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Review

Extraosseous Talotarsal Stabilization Devices: A New Classification System

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ABSTRACT

Displacement of the articular facets of talus on the tarsal mechanism, or partial talotarsal dislocation, is a condition seen in children, adult, and geriatric populations. A characteristic of this pathologic condition is a prolonged period of and excessive amount of pronation (hyperpronation) on weightbearing. The ill effects of this condition may lead to a multitude of other foot pathologies and to pathologies associated with the proximal lower extremity musculoskeletal structures. A variety of conservative and operative treatment options have been used to eliminate or minimize hyperpronation. Extraosseous talotarsal stabilization (EOTTS) devices have been used to realign and stabilize the articular facets of the talus on the tarsal mechanism, thereby attempting to restore the normal range of hindfoot motion while eliminating hyperpronation. A multitude of such devices, which are intended for the same purpose, are available for the surgeon to choose from. However, there is no literature discussing the differences among these devices, or the benefits of one device over the other. Based on current understanding and available knowledge base, the goal of this article was to classify EOTTS devices based on their design features and biomechanical functioning. A theoretical description of how these different types of devices function is laid out in an attempt to understand the reason for their success or failure. This new classification system is intended to help researchers and surgeons appreciate the subtle yet important differences among these devices, and to thus help them design future research studies when using these devices.

The stability of the talus on the tarsal mechanism is paramount in order for the foot to function normally (1). The talus mediates the transfer of vertical and rotational forces from the lower leg to both the calcaneus and navicular, and subsequently to the midfoot and forefoot structures (2). During weightbearing activities, the instability of the talus over the calcaneus and navicular, caused by pre-existing structural deformities or laxity of talar articulations, may lead to partial displacement (i.e., subluxation) of the talocalcaneal and talonavicular articular facets (3) (Supplemental Videos S1 and S2; Figs. 1 and 2). This results in excessive abnormal pronation or hyperpronation (also defined as flexible deformity of the hindfoot), which places an increased abnormal strain on the medial column of the foot (4,5). Eventually, this excessive motion and strain take their toll on the secondary supporting soft tissue structures such as the spring ligament, posterior tibial tendon, plantar fascia, and Achilles tendon, among others, which try to minimize the excessive abnormal motion of the talus on the tarsal mechanism (2,4). At a certain critical threshold limit, these soft tissue structures can no longer withstand the excessive compensatory forces, and pathological conditions such as posterior tibial tendon dysfunction, plantar fasciopathy, and so on, begin to appear (4,6). In addition, hyperpronation may also result in symptoms associated with the distal structures of the foot and the proximal structures of the lower extremity kinematic chain, that is, knee, hip, and lower back (7–12). Therefore, it is extremely essential to correctly diagnose and treat the underlying root cause of the deformity, which is dynamic partial dislocation of the talus on the tarsal mechanism upon weightbearing.

Since the beginning of modern foot and ankle specialty, many treatment options have been developed to stabilize the talus on the tarsal mechanism in the pathological foot, in an attempt to realign the osseous structures of the hindfoot, and reestablish the normal axis of motion and the normal distribution of joint forces. Both conservative and operative approaches have been implemented, each with their advantages and disadvantages. External modalities such as foot orthoses, foot strapping, braces, and splints are commonly used. Limitations of this form of treatment include patient compliance (i.e., inability to tolerate the application of the device), discomfort, limited ability to stabilize the talus on the tarsal mechanism, and

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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. Normal talotarsal motion. The articular facets remain in constant congruent contact (Supplemental Video S1).

Fig. 2. Abnormal talotarsal motion. Fluoroscopic imaging shows obliteration of the sinus tarsi on the lateral view and an increased talar second metatarsal angle on the anteroposterior view (Supplemental Video S2).

controversial long-term results (13–15). Likewise, limitations of traditional operative procedures such as soft tissue augmentation procedures, osteotomy, and arthrodesis include long recovery periods, potential surgical complications, a lengthy period of immobilization and non–weightbearing, and potential for secondary joint compensation damage, that is, arthrodesis of one joint may cause excessive motion in the adjacent joint(s), which may lead to arthritis in those joints (16–20). Traditional operative procedures are usually reserved for cases of severe hindfoot deformity.

The extraosseous talotarsal stabilization (EOTTS) procedure with the use of a subtalar implant has evolved as an alternative approach to the above described methods (21–31). An implantable EOTTS device can be thought of as an internal orthotic that provides stability without leading to issues of long-term patient compliance. Preoperative and postoperative clinical and radiographic data on the use of these devices have shown positive patient outcomes and successful realignment of osseous hindfoot structures, although with some variability based on the design of the device (25,30,32). During weightbearing activities, this realignment leads to restoration of the normal period/amount of pronation to the talotarsal mechanism, thus reducing excessive strain on the medial column of the foot and the surrounding soft tissue support structures. A major advantage with the use of an EOTTS device is that it involves a minimally invasive surgical procedure performed through a small incision over the tarsal sinus (6,27,30,32–34). Additionally, recovery from this procedure is expected to be sooner than that achieved with traditional hindfoot surgeries, and there is less risk of potential postoperative complications (6,27,30,32–34). Based on years of clinical experience, it is the authors' opinion that an EOTTS device can provide an excellent treatment option for individuals whose flexible/reducible hindfoot deformity is not adequately addressed with an external support device but is not severe enough to warrant traditional hindfoot surgery. Over the past several years, a variety of EOTTS devices or the so-called subtalar implants have been introduced. These primarily

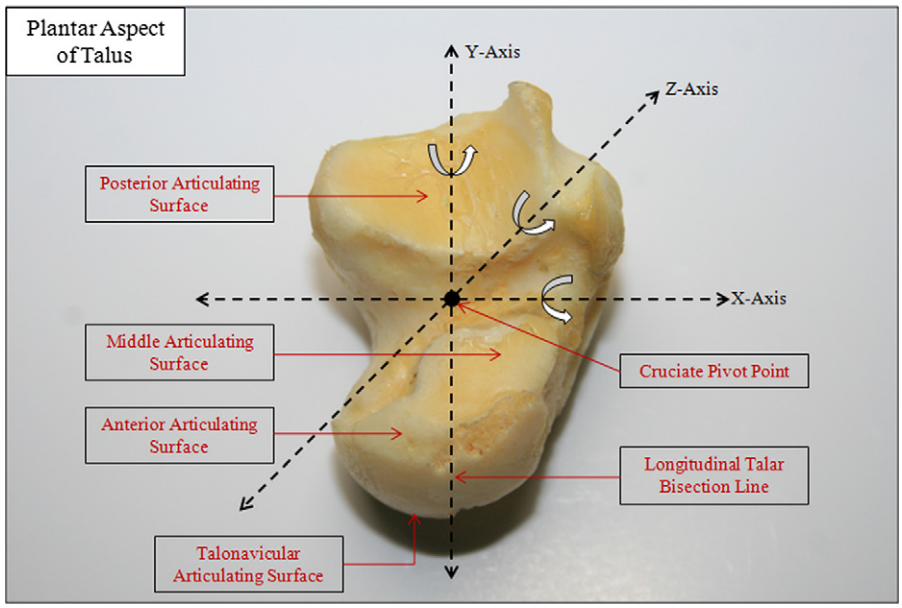

Fig. 3. Plantar aspect of talus. This image shows the plantar aspect of the talus with a rectangular coordinate system. Notice that the origin of this system coincides with the "cruciate pivot point." Also, the longitudinal talar bisection line coincides with the y-axis. Rotation of the talus about the x-, y-, and z-axis corresponds to plantar-dorsiflexion, inversion-eversion, and adduction-abduction, respectively.

Table 1
Classification system for EOTTS devices*

Type	Design	Orientation in Tarsal Sinus	Anchoring	Biomechanical Functioning
IA	Cylinder	Lateral to medial	Lateral	Talar impingement mechanism
IB	Conical	Lateral to medial	Lateral	Talar impingement mechanism
II	Cylinder + conical	Anterior-lateral-distal to posterior-medial-proximal	Medial	Allows normal talar helicoidal motion

* This table lists the classification criteria for type IA, IB, and II EOTTS devices. Notice that the only difference between type IA and IB devices is that the former has a cylindrical geometry and the latter has a conical geometry. Type II devices have a geometry that takes into account the anatomy of both the sinus and canalis portions of the tarsal sinus, that is, a medial cylindrical geometry coupled to a lateral conical geometry.

differ in their design characteristics, material properties, orientation of placement and anchoring within the tarsal sinus, and biomechanical functioning. As a result, the main purpose of this article was to define a new classification system for EOTTS devices based on the aforementioned properties. This will help the reader to appreciate the subtle yet important differences among the currently available devices, and may help future researchers design their studies on the use of these devices based on their specific goals and requirements.

Surgical Technique

The surgical procedure associated with the placement of EOTTS devices is well established in the medical literature. In brief, the patient is positioned supine, and an approximately 1.5-cm curvilinear incision is made on the lateral aspect of the foot over the tarsal sinus. The deep fascia and capsule overlying the tarsal sinus are identified and incised with blunt dissection to gain entrance into the tarsal sinus. Based on the device design, a guide wire is inserted in either a lateral-to-medial or anterior-lateral-distal to posterior-medial-proximal orientation along the floor of the tarsal sinus, anterior to the posterior talocalcaneal facet. Sequentially, either trial devices or cannulated trial sizers are advanced one at a time over the guide wire and into the tarsal sinus until the appropriate size is determined to achieve the desired correction. It is noteworthy to mention that based on the particular device design, the anterior leading edge of an implant may or may not be advanced beyond the longitudinal talar bisection line and into the canalis portion of the tarsal sinus. Next, the range of talotarsal joint motion is determined by passively pronating and supinating the hindfoot. Once the appropriate size is determined, intraoperative anteroposterior and lateral radiographs are captured to evaluate the placement of the trial sizer. After this, the trial device/sizer is removed and replaced with the actual device of the appropriate corresponding size. Again, the range of talotarsal joint motion is evaluated, and radiographs are captured to ensure that the device has been positioned as desired. Finally, the guide wire is removed and the incision on the lateral aspect of the foot is sutured. A dry sterile compression dressing is applied to the foot and ankle, and the patient is discharged with an appropriate postoperative shoe and crutch (if needed).

Discussion

It is important to understand certain anatomical, physiological, and biomechanical characteristics of the tarsal bones in order to appreciate the authors' newly defined classification system for EOTTS devices. First, the talotarsal mechanism is a constrained one, and it functions as a closed kinematic chain system (1). Motion imposed on one of the tarsal articulations forces motion on the others, with the talus being the keystone structure that experiences the majority of the motion in all 3 cardinal planes (1,35). During pronation and supination, the talus rotates along a complex helicoidal path within the tarsal mechanism (think of simultaneous adduction and plantarflexion that occurs when a foot pronates (Fig. 3) (1). Second, upon complete ossification of the talus and calcaneus bones in a normal foot, a natural cavity known as the tarsal sinus is formed. At this point it is important to mention that the tarsal sinus consists of a lateral sinus portion and a medial canalis portion. The sinus portion is conical in shape, whereas the canalis portion is cylindrical in shape. Also, the anatomical orientation of the tarsal sinus is anterior-lateral-distal to posterior-medial-proximal. Upon weightbearing in a normal foot, the tarsal sinus is unobliterated and the degree of talar motion is such that pronation is between 4° and 6° (31,36). However, in a pathologically hyperpronating foot (i.e., a foot exhibiting dynamic partial displacement of the talus) there is excessive talar adduction and plantarflexion, which leads to partial to complete obliteration of the tarsal sinus. In order to effectively correct this underlying instability and maintain normalcy, an EOTTS device should eliminate excessive

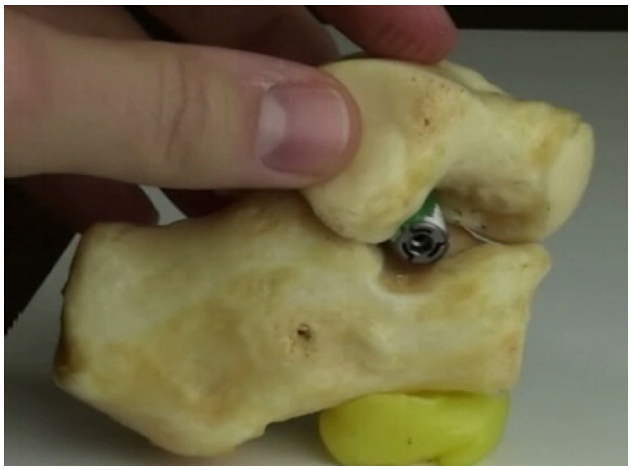

Fig. 4. Basic functioning of type IA device (Supplemental Video S3).

Fig. 5. Basic functioning of type IB device (Supplemental Video S4).

Fig. 6. Basic functioning of type II device. Type II has increased stability when compared with types IA and IB (Supplemental Video S5).

abnormal talar motion (hyperpronation) and maintain the normal tarsal sinus opening while simultaneously allowing the normal range of complex talar helicoidal motion to occur. This said, there are 4 critical aspects that need to be considered while classifying EOTTS devices:

1. Device geometry
2. Anatomic orientation or fit of the device within the tarsal sinus
3. Primary location at which the device is anchored within the tarsal sinus
4. Mechanism of talar stabilization and biomechanical functioning

Based on the aforementioned characteristics, and the currently available devices in the market, EOTTS devices can be classified into 2 major types, type I and type II. Furthermore, type I devices can be subclassified as either type IA or type IB devices. The characteristics distinguishing these 3 device types are listed in Table 1 and outlined as follows:

1. Type IA device is cylindrical in shape, is inserted into the tarsal sinus in a lateral-to-medial orientation (however, some newer device manufacturers do suggest a slightly oblique versus purely lateral-to-medial placement within the tarsal sinus), is laterally anchored in place by soft tissues within the sinus portion of the tarsal sinus, and functions by an impingement mechanism, as the leading anterior edge of these devices is inserted only up to the longitudinal talar bisection line (25,30) (Supplemental Video S3; Fig. 4).
2. Type IB device is similar to type IA device with the only difference being that type IB device is conical in shape; the other characteristics remain the same (Supplemental Video S4; Fig. 5).
3. Type II device is designed to have a lateral-conical and medial-cylindrical geometry, is inserted into the tarsal sinus in an anterior-lateral-distal to posterior-medial-proximal orientation, is medially anchored in place by soft tissues within the canalis portion of the tarsal sinus (i.e., the anterior leading edge of this device goes medially beyond the longitudinal talar bisection line), and it functions by allowing the normal helicoidal motion of the talus within the tarsal mechanism (Supplemental Video S5, Fig. 6).

The list of currently available EOTTS devices along with their categorization based on the authors' defined classification system is presented in Table 2. Popularity of the EOTTS procedure increased after Food and Drug Administration clearance of a titanium-based type IA device in 1996 (25,33,37). The design of this device was somewhat similar to that of the predicate Valenti subtalar implant, which was composed of polyethylene (25,31). As compared with polyethylene, titanium-based devices are much stronger and do not face the problem of in vivo postoperative fragmentation. Anatomically, the lateral half of the tarsal sinus is conical in shape; this caught the attention of other innovators who designed an expandable conical device, that is, a type IB device (cleared by the Food and Drug Administration in 2000) (30). However, the limitation of this newer device was that it was composed of both titanium alloy and ultra-high molecular weight polyethylene. As per the surgical indications of this device, it needs to be removed within 12 to 18 months after implantation because of the risk of polymer fragmentation. Currently, clinical and radiographic studies have been published on few select type IA and IB devices (23–26,30). These studies have shown significant improvement in the patient's condition postoperatively, and have reported successful clinical and radiographic outcomes with the use of these devices in both standalone and adjunctive procedures. After the success of these devices, similar cylindrical- and conical-shaped devices made of either titanium alloy or bioabsorbable poly-L-lactic acid were introduced (Table 1). However, to the best of our knowledge, we found no published scientific literature on the use of these other devices.

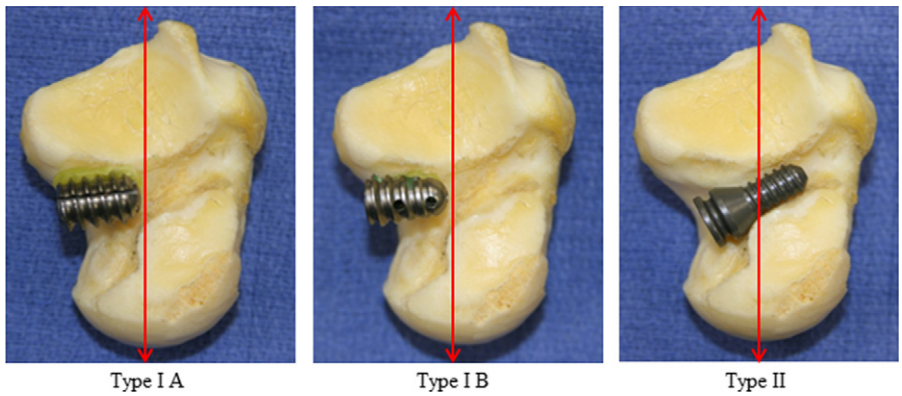

Fig. 7. Device placement on talus. This representative image shows the placement of type IA, IB, and II devices on the talus. The arrow indicates the longitudinal talar bisection line. For type I devices, the anterior leading edge of the device does not advance beyond the longitudinal talar bisection line, whereas for the type II device, the center of the device lies along the longitudinal talar bisection line. Also notice the lateral-to-medial placement of type I devices compared with the anterior-lateral-distal to posterior-medial-proximal placement of the type II device.

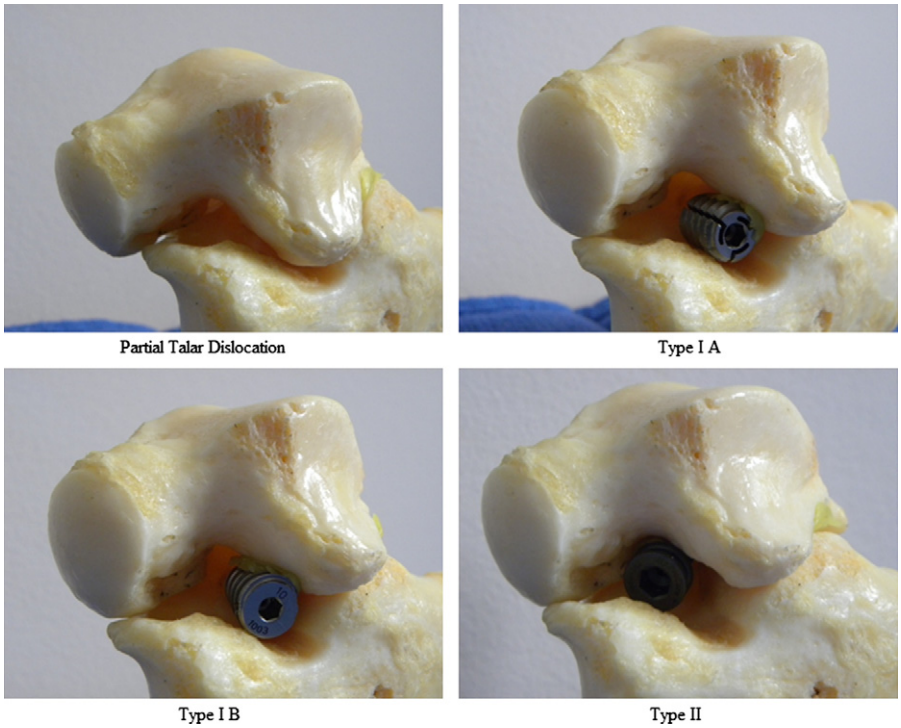

Fig. 8. Device placement within the tarsal sinus. This representative image shows the placement of the 3 types of EOTTS devices with the tarsal sinus. The image on the top left shows obliteration of the tarsal sinus caused by partial displacement of the talus. The subsequent images show the placement of the 3 EOTTS device types within the tarsal sinus. Differences between the type I and type II devices in terms of location of placement and orientation within the tarsal sinus can be clearly observed.

As previously mentioned, type I devices are anchored in place by the soft tissues within the lateral half of the tarsal sinus that attach and grow onto these devices. These laterally anchored devices attempt to prevent excessive abnormal talar motion by acting as a doorstop, that is, via an impingement mechanism. The lateral process of the talus presses against the dorsal posterior aspect of these devices as the talus moves from a supinated position to a pronated position. This causes the device to rotate in a helicoidal fashion along with the talus until the plantar-distal aspect of device, which acts as an anterior extension of the lateral process of the talus, comes in contact with the floor of calcaneus. During weightbearing activities, this impact occurs with every step taken. Even though the thought of this would be devastating to the involved osseous structures, there have not been any reported cases of calcaneal or talar fractures. Also, as the talus "unwinds" (think reverse helicoidal motion, that is, talar abduction and dorsiflexion) during supination, the laterally anchored device moves along with it. This indicates that the device itself may be unstable within the talotarsal mechanism as it is subject to undesired motion. This may explain the reason for the reported high rates of device removal (as high as 40%) with both type IA and type IB devices (25,27,33).

There exists a closed kinematic chain connection between the posterior, anterior, and medial talocalcaneal articular facets, and talonavicular articular facet. If one of these facets is maintained in its anatomic alignment, the others would also be maintained in their normal anatomic relationship. However, if the talus dislocates off one of these articular facets, it will cause dislocation along the other 3 articulations as well, leading to instability within the talotarsal

Table 2
EOTTS devices currently on the market*

Serial No.	Device Name	Material	Design	Company	Type
1	MBA®	Titanium alloy	Cylindrical	Integra LifeSciences Corporation	IA
2	bioBLOCK®	Poly-L-lactic acid	Cylindrical	Integra LifeSciences Corporation	
3	BioPro®	Titanium alloy	Cylindrical	BioPro, Inc.	
4	STA-FLEX™	Titanium alloy	Cylindrical	Biomet® Sports Medicine	
5	Talar-Fit™	Titanium alloy	Conical	Osteomed®	IB
6	Bioarch™	Titanium alloy	Conical	Wright Medical Technology, Inc.	
7	ProStop	Titanium alloy	Conical	Arthrex, Inc.	
8	ProStop Plus	Poly-L-lactic acid	Conical	Arthrex, Inc.	
9	Kalix®	Titanium alloy and UHMWPE	Conical	Integra LifeSciences Corporation	
10	Futura™ CSI	Titanium alloy	Conical	Tornier, Inc.	
11	SubFix™	Titanium alloy	Conical	Memometal, Inc.	
12	Sub-Talar Lok™	Titanium alloy	Conical	Instratek, Inc.	
13	TOV®	Titanium alloy	Conical	Vilex, Inc.	
14	HyProCure®	Titanium alloy	Conical + cylindrical	GraMedica, Inc.	II

* This table lists the 14 currently available EOTTS devices, their material properties, design characteristics, and manufacturer. The column on the extreme right categorizes these devices according to the newly defined classification system.

mechanism (1). The ideal method to stabilize a complicated triplanar motion is to instill stability at the axes of motion. In the middle to late 1800s, Farabeuf (38), Henke, and Henle identified what is now known as the "cruciate pivot point," which is located at the entrance of the canalis portion of the tarsal sinus along the longitudinal talar bisection line, and can be thought of as the origin of a rectangular coordinate system depicted in Fig. 3 (39). The helicoidal motion of the talus during pronation and supination occurs along the axes of this coordinate system, which are perpendicular to the 3 cardinal planes. It is advocated that the "cruciate pivot point" is the ideal location where the excessive anterior-medial-plantar displacement of the talus within the tarsal mechanism should be eliminated or minimized (38). In the case of type I devices, the anterior leading edge of the device just coincides with the "cruciate pivot point" (origin of the rectangular coordinate system in Fig. 3) and does not provide adequate stability where desired (Fig. 7). Also, many type I device manufacturers are quite against the cutting of the soft tissues deeper within the tarsal sinus so as to prevent over insertion beyond the longitudinal talar bisection line.

A type II device, on the other hand, has a 1-piece design with a lateral conical and medial cylindrical geometry designed to provide the closest anatomical fit with the sinus and canalis portions of the tarsal sinus (Fig. 7). The medially threaded cylindrical portion of this device type is positioned within the canalis portion of the tarsal sinus. For a type II device, the incised soft tissue fibers within the canalis portion reattach or "heal" back together, anchoring it into the most stable portion of the tarsal sinus. The lateral tapered portion of the device abuts the lateral aspect of the canalis portion (its entrance) to prevent over insertion. This conical section of the device helps stabilize the sinus portion of the tarsal sinus by preventing the anterior-medial-plantar deviation of the lateral process of the talus. The contour of this section allows the talus to smoothly glide over its dorsal aspect along its natural helicoidal trajectory. The final position of a type II device is in the central half of the tarsal sinus, that is, the center of this device (point of transition from the cylindrical to the conical aspect) lies along the longitudinal talar bisection line (Fig. 7). It is important to mention that the threaded cylindrical portion offers no resistance to talar motion. It functions primarily to lock the device into place, and without the lateral conical portion it would fail to prevent talar dislocation on the tarsal mechanism. Another very important aspect of the type II device is that it is oriented with the natural alignment of the tarsal sinus, that is, in an anterior-lateral-distal to posterior-medial-proximal aspect (Figs. 7 and 8). The orientation and angle of position of EOTTS devices are very important aspects to consider for its long-term survivability, to achieve the desired function of stabilizing the talus on the tarsal mechanism, to prevent hyperpronation, and to allow the normal talotarsal motion. Unlike the type I laterally anchored devices that function as a talar door stop, the type II device functions like a stent placed within an artery to keep it open. The anterior-lateral portion of the talus, distal to the posterior articular talocalcaneal facet, is in contact with the tapered conical portion of the type II device, which transforms the "negative" space into a "positive" space (6,32,34). Another way to look at the function is that the plantar aspect of the talus is reconfigured with the placement of such a device; instead of having an open void there is a solid extension resurfacing that fits anatomically within the calcaneal fossa. This has been referred to as a "key in a hole" type of mechanism. It has been acknowledged that a device that better matches the anatomical shape of the tarsal sinus and is placed along its natural orientation will allow for uniform force distribution and better biomechanical functioning (27). To that effect, recent research studies on a type II device have shown improved performance, with postoperative implant removal rates as low as 5.98% (32).

In summary, a new classification system was devised for EOTTS devices currently available on the market. The unique identifying characteristics of these devices were defined and are listed in Table 1. To the best of our knowledge, there are currently 4 type IA devices, 9 type IB devices, and 1 type II device (Table 2). Well-designed cadaveric, clinical, and radiographic studies on the use of these devices in the future will help us better understand and appreciate the advantages and disadvantages of one device type over the other.

Supplementary Material

Supplementary material associated with this article can be found in the online version at www.jfas.org (doi: 10.1053/j.jfas.2012.05.030).

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