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Medical Necessity and Evidence Basis for Extra-osseous Talotarsal Joint Stabilization

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Abstract

Extra-Osseous Talotarsal Joint Stabilization (EOTTS) is a minimally invasive surgical procedure that involves the insertion of an internal fixation device, stent, into the sinus tarsi. The goal of this stent is to realign and stabilize the "foundation joint" of the body, while still allowing a normal joint range of motion. There are more than 100 peer-reviewed, published articles that prove the medical necessity for and the effectiveness of EOTTS.

Background

EOTTS implants are cleared for use in more than 70 countries. Obtaining the clearance from the Food and Drug Administration (FDA) and CE mark for European countries is a major hurdle. This means that the government has validated the evidence that the device contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses. These sinus tarsi stents are advocated for and inserted by leading orthopedic and podiatric foot surgeons around the world. The end-users, foot surgeons, recommend and use these sinus tarsi stents for a reason. It works and patients get better. The only reason why more patients are not offered this solution is simply due to limited insurance coverage.

EOTTS Advantages

Of importance is the fact that EOTTS is a surgical procedure that does not involve cutting and/or shifting of any bones. It does not have a negative impact on the very important joints of the hindfoot. In fact, the EOTTS procedure should reverse or delay arthritic damage caused to joints due to the partial dislocation of the TTJ. There are many advantages of EOTTS over other forms of "treatment" of talotarsal joint dislocation. EOTTS can be used as a "stand-alone procedure", meaning there are situations where the only form of treatment required is EOTTS. It can also be used in conjunction with both external measures, or along with other surgical procedures to correct co-foot/ankle deformities. EOTTS can be performed on both children and adults. Patients can walk, run, and perform any activity of their choice, once the tissues have recovered from the initial procedure. The muscles, ligaments, and tendons will work more efficiently. Patients claim to "run faster" and "jump higher" due to their realigned talotarsal joint.

One of the many other advantages of this procedure is that it is reversible. This is very important when compared to other surgical procedures where tendons are sacrificed, bones are cut and shifted, or joints are fused to eliminate motion. EOTTS is the only reversible surgical procedure that can realign and stabilize the talotarsal joint.

Primary Indication of EOTTS

There is only one primary indication/diagnosis that a surgeon would recommend EOTTS to a patient and that is talotarsal joint dislocation. There are clear, validated clinical and radiologic measurements that are used to diagnose this complex orthopedic deformity. The majority of cases where EOTTS is performed are for Recurrent Talotarsal Joint Dislocation (RTTJD), as opposed to the minority of cases where there is a fixed deformity such as a tarsal coalition. RTTJD is a pathologic anomaly where the talus repeatedly dislocates on the calcaneus and/or the navicular bone. This deformity wills never auto-repair. It won't get better; it will only get worse and has been proven to be the underlying etiology to many chronic lower extremity pathologies [1-28].

"Recurrent" means something that happens repeatedly. With RTTJD, the talus repeatedly dislocates on the tarsal mechanism (calcaneus and/or navicular bones). There are two main phases during the walking, or gait cycle. The swing phase is when the foot is in the air not touching the

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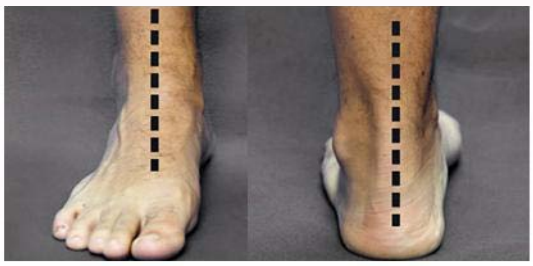

Figure 1: Aligned and stabile talotarsal joint.

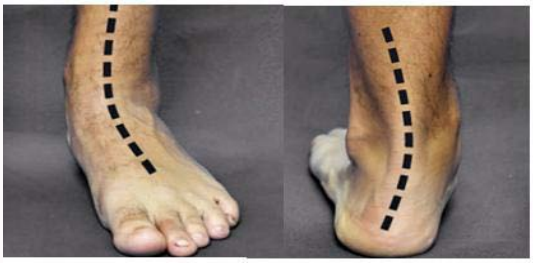

Figure 2: Misaligned and unstable talotarsal joint.

Figure 3: Aligned and stabile talotarsal joint with an "open" sinus tarsi.

Figure 4: Misaligned and unstable talotarsal joint with a collapsed/obliterated sinus tarsi.

weightbearing surface. During this phase, the talus will be aligned on the tarsal mechanism. The second phase is stance. This is when the foot makes contact or touches the weightbearing surface. The talus becomes dislocated or malpositioned during this portion of the gait cycle.

Dislocation is a generic term meaning the articular facets are no longer anatomically aligned. "Talotarsal Joint Dislocation" means that the joint surfaces of the talus are abnormally aligned on the heel and/or navicular bones. The articular surfaces, joints, of the body must remain in constant congruent contact to be considered stable and aligned. There are many additional descriptors that are added to dislocation because there are many forms of dislocation. A total dislocation where the articular facets have completely lost any contact. Partial dislocation means that a portion of the joint remains in contact. Both total and partial are considered pathology and neither is considered "normal". Dislocation can occur from trauma and would be considered "acute", where others could be congenital where the joint was always misaligned from birth.

Dislocation is a pathologic condition that is addressed with manipulation. There are situations where the dislocated parts can "pop" back into normal alignment, but there are also situations where surgery is required to maintain the alignment and stability. This is the situation with RTTJD. The only way to permanently maintain the alignment and stability of the talus on the tarsal mechanism is with surgical correction. External measures are not capable of realigning and stabilizing the talotarsal joint.

Clinical signs of RTTJD are found with non-weightbearing and weightbearing examination. The hindfoot is put through a range-of-motion while the patient is in the exam chair. The motions of the talotarsal joint are called supination and pronation. There should only be a minimum amount of pronation, up to 5 or 6 degrees maximum. The weightbearing exam occurs when the patient stands and walks. Typical findings include bulging of the head of the talus on the inner ankle, which gives the appearance of two inner ankle bones. There is also the "too-many-toes" sign which is being able to see more than the 5th toe when looking at the back of the heel forward. Arch height is not a very reliable finding. Many patients can have a lowering of their arch, but this is not a consistent finding. Also, another possible finding is looking at the back of the heel bone. Many times, the heel can turn outward, but this observation is not always present (Figure 1 and 2). Weightbearing radiographic imaging (x-rays) provides confirmation of RTTJD. There are validated radiographic measurements and findings that document it. The issue with clinical examination is that the findings are inconsistent from examiner to examiner, whereas radiographic findings are consistent measurements that provide specific measurements. The first indication of RTTJD is that there is partial to full obliteration of the sinus tarsi, as seen on the lateral radiograph. Partial closure of that space only occurs when the ankle bone is partially dislocated on the heel bone.

RTTJD can occur in one or more geometric planes: transverse, sagittal, and/or frontal. A diagnosis of RTTJD can be made if there is one plane of deformity. It does not require all three cardinal planes. There are many radiographic measurements to determine the alignment of the talotarsal joint. Two commonly used measurements are the talar second metatarsal angle on dorsoplantar view and the talar declination angle on the lateral x-ray. There can be many other possible radiographic findings that are also present Figure 3 and 4.

The Importance of an Aligned and Stable Talotarsal Joint (TTJ)

Walking is one of the most common conscious functions of the body, next to breathing. The average person takes approximately 6,000 to 8,000 steps a day. A healthy goal is to take at least 10,000 steps at least day. The average person will take more than 72 million steps by the time they reach 40 years of age and over 100 million steps by the time they are 60. This is why the alignment and stability of the foot and ankle is so important.

The entire weight of the body rests on the talotarsal or "foundation joint." This complex joint is composed of 4 separate articulations

Figure 5: Balanced joint forces.

Figure 6: RTTJD shifts the joint forces anteriorly.

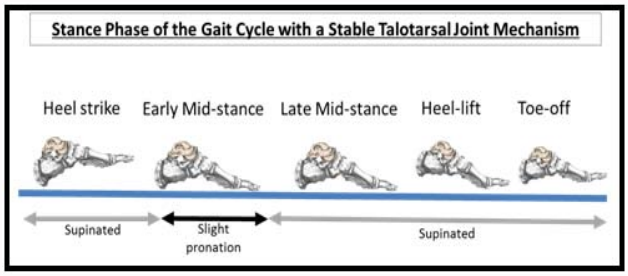

Figure 7: An aligned and stabile talotarsal joint allows a normal amount of pronation and supination.

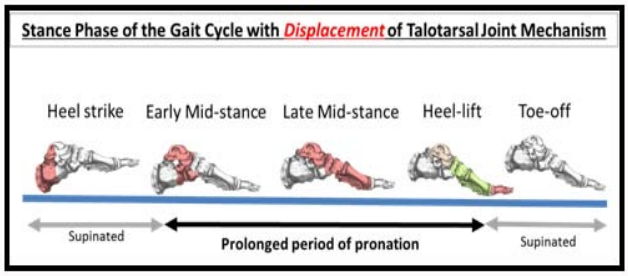

Figure 8: A misaligned and unstable talotarsal joint leads to an excessive duration of pronation. The supporting tissues have increased strain, and eventually over-use injuries develop.

Figure 9: The negative effect of RTTJD to the proximal joints of the body.

that balance the forces from the body above and the weight bearing surface below. These forces are subdivided so that slightly more than half of the force should act posteriorly to the back of the heel and the remaining forces pass through the front of the foot and out through the toes Figure 5 and 6. Just as important is the complex range of motion of the talotarsal joint, supination and pronation. Supination locks the bones of the foot to make them stable during the walking cycle. Pronation is the opposite of supination where there is an unlocking of the foot bones to allow the foot to adapt to an uneven weightbearing surface. The TTJ should only exhibit a very slight amount of pronation motion during the beginning portion of the stance phase of the walking cycle Figure 7. RTTJD creates an imbalance of joint forces. There is a shift of force from the back of the foot to the inner-front. Increased forces will now act on the front of the foot. This means the foot bones will be unlocked and weakened more than they should. The combination of excessive forces acting on a weakening joint structure will lead to increased strain to the ligaments. This signals a nerve reflex mechanism that causes certain muscle-tendon structures to contract in order to compensate for the excessive hindfoot motion. Because these excessive forces act on abnormally while standing, walking, or running, it is only a matter of time until a critical threshold is reached. At that point, the tissues can no longer withstand the repeated forces and they become damaged. Eventually, these damaged tissues will cause pain. If the TTJ is not internally realigned and stabilized, those tissues will continue to become further damaged until they partially or fully rupture. Once that occurs, other muscles and tendons will now have to make up for the failure of those tissues to stabilize the foot Figure 8.

Secondary Symptoms of RTTJD

A symptom is something that is experienced, physically or mentally, by someone. It is an indication that something is wrong. For instance, it shouldn't hurt when you breathe. If it hurts when you breathe, that means there is a problem. Pain is a warning signal. Pain is the symptom, but there is an underlying cause to the pain. There is an underlying etiology to every symptom. However, pain is not the only "symptom" that would warrant treatment. There are many diseases where "pain" is not found, yet those diseases are still treated.

There is wisdom in the adage "a chain is as strong as its weakest link." This translates to - the weakest tissue of the lower extremity will become the first to become symptomatic due to RTTJD. For some individuals, these symptoms show up in childhood, whereas there are others who don't develop symptoms until old age. There are many factors that contribute to the development of symptoms. But the bottom line is it's not "if," it's "when." Childhood symptoms of RTTJ begin with growing pains, shin splints, children not wanting to participate in sports, wanting to be carried more than usual,

Figure 10: The possible long-term progression of the RTTJD deformity.

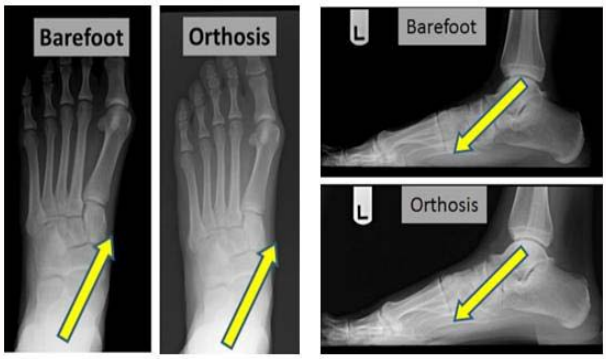

Figure 11: The inability of a foot orthosis to have a positive effect on talar position.

to suffering after a period of walking or running Figure 9. Later in life these RTTJD patients will develop heel pain, heel spurs, plantar fasciitis, posterior tibial tendon dysfunction, bunions, big toe joint arthritis, hammertoes, plantar neuropathy, ankle joint problems, knee joint instability and arthritis, hip pain, sciatica, sacroiliac instability, and many issues to their spine. Even worse are the long-term health issues that are related to inactivity. If it hurts when you walk, you stop walking or exercising. This leads to decreased metabolism and weight gain. Eventually, the person becomes obese. Obesity is a link to many other metabolic diseases such as diabetes, hypertension, heart disease, artery disease, and even certain forms of cancer. The leading recommendation to these diseases is simply to go out and walk, to increase their metabolic rate. But the patient is not able to perform this most simple form of exercise because they suffer, as a result. Therefore, those diseases slowly get worse and the patients are never "cured."

Treatment Option of RTTJD

RTTJD is an internal orthopedic deformity that requires internal correction. Medical literature has confirmed that external measures are not able to realign or stabilize the TTJ. The use of external measures should be considered subtherapeutic and therefore below the standard-of-care in the treatment of RTTJD. The goal of "treatment" is that the talus is realigned and stabilized on/with the calcaneus and navicular bones.

The role of "observation" by the physician should be considered "medical neglect." There is no evidence of "auto-correction" of RTTJD. There are no radiographic studies that show pediatric patients with RTTJD get better. Rather, the long-term evidence suggests that not only will it continue to get worse, but that other secondary tissues will

Figure 12: Example of typical hindfoot realignment surgery.

become damaged and destroyed. This is the worst form of "treatment" that could ever be recommended to a patient with RTTJD Figure 10. The use of arch supports or foot orthotics/orthosis is a multi-billion-dollar industry, globally. These unregulated devices claim that they can realign the foot bones, however, the medical literature continues to disprove these "claims." [29-44]. There is no published evidence that an arch support can realign and/or stabilize the talus on the tarsal bones. Therefore, the claim that these "foot orthotics" can realign the foot is false advertising. There are studies that showed these foot supports failed to realign the foot structure; they made it even more misaligned Figure 11.

Other forms of treatment to realign and stabilize the talus include aggressive, irreversible surgical procedures. Many surgeons have advocated cutting and shifting the back portion of the heel bone. This requires a long period of non-weightbearing and most of the patients must be taken back to the operating room to have painful screws removed. The published literature shows that this procedure still has a limited affect to realign and stabilize the talus [45-53]. Another option is to cut the outer front of the calcaneus and insert a bone graft. This again is a long surgery that has shown to cause arthritis at the adjacent joint and that is not able to realign the TTJ Figure 12.

Finally, the last option is to fuse the posterior subtalar joint. This is a very destructive, devastating option. The joint-articular surfaces are resected; the bones are pushed together and one or more screws are inserted from one bone into the other. The cutting out of the joints leads to a further loss in height to that limb and will lead to more secondary pathology to the lower extremity and spine. There are many patients whose bones don't fuse that will require more surgery. Most patients will require the removal of painful screws. There is a long list of complications including mal-union, non-union, and arthritic changes to adjacent joints [54-76]. EOTTS is the superior treatment of choice for many reasons. Unlike observation, foot orthotics, and many other surgical procedures, EOTTS is proven to realign and stabilize the TTJ while still allowing a normal range of motion [77-92].

Evidence Basis of EOTTS

The primary reason why many in the insurance industry have denied the reimbursement of the EOTTS procedure is due to "limited published data" on the effectiveness of EOTTS.

What is the minimum evidence required to show that EOTTS is an effective treatment option?

1. Is there evidence that the EOTTS procedure maintains the stability and alignment of the TTJ clinically and radiographically? YES!

2. Is there evidence that the EOTTS procedure normalizes the

range of motion of the TTJ? YES!

3. Is there evidence that the EOTTS procedure normalizes the joint forces acting on the tarsal mechanism? YES!

4. Is there evidence that the EOTTS procedure decreases strain acting on supporting soft tissue structures? YES!

5. What are the reported "worst case" complications? Limited and no long lasting "complications", simply the stent was removed without negative long-term issues.

Armed with that information, the insurance carriers should decide that the EOTTS procedure should be reimbursed.

There have been numerous scientific papers looking at the short and long-term effects of the EOTTS procedure [77-92]. There are multiple papers that have proven both clinical and radiologic normalization of TTJ alignment and stability. Research shows that following the EOTTS procedure, there are decreased forces acting on the front of the foot and increased forces acting on the heel [93]. Likewise, there are studies that have shown a significant decrease in tissue strain and elongation [94-98]. Furthermore, long-term studies have shown limited post-EOTTS complications. There have only been a few reported cases of "worst case" complications [99-103]. There estimates that as many as 250,000 EOTTS procedures have been performed globally. Yet, only a few "complications" have been reported? The worst of these involved sinus tarsi implant that shifted 180 degrees from where it was initially placed and it became partially embedded into the ankle bone. The device was removed and there was no long-term negative effect. The article made it appear as if the ankle bone was fractured. There are many surgeons who partially insert screws into either the ankle bone or heel bone in a similar fashion to block excessive ankle bone motion [104-113]. That is not a true "complication." Another "complication" case-report occurred when the surgeon failed to remove a dislocated stent and allowed the patient to continue to walk on their foot, knowing full well the stent was not placed in the desired alignment. Later that patient developed arthritic changes. The issue is that it occurred "spontaneously" after more than 2 years. It should have been a malpractice case against the surgeon, rather than a knock against sinus tarsi implants. This was a complication that could have been prevented if the surgeon would have intervened when the initial displacement was visualized on the x-ray. What has not been reported is that not a single patient ended up with a serious complication. Typically, the worst thing that can occur is prolonged pain and the EOTTS implant must be removed. There is not a single reported case where a patient required more extensive surgical procedures because of undergoing an EOTTS procedure. Most times, patients would be told they need more aggressive surgery and the EOTTS procedure is performed as a more conservative option.

Benefit-Risk Analysis of EOTTS

A few of the benefits include a minimally invasive procedure that internally realigns and stabilizes the TTJ while still allowing a normal range of motion. This procedure is reversible and can be used in conjunction with both external measures and other surgical procedures. It is commonly performed in both children and adults. Patients, once recovered, can participate in sporting activities of their choosing. Besides the very important benefits listed above, is the fact that not only is the TTJ realigned, but also the normalization of forces acting within the foot structures. Instantly, there are decreased forces acting on the bones, joints, tendons, ligaments, and neurovascular structures of the foot. The ankle joint is realigned, and there are positive effects to the knee, hips, pelvis, and spine. Patients who have had the EOTTS procedure have been able to increase their activity levels, increase their metabolism, decrease their weight, and improve their blood sugar levels and blood pressure. Simply put, they get their lives back. They don't have to think about whether an activity is worth the pain they would experience due to walking or standing. They just get back to living. What are the potential risks of EOTTS? First off, they are nowhere near the potential risks of traditional corrective surgery. There are no chances of non-union or implant breakage (orthopedic screws have been known to break from time-to-time). The worst possible issue is simply that there is prolonged pain due to soft tissue adaptation. The EOTTS stent can be removed or downsized. Occasionally the stent can displace. This is because it is only anchored by the soft tissues in the sinus tarsi space and many times those tissues no longer exist due to the duration of the RTTJD deformity. Other times, there could be a need to down or up-size the stent. The size of the EOTTS implant is determined while the patient is lying on a procedure table. The best way to determine size would be to insert the stent and have the patient walk. However, this cannot be performed during the procedure, so the surgeon must use their best judgment.

Summary

EOTTS is a time-tested, evidence-based solution that makes sense. The fact that this procedure has been approved for use by the health officials in 70 countries and it is performed by leading orthopedic and podiatric surgeons globally, is very telling. The EOTTS procedure makes sense, fixes the underlying etiology of many chronic lower extremity deformities, and the benefits far outweigh any potential risks. There is a crisis in the treatment of musculoskeletal disorders. The governments around the world are trying to figure out how they can lower healthcare expenditures to chronic diseases. The answer is prevention, yet it is all talk and no action. When one considers the existing healthcare frame of mind, it is focused on symptom-relief rather than fixing the underlying etiology. If you address the symptoms without fixing what is broken, it is only a matter of time until the symptoms reoccur. The underlying problem is still present and will continue to cause the same condition that made that symptom occur in the first place.

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