CHAPTER **19**

EVALUATION OF PATIENTS RECEIVING HYPROCURE EXTRAOSSEOUS TALOTARSAL STABILIZATION DEVICE

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INTRODUCTION

Flatfoot deformity is one of the most common foot pathologies among children and adults today (1-3). Its presentation varies from patient to patient, making its treatment in constant controversy. Typically, it is observed as an abduction of the forefoot onto the rearfoot, adduction and plantarflexion of the talus, collapsing of the medial arch, and eversion of the calcaneus (4). Although some people may remain asymptomatic for life, others may experience increasing pain, muscle fatigue, or even knee or low back pain as the deformity progresses (5-7). As the talus plantarflexes and adducts, it loses its articulation with the navicular and the medial arch begins to drop (2). This puts added strain on the soft tissue structures that pass along the medial side of the foot, consequently leading to more pathology, such as hallux abducto valgus deformity, tailor's bunion, posterior tibial tendon dysfunction, plantar fasciitis, tarsal tunnel syndrome, and Achilles tendinopathy (6,8-11).

Conservatively, patients with a flatfoot can be treated with orthotics, braces, arch pads, steroid injections, physical therapy, and/or immobilization (2,12). When conservative options fail, surgical treatment is considered and includes procedures such as tendon transfers, osteotomies, fusions, subtalar arthroereisis, gastrocnemius recessions, and Achilles tendon lengthening procedures (1,2-7,9,13-15).

Currently, there is no standardized protocol or algorithm for correcting the flatfoot deformity, due in part to the complexity of the deformity and the variations in its presentation. When determining the appropriate procedure for the patient, one needs to keep several variables in mind, such as the age, weight, and overall health of the patient, along with the stage of planal dominance and the deformity (2,5,13). Intra-articular procedures should be avoided in children, if possible. Tendon transfers or an arthroeresis may be used to adequately correct a more flexible flatfoot. In a more rigid deformity, however, these procedures will likely not fully correct the underlying deformity by themselves and the addition of osteotomies or fusions are necessary. Unfortunately, due to inconsistent and subjective radiographic measurements, along with the lack of randomized controlled trials and long-term outcomes, there still remains much controversy over what is best in terms of complete correction of the flatfoot deformity, overall patient satisfaction, and long-term results.

Over recent years, the subtalar arthroereisis has gained popularity among foot and ankle surgeons for the use of reducible or flexible flatfoot deformities (13,16,17). The goal of the arthroereisis is to block excessive anterior and medial movement of the talus on the calcaneus during the propulsive phase of the gait cycle, thus preventing overpronation at the subtalar joint (5,6). The arthroereisis procedure is advantageous in that, compared to osteotomies and fusions, it is minimally invasive and easily reversible, it can correct in multiple planes, and it is associated with quicker recovery times, less complications, and joint preservation (7, 18). The arthroereisis was initially popularized for pediatric patients, in the hopes of preserving joints; however, recent research has shown promising results in adult patients, as well (1,4,5,7,9-11,15,17-26).

The purpose of our study was to observe the clinical and radiographic outcomes of the HyProCure Extraosseous Talotarsal Stabilization Device (ETSD) in our patients and to compare these outcomes to those previously described in the literature. We also wished to evaluate patient satisfaction based on their experience with the HyProCure ETSD.

MATERIALS AND METHODS

Institutional review board approval was obtained for the retrospective review. A retrospective chart review was performed on all patients at Scripps in San Diego who underwent surgical correction for their flexible flatfoot deformity utilizing the HyProCure ETSD between July 2005 and September 2009. All surgical procedures were performed by one surgeon (GDC).

All patients were included for the clinical evaluation portion of the study, regardless of any concomitant procedures they received. Clinical evaluation included device removal rate and any other noted postoperative complications.

For the radiographic analysis, patients were included only if they had preoperative and postoperative weight-bearing films during the indicated time period. Patients were also excluded if they had undergone any concomitant rearfoot reconstruction procedure or if they received an adjunctive posterior tibial tendon augmentation procedure. Radiographic evaluation involved comparing preoperative and postoperative measurements. On the anterior-posterior view, the talar-navicular coverage angle and the talar-second metatarsal angle were evaluated. On the lateral view, Meary's angle and the navicular-to-cuboid distance were measured.

Lastly, all patients were sent a follow-up subjective questionnaire (Modified Maryland Foot Score), which asked questions regarding their physical limitations and satisfaction with the procedure (27). At the end of the questionnaire patients were also asked whether or not they would undergo the same operation again. The questionnaires were sent through the mail and the results were anonymous.

RESULTS

Between July 2005 and September 2009, a total of 29 patients (40 feet) underwent surgical correction for their flexible flatfoot deformity by one surgeon (GDC) utilizing the HyProCure device. There were 3 males (4 feet) and 26 females (36 feet). Average age at the time of surgery was 37.9 years (range 13-65 years). There were 5 adolescent patients (7 feet). Eight patients had a concomitant bunionectomy. One patient had a tailor's bunionectomy. Three patients underwent hammertoe correction procedures. One patient had a calcaneal exostectomy, but was included in the radiographic analysis because the procedure was not reconstructive and did not affect the angles evaluated.

All 29 patients were included in the clinical evaluation. There were 8 superficial wounds noted postoperatively. There were also 12 feet with lateral foot and/or ankle pain, some of which were also noted to have persistence or progression of their flatfoot deformity. These patients were treated conservatively with orthotics and/or given a steroid injection. Of these, 6 patients continued to have lateral foot pain and their implant was eventually removed.

Thirteen patients met the criteria for radiographic analysis. Preoperative and postoperative radiographic results are shown in Figure 1. On the AP view, the talonavicular coverage angle and the talar-second metatarsal angle were used to evaluate pronation in the transverse plane. Preoperatively, the average talonavicular coverage angle was 17.6°. Postoperatively, that angle improved to 8.4° for an average improvement of 9.2°. The average preoperative talar-second metatarsal angle was 19.8°. Postoperatively, the average talar-second metatarsal angle was 10.8° for a 9.0° average improvement from preoperative to postoperative.

On the lateral view, Meary's angle and the navicular-to-cuboid distance were used to evaluate pronation in the sagittal plane. Preoperatively, the average Meary's angle was 5.5°. Postoperatively, the average Meary's angle was 4.3° for an average 1.2° change. The average preoperative navicular-to-cuboid distance was 16.34 mm.Postoperatively, the average navicular-to-cuboid distance was 18.59 mm. This resulted in an overall 2.25 mm average improvement from preoperative to postoperative.

Thirteen patients filled out and returned the patient subjective questionnaire (Mod-MFS; Modified Maryland Foot Score). Tthree questionnaires were not filled out completely and were therefore, not used to calculate their total score; however, they were included when calculating the subcategories of the Mod-MFS. If a patient gave multiple answers for one question, the questionnaire was included, but the lowest answer was recorded and used for evaluation. The breakdown of the Mod-MFS is shown in Figure 2 and Table 1. Out of a possible 100 points, the patients averaged a total score of 80, postoperatively (range 32-100 points). Breaking the questionnaire down into its subcategories, the average pain score was 33.3 (out of 45), the average gait score was 18.7 (out of 22), the average cosmesis score was 8.8 (out of 10), the average activity score was 14.5 (out of 18), and the average satisfaction score was 3.3 (out of 5). Eight patients were very satisfied or satisfied, 2 patients were neither satisfied or dissatisfied and 3 patients were very dissatisfied. Eight patients said they would definitely undergo the procedure again, 1 patient said he would maybe undergo the procedure again, and 4 patients said they would definitely not undergo the procedure again.

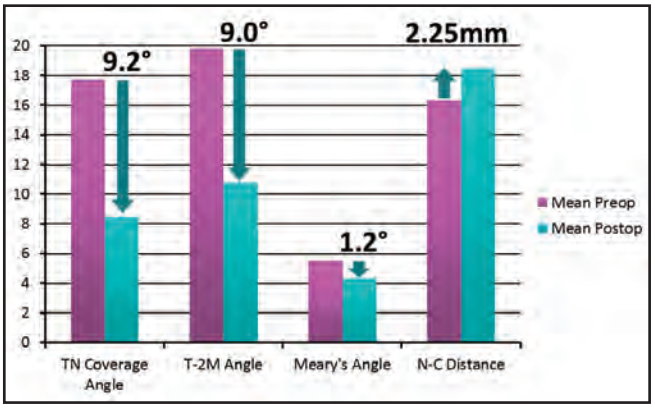

Figure 1. Radiographic measurements, preoperative versus postoperative.

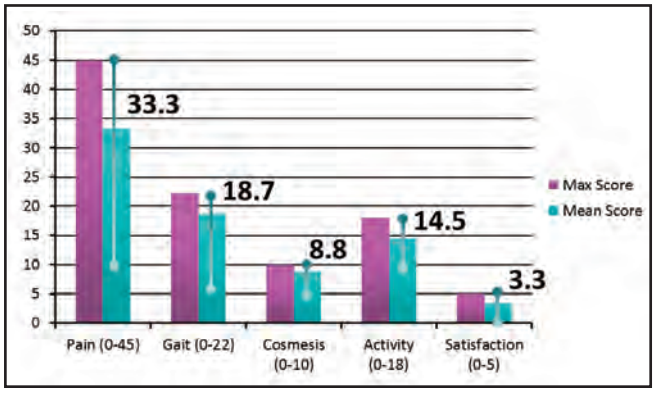

Figure 2. Modified Maryland Foot Score subcategories.

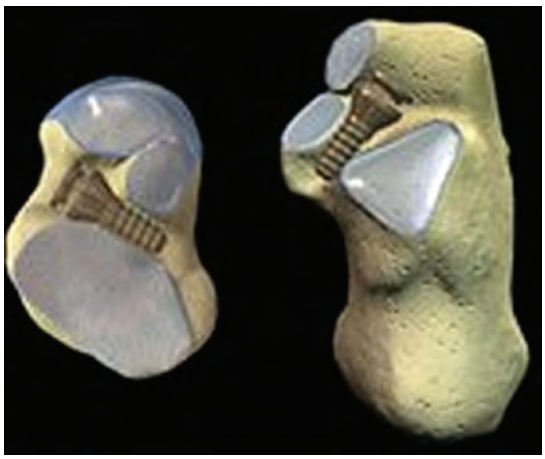

Figure 3. The HyProCure sinus tarsi stent (Reproduced from GraMedica HyProCure website).

DISCUSSION

The treatment of a flexible flatfoot with the use of a subtalar arthroereisis dates back to 1946. Since that time, several different implants have been produced, each trying to improve on the previous ones. The arthroereisis was initially popularized in adolescent patients in the hopes of preserving joints and avoiding fusions. Over the years, though, with growing popularity and high success rates, the use of arthroeresis has now been expanded to adults.

Not considered a true subtalar arthroereisis, the HyProCure implant is an extraosseous talotarsal stabilization device indicated for the flexible hyperpronated foot. It is inserted across the entire rearfoot, thus stabilizing the entire talotarsal joint complex (talus-calcaneus + talus-navicular) allowing normal motion of the subtalar joint and preventing dislocation of the subtalar joint (9). It functions as an internal foot orthosis; therefore, patient compliance with an external orthotic is not an issue. Compared to traditional surgical procedures for the correction of a hyperpronated foot, such as osetotomies and fusions, the implant is minimally invasive and reversible. It allows for quicker recovery times and less postoperative complications. Compared to its competing devices, the HyProCure ETSD has a distinct anatomy, which includes a tapered middle section, allowing the surgeon to know how far to insert the implant, and a smooth outer diameter that allows the implant to sit well against the talus without the threads digging into the bone (3).

Graham et al have published several studies utilizing the HyProCure ETSD on cadaveric specimens. He, along with his colleagues, have reported decreased strain placed along medial column soft tissue structures, improved tarsal tunnel pressures, and increased stabilization of the subtalar joint after the insertion of the HyProCure ETSD (20-24). Two radiographic studies have also been published by Graham et al utilizing the HyProCure ETSD. In one study, Graham et al looked at the talar-second metatarsal angle, the talar declination angle, and the calcaneal inclination angle and found that the talar-second metatarsal angle and talar declination angle both improved to normal values after the insertion of the HyProCure ETSD. The calcaneal inclination angle stayed about the same, though, which is to be expected since it is a structural angle (11). In that study, they reported a mean decrease of 19° in the talar-second metatarsal angle. In our current study, we found a mean improvement of 9.0°, overall.

In the second radiographic study, Graham et al evaluated the navicular-to-cuboid distance, which is a helpful marker in evaluating pronation in the sagittal plane. It also gives a good representation of arch height since the navicular is the high point of the medial longitudinal arch. They reported an average improvement of 5 mm after insertion of the device (10). In the present study, we examined the same measurement and noticed a mean increase of 2.25 mm. Overall, there was an average improvement in all of our radiographic measurements from preoperative to postoperative. Greater changes were noted on the anerior-posterior view compared to the lateral view films, indicating more correction took place in the transverse plane than in the sagittal plane.

Subjective outcomes have also been reported on the HyProCure ETSD. Graham et al performed a retrospective review on 83 adult patients (117 feet) with a mean follow-up of 51 months using the MFS. The MFS is a subjective patient questionnaire that evaluates the patient's pain, functional status, and overall satisfaction. In the study, the patients reported a mean postoperative total score of 88. Seven implants (6%) were removed and 9 additional revision surgeries were performed, a majority of which involved

Modified Maryland Foot Score

FOOT: **R** **L** **Both**

PAIN:

- None, including with sports 45
- Slight, no change in ADL's or work ability 40
- Mild, minimal change in ADL's or work 30
- Mod, significant decrease in ADL's taken ASA 20
- Marked, during minimal AD's (e.g. bathroom, simple housework). Stronger, more frequent analgesics 10
- Disabled, unable to work or shop 0

FUNCTION – GAIT:

- **Distance walked**
  - Unlimited 10
  - Slight limitation 8
  - Moderate limitation (2-3 blocks) 5
  - Severe limitation (1 block) 2
  - Indoors only 0
- **Stability**
  - Normal 4
  - Weak feeling – no true giving away 3
  - Occasional giving away (1-2 months) 2
  - Frequent giving away 1
  - Orthotic device used 0
- **Support**
  - None 4
  - Cane 3
  - Crutches 1
  - Wheelchair 0
- **Limp**
  - None 4
  - Slight 3
  - Moderate 2
  - Severe 1
  - Unable to walk 0

COSMESIS:

- Normal 10
- Mild deformity 8
- Moderate 5
- Severe 2
- Multiple deformities 0

FUNCTION – GAIT:

- **Shoes**
  - Any type 10
  - Minor concessions 9
  - Flat, laces 7
  - With orthotics 5
  - Space shoes 2
  - Unable to wear shoes 0
- **Stairs**
  - Normally 4
  - With banister 3
  - Any method 2
  - Unable 0
- **Terrain**
  - Any surface 4
  - Problems on hills, uneven surfaces 2
  - Problems on flat surfaces 0

OVERALL SATISFACTION WITH HYPROCURE DEVICE:

- Very satisfied 5
- Satisfied 4
- Neither satisfied nor dissatisfied 3
- Dissatisfied 1
- Very dissatisfied 0

WOULD YOU UNDERGO PROCEDURE AGAIN:

- Yes, definitely
- Maybe
- No, definitely not

Figure 4. Maryland Foot Score adapted from Sanders, R, Fortin, P, DiPasquale, T, Walling, A. Operative treatment in 120 displaced intraarticular calcaneal fractures. Results using a prognostic computed tomography scan classification. Clin Ortho Rel Research 1993;290:87-95.

either repositioning a migrated implant or changing out the implant for a different size (9). Bresnahan et al also evaluated subjective scores and removal rates using the MFS after the inserting of the HyProCure ETSD. They observed an improvement in the total MFS from a mean score of 69.53, preoperatively, to a mean score of 89.17, 1-year postoperatively. Only 2 (4.35%) of their implants were removed (19). In the present study, our patients had a mean postoperative score on our modified MFS of 78.7, which is lower than the prior studies. We also experienced a 15% (6) device removal rate, which was higher when compared to the previously mentioned studies. The most common reason for removal of the device was continued lateral foot pain round the sinus tarsi region.

Cook et al conducted a retrospective study on a self-locking wedge-type arthroereisis in order to help identify potential risk factors necessitating the removal of such implants. Looking back, they found that the patients who required removal of their implant had higher postoperative radiographic measurements (talar-first metatarsal angle, calcaneocuboid abduction angle), compared to patients with retained implants; therefore, their flatfoot deformity was likely undercorrected with the arthroereisis (28). Weight-bearing films were not available for all of our patients requiring explantation of the HyProCure ETSD; therefore, we are unable to determine whether or not the severity of the flatfoot deformity had any contribution to the potential of the patients' symptoms and subsequent removal.

In terms of satisfaction, 8 of our patients were satisfied or very satisfied with the procedure. Two patients were neither satisfied nor dissatisfied and 3 patients were very dissatisfied. Eight patients said they would undergo the procedure again, one reported "maybe," and 4 patients said they would not undergo the procedure again. Because only 13 questionnaires were analyzed and they were anonymous, it is difficult to infer much from these data or generalize it to the study population as a whole.

The goal of our study was to add a new perspective to the HyProCure ETSD and to either confirm or refute Graham's findings after utilization of the device in the treatment of the flexible flatfoot deformity. We noted improvements in similar radiographic measurements and subjective outcome scores relative to previous studies; however, we reported a higher device removal rate at 15% compared to Graham's 6% and Bresnahan's 4.35% (10,11,19). This could be related to surgical technique, under- or overcorrection of the deformity, or patient selection. We also found that our adolescent patients did better than our adult patients with no devices removed in our adolescents and only one noted transient post-operative complication.

The current study does have several limitations that are worth noting. First, it was a retrospective study. The diagnosis of the flexible flatfoot and decision to perform an arthroereisis was primarily based on the clinical examination with the aid of radiographs in certain cases; therefore, preoperative and postoperative films were not routinely taken. As a result, there were only a limited number of films available for analysis. Furthermore, we were unable to determine whether or not the severity of the flatfoot deformity contributed to the need for explantation of the HyProCure ETSD. Second, the sample size was small, thus making it difficult to generalize the findings. We did note improvements in similar measurements as compared to previous studies; however, our improvements were not as great in comparison. Third, there was lack of patient participation with only 13 of 29 questionnaires available for evaluation. Lastly, because the results of our patient questionnaire were anonymous, we were unable to correlate the objective findings (both clinical outcomes and radiographic analysis) with the subjective outcomes.

In conclusion, we found improved radiographic parameters and fair subjective outcomes after the insertion of the HyProCure ETSD, but reported a higher device removal rate compared to previously documented studies. Our adolescent patients clinically did better with only 1 noted transient postoperative complication and no devices removed. With limited films available for analysis, though, and low patient participation, it is difficult to make any reasonable conclusions as to whether or not the HyProCure is a good treatment option for the patient who presents with a severe recalcitrant flexible flatfoot deformity. Further research is needed in order to better analyze the subjective and objective outcomes of the device.

Table 1

BREAKDOWN OF MODIFIED MARYLAND FOOT SCORE.

Questionnaire #	Total Mod-MFS Score	Satisfaction Score	Undergo procedure again?
1	91	4	Yes
2	32	0	No
3	100	5	Yes
4	99	4	No
5	88	3	May
6	100	5	Yes
7	30	0	No
8	100	5	Yes
9	68	3	Yes
10	94	4	Yes

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