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Extraosseous Talotarsal Stabilization Using HyProCure® in Adults: A 5-year Retrospective Follow-up

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ABSTRACT

The purpose of this retrospective study was to determine long-term functional outcomes and device tolerance achieved in adult patients who chose to undergo an extraosseous talotarsal stabilization procedure HyProCure® for the treatment of flexible talotarsal joint deformity. Eighty-three adult patients participated in this study. Postoperative subjective assessment of device performance was evaluated using Maryland Foot Scores, which were collected at a mean follow-up period of 51 months. The mean postoperative Maryland Foot Score was 88 out of 100; postoperatively, 52% of cases reported complete alleviation of foot pain, 69% of cases had no limitations on their foot functional abilities, and 80% of cases reported complete satisfaction with the appearance of their feet. The implant was removed in 7 out of 117 cases (removal rate: 6%) due to prolonged pain of the anterior talofibular ligament (4 cases), psychogenic reaction (2 cases), and postoperative infection (1 case). The long-term positive subjective outcomes and excellent patient satisfaction obtained in this study may imply that extraosseous talotarsal stabilization was effective in stabilizing the talotarsal joint complex and eliminating excessive abnormal pronation, thus reducing pain and improving quality of life of the patients; it represents a possible treatment option for partial talotarsal dislocation in cases with flexible and reducible deformity.

The talocalcaneonavicular joint complex consists of 4 individual articulations (posterior talocalcaneal, middle talocalcaneal, anterior talocalcaneal, and talonavicular) forming a closed kinematic mechanism. The normal biomechanical functioning of this complex entity involves the relationship of articular facets between the talus and the calcaneus, and at the same time, the talus and the navicular. Because motion in any one of the aforementioned individual articulations forces motion to occur in the others, resulting in a 3-dimensional helicoidal movement, one should not discuss the motion occurring between the talus and the calcaneus without including the motion between the talus and the navicular (1). Historically, and for reasons of simplicity, the motion between these 2 joints has been discussed individually. For the purpose of this article, we consider the entire complex as a single functional unit and refer to it as the talotarsal mechanism or the talotarsal joint.

The stability of the talotarsal joint is crucial to maintain proper balance, uniform weight distribution, normal gait pattern, and biomechanical function, not only for the foot and ankle but also for the proximal musculoskeletal structures (knee, pelvis, and spine) (2–4). A partial or incomplete dislocation of one of the articular facets of the talotarsal joint may lead to an imbalance in the entire kinematic structure, ultimately leading to a shift in the balance of forces within this closed system of articulations. Specifically, abnormal forces within the talotarsal joint lead to excessive hindfoot motion, which results in a prolonged period and excessive amount of pronation during static and dynamic weight-bearing activities. Clinically, this more-than-normal, disproportionate period and excessive amount of pronation are termed as overpronation or hyperpronation, which is associated with a multitude of lower extremity pathologies (5–10). It has been recommended that interventions that reduce or eliminate excessive period and amount of pronation should be considered to alleviate the symptoms associated with these pathologies (6–8).

The purpose of this study was to provide a retrospective evaluation of the HyProCure® (GraMedica, Macomb, MI) device in a randomized adult population treated for symptoms associated with hyperpronation caused by partial talotarsal joint dislocation or talotarsal joint instability. HyProCure® (Fig. 1) is an extraosseous talotarsal stabilization (EOTTS) device designed to restore, as close as possible, the normal articular relationships of the talotarsal joint without compromising the normal range of hindfoot motion. The goal of this clinical investigation was to evaluate postoperative subjective

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Conflict of Interest: Michael E. Graham is the inventor of HyProCure®. He is the sole owner of GraMedica, LLC, the company that manufacturers and distributes HyProCure®.
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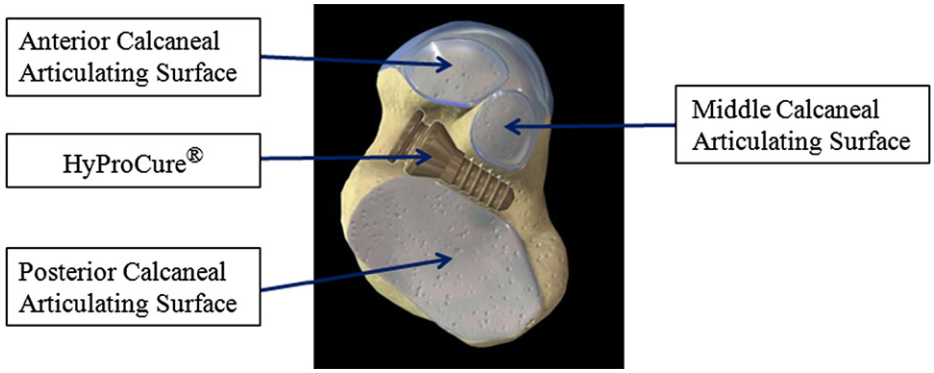

Fig. 1. The placement of HyProCure® in alignment with the sinus tarsi and abutting the lateral part of the canalis tarsi.

outcome measures on the use of HyProCure® in a standalone procedure for stabilization of the talotarsal joint. The data represented consists of postoperative patient satisfaction scores determined using the Maryland Foot Score (MFS) Questionnaire.

Patients and Methods

For this study we considered only adult patients (minimum age of 18 years at the time of surgery) treated with HyProCure® between October 2004 and December 2006. Patients who had received adjunctive soft tissue procedures such as tarsal tunnel release, neurolysis, plantar fasciectomy, excision of lipoma, or osseous procedures of the digits such as hammer toe surgery were also considered for participation in this study because these procedures do not aid in correcting talotarsal joint instability. Exclusion criteria for the study included patients who had received HyProCure® with adjunctive (i) hindfoot/midfoot osseous procedures, (ii) soft tissue procedures other than those listed in the inclusion criteria, and (iii) metatarsal procedures. All surgeries were performed by the primary investigator. The patients who met the inclusion/exclusion criteria were contacted via phone, fax, or e-mail in February 2010, in request to participate in the study. Eighty-three patients (34 men, 49 women) responded for participation. A total of 117 feet were treated in this patient group; 34 patients with bilateral procedures and 49 patients with unilateral procedures. The mean age for this group at the time of surgery was 58 (range 22 to 85) years. The patients were asked to provide their honest responses to the MFS Questionnaire and sign the Institutional Review Board (IRB)–approved consent form (mailed, faxed, or e-mailed to them during February/March 2010) to allow release of their subjective foot score data for publication. The present retrospective study was reviewed and approved by Quorum Institutional Review Board (Seattle, WA).

Operative Procedure

The operative procedure was identical for all patients. The patient was placed on the operating table in a supine position. The foot and ankle were prepped 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. There was no need to apply a tourniquet because there is minimal risk of blood loss with this procedure. The patient also received a preoperative antibiotic within 1 hour before the incision as per the protocol of the hospital. An approximate 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 both 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 sizer. Inadequate transection of these tissues would prevent the proper placement of trial sizers, which could compromise trial sizing and ultimately lead to failure of the final placement of HyProCure®. A guide wire (if used) supplied with the instrument set was gently inserted into both portions of the sinus tarsi, making sure to angle its insertion in the same direction, that is, anterior-distal-lateral to posterior-proximal-medial. Trial sizing was performed to determine which HyProCure® size would give the best correction. The no. 5 trial sizer was placed onto the guide wire and inserted into both the canalis and sinus portions of the sinus tarsi. The talotarsal joint was then placed through a full range of motion to determine how much correction was achieved with the corresponding trial sizer. The goal was to restore the motion to a normal range of hindfoot pronation, that is, 3° to 5°. If excessive hindfoot motion was present with size no. 5, the next incremental trial sizer was placed to determine the new range of hindfoot motion. This procedure was repeated until the appropriate trial sizer achieved the required amount of correction.

Once the proper size was determined, the corresponding HyProCure® was placed on the insertion driver and either moved along the guide wire, if used, or moved into position with a twisting motion. The driver was removed and the position of the device was examined by intraoperative fluoroscopy. The guide wire, if used, was removed from the foot once superficial placement of the device was achieved. In the patient group reported in this study, HyProCure® size 6 was used in 72 feet, size 7 in 28 feet, size 8 in 11 feet, size 9 in 4 feet, and size 10 in 2 feet. The incision was closed with a modified absorbable subcuticular closure reinforced upon itself. Deep tissue closure was not performed.

A dry, sterile compression dressing was applied to the foot and ankle. The patients received a postoperative shoe and crutch (if needed). The patients were instructed to elevate the foot as much as possible when awake for the first 24 to 36 hours, and were allowed limited weightbearing on the foot as tolerated. The patients were allowed to increase activity as tolerated until their first postoperative visit at 1 week. Patients were encouraged to transfer to and use new and supportive shoes as soon as tolerated, making sure the outer collar of the shoe would not rub against the incision site and were advised not to revert back to worn-out shoes.

Questionnaire Evaluation

The modified MFS Questionnaire was used for subjective evaluation of patient satisfaction with the HyProCure® device (11–13). The MFS scoring system comprises a total of 100 points. It can be divided into the following 3 major areas: pain, function, and appearance. The MFS designates 45 points for foot pain, wherein 0 indicates disabling pain and 45 indicates no pain. MFS evaluates foot function using various criteria such as walking abilities, stability while walking, motion at the big toe joint, support required (crutch, cane, wheelchair), limp, foot gear tolerance, walking upstairs/downstairs, and terrain stability; these designated a total of 45 points. Additionally, MFS also assigns 10 points to assess patient satisfaction with the appearance of their feet (Table 1). The MFSs were received from 78 out of 83 patients (110 of 117 feet) as the remaining 5 patients (7 feet) who had their implants removed did not fill out the questionnaires. The mean follow-up period of this retrospective subjective evaluation was 51 (range 38 to 65) months from the date of surgery.

Results

The mean postoperative MFS for 110 feet from 78 patients was 88 (range 31 to 100). The mean, standard deviation, and range values of foot pain, foot function, and appearance of the foot are presented in Table 2. The frequency distribution plots of these 3 individual categories and of the total MFSs are shown in Fig. 2. Five years after implantation of HyProCure® it was observed that 52% cases had complete alleviation of foot pain, whereas 2% (1 patient, bilateral procedure) had severe disabling foot pain (not due to HyProCure® itself, but because of pre-existing peripheral neuropathy). Also, 69% of cases had no limitations on their foot functional capabilities and 80% of cases reported complete satisfaction with the appearance of their feet.

Complications

HyProCure® was permanently removed from 7 feet (in 5 patients) out of 117 feet (in 83 patients), resulting in an overall removal rate of 6%.

Table 1
The Maryland Foot Score Questionnaire used to assess patient satisfaction after the insertion of HyProCure®*

Maryland Foot Score (Questions)			
1) Presently, regarding my foot surgery, I have		Left Foot	Right Foot
a) No pain, including physical activities (sports) (45)	a)	☐	☐
b) Slight pain, but it does not affect my work ability (40)	b)	☐	☐
c) Mild pain, but I have made only minimal changes in my regular daily activity (30)	c)	☐	☐
d) Moderate pain and I take aspirin, Tylenol, or Advil for it (20)	d)	☐	☐
e) Marked pain, even with minimal activities (10)	e)	☐	☐
f) Disabling pain, for which I take stronger pain pills (if so, what type?) (0)	f)	☐	☐
2) With regards to my foot surgery and walking, my walking ability is:		Left Foot	Right Foot
a) Unlimited (greater than 6 blocks) (10)	a)	☐	☐
b) Slightly decreased (4-6 blocks) (8)	b)	☐	☐
c) Moderately decreased (1-3 blocks) (5)	c)	☐	☐
d) Severely decreased (less than 1) (2)	d)	☐	☐
e) Restricted to indoors only (0)	e)	☐	☐
3) With regards to my foot surgery influencing my walking:		Left Foot	Right Foot
a) I feel completely stable when I walk (4)	a)	☐	☐
b) I have a weak feeling when I walk (3)	b)	☐	☐
c) I have an occasional giving away (2)	c)	☐	☐
d) I have instability when I walk (frequently giving away) (1)	d)	☐	☐
e) I need support to walk (0)	e)	☐	☐
4) With regards to my foot surgery area and support:		Left Foot	Right Foot
a) I need no support to walk (4)	a)	☐	☐
b) I need a cane to walk due to my foot (3)	b)	☐	☐
c) I need crutches to walk (1)	c)	☐	☐
d) I need a wheelchair (0)	d)	☐	☐
5) With regards to my foot surgery and walking:		Left Foot	Right Foot
a) I do not feel I have a limp (4)	a)	☐	☐
b) I have a slight limp (3)	b)	☐	☐
c) I have a moderate limp (2)	c)	☐	☐
d) I have a severe limp (1)	d)	☐	☐
e) I cannot walk (0)	e)	☐	☐
6) With regards to my foot surgery area and shoe wear:		Left Foot	Right Foot
a) I can wear any type of shoe I desire or want to wear (10)	a)	☐	☐
b) There are some shoes that I cannot wear (9)	b)	☐	☐
c) I can only wear flat heel shoes (7)	c)	☐	☐
d) I need to wear shoes with my orthotics (5)	d)	☐	☐
e) I wear special extra-depth or "orthopedic shoes" (2)	e)	☐	☐
7) With regards to my foot surgery area and walking:		Left Foot	Right Foot
a) I can walk on any surface or terrain (4)	a)	☐	☐
b) I have problems walking up and down hills (2)	b)	☐	☐
c) I have problems walking on flat surfaces (0)	c)	☐	☐
8) With regards to my foot surgery and walking:		Left Foot	Right Foot
a) I can go up stairs normally (4)	a)	☐	☐
b) I need to use the banister (3)	b)	☐	☐
c) I need assistance going up and down stairs (2)	c)	☐	☐
d) I am unable to go up and down stairs (0)	d)	☐	☐
9) With regards to my foot surgery area and how my foot looks:		Left Foot	Right Foot
a) I feel my foot looks normal (10)	a)	☐	☐
b) It looks like I have a mild deformity (7)	b)	☐	☐
c) It looks like I have a moderate deformity (5)	c)	☐	☐
d) It looks like I have a severe deformity (0)	d)	☐	☐
10) With regards to my foot surgery and the motion I now have in my big toe joint(s):		Left Foot	Right Foot
a) I feel I have normal motion (5)	a)	☐	☐
b) I feel my motion is slightly decreased (4)	b)	☐	☐
c) I feel my motion is markedly decreased (0)	c)	☐	☐

* Question 1 quantifies the level of pain (on a scale of 0 to 45). Questions 2 through 8 and 10 assess foot function (on a scale of 0 to 45). Question 9 assesses the appearance of the patient's feet. The maximum possible score is 100.

Excluding these, there were a total of 16 revision surgeries with HyProCure®. Nine of these revisions involved the repositioning of a partially displaced device or a change in size of a previously implanted HyProCure®, whereas in the remaining 7 cases HyProCure® was used to replace previously implanted subtalar devices (non-HyProCure®) that had become symptomatic or partially displaced (implanted before October 2004). The factors that led to permanent HyProCure® removal in 7 cases were pain in the superficial area over the anterior talofibular ligament (4 cases), psychogenic reaction (2 cases; there was no pain or limitation from the device except that the patient could not mentally handle the fact that there was a foreign object in his/her body), and postoperative infection (1 case). However, the satisfaction scores of the 16 cases who had revision surgeries with HyProCure® were excellent. There were no other major/significant complications reported by the patients. There were no lasting ill-effects as a result of the removal of HyProCure® in the 7 cases reported herein.

Short-term self-resolving complications also occurred including incision dehiscence, prolonged skin healing, synovitis, period of abnormal gait secondary to surgery, and the appearance of over-correction that disappeared once the swelling, pain, and inflammation resolved. There were no long-term complications.

Discussion

The alignment of the articular facets of the talotarsal joint during weightbearing is of great importance because the foot is the

Table 2
Mean, standard deviation (SD), and range of values of the total and the 3 individual categories of the Maryland Foot Score Questionnaire for a total of 110 feet in 78 patients evaluated in this study

Maryland Foot Scores				
	Pain (out of 45)	Foot Function (out of 45)	Appearance (out of 10)	Total (out of 100)
Mean (n = 110)	38	41	9	88
SD	11	6	2	17
Range	0 to 45	21 to 45	0 to 10	31 to 100

foundation of the body. The sinus tarsi, a naturally occurring space between the talus and the calcaneus, serves as a fulcrum point transferring the body weight onto the calcaneus posteriorly and the rest of the foot anteriorly. Farabeuf (14) described the cruciate pivot point as an anatomical landmark on the lateral aspect of the canalis portion of the sinus tarsi. This is where the body weight passes from the posteriolateral aspect of the foot through the subtalar joint to the anteriomedial aspect of the foot. Basmajian and Stecko (15) determined that there should be very little appreciable motion occurring in the subtalar joint. However, in cases of altered articulations within the talotarsal joint, the cruciate pivot point shifts anteriomedially because of partial dislocation of talus, thus leading to hyperpronation upon weightbearing. As a result, the supporting soft tissue structures such as the spring ligament, posterior tibial tendon, Achilles tendon, and plantar fascia experience excessive abnormal strain as they try to minimize the pathological hindfoot motion. Failure of these soft tissue support structures to limit hyperpronation continually places excessive strain on those structures with every step taken, leading to a progressive deformity of the foot (7). Instability within the talotarsal joint may lead to secondary deformities such as flatfoot, plantar fasciopathy, progressive posterior tibial tendon dysfunction, tarsal tunnel syndrome, sinus tarsi syndrome, hallux abducto valgus, neuromas, and postural abnormalities, which may lead to early development of degenerative joint disease (6–8,10,16–20). The integrity of the articulations within the talotarsal joint is paramount to the static and dynamic balance of the foot and ankle.

In a static weight-bearing stance, instability of the talotarsal joint is characterized by hindfoot valgus, adduction and plantar flexion of talus, and abduction of the forefoot on the rearfoot depending on the plane(s) of involvement (5,9). However, it must be noted that it is possible to have a dominant plane of deformity, that is, frontal plane deviation over sagittal plane or a transverse plane over frontal plane, etc. Collapse of the medial longitudinal arch may or may not be present depending on the severity of this deformity (5). Hyperpronation caused by talotarsal joint instability has been treated by a variety of conservative and operative methods. Conservative treatments include a wide range of over-the-counter or custom-made orthotic supports and braces, shoe modifications or changes, foot strappings, etc. (21–23). However, it has been acknowledged that limitations of conservative treatments exist, not only in achieving the required amount of correction but also in the alleviation of pain and/or associated symptoms (24–26). After the failure of conservative measures, it is very common to use operative methods involving soft tissue and/or osseous procedures to treat the underlying instability of the talotarsal joint. These include soft tissue plication procedures, tendon transfers, hindfoot/midfoot osteotomies and arthrodeses, or a combination of these (26–30). Most of these surgical procedures are highly invasive, having a lengthy immobilization period and prolonged recovery time. Moreover, these procedures may lead to degenerative joint disease or arthritis in the adjacent joints because of limitation or complete elimination of motion at the talotarsal joint (16,17). Other potential complications associated with these procedures include nonunion, infection, misalignment of the hindfoot, lateral impingement, and sural nerve injury (26–30). These confounding factors led to the development of subtalar implants, which are inserted into the sinus tarsi through minimally invasive procedures. These devices are designed to restore talotarsal joint stability and normal range of pronatory motion without compromising adjacent soft tissue, osseous,

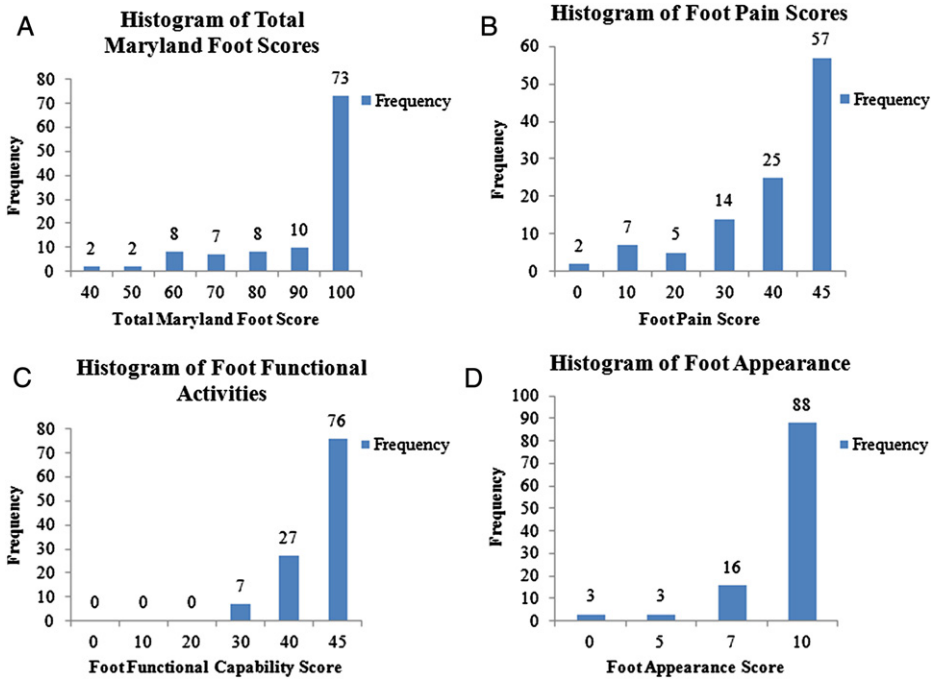

Fig. 2. Bar graph of the frequency distribution of the (*A*) total Maryland Foot Score, (*B*) Foot Pain Score, (*C*) Foot Functional Capability Score, and (*D*) Foot Appearance Score. The data labels indicate the number of feet (out of a total of 110) that fall in that particular bin (score) range.

and articular structures (16,31–39). The procedure involved with the insertion of such devices into the sinus tarsi was termed *subtalar arthroereisis*.

In a prospective study done in 2003 by Viladot et al (38) using the Kalix endorthesis (New Deal SA, Vienne, France) (composed of titanium and ultra high molecular–weight polyethylene) implanted into the sinus tarsi of 19 feet in 19 adult patients diagnosed with posterior tibial tendon dysfunction, 17 out of 19 patients were "satisfied" or "very satisfied" with the results. The mean American Orthopaedic Foot and Ankle Society score increased from a preoperative value of 47 to a postoperative value of 82. However, 11% of the implants were removed because of pain after the surgery. It is also important to mention that additional posterior tibial tendon repair procedures were performed in each of the 19 patients, along with Achilles tendon lengthening in 11 patients. Furthermore, it is required that the Kalix implant be removed within 15 to 18 months after its insertion, leaving long-term results on the procedure open for debate (Post-Operative Treatment, Kalix Surgical Technique; Integra LifeSciences Corporation). In another prospective study done in 2006 by Needleman (34) using the Maxwell-Brancheau-Arthroereisis sinus tarsi implant (composed of titanium), in 28 feet in 23 adult patients diagnosed primarily with flexible flatfeet, the mean American Orthopaedic Foot and Ankle Society score increased from a preoperative value of 52 to a postoperative value of 87. However, the implant was removed in 39% of the cases because of sinus tarsi pain. Additionally, adjunctive hindfoot, midfoot, and forefoot procedures such as soft tissue reconstruction, osteotomies, and arthrodeses were performed in almost all cases. Also, other conical-shaped implants have been used for the treatment of adult flexible flatfeet and posterior tibial tendon dysfunction. However, no research studies are available on the clinical outcomes of these devices (35). It has been identified that the sinus tarsi is conical in shape. Specifically, the sinus portion of the sinus tarsi is conical, whereas the canalis portion of the sinus tarsi is cylindrical in shape. Schon (35) mentions that he has performed hindfoot osteotomies and tendon repair procedures with adjunctive subtalar arthroereisis in more than 70 cases, in both adult and pediatric populations, using both the cylindrical- and conical-shaped implants with an overall removal rate of 30% to 40%. He acknowledges that high implant removal rate is a concern and also mentions that an implant having a shape that better matches with the anatomical course of the sinus tarsi provides normal distribution of forces and may result in lower incidence of pain and hence lower implant removal rates.

The shortcomings and limitations of these devices, namely the high implant removal rates, need for adjunctive hindfoot/midfoot osteotomies or arthrodeses procedures, high incidence of postoperative pain, and associated complications led to the development of HyProCure®. This device is composed of medical-grade titanium alloy, and, unlike nonmetallic devices, it will not fragment and is intended to remain in situ for the remainder of the recipient's life. HyProCure® has a unique design with a lateral conical shape coupled to a medial cylindrical geometry, intended to align perfectly with the sinus and canalis portions of the sinus tarsi. This device is cannulated and threaded for ease of insertion, and to allow tissue on-growth, making it a medially anchored device versus the laterally anchored devices such as the cylinder- and conical- shaped designs. Another feature of HyProCure® is that it is positioned from anterior-lateral-distal to posterior-medial-proximal, that is, in orientation with the sinus tarsi. This oblique orientation allows for uniform distribution of forces to the posterior and anterior aspects of the foot/sinus tarsi. The preferred procedure name associated with the implantation of HyProCure® is termed EOTTS, because the basic function of this device is to stabilize the talotarsal joint, leading to the elimination of hyperpronation and its resulting symptoms.

The ideal function of an EOTTS device is to eliminate excessive abnormal motion within the talotarsal joint while still allowing the normal range of hindfoot motion to occur. The majority of talar motion occurs within the lateral half of the sinus tarsi in comparison with the minimal motion occurring in its medial region. This is because of the anatomical orientation of the sinus and canalis portions of the sinus tarsi in addition to the forces acting on the talus. During a normal gait cycle, the talus rotates externally or supinates at heel strike, followed by internal rotation as forces from the body pass through the talus during the midstance/flatfoot phase. As the center of the body weight passes from the posterior-lateral to anterior-medial aspect of the foot, it stops medially at the cruciate pivot point before passing on to the front of the foot (14,40). The cruciate pivot point, located at the lateral entrance of the canalis, is the exact location where stability of the talotarsal joint is important, and this is the area that must be internally stabilized if instability exists. Because the forces from the talus pass to the rest of the tarsal and metatarsal bones in an oblique fashion from a posterior-lateral to anterio-medial aspect, the EOTTS device must allow for the same transfer of forces to occur. Thus, HyProCure®, which is placed in an oblique fashion, after the alignment of the sinus tarsi, would result in better biomechanical functioning of the talotarsal joint. The medial threaded cylindrical portion of HyProCure® is placed within the canalis portion of the sinus tarsi; before placement, the tissues within the canalis portion are transected, which will heal back together, incorporating around the threads to anchor HyProCure® in place. The middle tapered portion of the device abuts the medial sulcus of the sinus portion of the sinus tarsi to ensure proper placement and prevent overinsertion, and functions to stabilize the cruciate pivot point. Finally, the lateral conical portion of the device helps stabilize the sinus portion of the sinus tarsi by preventing the anterior deviation of the lateral process of the talus. Recently, Graham et al (41) conducted a biomechanical study on adult human cadaver specimens, in which they looked at the distribution of forces on the anterior and posterior aspects of the talocalcaneal joint. They report that HyProCure® assists in uniform distribution of the axial loads and prevents excessive talar subluxation over calcaneus, thus restoring normal biomechanics of the talotarsal joint.

The present study is the first to report subjective outcomes on the use of HyProCure® for the treatment of talotarsal joint instability and its associated pathologies. The patient satisfaction scores showed excellent long-term results, with a high level of tolerability and overall improvement in the quality of life of the patients. The low implant removal rate of 6% and minimum postoperative complications are attributed to the unique design and insertion properties of HyProCure®. A major advantage of this device is that it can be used as a standalone procedure for the treatment of mild to moderate cases of talotarsal joint instability. In cases in which severe instability exists, adjunctive procedures may be required to achieve the desired amount of correction. In the present study, 75 out of 110 feet, that is, 68% cases (in whom the implants were not removed) received HyProCure® in a standalone procedure, whereas the remaining 35 feet received adjunctive soft tissue procedures as mentioned previously. Also note that these adjunctive procedures were only performed for other reasons, and were not meant to add to the correction of the underlying instability, unlike previous reports in which soft tissue procedures were performed to aid in realigning the osseous hindfoot structures (34,38). We would like to mention here that studies done on the cylindrical- and conical-shaped devices have focused mainly on the treatment of pes planus or flatfeet, and posterior tibial tendon dysfunction, without considering the fact that talotarsal joint instability is associated with each of these conditions (31,32,34,35,38). As previously mentioned,

talotarsal joint instability may lead to conditions such as tarsal tunnel syndrome, plantar fasciitis, progressive posterior tibial tendon dysfunction, Achilles tendinitis, first ray disorders, and hallux abductovalgus among others (6–8,10,16–20). It follows from this that stabilization of the talotarsal joint as the first step in treatment is essential in preventing the occurrence of these secondary conditions. Also, the adult patient population considered in the present study was much larger than any of the previously published research studies looking at the outcome of similar devices (34,38).

An additional factor that must be taken into consideration while stabilizing the talotarsal joint is the stability of the first ray. The increased strain on the medial arch of the foot due to a medially deviated subtalar joint axis may result in instability adaptations occurring to the first ray. If left untreated, osseous compensation may occur, with the formation of exostoses at the first metatarsal cuneiform joint leading to a rigid forefoot deformity. Even if the talus is stabilized within the talotarsal joint, forefoot instability may still exist, requiring treatment based on the degree of deformity. Adjunct conservative or operative therapy may be necessary in such cases. None of the patients included in this study had severe first ray deformity and were not treated with any associated operative procedures.

It has also been suggested in the literature that talotarsal joint instability is caused by Achilles tendon shortening or contraction (20,42). The theory is that because of a tight muscle-tendon complex, the talus is forced out of position. It has been further suggested that along with the insertion of a subtalar implant, an Achilles tendon lengthening procedure must be performed (34). The author chose to test the validity of this theory and did not perform an Achilles tendon lengthening procedure in combination with the EOTTS using HyProCure®. As evident from the patient satisfaction score results, HyProCure® alone was effective in stabilizing the talotarsal joint and none of the patients developed any sort of postoperative Achilles tendon pain. In the investigation done by Harris and Beath (43), they provide persuasive evidence that anatomical abnormalities in the calcaneus, and to some extent in the talus, result in structural faults in the talotarsal mechanism, and are the etiological factors leading not only to hyperpronation but also to shortening of the Achilles tendon. The primary function of the gastrosoleus complex is to aid in supination of the foot, because it is one of the strongest supinators of the foot. In a hyperpronating foot, with the lateral shift of the medial tubercle of the calcaneus with respect to medially deviated subtalar joint axis, there are excessive pronatory moments produced from the ground reaction forces. As a result, the gastrosoleus complex generates supinatory moments to counteract these abnormal pronatory moments, thus resulting in excessive strain being placed on these structures in addition to requiring increased functional capacity to produce supinatory moments (44). Once the talus is repositioned within the talotarsal joint and the resulting hyperpronation is eliminated, it leads to decreased functional demands placed on the gastrosoleus muscle-tendon complex. Further investigation into this phenomenon is ongoing.

A limitation of the present study is that it is a retrospective investigation looking at the postoperative patient satisfaction scores as the IRB was obtained after the EOTTS procedures of the patients. As a result, we were not able to quantify the improvement in terms of the preoperative subjective patient satisfaction scores; however, a second prospective IRB-approved study is currently underway. Also, the preoperative and postoperative radiographs of the patient population considered in this study are being analyzed in detail to determine the amount of correction obtained after the placement of HyProCure®. The possible contraindications for the use of an EOTTS procedure with HyProCure® are the presence of a rigid, nonreducible hindfoot deformity, local active infection over the sinus tarsi, and children under the age of 3 years. Another possible limitation of using this procedure is that because of the nature of pathologic motion combined with a long-term disease process, there is a likelihood of the talus grinding on the calcaneus. This may lead to the flattening of the anterior chamber of the sinus tarsi on the calcaneus. Even though the device is properly placed within the undersurface of the talus, it would lead to a failure of the device to maintain position in the sinus tarsi and limit the excessive motion of the talus on the calcaneus. This is a rare but possible condition. One must also take into consideration the possibility of a hindfoot coalition with this procedure.

In summary, the EOTTS procedure using HyProCure® resulted in excellent patient satisfaction scores as assessed by the MFS questionnaire. This may imply that HyProCure® was effective in stabilizing talotarsal joint, thus eliminating pain and improving quality of life of the patients. A major advantage with the use of HyProCure® is its very low implant removal rate of 6%. This study provides an evidence-based analysis showing the importance of stabilizing the talus on the talotarsal mechanism in the treatment of hyperpronation and its associated pathologies.

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