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Original Research

Long-Term Outcomes of Corrective Osteotomies Using Porous Titanium Wedges for Flexible Flatfoot Deformity Correction

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A B S T R A C T

Common corrective osteotomies used in flexible flatfoot deformity reconstruction include Cotton and Evans osteotomies, which require structural graft to maintain correction. Auto-, allo-, and xenografts are associated with a number of limitations, including disease transmission, rejection, donor site morbidity, technical challenges related to graft fashioning, and graft resorption. Porous titanium is a synthetic substance designed to address these flaws; however, few studies have been reported on the efficacy, safety, and long-term outcomes. A multicenter retrospective cohort of 63 consecutive preconfigured porous titanium wedges (PTWs) used in flexible flatfoot reconstructions from June 1, 2009 to June 30, 2015 was evaluated. The primary outcome measure was the pre- to postdeformity correction efficacy. The secondary outcomes included maintenance of correction at a minimum follow-up point of 12 months, complications, graft incorporation, and graft safety profile. Multivariate linear regression found a statistically significant improvement in all radiographic parameters from preoperatively to the final weightbearing radiographs (calcaneocuboid 18.850 ± 4.020 SE, $p < .0001$; Kite's, 7.810 ± 3.660 SE, $p = .04$; Meary's 13.910 ± 3.100 SE, $p = .0001$; calcaneal inclination, 5.550 ± 2.140 SE, $p = .015$). When restricted to patients with >4 years of follow-up data, maintenance of correction appeared robust in all 4 measurements, demonstrating a lack of bone or graft resorption. No patients were lost to follow-up, no major complications or implant explantation or migration occurred, and all implants were incorporated. Minor complications included hardware pain from plates over grafts (8%), 1 case of scar neuritis, and a 5% table incidence of transfer pain associated with the PTWs. These results support the use of PTWs for safety and degree and maintenance of correction in flatfoot reconstruction.

Reconstructive procedures, as opposed to fusions, for correction of lower extremity deformities have become increasingly popular during the past couple of decades. With respect to flexible flatfoot deformity, 2 commonly used procedures are the Evans lateral column lengthening osteotomy and the Cotton opening wedge medial cuneiform osteotomy (1,2). Each of these osteotomies use interpositional graft material for maintenance of deformity correction. Successful deformity correction using correctional wedge grafting can be achieved with structural autograft, allograft, or xenograft and synthetic substances to facilitate and maintain the correction of various procedures. Each of these different modalities have distinct characteristics with advantages and disadvantages (3).

Autografts, most commonly harvested from the iliac crest, have the advantages of excellent osteoinductive and osteoconductive properties; however, it brings with it the potential complications associated with donor site morbidity and persistent pain (4,5). Allografts and

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xenografts provide a solution to the risk of harvesting an autograft; however, their drawbacks include the risk of disease transmission, nonuniform preservation/processing procedures, graft rejection, and a potential increase in nonunion rates (6). Allografts, xenografts, and autografts all have the disadvantage of increased operative time for harvesting, patient positioning, and shaping and the potential for graft resorption.

An ideal grafting material would be one that eliminates complications from harvesting, is inert (eliminating the potential for transmission for disease), has the ability to maintain long-term correction, and has good osteoconductive properties to ensure graft incorporation (5). Porous titanium wedges (PTWs) offer such a potential solution to some of the disadvantages associated with traditional allografts, xenografts, and autografts. Porous titanium for orthopedic-related use has its antecedents in porous tantalum, which has an established record of success in hip and knee arthroplasty (6,7,8).

Porous titanium is a viable substitute to traditional graft materials for many reasons. First, it is inert and, therefore, cannot serve as a vector for transmission of donor-mediated infection (6). Porous titanium's porosity and elastic modulus are similar to that of subchondral bone, these physical properties support its utility as a substrate for maintenance of deformity correction (6). Its titanium structure renders it immune to the osseous resorption associated with traditional grafts and also makes it considerably stronger than normal bone (9). A review of the scientific properties associated with porous titanium seem to make it an acceptable alternative to traditional grafting materials; however, the data on the subject have yet to demonstrate its value in foot and ankle reconstruction.

The aims of the present study were to evaluate the effectiveness, versatility, and safety profile of PTWs in the surgical correction of flexible flatfoot deformities. We hypothesized that PTWs would achieve statistically significant improved alignment after flexible flatfoot reconstruction at a minimum follow-up period of 12 months. We further assessed whether this alignment was maintained over time, the extent of graft incorporation, and whether any complications were associated with the use of PTWs.

Patients and Methods

A multicenter retrospective cohort study was undertaken to evaluate the outcomes of consecutive patients who had undergone surgical correction of flexible flatfoot deformities using PTWs from June 1, 2009 through June 30, 2015. Our institutional review board reviewed and approved the study, which was conducted in accordance with good clinical practices. The study included patients from the practices of 4 attending surgeons (E.C., J.C., L.J., P.B.) at 2 institutions. Because of the consecutive nature of enrollment, all the patients who had undergone flexible flatfoot reconstruction using PTWs within the study period were included in the study. The exclusion criteria were <1 year of follow-up and PTWs used for purposes other than flexible flatfoot reconstruction. Owing to the reality that flatfoot reconstruction requires the use of many procedures unique to each patient and deformity, the use of concomitant procedures was not an exclusion criterion, and these procedures were reported. Application of these criteria yielded a study population of 63 wedges in 43 feet (34 patients) eligible to undergo clinical, radiographic, and statistical analysis.

Based on the proposed pre-post study design after surgical intervention, a post hoc power calculation was performed for the 40 patients with complete data. To determine the power to detect a change in the preoperative and postoperative angles for the cuboid abduction angle, Meary's angle, Kite's angle, and calcaneal inclination angle, 4 separate power calculations were estimated. The data indicated that the difference in the response of each variable's matched, pre–post, pair was normally distributed with a corresponding standard deviation (SD) of 8.41°, 8.32°, 7.15°, and 4.88°. If the corresponding true difference in the mean response of matched pairs was 14.45°, 10.87°, 8.92°, and 5.55°, we would be able to reject the null hypothesis that the response difference was 0 with a probability (power) of >0.90. The type I error probability associated with this test of this null hypothesis was 0.05.

The surgical technique was consistent across all 4 participating surgeons. Once the surgical dissection for each of the Evans and Cotton osteotomies was complete, preparation of the graft site was performed. Regarding the Evans osteotomy, a sagittal saw was used to make an osteotomy 12 to 15 mm proximal to the anterior process of the calcaneus, making sure to leave a medial cortical hinge intact for enhanced stability.

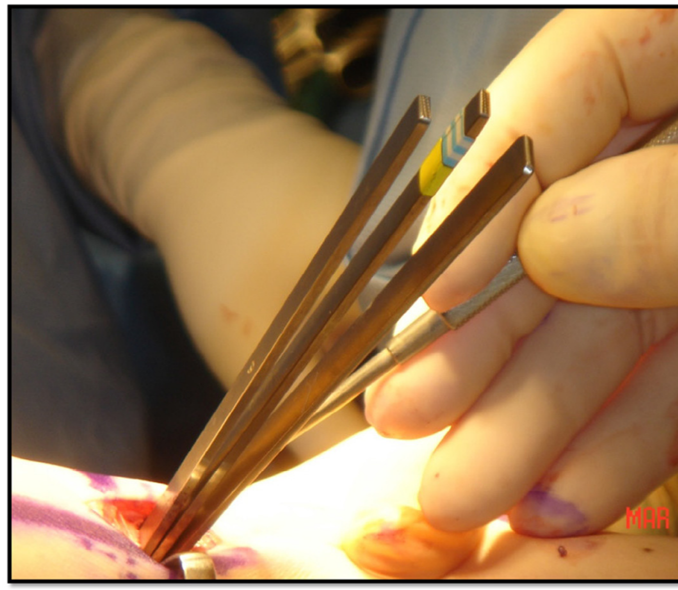

Fig. 1. Example of the "stacking osteotome technique" for preparation of an Evans graft site. Osteotomes of sizes 10, 8, and 6 mm were sequentially inserted into the graft site to distract the site to prepare for insertion of the appropriate porous titanium wedge trial.

The Cotton osteotomy was performed at the midpoint of the long axis of the medial cuneiform perpendicular to the short axis of the bone, being careful to leave an intact plantar cortex. After each of the osteotomies was completed, a stacked osteotome technique was used to gently dilate each of the sites open to accept the proper preconfigured PTW (Fig. 1). Next, the appropriate-size PTW was determined by sequentially examining the fluoroscopic reduction achieved with insertion of trial PTWs of varying sizes. The PTW sizes available for the Evans osteotomy were 8, 10, and 12 mm in size, and the PTW sizes available for the Cotton osteotomy was 4.5, 5.5, 6.5, 7.5, 8.5, and 9.5 mm (Fig. 2). All the wedges are available in varying preconfigured lengths, and care was taken to choose the appropriate length for each respective osteotomy. After adequate fluoroscopic reduction of each of the respective deformities was appreciated, the appropriate-size PTW was inserted into the osteotomy site by gently tapping it into place with a mallet (Figs. 3–5). Appropriate positioning and reduction of the desired deformity was then examined under fluoroscopy. Fixation of the PTWs was performed at the attending surgeon's discretion on a case by case basis.

The postoperative protocol was as follows. All patients were maintained nonweightbearing and immobilized in a well-padded below-the-knee cast with 90° of ankle flexion immediately postoperatively. The patients were seen for a cast and dressing change at postoperative week 1. The patients were then examined at 3 weeks postoperatively for suture removal and another cast application. At 6 to 8 weeks postoperatively, patients were transitioned to a controlled ankle motion walker, once radiographic consolidation was appreciated. At ~3 months postoperatively, patients were transitioned to full weightbearing, and physical therapy was initiated. Radiographs were obtained immediately postoperatively and at weeks 3, 6, 8, 12, and at any other times deemed clinically necessary until the eventual final follow-up radiographs.

Serial radiographs taken at regular intervals were used to evaluate the alignment and extent of graft incorporation. This allowed extraction of radiographs and medical record data retrospectively through the electronic medical records provided at both institutions. Weightbearing anteroposterior (AP) and lateral foot radiographs were taken at a minimum preoperatively, at ~4 weeks postoperatively and at the final follow-up visit ≥12 months postoperatively.

The primary outcome measure was the change in alignment achieved from the pre- to final postoperative weightbearing radiographs. The key radiographic parameters (10) included the following:

- Calcaneocuboid abduction angle (normal 0° to 5°)
- Kite's angle (normal 15° to 18°)
- Meary's angle (normal ±4°)
- Calcaneal inclination angle (normal 18° to 20°)

Maintenance of correction was also assessed and defined as the difference in angular correction from the first weightbearing postoperative radiograph to those at the final follow-up radiograph. Graft incorporation was also assessed and defined according to a previous report on PTWs (11). Grafts were considered incorporated if a lack of lucency