



# What Is the “Standard of Care” for the Use of Sinus Tarsi Implants?

What are the proper indications for their use?

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The lives of millions of children and adults are adversely affected due to their faulty foot alignment. The vast majority will be told to ignore their feet or will be given sub-therapeutic treatment options until the disease state has reached a critical threshold where their only option is extensive reconstructive surgery. Every day, pediatric and adult patients across the globe have their talus realigned and stabilized on the calcaneus with sinus tarsi stents, but these numbers are nowhere near where they should be. The extra-osseous talotarsal stabilization procedure acts as a treatment bridge between non-surgical options and surgical realignment procedures. The purpose of this article is to present a proven alternative to under- or over-treatment of a very common condition, regardless of insurance coverage.

## A Reversible, Conservative Surgical Option

It is estimated that over 250,000 devices, of varying designs, have been placed into both pediatric and adult patients over the past several decades. After all these years and a vast number of procedures, there have been only a handful of “complications.” These single cases were usually the result of anatomic variation, improper device placement, failure of the surgeon to remove a rotated implant, or a patient compliance issue. The complications

associated with “under-treatment” are the many secondary structural deformities associated with misaligned feet. Think about all of the potential complications of traditional hind foot re-alignment procedures. EOTTS is a proven solution that addresses the deformity at its root without the complications associated with traditional surgery.

Regrettably, the majority of foot surgeons have never been trained on the use of sinus tarsi implants.

An uninformed surgeon won’t know how to deal with post-placement issues and will simply recommend removing it without offering any conservative care that could have resolved the problems. This situation might make one hesitant to use these devices. There are complications from all sorts of medical implants, but that should not restrict a surgeon from advocating a procedure that might improve someone’s

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Therefore, this effective procedure remains a “mystery” until that surgeon finally decides it’s time to explore this powerful minimally invasive procedure. Once that veil is lifted, these surgeons can now offer their patients another possible treatment solution. It is really a shame, and very unfortunate, to those surgeons who refuse to even hear about this reversible, conservative surgical option.

Maybe one of the reasons why certain foot surgeons are resistant to recommend use of sinus tarsi implants is that they’ve had an unsatisfied patient present to them who had a sinus tarsi implant placed into the foot by another surgeon.

quality of life. The bottom line is that significantly more people are helped with the use of a sinus tarsi implant.

The physician’s goal is to offer and prefer conservative options prior to jumping to a non-conservative, irreversible option. However, there are many situations where a surgical procedure is the only realistic treatment option. For example, if someone has a pin stuck in the bottom of the foot, would the physician just recommend the application of pads around the pin and a prescription of pain pills? Of course not; the primary recommendation would be the removal of the foreign body.

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Another example is the conservative treatment of an ingrown toenail. Conservative care will not eliminate a nail spicule embedded into the lateral nail fold. Healing, the resolution of the associated symptom(s), will only occur after the underlying pathologic-etiologic force, the offending nail, is reduced or eliminated (Figure 1).

### The Etiology

Misaligned feet have been generally ignored by the vast majority of the medical industry. Yet, those misaligned feet serve as the underlying etiologic force that leads to paths of destruction proximally up the musculoskeletal chain and distally throughout the foot. Misaligned feet don't get better; they get worse (Figure 2). Children with misaligned feet don't out-grow this condition, as many are led to believe. Where is the evidence

to show radiographic realignment of misaligned osseous structures upon reaching osseous maturity?

Over-pronation is named as the root-cause etiologic destructive force to many lower extremity chronic diseases such as wear-and-tear of the joints, over-stretching of tissues, and strain on the knees, hips, and back.<sup>1-4</sup> It is very important to understand that the cause of over-pronation is due to loss of stability and misalignment of the talus on the calcaneus. An unstable talocalcaneal joint leads to an unlocking of the hind foot structures, resulting in excessive pathologic force acting on the foot and ankle. The displacement of the articular facets of the talus on the calcaneus and navicular (tarsal mechanism) is a pathologic condition that cannot auto-repair (Figure 3).

Once the underlying etiology to a secondary symptom or problem is understood, the treatment alternatives can be presented to the patient. Of course,



Figure 1: This ingrown toenail will not resolve until the underlying etiology is addressed, the offending nail margin is removed.

the failure to properly address the underlying cause will simply lead to the recurrence of the secondary conditions. The goal of a realignment treatment option is to restore the alignment and stability of the talus on the tarsal mechanism while allowing a "normal" range of motion, when possible.

The "standard of care" of a medical professional is to address the concerns of each patient with a solution that makes sense and in a manner that similar professionals would agree is an appropriate course of action for that

patient. A medical professional who ignores a discussion with a patient about the underlying etiology of a concern should be considered below the standard of care. Not offering an option that has been deemed safe and effective when indicated, regardless of insurance coverage, is going against the standard of care. Only ameliorating the symptoms without discussing and offering treatment recommendations for addressing the underlying etiology is going against the standard of care. Only availing of a less than effective, or proven to be ineffective, treatment option without discussing effective treatment options is also against the standard of care (Figure 5).

Plantar fasciopathy—or what is mis-commonly known as plantar fasciitis—is a very painful chronic condition for many patients and is routinely mistreated. We've known for years that this costly disease does not involve an inflammato-

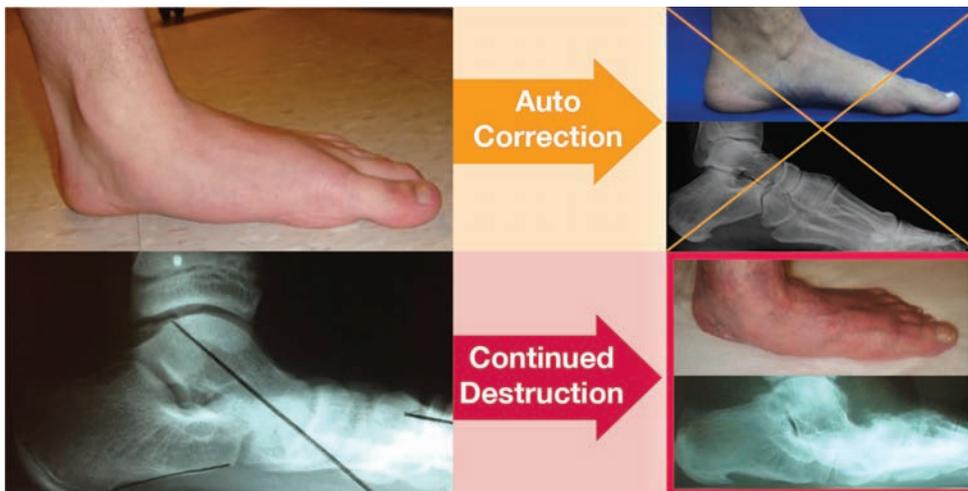


Figure 2: A partially displaced talus will not auto-correct. Excessive forces will continue to exert their negative impact on other secondary structures.



Figure 3: A hypermobile talus on the tarsal mechanism leads to an unlocking of the hindfoot. This is the specific cause of hindfoot instability and a prolonged period of pronation when weight-bearing.

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ry component, yet every day thousands of patients are given treatments to address the “inflammation.” Patients are just told to wait and eventually their fascia will auto-rupture with non-surgical options, or they are taken to the operating room where the medial band of the fascia is transected. The leading etiology of plantar fasciopathy is due to mechanical over-loading of the medial band of the plantar fascia.<sup>5</sup> How can oral medicine, an injection, or a night splint address the underlying etiology? Is there any published evidence that a foot orthosis can decrease the strain or over-loading to the medial band of the plantar fascia?

First ray disorders have been very difficult to fix long-term. There are numerous surgical techniques that have been suggested, each with various advantages and disadvantages. Yet, the leading issue after a surgical procedure is return of the misaligned osseous structures. This tells us that we have overlooked a piece of the diagnosis-treatment puzzle. The leading underlying etiology of first ray disorders stems from over-pronation. Is it below the standard of care to take a patient to the operating room without addressing the underlying etiology? Is there any supportive evidence that shoe inserts can prevent or delay recurrence of 1st ray deformities?

The healthcare industry is in a crisis because many healthcare insurance companies have limited the treatment options that medical professionals can

Talotarsal Joint Instability leads to:	
✓	Increased forces on the medial column of the foot
✓	Increased strain to the spring ligament
✓	Navicular drop
✓	Increased strain to the medial band of the plantar fascia
✓	Increased strain to the posterior tibial tendon
✓	Increased pressures within the tarsal tunnel and porta pedis
✓	Increased strain to the posterior tibial nerve
✓	Instability of the 1st ray
✓	1st metatarsal joint jamming
✓	Abductory twist
✓	Flexor tendon contracture
✓	Abnormal plantar force distribution
✓	Calcaneal eversion/valgus
✓	Abnormal alignment within the ankle joint

Figure 4: A hypermobile, misaligned talus is linked to many other secondary pathologies within foot and ankle.

provide to patients. Their focus of patient care is maintenance, not prevention. The overwhelming majority of the medical attention is driven to simply mask the symptoms while the underlying etiology is ignored. We have to get back to our orthopedic roots and follow the three basic tenets: realign that which is deviated; make stable that which is unstable; and use joint preservative over destructive techniques, when possible.

### Limitation of External Measures

The excessive talar motion on the calcaneus cannot be normalized by doing nothing, otherwise known as observation. Standing, walking, and running lead to repeated excessive forces acting on the tissues. Certain struc-

tures will contract in an attempt to stabilize the excessive motion, while others will be over-stretched (Figure 4). There is no evidence that any of these soft tissue structures can reverse or stabilize the talotarsal joint motion. There is no evidence that a child with talotarsal misalignment or over-pronation will outgrow this condition. There are countless articles written about the negative effects of over-pronation in both pediatric and adult patients. Yet the effective treatment of talotarsal instability is downplayed or undertreated in the majority of cases.

Many patients are told to buy either over-the-counter or expensive custom-made arch supports. Again, where is the proof that something placed on the bottom of the foot can realign and stabilize the pathologic talar motion? A recent multi-centered study compared weight-bearing radiographs with the patient standing in a foot orthosis.<sup>6</sup> There was no radiographic evidence of normalization of the talar position; in fact, a few patients’ radiographic angles were worsened with the custom foot orthosis. Many other studies have proven the limitation of external measures.<sup>7,8</sup> A realistic look at a foot orthosis reveals a limitation regarding talotarsal joint stabilization and realignment.

There have been more than 100 published studies on extra-articular talotarsal joint stabilization procedures in both orthopedic and podiatric medical journals. These manuscripts have established a strong evidence basis for the realignment and stabilization of the talotarsal joint. Many researchers have taken the time to publish their findings showing positive results clinically, radiographically, biomechanically, and demonstrating positive functional outcomes with this minimally invasive procedure. The research proves that sinus tarsi implants are a superior option to observation and foot orthoses (Figure 6).

Is there any supportive evidence that observation or foot orthotics can decrease the forces acting on the

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Figure 5: For every effect there is an underlying cause. The effects are the secondary deformities that patients present for medical advice and treatment. The goal is to address the underlying etiology.



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dial column of the foot? There is this evidence for sinus tarsi implants.<sup>9</sup>

Is there any supportive evidence that a foot orthosis can decrease the strain on plantar fascia? There is for sinus tarsi implants.<sup>10</sup>

Is there any supportive evidence that observation or foot orthoses can delay or reduce the formation of first ray disorders? Actually two papers have shown the opposite, that foot orthoses failed to stop the progression of first ray disease.<sup>11,12</sup>

Is there any factual evidence that a foot orthosis can decrease the strain on the posterior tibial tendon? There is none, yet there are papers proving the positive effects of sinus tarsi implants.<sup>13,14</sup>

Where is the research showing a positive effect for the use of a foot orthosis to decrease the pressures within the tarsal tunnel and porta pedis that can lead to posterior tibial nerve damage? Can an orthosis decrease the elongation and strain on the posterior tibial nerve? This has been proven with the use of a sinus tarsi stent.<sup>15,16</sup>

If the patient doesn't get relief from

a more conservative treatment, the next level of treatment modalities should be offered. It is the patient's decision to accept the next level of treatment. The next level of care should be the consideration of an extra-osseous talotarsal stabilization device. However, many times, patients are not told of this option and their diseased feet continue to worsen until their only option is aggressive, non-conservative surgery. Osseous and joint-destructive foot surgery is a big commitment for a patient. There are many risks and a long road to recovery. Again, this is the situation where it is possible that, if addressed earlier in life, the severity of the foot misaligned could have been lessened if hind foot stabilization would have been treated with a more effective option.

### A Look at the Evidence

We have to take a critical look at the evidence regarding the traditional foot alignment procedures. A lateral column lengthening (LCL) procedure (Evans) will not provide sagittal plane correction to a plantarflexed talus.<sup>17,18</sup> Also, an LCL is associated with many potential complications including associated joint destruction to the calcaneal cuboid, and over/under-correction. A medial displacement calcaneal osteotomy is also an aggressive procedure to cut and shift the posterior calcaneus to decrease the valgus heel. Yet there is no evidence of repositioning of the talus on the tarsal mechanism or decreased forces acting on the medial column.<sup>19</sup> Finally, a triple arthrodesis may be the only option, but again there are significant risks and complications long-term.<sup>20</sup>

One of the biggest issues with the use of sinus tarsi implants has been the need to remove the stent in some cases. Peer-reviewed evidence suggests that the type II non-arthroereisis device has a significantly higher success rate over type I arthroereisis devices.<sup>21,22</sup> Therefore, a type II stent should be considered the standard of care. It should be below the standard of care to use a medical device with a higher than acceptable removal rate when other proven medical devices are available (Figure 7).

There are situations where a patient may require a more "aggressive" surgery, yet s/he may not be a candi-

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	Foot Orthosis	EOTTS	Traditional Surgery
Ability to realign the TTJ while still allowing a normal range of motion		✓	
Proven to decrease strain on the medial band of the plantar fascia		✓	
Proven to decrease strain on the posterior tibial tendon		✓	
Proven to decrease forces acting on the medial column		✓	
Radiographic normalization of sagittal plane deformity while still allowing normal TTJ rom.		✓	
Radiographic normalization of transverse plane deformity will still allowing normal TTJ rom.		✓	
Provides internal correction and is reversible.		✓	
Best option to address the underlying etiology to many foot and ankle pathologies		✓	

Figure 7: The unique benefits of extra-osseous talotarsal stabilization (EOTTS) are compared to non-surgical or intra-osseous stabilization procedures.



Figure 6: Failure to adequately address the underlying etiology of an unstable, misaligned talus will lead to further destruction. The sooner effective medical attention is given, the better, as with most medical conditions.



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date, for one reason or the other, to undergo the more definitive procedure. Maybe the patient chooses to undergo a more conservative option over a more aggressive option. For instance, there are patients who need a major hallux valgus-metatarsus primus varus correction, yet they opt to have only a “bumpectomy.” Or maybe the patient wants only to attempt “some” correction with a sinus tarsi implant even though s/he may be a less-than-ideal candidate. As long as the patient is given proper informed consent and

realistic expectations, what is wrong with providing this option? Maybe the more conservative surgical option is all that is needed to give the patient

surgical correction. But that discussion is between the patient and the surgeon.

Foot specialists must recognize that the field of orthopedics will continue to

## Research proves that sinus tarsi implants are a superior option to observation and foot orthoses.

symptom relief. Of course, a patient like that would be at greater risk of not achieving a positive outcome and the patient, if still not satisfied with the final result, may need to undergo more

evolve. New procedures will become available during their careers. The time for the medical community to embrace the use of subtalar implants has arrived. More people are helped than hurt by offering this internal solution. Of course, the indications and contra-indications must be considered for each patient. There are ideal and less-than-ideal patients, but again, the goal is to offer patients a treatment option that is more effective than an external device to realign the hindfoot, without having to resort to osteotomies or arthrodesis procedures. **PM**

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## About the Graham International Implant Institute

**T**he Graham International Implant Institute (GIII) is a global organization focused on advanced education, certification and clinical support for foot and ankle surgeons. Founded in 2006 by Dr. Michael E. Graham, GIII is an industry leader in lower extremity research, with more than a dozen peer-reviewed, published studies in various medical journals.

GIII originated to train surgeons on Extra-Osseous TaloTarsal Stabilization (EOTTS) with HyProCure. Frustrated with the significant limitations of previous sinus tarsi implants, Dr. Graham developed HyProCure and established GIII as the core training and certification entity for this new procedure.

The Graham International Implant Institute is the sister organization of GraMedica, the manufacturer of HyProCure and other premier product lines including osteo-WEDGE, opti-Toe, and Soleus Foot Care Collection. Over the last decade, GIII has evolved into a well-respected and trusted educational institute for foremost orthopedic and podiatric surgeons.

GIII is committed to improving the standard of care for both patients and physicians through advanced seminars and hands-on educational labs led by prominent foot and ankle surgeons in cities throughout the world. The institute also offers complementary, specialized online training programs year-round to accommodate those looking to learn at their own pace.

GIII challenges mainstream thinking to embrace and propel true solutions that deliver real and innovative answers to patients' problems. GIII ensures its surgeons are on the cutting edge of groundbreaking technologies with the clear goal to restore, preserve and improve the overall quality of life of the patient.

For more information on the Graham International Implant Institute, please visit [www.grahamiii.com](http://www.grahamiii.com) or call (586) 677-9600. •





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