

EXTRA-OSSEOUS TALOTARSAL STABILIZATION: NARROWING THE INDICATIONS



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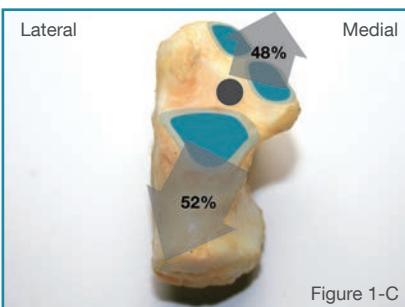
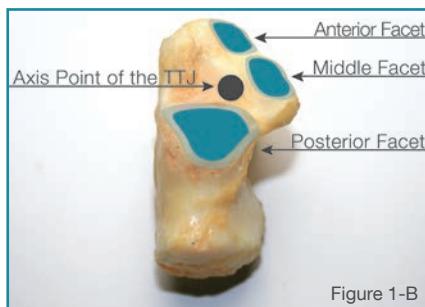
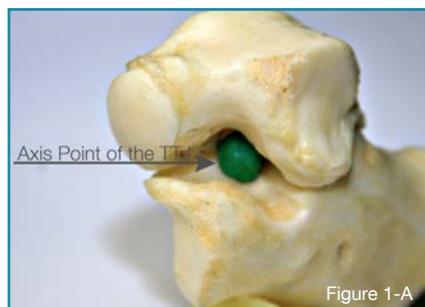
Introduction

Sinus tarsi implants stabilize the talus on the tarsal mechanism in a procedure that is minimally invasive, cost and time effective, reversible and a possible alternative to traditional hindfoot reconstructive procedures when conservative care has been unsuccessful. Physician usage of sinus tarsi implants has grown due to improved designs, better device tolerance and positive, evidence-based studies. However, there are limited standards of use for these devices. This article will help to define when a sinus tarsi implant could be placed as a stand-alone procedure and when it should be combined with other surgical procedures.

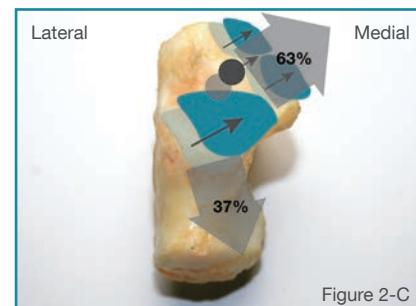
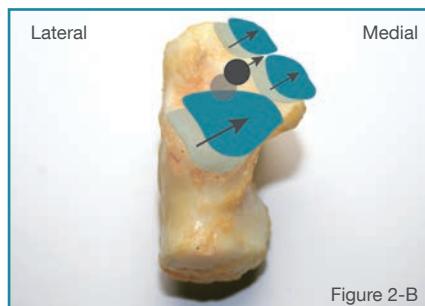
TaloTarsal Joint Normal vs. Abnormal

The talotarsal joint (TTJ) is extremely important for proper foot function and stability. Supination of the TTJ results in the locking of the foot structures while pronation creates instability of the foot, allowing it to adapt to an uneven weightbearing surface.

The sinus tarsi, as viewed laterally (Figure 1-A), provides a very important clue to the alignment or misalignment of the TTJ. The axis of the TTJ is located at the entrance to the canalis tarsi (Figure 1-B). This is the axis point around which TTJ pronation and supination occur. The sinus tarsi is orientated in an oblique manner that is anterior-distal-lateral to posterior-proximal-medial. This angle allows the transfer of the weightbearing forces posterolateral through the calcaneus at heel strike, and anteromedial as the talus pronates on the tarsal mechanism (calcaneus/navicular), in order for those forces to pass distally throughout the rest of the foot (Figure 1-C).



A partial dislocation of the talus on the tarsal mechanism leads to a partial-to-full obliteration of the sinus tarsi (Figure 2-A). This indicates an abnormal shift of the normal axis point and also creates an imbalance in the redistribution of forces. The forces that would normally pass posterolateral through the calcaneus will now act anteromedially, negatively impacting the medial column of the foot (Figure 2-B). These unrelenting hyperforces — assuming a flexible/reducible TTJ dislocation — cumulatively take their toll on the medial column during every weightbearing activity (Figure 2-C).



PARTIAL TALOTARSAL DISLOCATION

Partial dislocation of the TTJ leads to a prolonged period of pronation. When the hindfoot/TTJ should be supinated and in a locked, stable position, it is unlocked and therefore unstable. This places excessive forces on the plantar fascia, ligaments and tendons as they try to stabilize the foot's osseous structures of the medial column.

Eventually these soft tissue structures can no longer compensate for the prolonged abnormal forces: they become symptomatic, show signs of fatigue and ultimately fail — leading to further osseous instability and/or deformity.

Stabilization of the TTJ is critical to correcting the underlying etiology of many foot and ankle pathologies that are inadequately treated on a daily basis. Unfortunately, the majority of current attention is focused on secondary deformities, such as plantar fasciopathy, posterior tibial tendon dysfunction, 1st ray deformities, posterior tibial neuropathy and multiple other lower-extremity conditions, rather than on 1st eliminating the underlying etiology: partial TTJ dislocation.

TTJ dislocation is not a life-threatening condition; however, TTJ dislocation can be lifestyle-threatening. Eventually, the cumulative tissue hyperstrain results in pain and limited function. Ultimately, a person with TTJ dislocation realizes that the more active they are, the more they suffer - so they decrease their activity level. This, in turn, decreases their metabolism, which can lead to weight gain and possible obesity. Obesity leads to several other medical conditions such as diabetes, hypertension, cardiac disease and even certain forms of cancer.¹

Patients with these medical conditions are told that it's important to "get out and walk/exercise," but the more these patients walk, the worse their pain gets, so most — if not all — stop. There are also those who will continue through the pain and, as a result of the hindfoot mal-alignment, develop chronic knee, hip or back pain.

EOTTS PATIENT SELECTION CONSIDERATIONS



Although the surgical insertion of an extra-osseous talotarsal stabilization device may seem simple enough, there are numerous factors that must be considered and important surgical techniques that must be followed to increase the chances of successful restoration of talotarsal joint biomechanics.

To aid in patient selection, this section addresses the following questions:

- When should a sinus tarsi stent be considered for your patient?
- When does a secondary procedure need to be considered?
- What factors dictate when a sinus tarsi stent should not be used?

The Primary Considerations are:

1. Determine if the TTJ dislocation is flexible, semi-flexible, or a rigid deformity.
2. Identify other co-deformities and determine if they can be addressed conservatively or surgically.
3. Ascertain if other factors exist that would increase the likelihood of failure of an Extra-Osseous talotarsal Stabilization (EOTTS) procedure.

Dynamic Weightbearing Radiographic Evaluation

A simple way to evaluate the reducibility/flexibility of the TTJ dislocation is to order two sets of radiographs. For the first set, position the patient in a "relaxed stance position" (RSP) — ([See figures 3-A and 3-B on page 4](#)). For the second set, position the patient in the "neutral stance position" (NSP) ([See figures 4-A and 4-B on page 4](#)). If the TTJ returns to neutral position and the sinus tarsi "opens," then there is a good chance the EOTTS procedure will work. It must be emphasized that this is not a guarantee; as with any procedure, treatment results vary.

Ideally, the radiographs should be taken with the patient standing on one limb at a time, as this will better illustrate the forces acting on the hindfoot during the mid-stance phase of the gait cycle. These images not only help the clinician, they also educate the patient as to the true cause of their foot/ankle deformity.

Resting Stance Position Lateral X-Ray

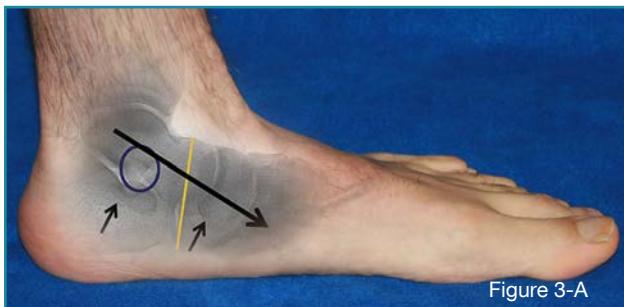


Figure 3-A

Neutral Stance Position Lateral X-Ray

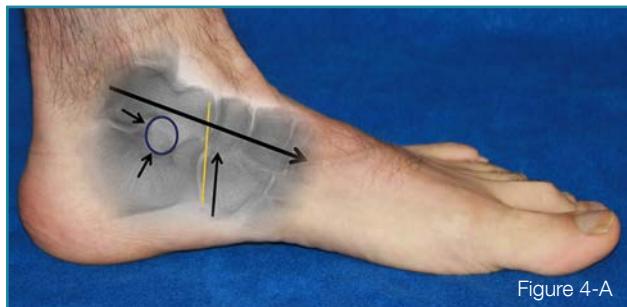


Figure 4-A



Figure 3-B



Figure 4-B

Radiographic Evidence of TaloTarsal Dislocation

The two best radiographic measurements to diagnose the alignment or displacement of the talotarsal joint are the talar second metatarsal angle (T2MA) on the dorsoplantar radiograph and the talar declination angle on the lateral radiograph.

Ideal TTJ alignment reveals a T2MA of 3° to 6°, when the hindfoot is in a somewhat neutral balanced position. This angle has been scientifically validated.^{2,3} To validate it yourself, place your patient's hindfoot in rectus alignment and take an x-ray. The acceptable range for a "normal" T2MA is from 0° to 16°. The accepted normal talar declination angle has been determined to be less than 21°.⁴ A value greater than 21° is considered pathologic and also an indication of TTJ displacement deformity.

The **HyProCure®** sinus tarsi stent offers an internal option that has the potential to correct the apex of the deformity – the axis of motion of the talotarsal joint found within the sinus tarsi (See Figure 5-A). Many patients are offered arch supports or orthoses to realign their feet, but orthoses do not demonstrate radiographic evidence of realignment of the TTJ (Refer to page 10). After the insertion of a sinus tarsi stent, post-procedure radiographs can be taken to show the realignment/normalization of the TTJ.

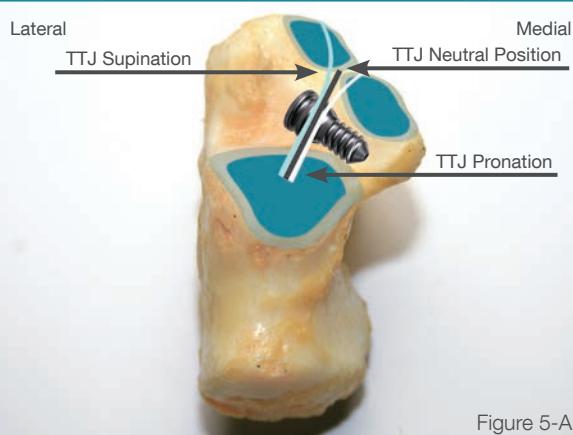


Figure 5-A

Also, there are compliance issues with arch supports as well as varying degrees of quality. Most of the time, if the supports are customized to truly attempt to realign the hindfoot, the patient is unable to tolerate the use of the arch supports.

BENEFITS OF EOTTS VS. TRADITIONAL HINDFOOT RECONSTRUCTION

EOTTS stabilizes the TTJ while permitting a range of joint motion. This makes EOTTS very different from traditional hindfoot surgery where the bones or soft tissues are altered. Many non-talotarsal joint stabilization procedures (such as posterior tibial tendon augmentation, calcaneal osteotomy) fail due to excessive re-loading of TTJ joint forces during supination and the continued dislocation of the talus.

After a non-talotarsal joint stabilization procedure, the joint dislocation continues adversely affecting/over-straining the hindfoot structures. Arthrodesis of the talonavicular and/or talocalcaneal joint also presents various issues including:

- long post-operative follow up
- prolonged period of non-weightbearing
- osteomyelitis
- over/under-correction
- hardware removal
- prolonged edema/pain
- delayed/non-union
- possible complications of incision/wound healing

The complete loss of joint motion immediately places additional strain on the proximal and distal joints. The natural motion that should be occurring within the “arthrodesed” joint is now compensated by an increased amount of motion. An increased amount of motion must now occur in these adjacent joints. This hypermobility eventually leads to over-use, wear-and-tear and osteo-arthritis in the adjacent joints.

Bottom Line

When an external modality (orthoses) is insufficient or impractical, or when rearfoot reconstructive surgery is “too aggressive,” that is when the use of an extra-osseous talotarsal stabilization device should be considered.

When is a TTJ displacement too severe to consider an EOTTS stent?

Refer to the evidence.⁵ An independent radiographic evaluation on the correction achieved with the use of the **HyProCure®** EOTTS stent as a stand-alone procedure revealed:

- **Average correction of a transverse plane deformity was 19°**
- **Maximum correction of the transverse plane deformity was 37°**
- **Sagittal plane correction revealed an average of 7°** (Note, not every evaluated patient had a primary sagittal plane deformity to begin with.)
- **The maximum correction was 19°**

Talar supination and pronation is restored at the TTJ axis, after the insertion of the **HyProCure®** stent. In other words, if the patient only had a transverse plane deformity with a normal sagittal plane, the EOTTS procedure did not result in the overcorrection of the sagittal plane, since the stent only restores the abnormal angle(s).

ADDITIONAL FACTORS TO CONSIDER

Evaluate the entire foot structure for co-deformities that could undermine the results of the EOTTS procedure. Additionally, consider the anatomic configuration of the sinus tarsi chamber. Years/decades of TTJ dislocation deformity may have led to the erosion of the middle and/or anterior facets. Finally, the existence of osseous malformations on the floor of the sinus tarsi could also prevent the ideal placement of a sinus tarsi implant.

Calcaneal Inclination Angle – Lateral View

The EOTTS procedure alone has not been shown to significantly alter a lower than normal calcaneal inclination/pitch angle (CIA).^{5,6} However, there is no doubt that the shift in forces that should be passing posteriolateral that are now acting anteriomedially will have a negative impact on the CIA. The effect of TTJ realignment on the CIA is also evident on the RSP lateral x-ray compared to the NSP x-ray

Navicular Drop – Lateral View

If the navicular sags check to see if can be repositioned. A post-EOTTS orthosis could be beneficial to support the navicular and further reduce strain to medial column structures. Again, compare navicular drop on the RSP lateral x-ray to the NSP image.

Talar First Metatarsal Angle - Lateral View

This angle provides valuable information regarding the structural alignment and stability of the 1st ray. An abnormal finding indicates another pathologic event – such as a hyperextended/dorsiflexed 1st ray that should be identified and addressed conservatively or surgically. The normal talar-1st metatarsal angle is 4°.³

The stability of the 1st ray is crucial for proper foot function.⁷ The body's weight, as mentioned previously, passes posterior laterally through the heel at heel strike and it should terminate through the 1st interspace at toe-off. A deviated T1MA indicates a structural defect that translates to a lateral shift of forces contributing to increased forces under the heads of the lesser metatarsal. These excessive forces, combined with an abductory twist and the repetitive number of steps taken daily, will eventually lead to callus formation, metatarsalgia and, if there is decreased sensation (neuropathy), to eventual ulceration.

BE ON THE LOOK-OUT

Metatarsus Adductus/Primus Varus Deformity

Stabilization of the talotarsal joint could possibly exacerbate a metatarsus adductus/metatarsus primus varus deformity. However, if there is only a mild, flexible case, stabilization of the TTJ could actually decrease the deformity over time since the deforming forces could decrease and the peroneus longus tendon could gain an advantage with realignment of the TTJ.

Calcaneal Varus

It is possible that once the talus is stabilized on the tarsal mechanism a pre-existing varus deformity of the calcaneus could be increased. If you suspect a calcaneal varus deformity order a calcaneal axial x-ray.

Tarsal Coalition

Understandably, it is not possible for every EOTTS candidate to have a CT scan in order to rule out a tarsal coalition. The best way to evaluate/check is by comparing weightbearing radiographs of RSP to NSP x-rays. The comparison films should show the realignment of the talus on the calcaneus/navicular. If the TTJ realignment does not occur, a coalition could be possible and a CT scan should be ordered. Also, look for the typical radiographic signs of tarsal coalition such as "halo" or "ant-eater" signs. Finally, be aware of when these coalitions typically become radiographically evident.

- **Calcaneonavicular coalition** - fuses between 8 and 12 years, is best visualized on an oblique view, and typically shows a calcaneal beak or an "ant-eater" sign;
- **Talocalcaneal coalition** - fuses between 12 and 16 years, best seen with a lateral radiograph, and typically shows a "halo" sign around the talar body.

The Role of Equinus

There is no question that a large number of patients with TTD have an associated contracture of the tendoAchilles/gastrosoleal muscles. There remains a "chicken or the egg" debate as to which came first. Did the tight Achilles tendon pull the calcaneus out from the talus, forcing the talus to partially dislocate anteriomedially? Or was it the partial talotarsal dislocation that led to an increased strain on the posterior muscle group? A lengthening of the tendoAchilles does not result in realignment of the talotarsal joint. More research is required to solve this biomechanical mystery. The most important fact for us today is to know when to address this condition.

Must we lengthen/weaken the tendoAchilles/muscle belly or can we leave it alone?

The answer depends on the severity of tendoAchilles contracture and if the patient has an structural-anatomic or functional-physiologic shortening.

Ask Yourself:

- What degree of dorsiflexion is available during the gait cycle?
- Is there enough anterior leg muscle strength to lift the forefoot after toe-off to clear the foot during swing phase of the gait cycle?

In the author's experience, if the foot can be passively dorsiflexed 90° to the leg, a lengthening/weakening procedure is not always necessary. If there is less than 90° of dorsiflexion, it is possible that once the talus is stabilized, the tendoAchilles/gastrosoleal complex can still undergo a "relaxation-lengthening" without surgical intervention, provided the Golgi-tendon neurosensors are no longer activated.

A patient with a tendoAchilles contracture should be told there is a chance that this self-lengthening won't occur due to the degree of contracture deformity; they may still require a lengthening procedure. The patient may elect to either have a lengthening procedure performed at the same time as the EOTTS, or it could be performed as part of a staged procedure. If the patient has a true anatomic shortening of the tendoAchilles, it would be quite apparent that a lengthening procedure should be performed at the same setting as the EOTTS procedure.

Posterior Tibial Tendon Dysfunction

Typically, if the patient presents with a stage I posterior tibial tendon dysfunction, no additional soft tissue augmentation of the tendon is required. If the patient has an early stage II, meaning the tendon is still intact with minor partial tears, it is possible that only the EOTTS procedure is needed. However, if there are significant tendon tears— more than 50 % tendon compromise — then posterior tibial tendon augmentation along with talotarsal stabilization is recommended. When complete loss of function of the posterior tibial tendon is present, stage III or IV, then rearfoot reconstructive surgery is required.

First Ray Stability/Instability

The leading cause of deformity to the 1st ray (metatarsus primus varus/hallux abductovalgus, hallus limitus/rigidus) is excessive hindfoot motion, over/hyperpronation or partial talotarsal dislocation. It is possible to realign/stabilize the TTJ and still have a faulty 1st ray disorder. Instability of the 1st ray will contribute to forefoot weakness and ultimately could result in excessive force acting on the TTJ.

The determination as to whether the 1st ray deformity will respond to a conservative option, such as an arch support or whether it requires realignment/stabilization surgery depends on the severity and reducibility of the deformity. A more mild/moderate flexible deformity could respond to a custom-made foot orthosis whereas a moderate/severe rigid deformity would require a reconstructive surgical procedure.

Again, it is very important to identify and address this condition. Failure to re-establish 1st ray stability/alignment could lead to loss of correction from or other complications of the EOTTS procedure. Imagine the tires on a car are worn-out because the wheel was not balanced. If the worn out tires are replaced with new unbalanced tires, it is simply a matter of time until the new replacement tire will wear-out again.

First Metatarsophalangeal Joint (1st MPJ) Range of Motion

Another factor that must be considered is the range of motion to the 1st MPJ. Hallus limitus/rigidus occurs as a direct result from the anterior displacement of the talus on the calcaneus. Limited dorsiflexion of the hallux on the 1st metatarsal may lead to an abducted gait. It is possible that once the talus is realigned on the tarsal mechanism that limited 1st MPJ motion would lead to a decreased period of TTJ pronation during the early stages of the gait cycle's stance phase. This could lead to loss of correction or displacement of the sinus tarsi implant.

Patients who undergo 1st ray/bunion surgery often develop limited 1st MPJ range of motion as a result of the normal tissue-healing process. A guarding mechanism occurs to the surgical site(s) as part of the recovery process that could negatively impact an EOTTS procedure that is performed at the same time as a 1st ray/1st MPJ procedure. This factor must be taken into consideration for pre-operative discussion with the patient and post-operatively as the patient/surgeon may feel they over-corrected the issue, but once the soft tissues have normalized there will also be normalization to the TTJ range of motion.

EOTTS RISK FACTOR CATEGORIES

The following section is presented in an attempt to better inform patients about the chances of success, or failure of EOTTS. The table below gives a detailed description of the x-rays (Figures 6-A, 6-B and 6-C) shown on page 9.

RISK FACTOR CATEGORIES - HYPROCURE® SINUS Tarsi STENT			
	Risk	Details	Removal Risk
Category I	Low	<ul style="list-style-type: none"> ● Mild-Moderate flexible/reducible talotarsal dislocation deformity <ul style="list-style-type: none"> - Talar Second Metatarsal Angle: 16°– 28° - Talar Declination Angle: 21°– 27° ● Normal calcaneal inclination angle ● No equinus contracture ● Intact plantar fascia/posterior tibial tendon ● Stable 1st ray ● Good 1st MPJ range of motion 	< 10%
Category II	Medium	<ul style="list-style-type: none"> ● Moderate flexible/reducible talotarsal dislocation deformity <ul style="list-style-type: none"> - Talar Second Metatarsal Angle: 28°– 40° - Talar Declination Angle: 27°– 33° ● Lower than normal calcaneal inclination angle ● Slight/moderate equinus contracture (-5 degrees dorsiflexion) ● Questionable integrity of the plantar fascia/Stage I posterior tibial tendon dysfunction ● Moderate instability to 1st ray ● Limited 1st MPJ range of motion ● Patient may benefit from/need/require: <ul style="list-style-type: none"> - TAL/Gastrocnemius Recession (open/endoscopic) - Post-EOTTS foot orthosis to stabilize/accommodate 1st ray/1st MPJ - Posterior tibial tendon augmentation - 1st ray stabilization/angular correction procedure - 1st MPJ arthroplasty/cheilectomy with/without partial/total joint replacement 	10 – 15%
Category III	High	<ul style="list-style-type: none"> ● Severe semi-flexible/partially reducible talotarsal dislocation deformity <ul style="list-style-type: none"> - Talar Second Metatarsal Angle: > 40° - Talar Declination Angle: > 33° ● Calcaneal inclination angle < 10 degrees ● Stage II-A posterior tibial tendon pathology ● Significant 1st ray instability – hyperextension deformity flexible/rigid hallux limitus/rigidus ● Patient may benefit from/need/require: <ul style="list-style-type: none"> - TAL/Gastrocnemius Recession (open/endoscopic) - Post-EOTTS foot orthosis to stabilize/accommodate 1st ray/1st MPJ - Posterior tibial tendon augmentation - 1st ray stabilization/angular correction procedure - 1st MPJ arthroplasty/cheilectomy with/without partial/total joint replacement 	> 15%

Note: Risk factors are non-evidence based and provide a more pessimistic than optimistic predictor of the likelihood a *HyProCure®* sinus tarsi device would require removal.



Patient would benefit from an EOTTS procedure assuming flexible/reducible TTD deformity.

Lower than normal CIA, patient would benefit from EOTTS, TAL/Gastrocnemius recession along with custom-molded orthosis.

Patient requires a TAL/Gastrocnemius recession along with medial column and 1st ray Stabilization.

High Risk Scenarios

Certain patients may fall outside of the known parameters. There are many patients who choose an EOTTS procedure as a “last ditch effort” to prevent an arthrodesis or other more aggressive surgical procedure. These patients may be at a higher risk of device failure, but as long as the patient has some joint flexibility, use of an EOTTS device could still be justified, especially considering the fact that an arthrodesis procedure will completely eliminate all motion. There have been many procedural successes where the sinus tarsi stent gave enough correction so that the patient’s foot function was improved; however, there are also cases where it did not. Patients of this type should be told that there is a > 50% chance that the sinus tarsi implant will have to be removed.

Unfortunately, patients with problematic outcomes may end up consulting other surgeons about device removal. The unintended side-effect of this can be a clinician that now has a negative feeling about sinus tarsi implants and who wonders why it was used in this situation. The clinician has no way of knowing about the pre-surgery discussion where the patient was informed about possibility of the need for device removal or more aggressive surgery.

Conclusion

Internal extra-osseous stabilization of the talotarsal joint is an extremely powerful orthopedic procedure that has been used in tens of thousands of pediatric and adult patients of all activity levels for decades. EOTTS is a proven, cost-effective treatment for TTJ dislocation that provides a viable option to orthoses or traditional reconstructive surgery.

EOTTS can be used successfully as a stand-alone procedure or in combination with other surgical procedures, depending on the needs of the patient. Follow the guidelines explained here to ensure your patient is a good candidate for an EOTTS procedure.

It is important to identify other secondary issues that could ultimately compromise the results of the EOTTS procedure. However, don’t be discouraged from considering patients whose medical conditions make them less suitable EOTTS candidates as they may still benefit from the procedure. Just make sure these patients understand that they may be at a higher risk of not tolerating the device.

Appropriate post-EOTTS patient management is also extremely important. As there are many reasons why patients develop pain or soreness following EOTTS procedures, it is imperative to identify and treat the cause of the reported discomfort. Please keep in mind that any pain or discomfort is not inherently the result of patient non-compliance, the surgery, the device or the surgeon.

Surgeons who perform this procedure on the right candidates will tell you that it is extremely rewarding when patients return for follow up and are able to report the benefits of EOTTS. Patients typically share that they have a spring in their step, that their muscles are working more efficiently and they can be more active. They are simply happier because they now have less pain and disability.

Comparison of Weightbearing Relaxed Stance Position Radiographs



Barefoot-No Intervention

Increased/Pathologic T2MA



Customized Orthosis

Increased/Pathologic T2MA



EOTTS-HyProCure®

Decreased/Normal T2MA

Decreased 1st IMA



Barefoot-No Intervention

Increased/Pathologic Talar Declination
Notice Navicular Drop



Customized Orthosis

Increased/Pathologic Talar Declination
Notice Navicular Drop



EOTTS-HyProCure®

Normal Talar Declination
Navicular Elevation

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About **HyProCure®**

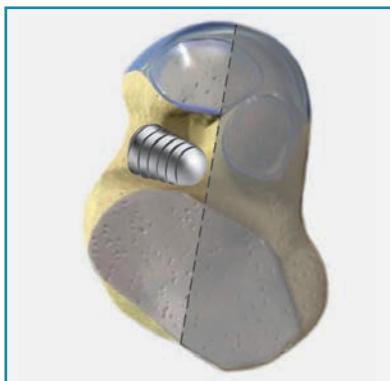
The **HyProCure®** Facts

- Extensive peer-reviewed, evidence-based studies
- Over 25,000 procedures and counting
- Provides internal correction for internal deformity
- Pediatric and adult indications
- Less than 6% removal rate
- Used by foot & ankle surgeons in over 30 countries



Other Arthroereisis Devices

- Inserted into the sinus portion
- Acts as a joint blocker
- Removal rates > 40%
- Limited EB studies



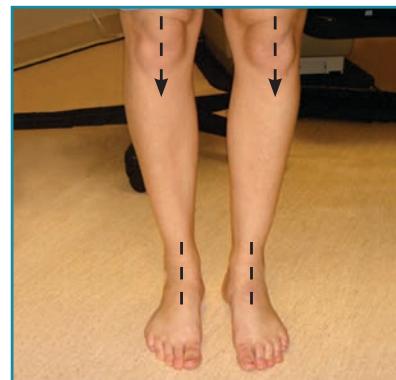
- Centrally placed talotarsal stent
- Medially anchored into the canalis
- Stabilizes at the axis point
- Significantly lower removal rate



Before **HyProCure®**



After - **HyProCured®**



To learn more about the benefits of Extra-Osseous TaloTarsal Stabilization and **HyProCure®** visit us at gramedica.com and www.hyprocuredoctors.com

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