft, multiple patient risk factors, nail designs, biologic adjuncts, and the use of additional fixation. In a high-risk patient population requiring femoral head allograft for large bone defects, Jeng et al found an overall nonunion rate of 50% and a nonunion rate of 100% among diabetics when performing TTC arthrodesis with nondynamized (ND) nails. A systematic review by Jehan et al documented a fusion rate of 86.7% with a greater than 50% complication rate. A recent multicenter study revealed an overall fusion rate of 84%, with a total complication rate of 24% in 38 patients using either static or dynamically locked intramedullary nails. Clearly, improvements can be made in union and complication rates with TTC arthrodeses.

The majority of retrograde intramedullary nails for TTC arthrodesis involve intraoperative, one-time compression, with application of locking screws to maintain compression. Unfortunately, loss of compression with internal compression nails has been demonstrated on “day zero,” and further compression is lost, with inevitable bone resorption. One study evaluating compression forces of various internal and external fixation devices found a 90% reduction in load through statically locked retrograde intramedullary nails with just 1 mm of bone resorption, demonstrating their inability to provide sustained compression with any considerable amount of bone resorption.

The DynaNail (MedShape, Inc, Atlanta, GA) is an intramedullary nail with an internal Nitinol element that when stretched across the tibiotalar and subtalar joints can transform or compress back to its original length in the setting of bone resorption. This allows sustained, dynamic compression across the fusion sites in response to bone resorption and remodeling during the fusion process. In addition, the implant allows immediate dynamization, which results in more load being transferred to the bone and less stress shielding than with other statically locked nails. These properties have the potential to increase fusion rates and improve time to union, especially in the high-risk cohort of patients who undergo TTC arthrodesis. Early case reports and series have shown promising results, with demonstration of sustained compression on serial radiographs and successful arthrodesis in patients at high risk of nonunion.

To our knowledge, there has not been any study evaluating fusion and complication rates following TTC fusion using different designs of intramedullary nails. The purpose of this study was to compare fusion rates and times as well as complication rates of TTC arthrodesis procedures at a tertiary care center using the DynaNail versus other statically locked intramedullary nails. We hypothesized that the sustained dynamic compression (SDC) nail will obtain higher fusion rates in less time in patients with similar comorbidity profiles than other statically locked intramedullary nails.

Methods

Study Design

This was a retrospective, comparative cohort study of all patients undergoing TTC fusion with intramedullary nails between November 2013 and July 2017 at a single, academic institution. All patients undergoing TTC fusion with intramedullary nails were considered eligible for inclusion in this study. The decision to undergo TTC versus alternative hindfoot surgery was made jointly by the treating surgeon and patient. The choice of implant was at the discretion of the attending surgeon.

There were 5 attending surgeons who each used multiple different implants. Patients were grouped based on the choice of implant. Patients who received the DynaNail were placed in the SDC group. All other nails were statically locked and, therefore, placed in the ND group. The purpose of the study was to evaluate the impact of patient and operative factors on rates of radiographic fusion, with particular focus on intramedullary nail design. This study was designed and reported in accordance with the STROBE statement on strengthening the reporting of observational studies.

Variables and Data Sources

Age at index operation, sex, race, perioperative body mass index (BMI), American Society of Anesthesiologists score, comorbidities, current smoking, ankle history, preoperative deformity, additional fixation, custom 3D cage, biological adjuncts, length of stay, and duration of follow-up were recorded through review of records. The study’s primary outcomes of presence versus absence of radiographic union at latest clinical follow-up and time to radiographic union were evaluated using previously described methods based on X-ray or computed tomography (CT) results. Successful arthrodesis was defined by consensus between 2 foot and ankle fellowship-trained investigators after assessing radiographs and CT scans, when available. Successful radiographic fusion required the presence of bridging bone, lack of radiographic signs of nonunion, and maintenance of fixation across the operative site as previously defined. CT scans were obtained at the treating surgeon’s discretion to determine fusion, and successful
arthrodesis on CT scan was defined as at least 50% osseous bridging as defined by Glazebrook et al. Secondary outcomes of surgical site infection, wound healing complication, hardware failure, and revision were also recorded through review of records. In the case of revision or bilateral TTC nails, only patients’ first TTC nail on each extremity performed at this institution were included. Follow-up was measured from the time of the index operation.

Specific Elixhauser and Charlson-Deyo comorbidities were recorded using previously established diagnosis code sets that had been listed in patient records up to the date of surgery. These indices have been used to predict length of stay, hospital charges, in-hospital death, and 1-year mortality. Renal disease, diabetes mellitus, rheumatic disease, peripheral vascular disease, and chronic obstructive pulmonary disease were displayed because of their high prevalence and potential association with union rates after arthrodesis. A cumulative Charlson comorbidity index was also calculated in a manner previously described.

Bias and Missing Data
Patients with less than 1 year of clinical follow-up were excluded to allow for adequate time for union. Of 149 potential patients who underwent TTC nail during the study timeframe, 63 were excluded because of inadequate follow-up. This could lead to selection bias if baseline and operative factors or outcomes were considerably different between patients with and without 1 year of clinical follow-up.

Statistical Analysis
Baseline data were displayed as means with SD for continuous data or proportions and percentages for categorical data. Patient and operative characteristics were assessed for imbalance between patients with and without DynaNail implantation using Student t-tests or χ² analyses. Each factor was also assessed for association with the primary study outcome of radiographic union in a similar manner. Then, a multivariable logistic regression model was constructed that incorporated presence or absence of DynaNail while also incorporating all patient and operative factors that were either significantly imbalanced between the 2 cohorts or associated with the study outcome in univariate analysis. Similar models were created to evaluate time to union in the cohort of patients that ultimately achieved radiographic union during follow-up. Factors with P values less than .05 in final multivariable outcome models were considered significantly associated with outcomes. Odds ratios and 95% CIs were displayed. JMP Pro Version 13.0.0 (Statistical Analysis Software, Cary, NC) was used for analyses. Secondary outcomes were assessed in univariate analysis rather than multivariable regression because of the relative rarity of these events.

Funding
There were no relevant sources of funding for the investigators in this study.

Results
In total, there were 86 patients included in this study. There were 50 patients in the SDC group and 36 patients in the ND group. The mean follow-up for the SDC group was 21 months, and the mean follow-up for the ND group was 23 months. There was no statistical difference between the follow-up durations for the groups. The ND group was composed of the following TTC nails: A3 Fusion Nail (Stryker, Kalamazoo, MI), Panta Nail (Integra LifeSciences, Plainsboro, NJ), Trigen (Smith & Nephew Inc, Memphis, TN), Phoenix (Zimmer Biomet, Warsaw, IN), Valor (Wright Medical Group, Memphis, TN), and ACN (Orthofix, Lewisville, TX). Patients in the SDC group versus ND group had similar preoperative profiles with respect to comorbidities (Table 1), with the exception of a higher prevalence of renal disease in patients in the ND group. Alternatively, patients in the SDC group were significantly more likely to be female, be current smokers, or have had prior ankle surgery or prior trauma to the ankle. They also had a significantly lower rate of placement of additional fixation, such as plates and/or screws, and significantly higher rates of 3D cage implantation for bulk bone defects. There were no significant differences in usage rates of autograft, allograft, or total number of biologics.

Patients in the SDC group had a slightly higher union rate, though this difference was not statistically significant (Table 2). Among patients who ultimately achieved union, time to union was significantly shorter in the SDC group in univariate analysis (P = .049).

A multivariable outcome model was constructed that incorporated all factors significantly imbalanced between cohorts and associated with radiographic union in univariate analysis (Table 3). Increased BMI was associated with significantly greater odds of union. There were no significant differences in odds of union between the SDC and ND groups.

A similar set of multivariable outcome models were constructed for the outcomes of time to union that included adjustment for factors significantly imbalanced between the cohorts or associated with outcomes in univariate analysis. The SDC group had odds for faster union than the ND group by 1.4 months, although this was not statistically significant (P = .58).

Secondary complications such as surgical site infection, wound healing complication, hardware failure or bone fracture, and revision were relatively rare as shown in Table 5. There were no significant differences between groups in secondary outcomes. However, superficial and deep wound infections were slightly more common in the SDC group, though patients in this group were more likely to have prior foot and ankle infection (24%) as patients in the ND group (8.3%). Wound healing complications were more common in patients in the ND group. Hardware failure rates were similar between groups. Additional revision surgery was more common in the ND group.

There were no significant differences in the use of autograft, allograft, or total...
number of biologics between the SDC and ND groups. Allograft supplementation was used in more than 90% of cases in both groups. Autograft was used in 26% of cases in the SDC group and 11% of cases in the ND group, although this difference was not statistically significant. The total number of biologics, defined as the total number
Discussion

The purpose of this study was to evaluate TTC fusion rates and times between a novel pseudoelastic intramedullary nail (DynaNail, MedShape, Inc, Atlanta, GA) and conventional ND nails as well as to compare risk factors for nonunion between both cohorts. We hypothesized that the fusion rate would be higher and time to union would be faster with the SDC nail as compared with other ND TTC nails because of its ability to provide SDC with the pseudoelastic properties of its internal Nitinol component. Our results indicated that the SDC nail had a higher, although not statistically significant, fusion rate and a significantly faster time to union than other TTC nails despite being used in a population with significantly higher risk factors for nonunion.

Previous studies using standard retrograde intramedullary nails (IMN) with intraoperative compression and proximal locking screws reported fusion rates of 53% to 100%.2,6,10,26-30 There are many different factors that may contribute to the development of nonunion. Patient factors such as diabetes and smoking are known risk factors for nonunion.29,31 The use of femoral head allograft secondary to bone defects is also associated with a decreased rate of fusion.9,32 However, surgical technique also plays a role because obtaining adequate compression, maintaining proper ankle alignment, and using a stable and rigid construct all contribute to successful arthrodesis.

Studies have shown that 90% of compression is lost over time with just 1 mm of bony resorption with statically locked IMN.33 This is likely a contributing factor to nonunion in patients undergoing TTC fusion with a static IMN. Dynamization of the nail can be performed, but this requires invasive manipulation of the proximal
interlocking screw. Ring fixators remain an option to provide sustained compression; however, they are cumbersome, not patient-friendly, and have their own complications such as pin-site infections. Thus, the rationale behind IMNs with pseudoelastic alloys is to provide sustained compression and to optimize primary bone healing with the goal of increasing union rates and decreasing time to union. Previous studies have shown that the internal nitinol element within the novel SDC nail does migrate proximally over time an average of 5.58 mm, similar to the 6 mm of recovery distance shown in the laboratory setting.\textsuperscript{14,34} This likely indicates that there is continuous compression at the arthrodesis sites in response to bone resorption. However, no studies to date have reported on union rates with SDC nails compared with traditional TTC nails. We report a slightly higher, although not statistically significant, rate of tibiotalar and subtalar arthrodesis with the SDC nail as compared with traditional nails at 78.0\% versus 75.0\%, respectively (\(P = .75\)). However, there were several preoperative and operative factors significantly associated with the SDC nail group that would portend a higher risk of nonunion. These included a higher proportion of women, a higher rate of smokers, a higher rate of prior ankle surgery, a higher rate of 3D cage implantation for bulk bone defects, and a lower rate of additional hardware use, including plates and screws in the SDC nail group compared with the traditional nail group. In addition, we report that the time to union was significantly shorter in the SDC nail group compared with the traditional nail group by 3.9 months (\(P = .049\)). There were no differences in the rates of complications between the SDC nail group and traditional nail groups.

Limitations to our study include its retrospective nature and significant differences in patient and operative variables between the 2 cohorts. Despite being retrospective, the SDC cohort actually had higher rates of patient preoperative risk factors for nonunion. However, controlling for all preoperative and operative variables between cohorts would allow a true comparison of fusion rates of SDC versus ND IMNs. This could be achieved with a randomized controlled trial. Furthermore, larger sample sizes may show significant differences in union rate. Given that the DynaNail is a relatively new device to market, these are early results, and future studies with more patients may show different results.

In conclusion, the novel SDC nail is a viable option for TTC arthrodesis and has proven to achieve an acceptable fusion rate in a patient population at high risk for nonunion. At intermediate follow-up, it has shown a fusion rate slightly higher than that for traditional IMNs and a significantly faster time to union despite its use in patients at higher risk of nonunion. The SDC nail is a promising new technology, and as the device is used in more patients, future studies will be able to better define the indications, cost-effectiveness, and long-term outcomes.

### Table 5.

Secondary Study Outcomes for Patients With and Without DynaNail Implantation.

<table>
<thead>
<tr>
<th>Patient and Operative Factors</th>
<th>Nondynamized</th>
<th>Sustained Dynamic Compression</th>
<th>(P) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep infection</td>
<td>1/36 (2.8%)</td>
<td>4/50 (8%)</td>
<td>.31</td>
</tr>
<tr>
<td>Superficial infection</td>
<td>0/36 (0%)</td>
<td>1/50 (2%)</td>
<td>.39</td>
</tr>
<tr>
<td>Wound healing complication</td>
<td>3/36 (8.3%)</td>
<td>1/50 (2%)</td>
<td>.169</td>
</tr>
<tr>
<td>Hardware breakage</td>
<td>1/36 (2.8%)</td>
<td>1/50 (2%)</td>
<td>.81</td>
</tr>
<tr>
<td>Bone fracture</td>
<td>1/36 (2.8%)</td>
<td>3/50 (6%)</td>
<td>.48</td>
</tr>
<tr>
<td>Revision</td>
<td>4/36 (11.1%)</td>
<td>2/50 (4%)</td>
<td>.2</td>
</tr>
</tbody>
</table>
Appendix A

Appendix Table A.1.
Frequency of Biologic Adjunct Use.

<table>
<thead>
<tr>
<th>Biologic</th>
<th>Allograft or Autograft</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allofuse</td>
<td>Allograft</td>
<td>1/86 (1.2%)</td>
</tr>
<tr>
<td>Augment</td>
<td>Allograft</td>
<td>1/86 (1.2%)</td>
</tr>
<tr>
<td>BMP</td>
<td>Allograft</td>
<td>1/86 (1.2%)</td>
</tr>
<tr>
<td>Bone graft paste</td>
<td>Allograft</td>
<td>1/86 (1.2%)</td>
</tr>
<tr>
<td>DBM</td>
<td>Allograft</td>
<td>2/86 (2.3%)</td>
</tr>
<tr>
<td>Femoral head allograft</td>
<td>Allograft</td>
<td>26/86 (30.2%)</td>
</tr>
<tr>
<td>Frozen cancellous allograft</td>
<td>Allograft</td>
<td>19/86 (22.1%)</td>
</tr>
<tr>
<td>Infuse</td>
<td>Allograft</td>
<td>32/86 (37.2%)</td>
</tr>
<tr>
<td>MAP3</td>
<td>Allograft</td>
<td>40/86 (46.5%)</td>
</tr>
<tr>
<td>Optecure</td>
<td>Allograft</td>
<td>1/86 (1.2%)</td>
</tr>
<tr>
<td>Osteoamp</td>
<td>Allograft</td>
<td>1/86 (1.2%)</td>
</tr>
<tr>
<td>Progenix</td>
<td>Allograft</td>
<td>1/86 (1.2%)</td>
</tr>
<tr>
<td>Trinity</td>
<td>Allograft</td>
<td>11/86 (12.8%)</td>
</tr>
<tr>
<td>Vitoss</td>
<td>Allograft</td>
<td>1/86 (1.2%)</td>
</tr>
<tr>
<td>BMAC</td>
<td>Autograft</td>
<td>15/86 (17.4%)</td>
</tr>
<tr>
<td>Morselized fibula autograft</td>
<td>Autograft</td>
<td>2/86 (2.3%)</td>
</tr>
<tr>
<td>Reamer-irrigator-aspirator reamings</td>
<td>Autograft</td>
<td>1/86 (1.2%)</td>
</tr>
</tbody>
</table>

Declaration of Conflicting Interests
The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding
The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethical Approval
Not applicable, because this article does not contain any studies with human or animal subjects.

Informed Consent
Not applicable, because this article does not contain any studies with human or animal subjects.

Trial Registration
Not applicable, because this article does not contain any clinical trials.

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