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Extraosseous Talotarsal Stabilization Using HyProCure[®]: Preliminary Clinical Outcomes of a Prospective Case Series

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ABSTRACT

The present multicenter, prospective study evaluated the subjective outcomes in patients after extraosseous talotarsal stabilization using the HyProCure® stent as a standalone procedure for the treatment of recurrent and/or partial talotarsal joint dislocation (RTTD) in a population of pediatric and adult patients. RTTD has been cited as a possible etiology for a number of foot ailments and might contribute to the development of pathologic features localized more proximally in the weightbearing musculoskeletal chain. Correction of RTTD might, therefore, lead to the reduction of pathologic features associated with this deformity. A total of 46 feet in 35 patients were included in the present investigation. Subjective evaluation used the Maryland Foot Score assessment, which was obtained preoperatively and 1, 2, and 3 weeks, 1, 2, 3, and 6 months, and 1 year postoperatively. The mean overall scores improved from a preoperative value of 69.53 ± 19.56 to a postoperative value of 89.17 ± 14.41 at the 1-year follow-up. Foot pain decreased by 36.97%, foot functional activities improved by 14.39%, and foot appearance improved by 29.49%. The greatest magnitude of improvement occurred 4 weeks postoperatively, with gradual improvement continuing through to the 1-year follow-up. Implants were removed from 2 patients (2 feet, 4.35%). No unresolved complications were observed. The positive subjective outcomes resulting from the extraosseous talotarsal stabilization procedure suggest that the intervention employing the device we have described alleviates pain and improves foot function and appearance in patients with RTTD.

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The talotarsal joint (TTJ) complex is crucial to maintaining the balance and functional adaptations of the foot and ankle. It is composed of the articulations of the talus with the calcaneus and navicular. The optimal function of the TTJ is dependent on proper alignment of the tarsal articulating facets, namely the anterior, middle, and posterior talocalcaneal and talonavicular facets, through all phases of the gait cycle. Taken together, the talus, calcaneus, navicular, and TTJ constitute the talotarsal mechanism (TTM). A stable TTM allows for transfer of normal and acceptable forces from the weight of the body through the proximal kinematic chain (lumbar

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spine to the ankle) and then through the foot and ankle complex to the weightbearing substrate. The ideal alignment allows for a specific, measurable amount of motion between the bones of the TTM. The unique facets of the TTJ complex are interdependent; thus, motion at 1 facet causes motion to occur at the other facets owing to the soft tissue connections (1). Partial displacement (misalignment) of any 1 of the 4 facets leads to an abnormal distribution of the forces within the TTJ complex. When this causes unlocking of the TTM by prolonged pronation (hyperpronation or overpronation) during the stance phase of the gait cycle (2,3), a myriad of pathologic entities can ensue. Recurrent, partial talotarsal dislocation (RTTD) is a dynamic triplane deformity characterized by talar displacement medially, plantarly, and/or anteriorly, depending on the plane(s) of dominant motion. It occurs to some degree with all weightbearing activity. Eventually, owing to the corresponding increased strain of osseous and soft tissue structures in the foot and ankle, secondary deformities and pathologic degeneration of the ligaments, tendons, cartilage surfaces, and bones ensue. Furthermore, because the TTJ is a fundamental functional component of the foot, instability of this complex can further alter biomechanical functioning of the proximal musculoskeletal structures and has been attributed to the development of signs and

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Conflict of Interest: Anuja Vedpathak, MS, is an employee of the Graham International Implant Institute, Macomb, MI. At the request of the authors, she collated and performed the statistical analysis on the data received from the MFS questionnaires. She also assisted with background research on prior studies.

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symptoms of abnormal function localized to the knee (5–11), pelvis (4,5,7,8,10), spine (4,7,8,12), neck (7), shoulder (7), and even the temporomandibular joint (7).

RTTD is a common form of foot pathology. Patients with RTTD generally present with primary symptoms such as pain in the foot and/or leg, walking temperance, nocturnal foot and leg cramps, and abstinence from athletic activities. Adverse foot conditions that can be attributed to, or increased by, RTTD include plantar fasciopathy (12–14), progressive posterior tibial tendon dysfunction (12,13,17), hallux abductovalgus (12,13), metatarsalgia (13,14), hammertoe syndrome (14), plantar intermetatarsal neuroma (12,14), and degenerative joint diseases of the foot and ankle (14,15). Knee (11), hip (4,9), spine (4,7,8), shoulder (7), and neck (7) pain are also prevalent maladies that have been linked to RTTD. Occasionally, patients will not have symptoms, despite overt signs of talotarsal instability. Clinically, this condition is characterized by talar adduction and/or plantarflexion, forefoot abduction on the rearfoot, and/or calcaneal eversion. The existence of RTTD can be considered a precursor to the development of many of the aforementioned pathologic entities that can further worsen function in the foot and ankle and the more proximal structures of the kinematic chain.

Clinically, patients exhibiting symptoms of any of the secondary pathologic entities associated with talotarsal displacement should be examined for the condition, owing to the interrelationship of the foot with the remainder of the body. Thus, treatment should focus on stabilizing the TTJ complex rather than only addressing the secondary symptoms. Because RTTD might be a precursor to these symptoms, failure to correct the underlying recurrent dislocation of the TTI can result in failure of other treatments. It is our belief that asymptomatic patients with RTTD should also be treated, because stabilization of the TTI complex could prevent or decrease the development of secondary conditions and therefore prevent or decrease the associated economic burden of this disorder, such as time off work and money spent on treatment. Previous reports have indicated that a minimally invasive procedure involving placement of the HyProCure[®] (GraMedica, Macomb, MI) device in the sinus/ canalis tarsi can effectively stabilize the TTJ complex (18-20). HyProCure[®] (Fig. 1) is a type II extraosseous talotarsal stabilization (EOTTS) device intended to restore the normal alignment of the articular facets of the talotarsal joint, eliminating abnormal excessive motion within the talotarsal joint and preserving the normal range of joint motion (21). Normal range is defined by measurements of the talar second metatarsal (T2M) angle in the transverse plane and the talar declination (TD) angle in the sagittal plane that remain within the normal parameters in relaxed stance weightbearing position. Normal range is reported as $<16^{\circ}$ for the T2M (23) and $<21^{\circ}$ for the TD (24).

The purpose of the present prospective study was to evaluate the preliminary subjective outcomes of EOTTS with the HyProCure[®] device as a standalone procedure for the treatment of RTTD in

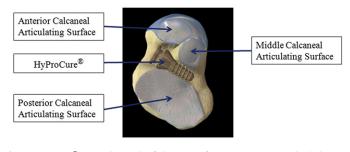


Fig. 1. HyProCure[®] inserted in angle of alignment of sinus tarsi, occupying both the sinus and canalis tarsi. The conical, stabilizing portion abuts the lateral aspect of the canalis tarsi.

a population of pediatric and adult patients. It was hypothesized that stabilization of the TTM using EOTTS would result in improved postoperative subjective scores for foot pain, function, and appearance compared with the preoperative scores.

Patients and Methods

The Quorum Review institutional review board (Seattle, WA) reviewed and approved the study protocol (protocol #G12_10). A total of 35 consecutive patients (46 feet) treated for RTTD from March 2010 to November 2011 were identified and agreed to participate in the prospective observational study. The diagnosis, enrollment, and treatment were performed by 4 foot and ankle surgeons from 3 different facilities (Indian Valley Podiatry Associates, PC, Souderton, PA; Complete Foot and Ankle Care, Randolph, MA; and Mendota Foot and Ankle Clinic, Mendota, IL). Two of the surgeons also conducted the present investigation and coauthored the present report (P.J.B., J.T.C.). The diagnosis of RTTD was determined through detailed clinical evaluation and confirmed by radiographic analysis (see the inclusion and exclusion criteria, next). The primary indication for EOTTS included failure of at least 6 months of conservative treatment to alleviate symptoms to the patients' satisfaction.

The inclusion criteria were pediatric (>3 years old) and adult (\geq 18 years old) patients diagnosed with RTTD according to the following clinical and radiographic findings:

- Deformity characterized by talar displacement medially, plantarly, and/or anteriorly
- Collapse of the medial longitudinal arch if the deformity existed in the sagittal plane or the "too many toes" sign if the deformity existed in the transverse plane
- Hyperpronation (>3° to 5°) about the subtalar joint axis in the relaxed stance, weightbearing position
- · Ability to manipulate the foot to correct the deformity in the neutral stance
- A prolonged period of pronation or delayed resupination and/or flatting of the arch due to loss of navicular height in gait
- Anteroposterior/dorsoplantar and lateral weightbearing radiographs taken in both neutral and resting stance positions, revealing talotarsal misalignment (a transverse plane talar second metatarsal angle >16° (23), sagittal plane talar declination angle >21° (24), obliteration of the sinus tarsi on the lateral radiographs, a lateral shift of the vertical axis of the calcaneus with respect to that of the tibia, and eversion of the calcaneus as viewed on the anteroposterior radiographs)

The exclusion criteria were as follows:

- Rigid deformity of the hindfoot or destructive osteoarthritis
- Posterior tibial tendon dysfunction stage IIb or greater
- Grossly severe clinical abduction of the forefoot on the rearfoot as evidenced by a transverse plane concavity at the calcaneocuboid joint and convexity at the talonavicular joint with more than 30% uncovering of the talar head at the talonavicular joint as viewed on the standing anteroposterior radiograph of the foot (22)
- Previous or concurrent metatarsal, tarsal, or ankle hindfoot or soft tissue surgical intervention on the involved extremity
- Active infection overlying the sinus tarsi of the involved foot

Patients in need of concurrent correction of osseous deformities of the toes, such as clawtoe or hammertoe deformity, were not excluded in an effort to promote accrual into the series. In an effort to promote external validity, the inclusion and exclusion criteria were kept intentionally broad, and no requirements were present related to patient height, weight, gender, race or ethnicity, biomechanical planal dominance, or the activity level of the individual patient.

It should be noted, however, that if a digital surgery was included in the surgical treatment of the patient, it was not aimed at or thought to be therapeutic in regard to the RTTD, and no other interventions (except the EOTTS) were undertaken in an effort to treat the RTTD. As such, we considered the EOTTS procedure to be a "standalone" form of treatment used to address the unstable and collapsing hindfoot and midfoot.

After clinical and radiographic evaluations, the patients in whom RTTD was diagnosed and who met the inclusion criteria for the study were asked to participate by their treating physician. Initial consent consisted of signing an institutional review board-approved consent form, after which they also completed the preoperative Maryland Foot Score (MFS) questionnaire (Table 1). Preoperative MFS scores were procured at the time of enrollment and before the EOTTS surgery for each foot. Pediatric patients completed the evaluations with a parent or guardian present, and the parent or guardian also provided consent for the patient to participate in the present study. Subsequently, the patients underwent the EOTTS procedure with the HyProCure[®] stent. The surgeries were performed by 4 surgeons from 3 different facilities (Indian Valley Podiatry Associates, PC, Souderton, PA; Complete Foot and Ankle Care, Randolph, MA; and Mendota Foot and Ankle Clinic, Mendota, IL). Postoperative MFSs were obtained from the patients at 1, 2, and 3 weeks, 1, 2, 3, and 6 months, and 1 year postoperatively to determine the outcomes in regard to pain relief, functional activity, and the appearance of the operated foot.

Intervention

The operative procedure was essentially identical for all patients, because all 4 surgeons had previously trained in the procedure through the Graham International Implant Institute and had a minimum duration of experience of 2 years with the specific device. The patient was placed on the operating table in the supine position. The foot and ankle were prepared and draped in the usual sterile fashion after the administration of monitored anesthesia care and local anesthesia in the area around and into the sinus tarsi. In all the cases, a tourniquet was not used. The patients also received a preoperative antibiotic within 1 hour before the incision, according to each surgeon's preference. An approximately 1.5-cm linear skin incision was made obliquely over the sinus tarsi at a distance of 1 cm from the distal aspect of the fibula. Blunt dissection with curved tenotomy scissors created a path to the sinus tarsi. The soft tissues within the sinus and canalis portions of the sinus tarsi were transected to create a soft tissue pocket for the insertion of the guide wire (if used) and trial sizers to allow for proper placement of the trial sizers. A guide wire (if used) supplied with the instrument set was gently inserted into both portions of the sinus tarsi, angled obliquely to the orientation of this space (i.e., anterior-distal-lateral to posteriorproximal-medial). Trial sizing was performed to determine the appropriate stent (implant for EOTTS) size to achieve the best correction. The no. 5 trial sizer was placed onto the guide wire (if used) and inserted into the sinus and canalis portions of the sinus tarsi. The talotarsal joint was then placed through a full range of motion to determine the amount of correction achieved with the corresponding trial sizer. The goal was to restore the motion to 3° to 5° of pronation. If excessive pronation was present with the no. 5 trial sizer, the next incremental trial sizer was inserted and the same testing administered. This procedure was repeated until the appropriate trial sizer achieved the required amount of correction. Once the proper size was determined, the corresponding stent was placed on the insertion driver and inserted. The guide wire, if used, was removed from the foot once superficial placement of the stent was achieved. The device was then moved into position within the sinus and canalis tarsi with a twisting motion. The driver was removed, and the position of the device was examined using intraoperative fluoroscopy. The incision was closed with absorbable subcuticular suture reinforced on itself. Deep tissue closure was not performed. A dry, sterile compression dressing was applied to the foot and ankle. Patients received a postoperative shoe and crutch (if needed). The patients were instructed to elevate the foot when awake as much as possible for the first 24 to 36 hours and were allowed limited weightbearing on the foot, as tolerated, immediately after the operation. The patients were allowed to increase activity as tolerated until their first postoperative visit at 1 week. The patients were encouraged to transfer to, and use, new and supportive shoes as soon as tolerated, making sure the outer collar did not rub against the incision site, and they were advised not to revert back to their worn-out shoes (18).

Outcomes

The MFS questionnaire (25) was used to evaluate subjective outcomes and patient satisfaction with the EOTTS procedure. The MFS questionnaire has been shown to display criterion validity with the pain and physical functioning domains of the SF-36 general health questionnaire (26) for calcaneal fractures (27–29) and has been used to assess the outcomes after bunion surgery (30). The wording of 1 of the questions of the MFS questionnaire was modified to more clearly serve the purpose of evaluating the foot function associated with partial talotarsal dislocation. The MFS is composed of 3 domains: pain (\leq 45 points, ranging from 0 for disabling pain to 45 for no pain), foot function (\leq 45 points), and appearance (\leq 10 points), for a maximal total of 100 points. The MFS assesses foot function using criteria such as walking ability (flat surface, upstairs/downstairs, terrain), walking support (cane, crutch, wheelchair), stability while walking (limp), flexibility of the big toe joint, and tolerance of shoe gear. The various components of the MFS questionnaire are listed in Table 1.

Statistical Analysis

A test of normality was performed to determine the distribution of the sample population. Statistical significance was evaluated between the preoperative and post-operative scores, at each follow-up interval, using parametric and nonparametric tests of the null hypothesis. A paired Student's *t* test was performed for normally distributed data, and the Mann-Whitney *U* (Wilcoxon signed ranks) test was performed for non-normally distributed data. Statistical analysis was conducted using SigmaStat® software, version 3.5 (Systat, Chicago, IL), and statistical significance was defined at the 5% level ($p \leq .05$).

Results

A total of 46 feet in 35 patients were included in the present study. The patient population included 10 males (28.57%) and 25 females

Table 1

Maryland Foot Score questionnaire*

- Maryland Foot Score Questions
 - 1. Presently, regarding my foot surgery, I have
 - a. No pain, including physical activities (sports) (45)
 - b. Slight pain, but it does not affect my work ability (40)
 - c. Mild pain, but I have made only minimal changes in my regular daily activity (30)
 - d. Moderate pain and I take aspirin, Tylenol, or Advil for it (20)
 - e. Marked pain, even with minimal activities (10)
 - f. Disabling pain, for which I take stronger pain pills (if so, what type?) (0)

2. With regard to my foot surgery and walking, my walking ability is

- a. Unlimited (greater than 6 blocks) (10)
- b. Slightly decreased (4 to 6 blocks) (8)
- c. Moderately decreased (1 to 3 blocks) (5)
- d. Severely decreased (<1 block) (2)
- e. Restricted to indoors only (0)

3. With regard to my foot surgery influencing my walking

- a. I feel completely stable when I walk (4)
- b. I have a weak feeling when I walk (3)
- c. I have an occasional giving away (2)
- d. I have instability when I walk (frequently giving away) (1)
- e. I need support to walk (0)

4. With regard to my foot surgery area and support

- a. I need no support to walk (4)
- b. I need a cane to walk due to my foot (3)
- c. I need crutches to walk (1)
- d. I need a wheelchair (0)

5. With regard to my foot surgery and walking

- a. I do not feel I have a limp (4)
- b. I have a slight limp (3)
- c. I have a moderate limp (2)
- d. I have a severe limp (1)
- e. I cannot walk (0)

6. With regard to my foot surgery area and shoe wear

- a. I can wear any type of shoe I desire or want to wear (10)
- b. There are some shoes that I cannot wear (9)
- c. I can only wear flat heel shoes (7)
- d. I need to wear shoes with my orthotics (5)
- e. I wear special extra depth or "orthopedic shoes" $\left(2\right)$

7. With regard to my foot surgery area and walking

- a. I can walk on any surface or terrain (4)
- b. I have problems walking up and down hills (2)
- c. I have problems walking on flat surfaces (0)

8. With regard to my foot surgery and walking

- a. I can go up stairs normally (4)
- b. I need to use the banister (3)
- c. I need assistance going up and down stairs (2)
- d. I am unable to go up and down stairs (0)
- 9. With regard to my foot surgery area and how my foot looks
 - a. I feel my foot looks normal (10)
 - b. It looks like I have a mild deformity (7)
 - c. It looks like I have a moderate deformity (5)
 - d. It looks like I have a severe deformity (0)
- 10. With regard to my foot surgery and the motion I now have in my big toe joint(s) a. I feel I have normal motion (5)
 - b. I feel my motion is slightly decreased (4)
 - c. I feel my motion is markedly decreased (0)

Preoperative evaluation included same questionnaire as for postoperative assessment. Question 1 evaluates pain level (scale of 0 to 45); questions 2 through 8 and 10 assess foot function (scale of 0 to 45); and question 9 assesses appearance of the foot. The possible maximum score is 100; answers possible for each foot individually.

From Graham ME, Jawrani NT, Chikka A. Extraosseous talotarsal stabilization using HyProCure in adults: a 5-year retrospective follow-up. J Foot Ankle Surg 51:23–29, 2012.

* Data in parentheses are scores for each answer.

(71.43%). The mean age of the patients at surgery was 41 (range 8 to 72) years. A total of 25 feet (54.35%) in 21 patients (60%) were diagnosed with a secondary condition, in addition to RTTD, including plantar fasciitis in 5 feet (10.87%), posterior tibial tendon dysfunction in 3 feet (6.52%), hallux valgus/bunion in 12 feet (26.09%), hammertoes in 4 feet (8.7%), and hallux limitus and plantar calcaneal spur in 1 foot (2.17%) each. Of the 35 patients, 24 (68.57%) underwent unilateral procedures and 11 (31.43%) bilateral procedures during separate procedures. No additional (adjunct) surgical procedures were performed to address the RTTD, although 1 patient (2.86%; 1 foot [2.17%]) underwent arthrodesis of the second digit at the same time as the EOTTS procedure. After procuring the preoperative MFSs at enrollment into the present study, every effort was made to obtain postoperative MFSs for all the patients at each of the follow-up, studyrelated intervals. These follow-up periods did not always correspond to clinical follow-up visits that would be part of the standard of care for the EOTTS procedure. Therefore, some patients were not able to provide responses at the scheduled follow-up intervals. Thus, the final data available for each patient did not always include the postoperative MFSs at each follow-up period (Tables 2 to 5). At no interval was data available for all 46 feet. The overall mean duration of follow-up was 37.75 ± 20.49 weeks (minimum = 1 week; maximum = 52 weeks/1 year).

The mean \pm standard deviation and median (range) for the preoperative and postoperative MFSs are presented in Tables 2 to 5. The postoperative scores were compared with the corresponding preoperative scores (Fig. 2). At 1 week of follow-up (n = 41 feet in 33 patients), the MFSs showed a statistically significant decrease from a mean preoperative score of 70.05 \pm 19.59 to a mean postoperative score of 54.20 \pm 25.7. At 2 weeks (n = 37 feet in 29 patients), 3 weeks (n = 34 feet in 27 patients), 1 month (n = 33 feet in 26 patients), 2 months (n = 35 feet in 26 patients), 3 months (n = 27 feet in 21 patients), 6 months (n = 26 feet in 20 patients)and 1 year (n = 30 feet in 21 patients), the mean preoperative MFSs increased from 68.65 \pm 19.24, 68.38 \pm 17.89, 69.09 \pm 18.48, 70.66 \pm 18.88, 70.89 \pm 17.18, 74.00 \pm 16.2, and 71.57 \pm 17.58 to mean postoperative scores of 67.89 \pm 16.8, 74.68 \pm 12.64, 84.14 \pm 10.72, 85.14 \pm 16.26, 88.74 \pm 16.94, 89.31 \pm 11.54, and 89.17 \pm 14.41, respectively. Postoperative MFSs showed statistically significant improvements compared with the preoperative scores at 1 month, with continued gradual improvement through 1 year. For patients with 1-year follow-up scores, foot pain was decreased by 36.97%, foot functional activities had improved by 14.39%, and foot appearance had improved by 29.49%. Assessment of the frequency distribution of the preoperative MFSs showed 6 feet (20%) with scores in the range of 70 to 80 with 2 (6.67%), 2 (6.67%), 5 (16.67%), 5 (16.67%), and 5 (16.67%) feet with a score range of 30 to 40, 40 to 50, 50 to 60, 60 to 70, 80 to 90, and 90 to 100, respectively (Fig. 3A).

Table 2

Comparison of preoperative and postoperative pain scores * (N = 46 feet in 35 patients at baseline)

Follow-up Point (no. of feet)	Preoperative*	Postoperative*	p Value†
1 wk (n = 41)	26.95 ± 13.41 (30, 0 to 45)	21.46 ± 15.74 (30, 0 to 45)	.116
2 wk (n = 37)	$26.22\pm13.14(30,0\text{ to }45)$	$26.62\pm11.55~(30,0\ to\ 45)$.96
3 wk (n = 34)	25.88 \pm 13 (30, 0 to 45)	30.59 ± 9.52 (30, 10 to 40)	.142
1 mo (n = 33)	$26.36 \pm 13.36 (30, 0 \ to \ 45)$	36.21 ± 7.4 (40, 10 to 45)	.002
1 mo (n = 35)	$27.43 \pm 13.52 \ (30, \ 0 \ to \ 45)$	35.86 ± 11.54 (40, 10 to 45)	.005
3 mo (n = 27)	27.41 ± 12.51 (30, 10 to 45)	39.07 ± 9.71 (40, 10 to 45)	.001
6 mo (n = 26)	$29.62\pm11.66~(30,10~to~45)$	37.88 \pm 9.18 (40, 10 to 45)	.005
1 yr (n = 30)	27.5 ± 12.78 (30, 0 to 45)	37.67 ± 10.81 (40, 10 to 45)	<.001

Data presented as mean \pm standard deviation (median and range).

* Pain domain (range 0 to 45 points) of Maryland Foot Score (25,27-30).

[†] Paired Student's *t* test for normally distributed data, Mann-Whitney *U* (Wilcoxon signed ranks) test for non-normally distributed data.

Table 3

Comparison of preoperative and postoperative function $\operatorname{scores}^*(N=46 \text{ feet in 35} \text{ patients at baseline})$

Follow-up Point (no. of feet)	Preoperative*	Postoperative*	p Value†
1 wk (n = 41)	$35.88 \pm 6.29 (37, 19 \text{ to } 45)$	24.73 ± 11.56 (25, 3 to 45)	<.001
2 wk (n = 37)	35.43 \pm 6.3 (37, 19 to 43)	$32.81 \pm 7.11~(34,15~to~48)$.053
3 wk (n = 34)	$35.47 \pm 5.62 \ (37, 20 \ to \ 43)$	$35.76 \pm 5.27~(37, 24~to~45)$.782
1 mo (n = 33)	35.64 ± 5.55 (37, 20 to 43)	38.85 \pm 4.4 (39, 29 to 45)	.005
1 mo (n = 35)	36.03 ± 5.65 (37, 20 to 43)	$40 \pm 5.49~(42, 24~to~45)$	<.001
3 mo (n = 27)	$36.41 \pm 5 \ (38, 22 \ to \ 43)$	$40.37 \pm 6.51 \ (43, 14 \ to \ 45)$	<.001
6 mo (n = 26)	$37.27\pm5.17~(38,22$ to $43)$	$41.73 \pm 4.01 \ (43.5, 32 \ to \ 49)$	<.001
1 yr (n = 30)	36.83 \pm 5.34 (38, 22 to 43)	$42.13\pm4.13~(44,27$ to $48)$	<.001

Data presented as mean \pm standard deviation (median and range).

* Function domain (range 0 to 45 points) of Maryland Foot Score (25,27-30).

[†] Paired Student's *t* test for normally distributed data; Mann-Whitney *U* (Wilcoxon signed ranks) test for non-normally distributed data.

Postoperatively at 1 year, 21 (70%) of 30 feet were within the score range of 90 to 100, with 2 (6.67%) feet each in 50 to 60 and 70 to 80 score range, 1 (3.33%) in the 40 to 50 score range and 4 (13.33%) in the 80 to 90 score range (Fig. 3*B*).

The mean preoperative MFS for all 46 feet was 69.53 ± 19.56 points. Of the 46 feet, 23 (50%) feet fell on either side of the mean average. The mean preoperative score for those with a score less than the total group mean was 53.41 ± 13.37 . By week 4, the scores for this group had increased to 83.75 ± 10.56 (18 [78.26%] feet). At 1 year after the EOTTS procedure, the MFS had improved to 84.64 ± 19.68 points (14 [60.87%] feet). The mean preoperative score for those with a score greater than the total group average was 85.65 ± 7.77 . For this group, the 1-year postoperative scores improved to a mean of 93.13 ± 5.5 (16 [69.57%] feet). For the 21 patients (60%) (25 feet [54.35%]) diagnosed with a secondary condition in addition to RTTD, the preoperative mean MFS was 68.4 ± 20.61 . At the 1-month follow-up visit, the mean MFS had increased to 82.97 ± 12.1 (18 [72%] feet), and at 1 year, it had improved to 87.69 ± 16.59 (16 [64%] feet).

Postoperative Complications

No clinically significant postoperative complications were reported for the 46 feet in 35 patients. At the time of this preliminary report, 2 patients (2 feet, 4.35%) had their implants removed. The removals were due to discomfort when walking and during activities (1 patient/ foot) and failure of the procedure to relieve symptoms (1 patient/foot). One (2.86%) patient (1 [2.17%] foot) had delayed wound healing that later resolved. At 6 months, 4 (11.43%) patients (6 [13.04%] feet) showed a failure to improve from preoperative MFS, and at 1 year 3 (8.57%) patients (6 [13.04%] feet) showed no improvement. These

Table 4

Comparison of preoperative and postoperative appearance $\mathsf{scores}^*\,(N=46\ \text{feet in 35}\ \text{patients at baseline})$

Follow-up Point (no. of feet)	Preoperative*	Postoperative*	p Value†
$ \begin{array}{r} 1 wk (n = 41) \\ 2 wk (n = 37) \\ 3 wk (n = 34) \\ 1 mo (n = 33) \\ 1 mo (n = 35) \\ 3 mo (n = 27) \end{array} $	$\begin{array}{c} 7.22\pm2.85(7,0to10)\\ 7\pm2.89(7,0to10)\\ 7.03\pm2.66(7,0to10)\\ 7.09\pm2.67(7,0to10)\\ 7.20\pm2.71(7,0to10)\\ 7.07\pm2.88(7,0to10)\\ \end{array}$	$\begin{array}{c} 8 \pm 2.13 \ (7, 0 \ {\rm to} \ 10) \\ 8.46 \pm 1.68 \ (10, 4 \ {\rm to} \ 10) \\ 8.32 \pm 2.29 \ (10, 0 \ {\rm to} \ 10) \\ 9.08 \pm 1.49 \ (10, 5 \ {\rm to} \ 10) \\ 9.29 \pm 1.93 \ (10, 0 \ {\rm to} \ 10) \\ 9.3 \pm 2.09 \ (10, 0 \ {\rm to} \ 10) \end{array}$.2 .017 .02 <.001 <.001 <.001
6 mo (n = 26) 1 yr (n = 30)	$\begin{array}{c} 7.12 \pm 3.02 \; (7, 0 \; to \; 10) \\ 7.23 \pm 2.93 \; (7, 0 \; to \; 10) \end{array}$	$\begin{array}{l} 9.69 \pm 1.12 \; (10, 5 \; to \; 10) \\ 9.37 \pm 1.5 \; (10, 5 \; to \; 10) \end{array}$	<.001 <.001

Data presented as mean \pm standard deviation (median and range).

* Appearance domain (range 0 to 10 points) of Maryland Foot Score (25,27–30).

[†] Paired Student's *t* test for normally distributed data; Mann-Whitney *U* (Wilcoxon signed ranks) test for non-normally distributed data.

 Table 5

 Comparison of preoperative and postoperative total scores* (N = 46 feet in 35 patients at baseline)

Follow-up Point (no. of feet)	Preoperative*	Postoperative*	p Value†
1 wk (n = 41)	70.05 ± 19.59 (69, 27 to 100)	54.2 ± 25.7 (61, 10 to 95)	.002
2 wk (n = 37)	68.65 ± 19.24 (69, 27 to 96)	$67.89\pm16.8~(71,32~to~98)$.072
3 wk (n = 34)	$68.38 \pm 17.89~(69,27~to~96)$	74.68 \pm 12.64 (78, 47 to 95)	.072
1 mo (n = 33)	$69.09\pm18.48~(69,27~to~96)$	84.14 ± 10.72 (87, 55 to 100)	<.001
1 mo (n = 35)	$70.66 \pm 18.88 \ (69, 27 \ to \ 96)$	$85.14\pm16.26~(90,40$ to $100)$	<.001
3 mo (n = 27)	70.89 \pm 17.18 (69, 32 to 96)	$88.74\pm16.94~(93,24~to~100)$.002
6 mo (n = 26)	74 ± 16.2 (77.5, 32 to 95)	89.31 ± 11.54 (94, 56 to 100)	<.001
1 yr (n = 30)	71.57 ± 17.58 (76.5, 32 to 96)	89.17 ± 14.41 (94, 42 to 100)	<.001

Data presented as mean \pm standard deviation (median and range).

* Total Maryland Foot Score (25,27-30).

^{\dagger} Paired Student's *t* test for normally distributed data; Mann-Whitney *U* (Wilcoxon signed ranks) test for non-normally distributed data.

patients began with higher than average preoperative scores on the MFS assessment (91.50 \pm 3.56, 91.67 \pm 3.78).

Discussion

A stable talotarsal joint mechanism, with normal alignment of the articular facets of the talus, calcaneus, and navicular, is essential for proper functioning of the foot and ankle. This involves the proper distribution of forces from the body above through proximal musculoskeletal structures and then transferring them first to the hindfoot and then to the forefoot. The sinus tarsi, a naturally occurring

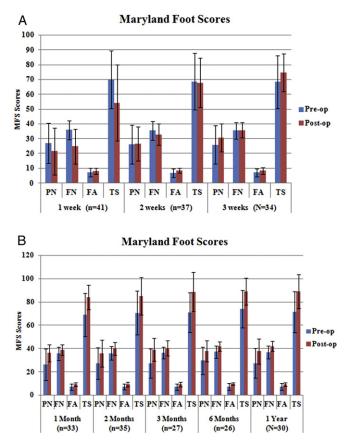
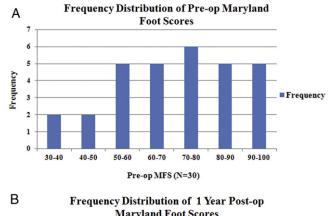


Fig. 2. Mean preoperative and postoperative Maryland Foot Score showing change in pain (PN), foot function (FN), foot appearance (FA), and overall total scores (TSs) at follow-up periods of (A) 1, 2, and 3 weeks and (B) 1, 2, 3, and 6 months and 1 year. N, number of feet with both preoperative and postoperative scores available for specific follow-up point.



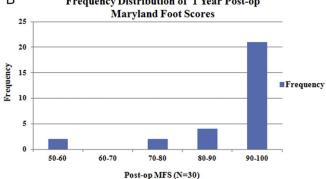


Fig. 3. (*A*) Frequency distribution of preoperative (*pre-op*) Maryland Foot Score showing the number of feet in each score range. (*B*) Frequency distribution of postoperative Maryland Foot Scores showing maximal number of feet (21 of 30) in score range of 90 to 100, indicating outstanding improvement in these patients after the extraosseous talotarsal stabilization procedure.

space between the talus and calcaneus, is a key indicator of the alignment of the TTJ complex. The cruciate pivot point (axis of TTJ motion), described by Farabeuf (31), located on the lateral aspect of the canalis portion of the sinus tarsi, is the point at which the body weight is transferred from the posterolateral aspect of the foot through the subtalar joint to the anteromedial aspect of the foot. Lateral deviation of this point indicates partial dislocation of the talus on the tarsal mechanism, which leads to prolonged periods of pronation during the stance phase of the gait cycle (2,3). Partial dislocation of the facets of the talus on the tarsal mechanism further produces excessive abnormal strain on the soft tissues, such as the spring ligament, posterior tibial tendon, and plantar fascia, owing to the repeated forces acting on these tissues as they try to minimize the pathologic osseous misalignment. This can, in turn, lead to secondary deformities of the foot and ankle (13–17,32).

Several treatment methods have been used to correct talotarsal joint deformity, including conservative and operative measures. Conservative treatment includes a wide range of over-the-counter or custom-made orthotic supports and braces, shoe inserts, shoe modifications or changes, and foot strappings. However, clinical investigations have not demonstrated that the correction achieved with the use of foot orthotics is adequate to alleviate the associated symptoms or prevent the development of new pathologic features (33–36). We are not aware of any published clinical evidence that confirms that externally applied foot orthotics are effective in realigning the osseous structures to restore the foot to the normal position. Moreover, externally worn foot orthoses are subject to patient adherence to use (compliance), because they must be worn consistently to be therapeutically effective.

With the failure of conservative measures to achieve results satisfactory to the patient, operative methods are recommended. These include soft tissue procedures, hindfoot and midfoot osteotomies and arthrodeses, or a combination of these (37–45). These procedures often involve extensive surgical dissection, a long recovery period, and prolonged immobilization during the early healing phase. Furthermore, they often result in complications and damage to the adjacent joints (45). The limitations of these procedures led to the development of subtalar implants, which are inserted into the sinus tarsi through a minimally invasive procedure.

A number of subtalar implants, commonly referred to as subtalar arthroereisis devices, are available for insertion into the sinus portion of the sinus tarsi only, acting as an anterior extension of the lateral process of the talus. In this position, the device blocks, limits, or elevates the lateral process of the talus as the hindfoot attempts to pronate, thereby limiting excessive anterior progression and hyperpronation (21). These devices function primarily in the sagittal plane, resulting in limitation of talar declination. Although the clinical outcomes have been favorable for some patients, these devices are known to require removal in up to 40% of cases (46,47).

The HyProCure[®] implant is an EOTTS device intended to restore the normal alignment of the articular facets of the talotarsal joint, eliminating abnormal, excessive motion within the talotarsal joint while preserving the normal range of hindfoot motion. It is composed of a medical-grade titanium alloy that is intended to permanently remain in situ. It is classified as a type II EOTTS device (21) and has a lateral conical-shaped portion that is coupled with medial cylindrical geometry to allow an anatomic fit that is aligned with the sinus and canalis portions of the sinus tarsi. It is cannulated for ease of insertion and threaded to allow tissue on-growth within the canalis tarsi so that it becomes anchored to the sinus on its medial aspect. The device is positioned from anterior-lateral-distal to posterior-medialproximal (i.e., in the orientation of the sinus tarsi), allowing for uniform distribution of the forces to the anterior and posterior aspects of the foot. The medial threaded cylindrical portion of the device is placed within the canalis portion of the sinus tarsi. Before placement, the tissues within the canalis portion are transected, which promotes stable incorporation of the implant as the tissues heal. The middle, tapered portion of the device abuts the medial sulcus of the sinus portion of the sinus tarsi, ensuring proper placement and preventing overinsertion, thereby stabilizing the cruciate pivot point (31). The lateral conical portion of the device prevents anterior deviation of the lateral process of the talus and thus stabilizes the sinus portion of the sinus tarsi. Recently, Graham et al (20) conducted a biomechanical investigation on adult human cadaver specimens, in which the distribution of forces on the anterior and posterior aspects of the talocalcaneal joint was studied. They reported that HyProCure[®] promoted uniform distribution of the axial loads and prevented excessive talar subluxation over the calcaneus, which led to improved talotarsal biomechanics. Another study (50) showed that HyProCure® placement resulted in normalization of pathologic talar-second metatarsal and talar declination angles. Radiographic angles that were normal in the preoperative period remained normal even after the implant was inserted, demonstrating that the device was effective in controlling motion in the desired planes without causing overcorrection or misalignment in other joints (50).

In the present prospective study, 4 different surgeons used EOTTS as a standalone procedure for the treatment of RTTD (with 1 foot in 1 patient having concomitantly undergone second toe proximal interphalangeal arthrodesis on the ipsilateral foot). Subjective outcome measurements using the MFS showed statistically significant pain reduction and improved foot function and appearance after the intervention. Follow-up assessments were conducted at 1, 2, and 3 weeks, 1, 2, 3, and 6 months, and 1 year after the EOTTS procedure. Short follow-up intervals were chosen to gain an understanding of the gradual changes associated with the surgery. The results showed that

the postoperative MFSs had decreased 1 week after the EOTTS procedure, which we attributed to normal postoperative discomfort and swelling. However, the overall scores, compared with the preoperative scores, improved starting 3 weeks postoperatively, with significant improvement observed by 3 to 4 weeks after surgery and continuing gradually through the first postoperative year. At the 1-year follow-up, 15 feet (32.61%) had scores in the range of 90 to 99 and 6 feet (13.04%) resulted in a MFS of 100 points.

A subgroup analysis of the patients diagnosed with a secondary condition of the foot (in addition to RTTD) showed similar results to the entire patient population in regard to the postoperative MFSs at the same intervals (overall MFS at 1 year postoperatively was 89.17 ± 14.41 and for the subgroup with secondary pedal malady, the MFS at 1 year postoperatively was 87.69 ± 16.59 , p = .005). This suggested to us that treating the underlying TTD could have a positive effect on the progression of secondary deformities and might even help in the reversal of the symptoms associated with these deformities. Biomechanical investigations conducted by Graham et al showed that correcting osseous misalignment significantly decreased strain in the posterior tibial tendon (51% reduction) (48), plantar fascia (33% reduction) (49), posterior tibial nerve (43% reduction) (51), and pressure in the tarsal tunnel (34% reduction) and porta pedis (38% reduction) (52) in adult human cadaver specimens.

In a foot with RTTD, subtalar joint pronation occurs beyond the contact period of the stance phase of gait, which causes the midtarsal joint to remain unlocked for a longer period, delaying resupination of the subtalar joint complex (2). This causes excessive strain in the soft tissues supporting the osseous structures in this area, plantardirected movement of the head of the talus, and navicular drop. Additionally, excessive subtalar pronatory movement produces prolonged internal rotation of the leg, which transmits abnormal forces to the upper kinetic chain, resulting in medial knee stresses and lateral dislocation of the patella over the femur (9–11). Eventually, this can lead to pelvic tilt, which in turn affects the spine and more proximal joints (7,8). This transfer of abnormal forces can lead to multiple pathologic features.

The study described in the present report focused on evaluating subjective outcomes in patients undergoing EOTTS using HyProCure[®] as a standalone procedure to treat the instability of the talotarsal mechanism (RTTD), with 1 patient also undergoing ipsilateral second toe arthrodesis. Several studies describing subtalar implants have shown positive outcomes only combined with additional procedures such as tendon transfer or lengthening, calcaneal osteotomy and medial and lateral column lengthening (46,53–55). The outcomes of the present study supports the use of HyProCure[®] as a standalone procedure for stabilization of the talotarsal joint complex, which could improve symptoms or limit progression of associated conditions such as plantar fasciitis, posterior tibial tendon dysfunction, tarsal tunnel syndrome, and other pathologic features of the foot and ankle. In a prospective study by Needleman (46), the Maxwell-Brancheau arthroereisis sinus tarsi implant placed in the sinus tarsi resulted in favorable outcomes with a patient satisfaction rate of 78%. However, 11% of the patients needed permanent removal of the implant because of sinus tarsi pain. In addition, adjunctive procedures such as Cotton osteotomy and Lapidus arthrodesis were also performed on the patients under investigation; hence, the influence of the arthroereisis implant was difficult to ascertain. Although the present study focused on EOTTS as a standalone procedure for the treatment of RTTD (with 1 adjunct toe surgery, as described, that was not considered treatment that focused on the RTTD), several of the patients found relief from their secondary ailments without additional procedures. Therefore, we believe it is important to evaluate the whole foot and the severity of coexisting deformities when choosing treatments. In cases in which patients exhibit severe secondary

deformities, EOTTS can be used in conjunction with other procedures and could improve the outcomes in such patients. For example, if a patient has a hypermobile first ray or a fixed forefoot varus diagnosed in addition to RTTD, a procedure to address these adjunct conditions should be done in conjunction with the EOTTS procedure.

A retrospective study by Graham et al (18) showed that HyProCure[®] resulted in positive outcomes in 83 patients with a slightly less than 6% incidence of implant removal and few post-operative complications (18). The results of that retrospective study, coupled with the results of the present prospective investigation, have shown that EOTTS with the use of the HyProCure[®] implant as a standalone procedure for the treatment of RTTD is safe and effective. Also, additional follow-up examinations will be conducted of the patients described in the present report at 2-, 3-, 4-, and 5-year postoperative intervals, and additional patients will continue to be enrolled for 4 more years.

In regard to the loss of cases to follow-up and incomplete data, 46 feet in 35 preoperative patients decreased to 30 feet in 21 patients by the 1-year postoperative follow-up assessment. This degree of loss to follow-up, specifically 16 feet (34.78%), likely imparted bias, unless the loss was completely at random. In our opinion, the primary reason for the loss of follow-up was that the assessment follow-up periods do not always correspond to clinical follow-up visits that would be considered part of the normal standard of care for this procedure. Typically, patients are not seen in office related to this procedure after 2-3 months postoperative unless pain or other complications arise. Follow-up assessments conducted for periods that did not correspond to a clinical visit where conducted over the phone or via mail. Another shortcoming of our investigation was the broad nature of the inclusion and exclusion criteria and lack of measurement of certain variables that surgeons consider important, such as the planar dominance of the RTTD deformity, the presence of certain secondary conditions, and the relative activity level, all of which could have affected the subjective outcomes. However, the patients with secondary foot deformities diagnosed experienced similar improvements in their subjective outcomes, without undergoing adjunct surgery to correct the additional deformities (with the exception of the 1 patient who underwent ipsilateral second toe arthrodesis). The inclusion of that toe surgery could have influenced the MFSs. Although this shortcoming pertained to a single foot in the present study, we appreciate that it could have biased our results. However, we do not believe that the toe surgery significantly influenced the stability of the hindfoot clinically or the outcome of the EOTTS procedure. If it did contribute, once again, it likely biased the results toward the null or in direction of an adverse outcome. Of even greater importance was that the study included patients without subjective symptoms in the foot, which we believe biased our results toward a null effect or even an adverse effect. Still further, we could not state for certain that the "appearance" domain of the MFS is a valid health measurement, although the pain and function domains have been shown to have criterion validity (27,28). Our alteration of the wording of the MFS, moreover, was unlikely to have altered the reliability of this health measurement instrument. Finally, the surgeons who treated the presented patients all had experience with the implant under investigation. We believe this was more likely to have biased our results toward better outcomes, rather than a null or hazardous influence (e.g., repetition of a systematic error that led to harm). Despite these biases, we were able to show clinically and statistically significant improvements in the subjective outcomes that we measured.

In conclusion, from our understanding of the published data and our experience with the present patients, EOTTS using the HyProCure[®] implant resulted in improved subjective outcomes as measured by the MFS, which led us to infer that the procedure effectively stabilized the talotarsal complex and reduced the symptoms associated with talotarsal instability. The procedure also appeared to be safe and durable, up to the 1-year postoperative visit. We also believe that the results of the present study could be used in the development of future randomized controlled trials that focus on EOTTS with a Type II implant for the treatment of talotarsal instability.

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