

Sinus Tarsi Implants: The Necessity for Insurance Coverage

The author delineates why insurance carriers need to approve EOTTS as a covered benefit.

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There has been a decades-long challenge to design and develop an implant that is placed into the sinus tarsi to stabilize and realign the talotarsal joint, while still allowing a normal range of motion. The medical necessity for such a device became known more than 100 years ago when surgeons were discovering the ill effects of subtalar arthrodesis in the treatment of flatfeet. Early pioneers of extra-articular, non-arthrodesis procedures experimented

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with different designs and materials, but unfortunately there were many limitations that included material defects and greater-than-desired removal rates.

A major evolutionary leap occurred when the first titanium devices were created. The strength of titanium solved the material weakness issue and the retention rates greatly increased. Multiple, peer-reviewed studies showed normalization of pathologic angles, decreased symptoms/pain, and increased functional scores. Moreover, there were positive effects to other diseased tissues such as the plantar fascia and posterior tibial tendon.

During the time of proof-of-concept for the newly designed sinus tarsi implants, insurance carriers would cover the procedure without question. Patients would undergo the procedure, get better, and the surgeon was paid for a job well done. Meanwhile, continued advancements in device design emerged that showed even greater patient satisfaction and retention rates. More and more surgeons were recommending and performing the procedure and more and more patients were helped. More studies were published showing the positive effects of talotarsal joint realignment and stabilization with a sinus tarsi implant. Then, all of a sudden there was an abrupt halt to

insurance coverage to this beneficial, minimally invasive procedure.

Most insurance carriers terminated the billing code that was created for hindfoot stabilization with a sinus tarsi implant. Why? The vast majority of published reports were all positive. Yes, there were cases where the implant had rotated out of position and the implant needed to be removed, yet without any long-term adverse complications. The ability to remove the implant without harm to the talus or calcaneus is one of the many benefits of this procedure.

There is a strong medical necessity for extra-osseous talotarsal stabilization (EOTTS). No other internal or external modality can provide a similar result. EOTTS is an internal option that fixes an internal pathology—recurrent talotarsal joint dislocation, the partial dislocation of the talus on the calcaneus and navicular. This pathology has never been proven to reverse or auto-repair. How could it? The talus has lost its stability on the calcaneus and navicular. During non-weightbearing, the talus is aligned, and upon weightbearing the talus is forced out of alignment. This process repeatedly occurs with every step taken. Excessive, abnormal forces are thrust upon the medial column of foot bones. It is just a matter of time until the supporting structures become diseased and symptomatic. Even worse are the negative effects of RTTJD to the knees, hips, and back.

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The Clinical Forum

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We have to acknowledge that external measures, such as arch supports, are not proven to realign and stabilize the talotarsal joint. There are no radiographic studies to show a realigned talus when standing on an arch support. Reconstructive surgery can show radiographic correction and positive results, but this type of correction is associated with a degree of potential complications that are not seen with EOTTS.

It is easy to prove the medical necessity for EOTTS. The majority of non-traumatic foot and ankle pathologies trace their etiology to a partially dislocating talus. Subtalar joint instability leads to a prolonged period of pronation, over-pronation or hyperpronation. Over-pronation is a “bad thing” because when the TTJ/STJ is supposed to be in a strong state of supination, it is in a weakened state of pronation. Simply put, the joints are unlocked at a time when they should be locked as the heel is lifted from the weightbearing surface during the gait cycle.

The weakened foot structure places a strain on the ligaments of the involved joints. This triggers a neuromuscular response to force muscle and tendon contractions to stabilize that weakened joint. An increased strain to the

sis studies showing the positive effects of EOTTS. There are cadaveric studies (essential when the same data cannot be studied on living individuals) that all report on decreased strain on the supporting tissues of the foot and even rebalancing of forces to the tibial condyle.

Multiple comparative studies showing the effectiveness of EOTTS to lateral column lengthening, medial displacement calcaneal osteotomy, and even subtalar joint arthrodesis have all recommended EOTTS as a superior option, when indicated.

Ethically, we are to recommend and provide our patients with conservative options that make sense and that are proven to be safe and effective. That’s where a critical failure in the treatment planning process is currently occurring and physicians are not following these ethical principles. The majority of patients are not even told about the EOTTS option due to the lack of insurance coverage. Patients are given the option to buy an arch support that is not proven to realign and stabilize the hind-foot, or to undergo an irreversible osseous reconstructive surgery. Most patients will not undergo the osseous reconstructive surgery until their condition is very severe. Meanwhile, those misaligned feet are continuing to exert damage to their feet, knees, hips, and back. EOTTS is not a cure-all or fix-all, yet it offers a real solution when orthotics are ineffective and prior to osseous reconstruction.

The cost-effectiveness of EOTTS compared to osseous reconstruction must also be considered. EOTTS offers a “less expensive” option to osseous reconstruction. EOTTS has an anticipated quick recovery with less significant complications. EOTTS has not been known to cause osteomyelitis, nor has it been associated with a delayed or non-union. Yes, there are a small number of cases where a sinus tarsi recipient must be taken back to the operating room for a revision or permanent removal of the implant. To be fair, think about the number of patients who have to return to the operating room for removal of painful screws from a medial displacement calcaneal osteotomy or lateral column lengthening. Some surgeons “routinely” schedule their patients for a second surgery to remove the screws because they are painful and are no longer needed.

The time has come for the insurance carriers to accept and approve EOTTS as a covered benefit. This time-tested procedure has been studied and reported on by both podiatric and orthopedic surgeons globally. Far more patients have benefited from this conservative surgical procedure than the ones who have had to have their device removed. We as a profession need to collectively band together to do what we can at the local, state, and national levels to gain insurance coverage. This effort will benefit our patients and the profession, and even the insurance carriers will see that patients will get better faster and at a lower cost. **PM**



Dr. Graham is the inventor of HyProCure and is the Founder and Chief Medical Officer at GraMedica.

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inner band of the plantar fascia is created. The first ray is unlocked, and excessive force will push the head of the first metatarsal away from the second. This is the primary deforming force that leads to progression of metatarsus primus varus and subsequent hallux abductovalgus.

EOTTS instantly stabilizes the talus on the calcaneus and restores the triplane motion. There is a reduction of excessive pronation during the gait cycle. The subtalar joint forces are re-balanced. This decreases the force and strain to the medial column, decreases strain on the inner band of the plantar fascia and posterior tibial tendon. Even a normalization of the first intermetatarsal angle has been observed. These are just a few of the positive changes that are reported.

The question has to be asked: if there continues to be more and more positive data published on the use of sinus tarsi implants, why is there such a determination to prevent or deny coverage? The reason that has always been provided is a lack of studies. Well, there are studies that exist covering all aspects of EOTTS. Specifically, studies have been published showing stabilization of subtalar joint forces, and normalization of pre-EOTTS pathologic radiographic angles. There are multiple reports showing a decrease in pain after EOTTS and an increase in foot function and quality of life. There are both prospective and retrospective reports that time and time again conclude that sinus tarsi stents are beneficial and advantageous over other forms of non-surgical and surgical treatments. There are finite-element analy-