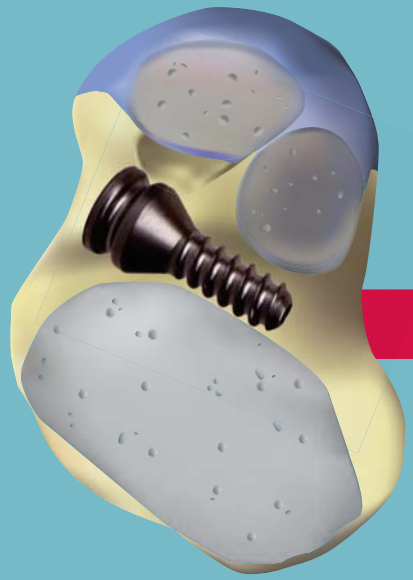

Extra-Osseous TaloTarsal Stabilization

A Proven Biomechanical Solution.

By Michael E. Graham, D.P.M.

This book is dedicated to the foot specialists of the world.

The time has come for the medical community to give proper foot alignment the attention and care it deserves. Everyday, millions of people suffer as a result of misaligned feet. Our goal is to increase awareness and provide a solution to a destructive, and often-overlooked, deformity of the foot.

I would like to make special mention to my wife and daughter, Nancy and Summer. They have stood by my side and encouraged me through my life's mission to help people around the world who suffer as a result of misaligned feet. None of this would be possible without their love, affection and constant support. I love you two very much.

Finally, I would like to thank the team at GraMedica. Everyday they go the extra mile to ensure we are doing everything we can to assist our doctors and patients. A huge part of the success of HyProCure is due to their dedication. Thank you for all you do.

“ There's nothing more powerful than an idea whose time has come. ”

~ Victor Hugo

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Contents

“ Abnormal position of a part of the body demands a subsequent relative transformation in the inner structure, contour & physiological function of the bones supporting this part. ”

~ Julius Wolff, MD
1892, The Law of Bone Remodeling

“ Ligaments, or any soft tissue, when put under even a moderate degree of tension, if that tension is continuous, will elongate by the addition of new tissue. On the contrary, when ligaments, or other soft tissues, remain uninterruptedly in a loose or lax state, they will gradually shorten, until they come to maintain the same relation to the bony structures with which they are united that they did before their shortening. ”

~ Henry Gassett Davis, MD
1867, Conservative Surgery

Glossary

ATFL
Anterior TaloFibular Ligament

CIA
Calcaneal Inclination Angle

CT
Computed Tomography

DP
Dorsal Plantar

EOTTS
Extra-Osseous TaloTarsal Stabilization

HAV
Hallux AbductoValgus

HL
Hallux Limitus

HR
Hallux Rigidus

IM
Intermetatarsal

MPJ
Metatarsal Phalangeal Joint

MPV
Metatarsus Primus Varus

NSP
Neutral Stance Position

PF
Plantar Fascia

PTTD
Posterior Tibial Tendon Dysfunction

ROM
Range of Motion

RR
Removal Rate

RSP
Resting Stance Position

RTTJD
Recurrent TaloTarsal Joint Displacement/Dislocation

T2MA
Talar Second Metatarsal Angle

TCIL
TaloCalcaneal Interosseous Ligament/Ligament to the Sinus Tarsi

TDA
Talar Declination Angle

TTJ
TaloTarsal Joint

TTJD
TaloTarsal Joint Displacement/Dislocation

Section 1

Getting Started

“ The term balance as applied to the foot structure does not refer to muscle activity, but to the arrangement of the bones and ligaments which furnishes a stable base upon which body-weight can be supported with the least demand for muscular exertion and propelled evenly balanced upon the lever axis. ”

~ Dudley J. Morton, MD

1.1 Introduction

The misalignment of the hindfoot most commonly involves the partial displacement of the talus on the tarsal mechanism (calcaneus & navicular). This talotarsal joint displacement leads to an unlocking and increased strain placed on the medial column of the foot. There is an additional negative effect proximally to the knee(s), hip(s), and back.

For some, symptoms of hindfoot misalignment can appear early in childhood. For others, symptoms will appear much later in adulthood. The exact area of the body where the symptom(s) will appear will vary for each individual.

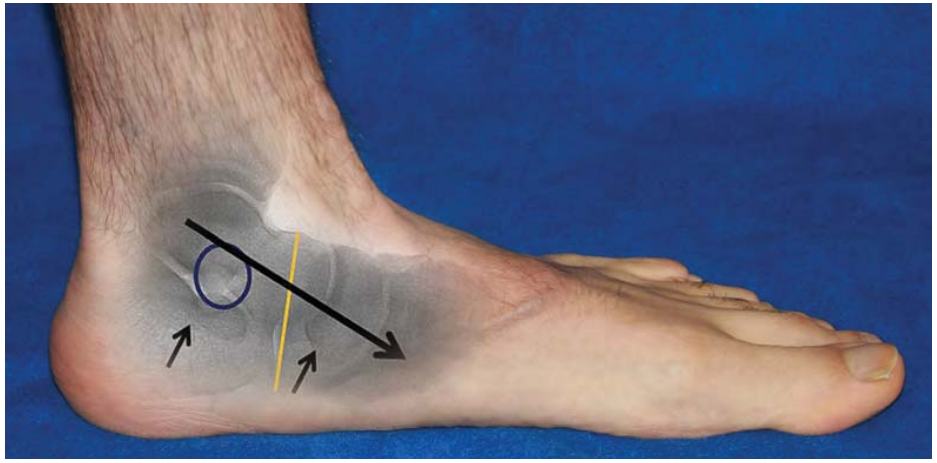
As the saying goes, "the chain is only as strong as its weakest link". The clinical signs of a misaligned hindfoot may be masked. While some patients will have a lower-than-normal arch, there will be others where the arch height appears to be normal. Likewise, some patients may have an associated calcaneovalgus heel alignment, while others will have a normal appearing heel position.

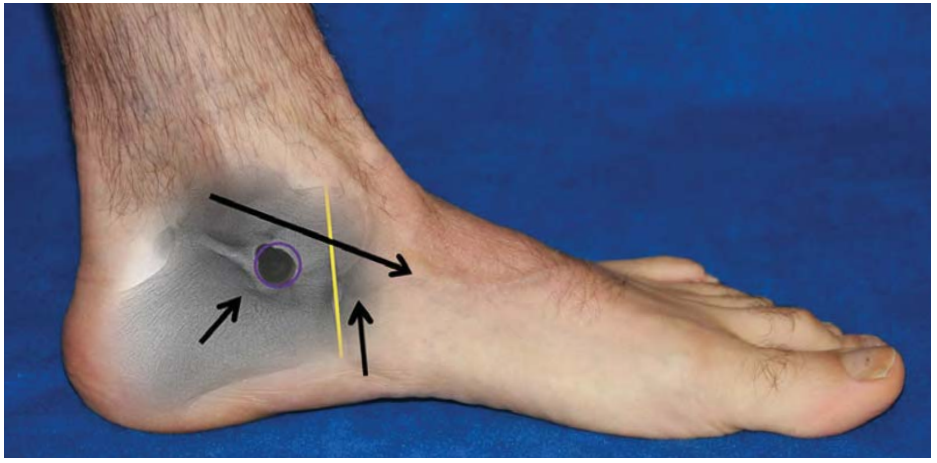
The gold standard for the diagnosis of bone disorders is radiographic evaluation. There are many validated radiographic angular measurements that clearly establish normal and abnormal. The symptoms and clinical signs of a talotarsal joint displacement deformity must be ruled-in or out via weightbearing radiographic analysis.

The treatment of orthopedic musculoskeletal disorders must begin with the realignment of displaced skeletal structures. Failure to realign misaligned structures will result in a failed treatment plan and the recurrence of the presenting condition.

The exact treatment plan will vary depending on many different factors. There is not an orthopedic treatment measure that is suitable for every situation. The totality of the entire foot and ankle structure must be taken into consideration. Conservative and surgical options must be explored. Every patient that seeks out health professional guidance deserves to know all available treatment options, so they can make an educated decision as to which plan is right for them.

This book was created to explore the option of Extra-Osseous TaloTarsal Stabilization (EOTTS). This option has proven to be the most powerful, minimally invasive orthopedic procedure, when indicated. As you read this book, you will see that the benefits of this option far outweigh any potential risks.

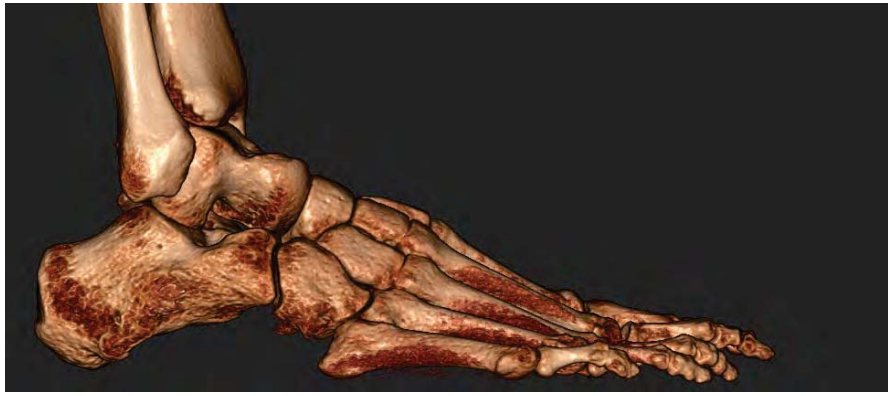


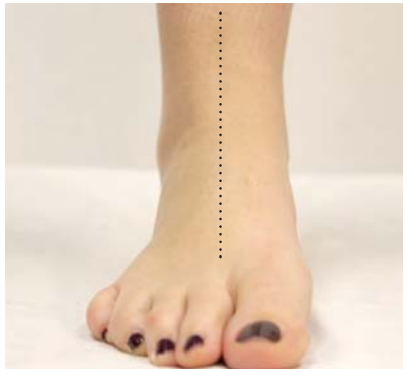


1.2 Hindfoot Alignment

Common Traits of a Healthy Foot Structure:

- ✓ The sinus tarsi is open-normal.
- ✓ There is a normal talar declination angle.
- ✓ There is a normal calcaneal inclination angle.
- ✓ There is a normal cyma line.
- ✓ There is less likelihood of tissue strain.
- ✓ This foot is less prone to chronic deformities.
- ✓ The talus is balanced on the calcaneus.
- ✓ This foot is less likely to have:
  - Plantar fasciopathy/fasciitis
  - 1st ray/MPJ/hallux pathology
  - Flexor stabilization hammertoes
  - Posterior tibial tendon dysfunction





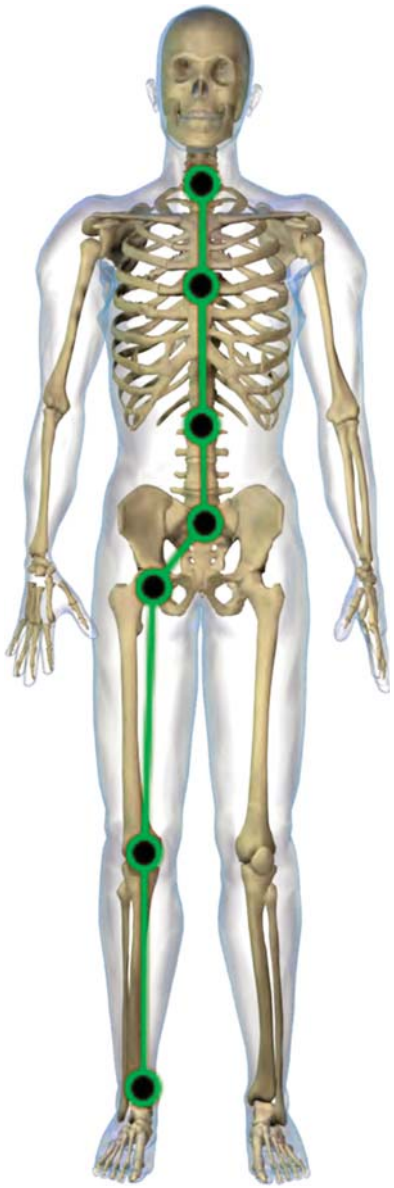
1.3 Hindfoot Misalignment

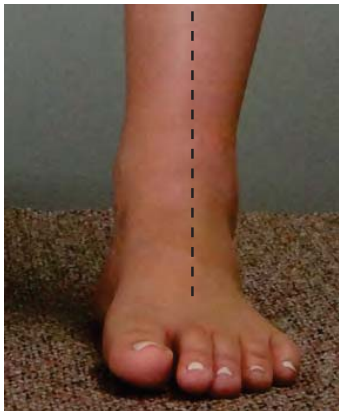
Common Traits of an Unhealthy Foot Structure:

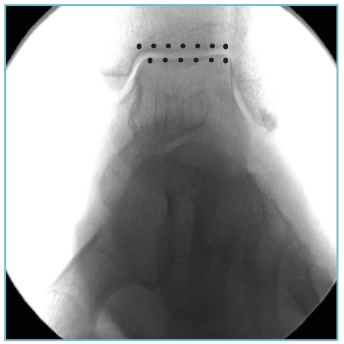
- ✓ There is a pathologic obliteration of the sinus tarsi.
- ✓ There is a greater likelihood of tissue strain.
- ✓ This foot is more likely to have foot deformities.
- ✓ The talus is displaced on the calcaneus.
- ✓ There is a pathologic talar declination angle.
- ✓ There can be a normal calcaneal inclination angle.
- ✓ There is a pathologic cyma line.
- ✓ This foot is more likely to have:
  - Plantar fasciopathy/fasciitis
  - 1st ray/MPJ/hallux pathology
  - Flexor stabilization hammertoes
  - Posterior tibial tendon dysfunction

1.4 Aligned Talus vs. Misaligned Talus

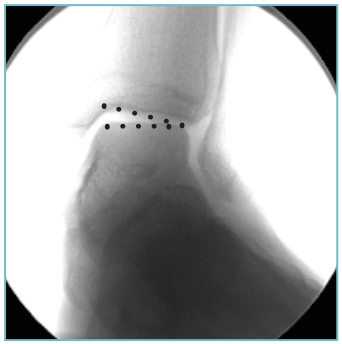
Aligned

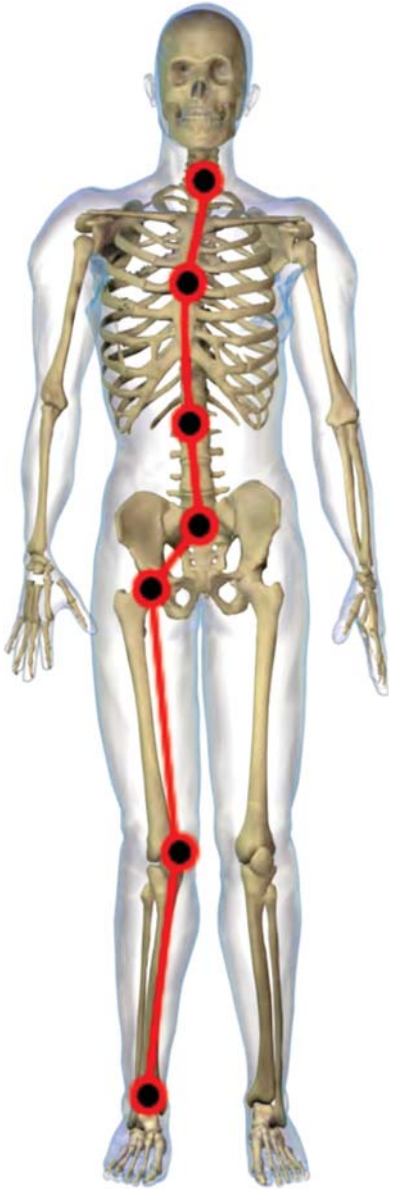






Misaligned





Partial displacement of the talus on the calcaneus leads to a chain reaction of destructive forces distally and proximally. Notice the primary difference between the aligned foot and misaligned foot is controlled by the alignment, or lack of alignment, of the talus on the calcaneus.

Note
It is important to understand that not all patients with a talotarsal joint displacement have flat arches. In fact, most have a normal appearing arch. The root of the problem is the hypermobile talus, NOT a fallen arch.

1.5 It Starts with Over-Pronation

A Hypermobile TaloTarsal Joint Leads to Over-Pronation.

Over-pronation is named as the leading cause of:

- Growing pains/Shin splints
- Chronic knee related issues
- Chronic hip related pain/Sciatica
- Functional leg length discrepancy
- Pelvic tilt
- Back strain–upper and lower

80% of patient symptoms are in the knees, hips and back.

- Plantar fasciopathy/fasciitis
- Flexor stabilization hammertoes
- Hallux valgus, limitus and rigidus
- Metatarsus primus varus/Increased IM angle
- Posterior tibial tendon dysfunction
- "Too many toes" sign—abductory twist
- Abnormal plantar force distribution
- Tarsal tunnel syndrome/Posterior tibial nerve pathology

Only 20% of patient symptoms are found in the foot.

Recurrence is the leading complication of treatment.

Why is there recurrence after treatment?

Because the subtalar joint wasn't realigned or stabilized. The pathological factors that created the symptoms are still present and continue to act as a destructive force.

1.6 Clinical Findings

Non-weightbearing exam

- TaloTarsal joint range of motion exam results are greater than 5° of pronation

Weightbearing exam

- Medial talar head bulging
- Forefoot valgus
- "Too many toes" sign
- Heel/Calcaneal valgus
- If a patient can realign their hindfoot back into neutral TTJ alignment, this represents a reducible deformity
- If a patient can partially realign their hindfoot back into neutral TTJ alignment, this represents a semi-reducible deformity
- If a patient cannot realign their TTJ into neutral, this represents a non-reducible deformity

RTTJD

Recurrent talotarsal joint displacement is an orthopedic deformity where the talus continuously becomes misaligned on the tarsal mechanism. This is a hypermobile talotarsal joint, also known as peri-talar subluxation or subtalar joint instability.

TTJD can be flexible, semi-flexible or rigid. RTTJD indicates a reducible dislocation deformity.

Gait analysis

- Abductory twist
- "Too many toes" sign

Slight Supination

TTJ Neutral Position

Over-pronated TTJ = Talar Displacement

Note: Cupping the heel and inverting/everting the heel tests the posterior talocalcaneal joint, not the talotarsal joint.

1.7 Radiographic Confirmation of TTJD

The gold standard for the diagnosis of biomechanically-related orthopedic deformities of the foot is via weightbearing radiographic imaging. The accepted normal and abnormal radiographic angles are listed below.

Keep in Mind

It is possible to have a single plane of deformity while another plane is normal. The TTJ is still considered to be displaced with only one plane of deformity present.

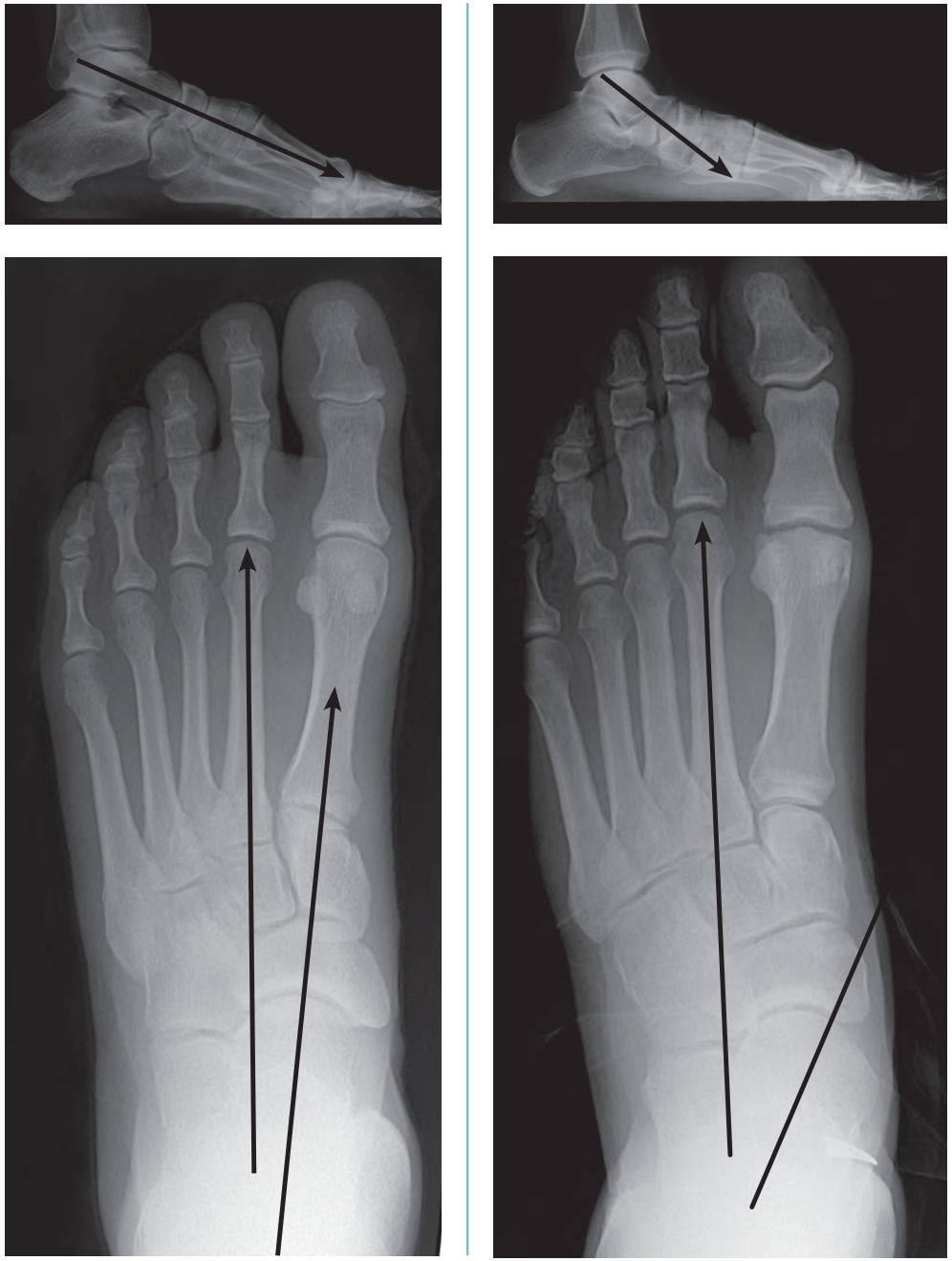
Normal TaloTarsal Joint Alignment

- Open Sinus Tarsi
- DP X-ray:
  - Talar 2nd Metatarsal < 16°
  - Talonavicular Coverage < 7°
- Lateral X-ray: Talar Declination < 21°

Diagnosis of TaloTarsal Joint Displacement

One or more positive findings:

- Obliterated Sinus Tarsi
- DP X-ray:
  - Talar 2nd Metatarsal > 16°
  - Talonavicular Coverage > 7°
- Lateral X-ray: Talar Declination > 21°



Section 2

Foot Related Secondary Conditions Directly Linked to RTTJD

“ If you don't know, you don't see.

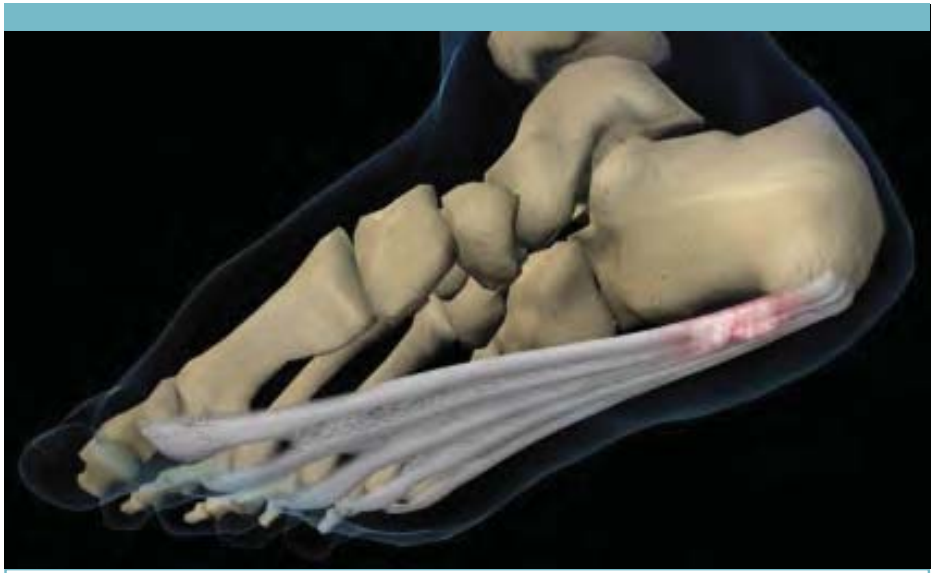
If you don't see, you don't treat.

If you don't treat, the problem continues. ”

2.1 Plantar Fasciopathy

Plantar Fascia

- Important "dynamic" structure that stabilizes the arch of the foot
- Composed of thick connective tissue
- Medial band stabilizes the medial column of the foot
- Carries 14% of the load of the foot
- Helps to put a “spring” in your step



Plantar Fasciopathy (Insertional)

- Mistakenly referred to as plantar fasciitis
- Non-inflammatory structural breakdown of the plantar fascia
- Estimated cost of treatment within the U.S. is $284 million from mechanical over-loading as a direct result of chronic subtalar joint hypermobility
- A hypermobile talus leads to excessive forces on the medial column of the foot while standing, walking and running

Plantar Fasciitis Myth

Unfortunately, the addition of “iitis” indicates there is an inflammatory component. Multiple histologic studies have proven this to be a myth. Yet, patients with this condition are primarily treated by anti-inflammatory methods and little attention is paid to the reduction of forces acting on the plantar fascia.

A greater tragedy occurs when the fascia is allowed to “auto-rupture” or is surgically transected, which leads to destabilization, or greater instability to the medial column of the foot. Reduction of the mechanical overloading of the plantar fascia should be the primary aim of treatment.

2.2 Posterior Tibial Tendon Dysfunction

Posterior Tibial Muscle-Tendon

- Supinatory muscle-tendon complex counters pronation
- Responsible for stabilizing and lifting the medial column of the arch

Posterior Tibial Tendon Pathology

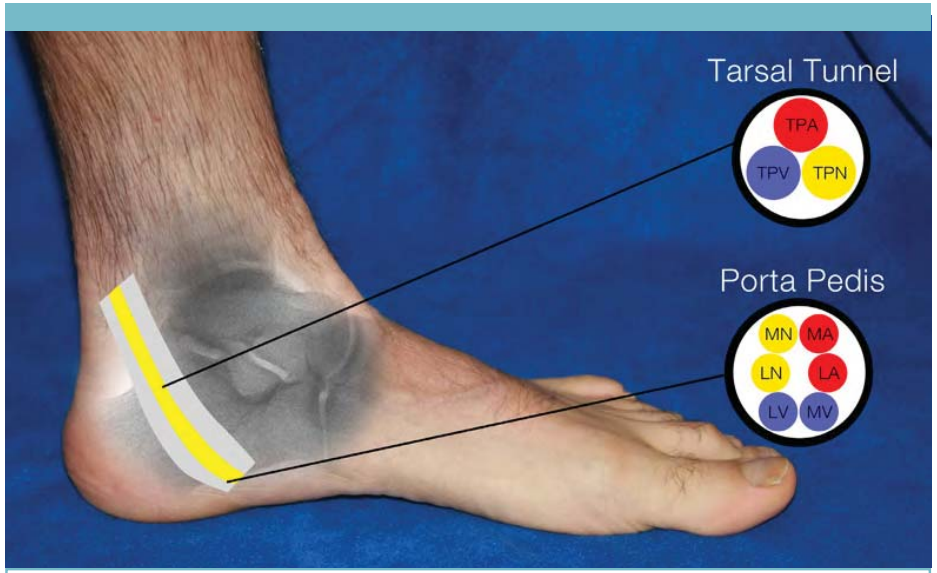
- TTJ instability places an excessive elongation force on the tendon
- Abnormal forces eventually lead to destructive changes within the tendon creating an inability to supinate the medial column of the foot
- The pathologic strain-elongation leads to the creation of the "watershed" area of the tendon

Traditional Treatment Limitations

Typically, little effort is made to decrease the excessive pathologic forces acting on the posterior tibial tendon. The primary treatment methods include anti-inflammatory regimens, or arch supports. These treatments are incapable of decreasing the stain on the tendon.

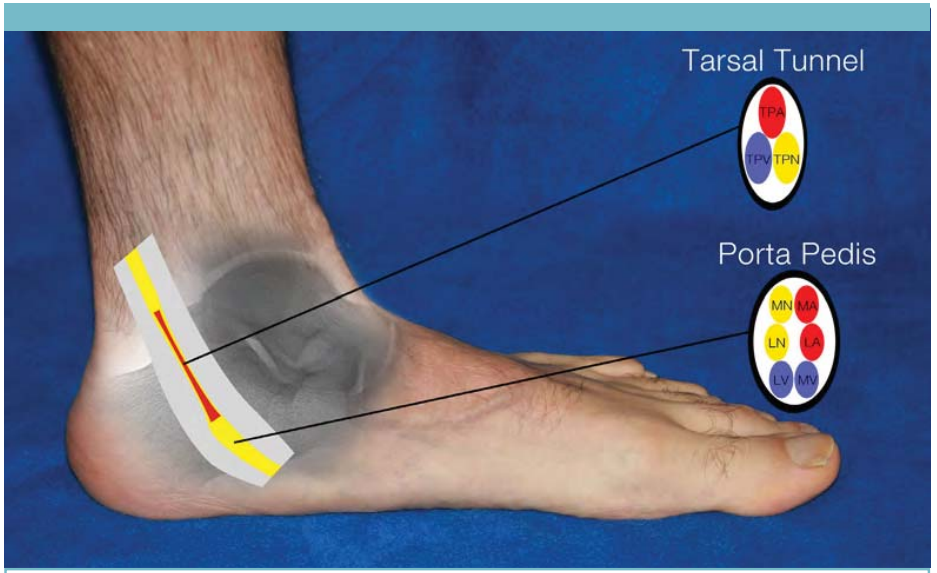
Traditional tendon augmentation also fails long-term due to continued presence of talar hypermobility. Finally, the patient's foot is allowed to completely collapse until the only option is arthrodesis and tendon transfers.

2.3 Plantar Neuropathy



Posterior Tibial Nerve

The posterior tibial nerve travels through the tarsal tunnel and passes through the porta pedis to transport neural impulses from the tips of the toes and the plantar surface of the foot.



Posterior Tibial Neuropathy

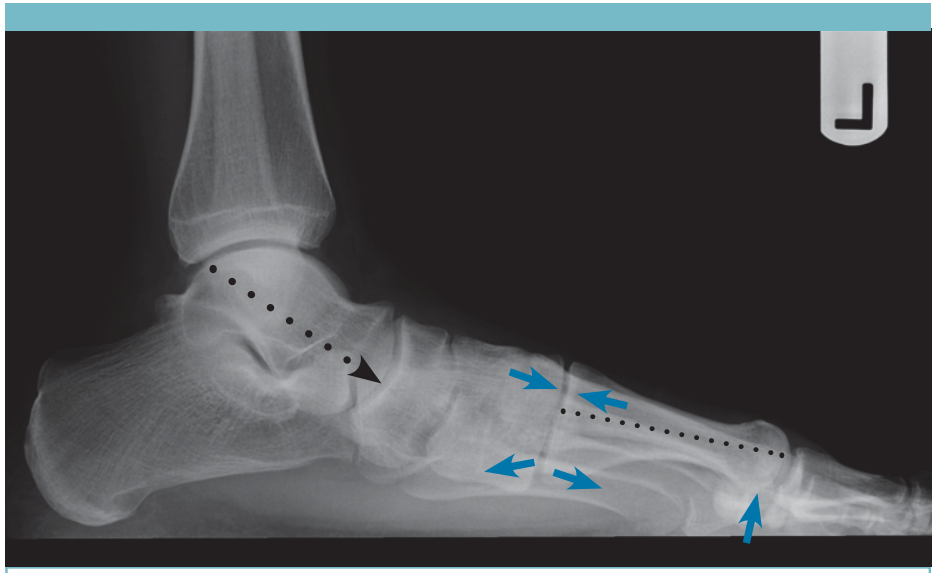
RTTJD leads to compression of both the tarsal tunnel and porta pedis along with slight wringing and elongation of the nerve. This leads to a reduction of blood flow within the nerve and decreased axoplasmic flow. Toes are affected first, then the ball of the foot and up the leg.

Hypermobile Talus has been Scientifically Linked to Plantar Neuropathy.

Plantar neuropathy is a pathologic condition where the nerves on the bottom of the foot become symptomatic, or simply don't function as they should due to compromised nerve function. The majority of the medical community is focused on metabolic implicating factors, yet few realize the importance of hindfoot misalignment and the biomechanical implications.

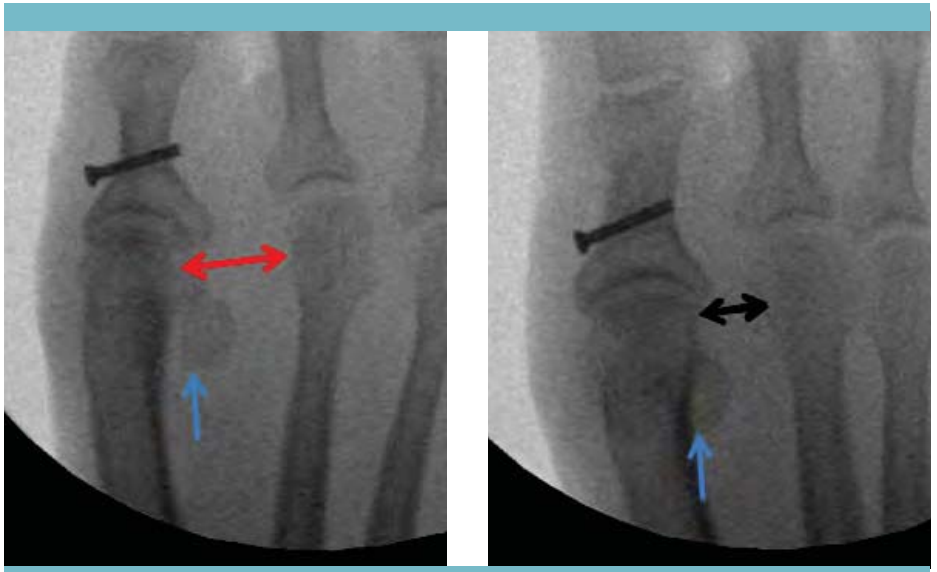
Patient symptoms are less severe when they first get out of bed in the morning after being non-weightbearing during the night. The plantar foot symptoms appear during or after a weightbearing period. The older the patient is, the more likely it is that they will develop neuropathy regardless of other disease factors. The constant factor is standing and walking.

2.4 Hallux Valgus–Metatarsus Primus Varus



Relaxed Stance Lateral X-Ray

Here you can see the hindfoot controls the forefoot. RTTJD leads to an "unlocking" of joints of the medial column of the foot. Ground reaction forces exert an excessive dorsomedial force on the first metatarsal while standing, walking, or running. The hallux abducts and slightly rotates in a valgus rotation as a compensatory reaction. These forces are reloaded with every step taken.



Relaxed Stance | TTJ in Neutral Position

DP weightbearing x-ray of a patient with a bunion recurrence.

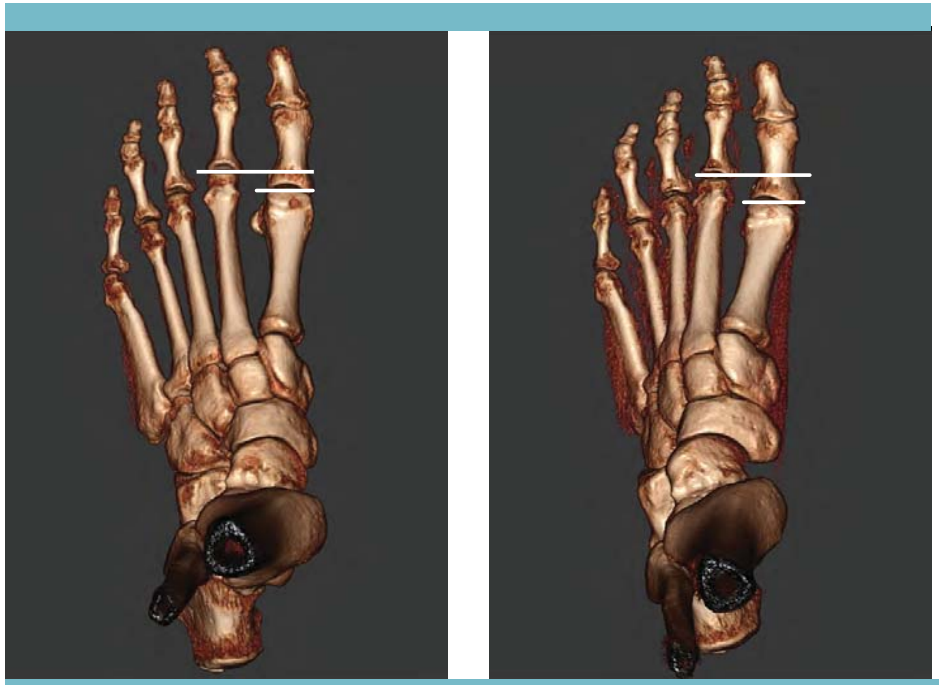
Compare the views of the TTJ in relaxed stance to the TTJ with the talus realigned on the calcaneus in neutral stance. There is an obvious increase in the IM angle, as well as a worsening of the tibial sesamoid position in relaxed stance vs. normalization of TTJ alignment.

Treatment Myths

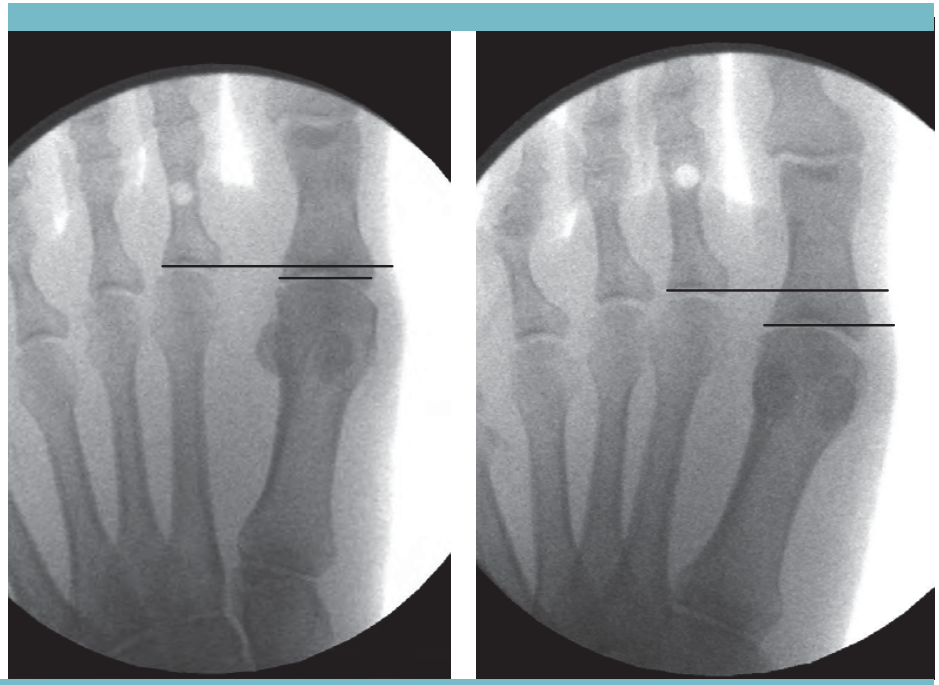
External measures such as arch supports or splints are incapable of preventing or reversing misaligned, unstabilized osseous structures. Surgical attempts at realignment typically lead to recurrence of the misalignment. This is because the underlying talar hypermobility was not adequately addressed.

Realignment and stabilization of the talus on the calcaneus decreases the forces acting on the medial column and will have a positive effect on the first ray and hallux.

2.5 Hallux Limitus/Rigidus



Relaxed TTJ Stance | Neutral Aligned TTJ



Relaxed TTJ Stance | Neutral TTJ Stance

1st MPJ ROM

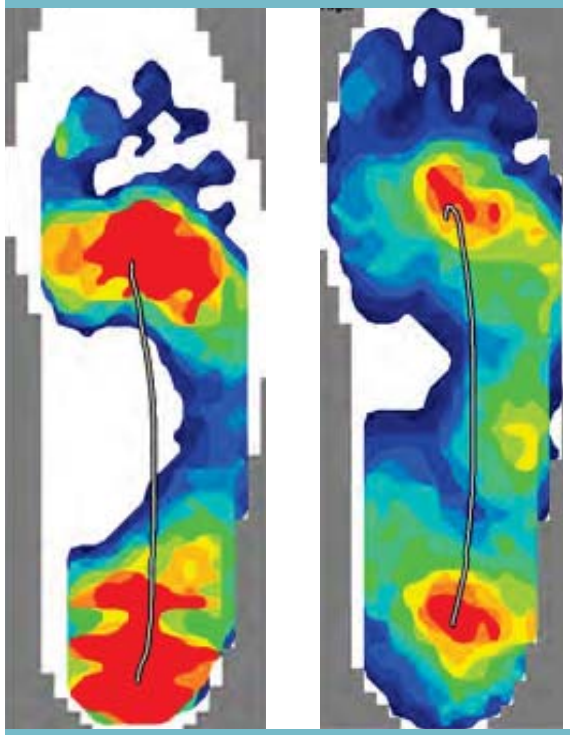
Here you can see that the hindfoot controls the forefoot. RTTJD can lead to an anterior talar displacement that creates a distal chain reaction leading to a jamming of the 1st MPJ. The forces are reloaded with every step taken until adaptive changes occur in the MPJ. Failure to realign and stabilize the talus on the tarsal mechanism will lead to a recurrence of limited 1st MPJ motion.

Failed Treatments

Arch supports may provide some patients with relief, however, they do not internally realign and stabilize the talus on the calcaneus. Many patients undergo 1st MPJ surgery only to suffer from a recurrence due to failure to internally reduce pathologic forces.

In this case, it makes more sense to realign the talus with an EOTTS device, prior to performing an arthrodesis procedure of the 1st MPJ.

2.6 Plantar Foot Pressures



Pre-EOTTS

Post-EOTTS

Plantar Foot Pressures

The weightbearing plantar forces on the foot are very important, especially when the patient has diminished sensation. An increased focal area of pressure leads to a thickening of the skin and the formation of calluses. Continued force to the specific area continues to form a callus until it becomes painful and alters the patient's gait.

Diminished plantar sensation breaks the pain circuit and when combined with continued pressure, inflammatory cells gather and accumulate under the callus until an ulcer is formed.

Plantar Ulcer Failed Treatment

As difficult as it may be to heal a plantar foot ulcer, the real challenge is to prevent a recurrence. The goal is to normalize the center of gravity passing through the foot and reduce any etiologic factors leading to a focal area of pressure.

Section 3

Available Treatment Options

“ The treatment of postural defects is primarily the removal of the constitutional predisposing factors. ”

~ William Jackson Merrill, MD

JBJS 1919 (13) 33-39

3.1 Observation

What is it

This is a non-treatment option. The excessive abnormal forces continue to exert damage distally and proximally. Hindfoot alignment will not auto-correct.

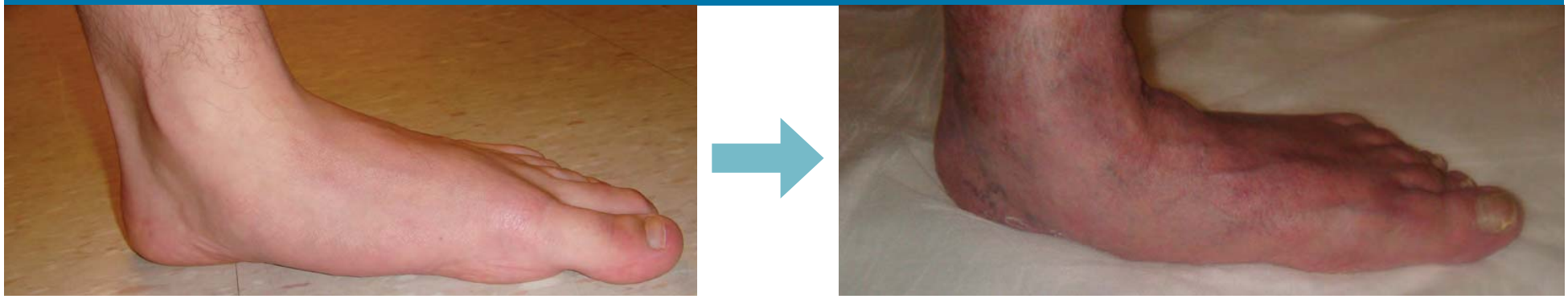
Why it isn't effective

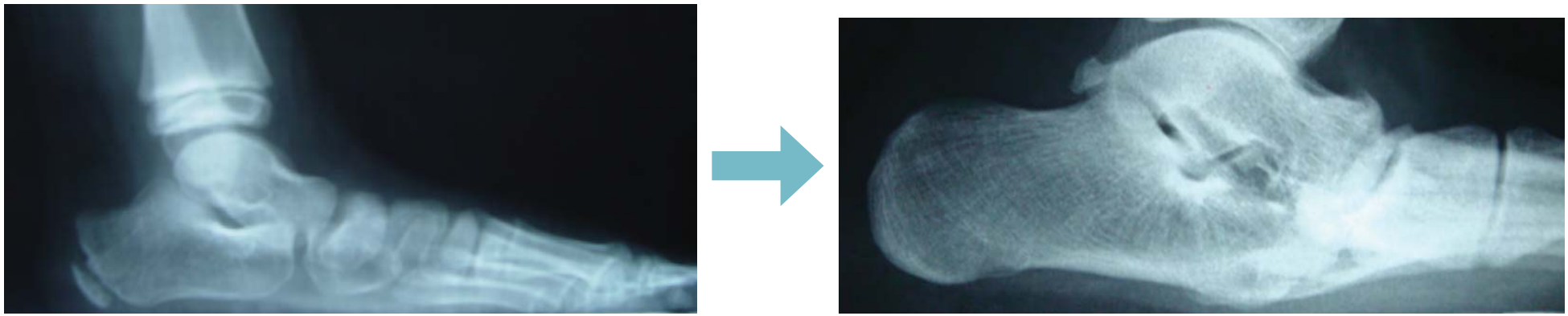
Observation is not a form of treatment. It is simply doing nothing while the existing condition becomes worse. Misaligned feet are caused by an internal structural problem with the talus and calcaneus. The problem will not correct itself and will only continue to get worse over time.

Key Points

- Observation is supervised neglect.
- The deformity will not get better over time, it gets worse.
- Every step leads to increased, excessive forces acting on the feet, knees, hips and back.
- There are no studies that show a patient can "outgrow" a hypermobile talus. It will not auto-cure.

You are not helping your patients by down playing this destructive condition, or offering a less effective subclinical form of treatment.





3.2 Arch Supports & Foot Orthotics

What is it

Arch supports are inserts that are placed inside the shoe and are typically used to restore a fallen arch and cushion the bottom of the foot.

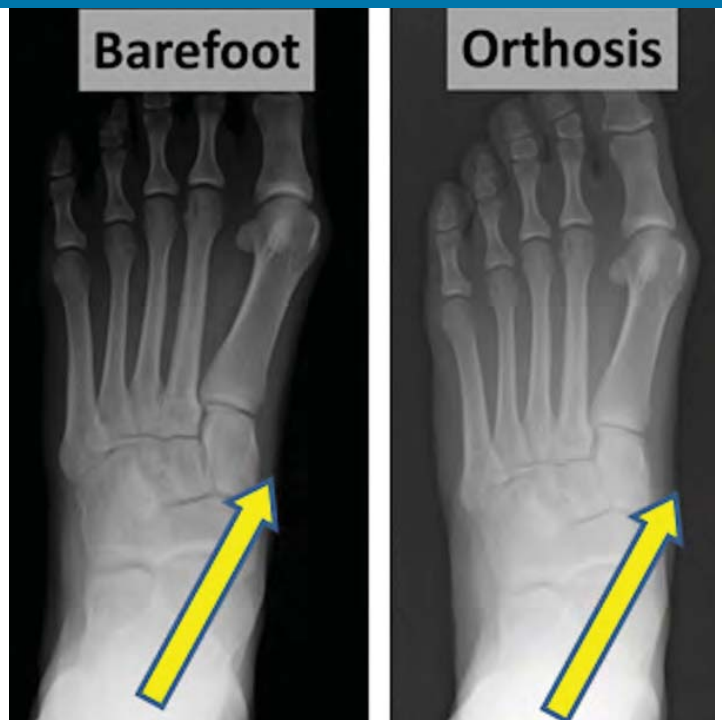
Why it isn't effective

While arch supports and foot orthotics may temporarily alleviate pain and may be useful for some foot pathologies, they are placed below the calcaneus and cannot realign or stabilize the talus. Like glasses, they only work when you wear them and give a false sense of correction. Also, due to a large number of manufacturers, there is a substantial amount of variability in quality and durability.

Key Points

- Provides a "false" sense of correction when it comes to realigning and stabilizing the talus.
- Excessive abnormal forces are still acting on the feet, knees, hips and back.
- Not corrective, "supportive" at best.
- There are no studies that show that an arch support can realign and stabilize the talus on the calcaneus.

You are not helping your patients by offering a less effective subclinical form of treatment.



These radiographs show proof that something placed below the foot cannot realign and stabilize the TTJ.

3.3 Reconstructive Surgery

What is it

There are patients whose only option is traditional reconstructive surgery. These are joint destructive procedures and should only be used for a complex deformity.

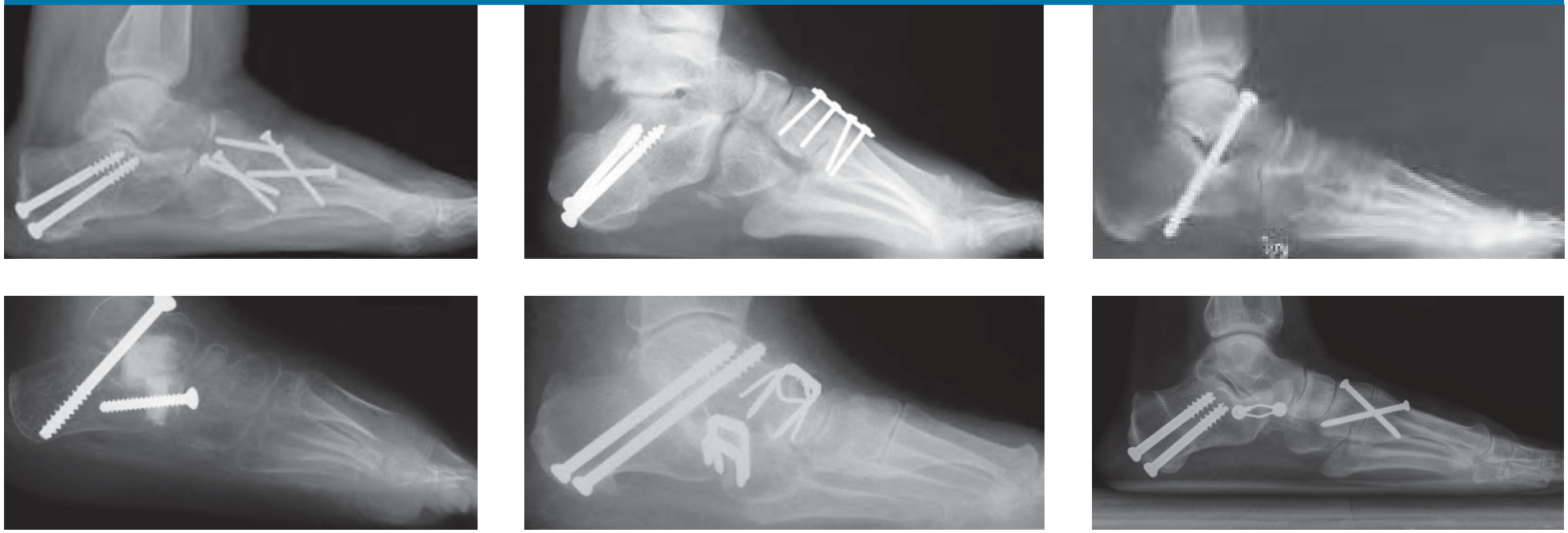
Why it isn't effective

While it can be effective for severe foot pathologies, reconstructive surgery is often too aggressive for patients with mild to moderate TTJD. It involves large incisions, a long recovery process and many potential complications. These procedures cannot be reversed.

Key Points

- Is a joint destructive, irreversible option.
- The "cure" may be worse than the disease.
- Typically involves a long recovery with many potential complications.
- Many patients require additional surgeries to revise and/or remove internal hardware.

There are better, less invasive methods of correction to consider before going this route.



Some of these patients may have been candidates for EOTTS with HyProCure if they would have been given the option earlier in life.

3.4 Arthroereisis

What is it

This is a joint-blocking procedure of the lateral process of the talus.

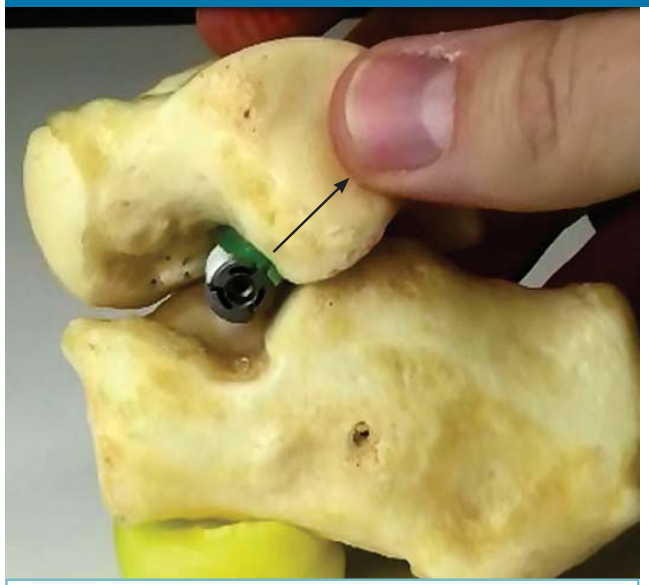
Why it isn't effective

These devices function against, and not with, normal subtalar joint motion. The talus smashes into the device thousands of time a day, leading to a loosening of the implant within the sinus tarsi. This causes an unusually high removal rate.*

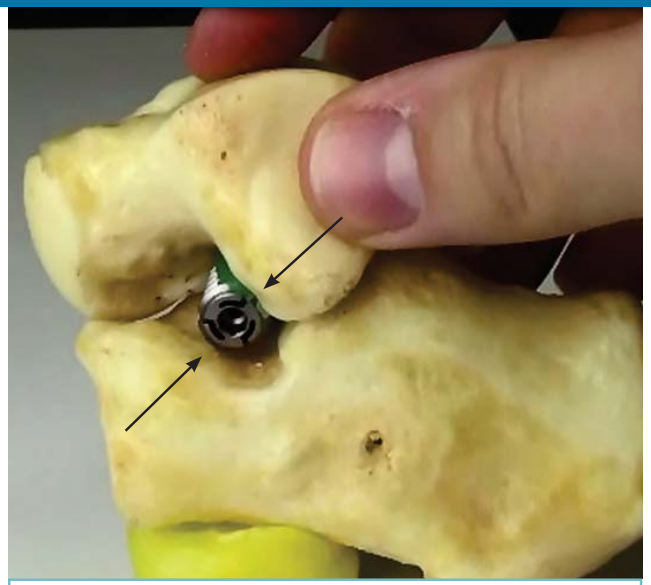
Key Points

- Placed in a medial-to-lateral orientation so that the medial tip touches the horizontal bisection of the talus.
- Talar supination leads to a reloading of traumatic forces.
- With every step taken, the lateral portion of the talus smashes into the implant during pronation.

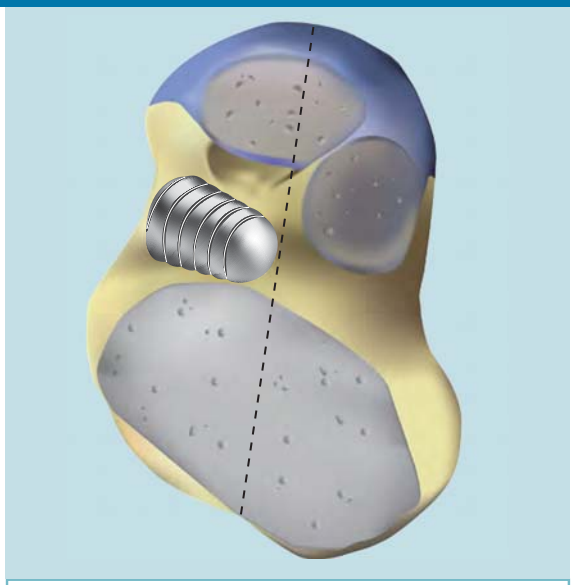
There is a better, more effective alternative.



Supination
This reloads traumatic forces acting on the device.



Pronation
This pushes and exerts a force on the device.



Placement
Placed into the lateral half of the sinus tarsi. The tip touches the bisection of the talus.

* See appendix for references regarding removal rates of arthroereisis devices

Section 4

The EOTTS with HyProCure® Solution

“ Simplicity is achieving maximum results in minimal effort. ”

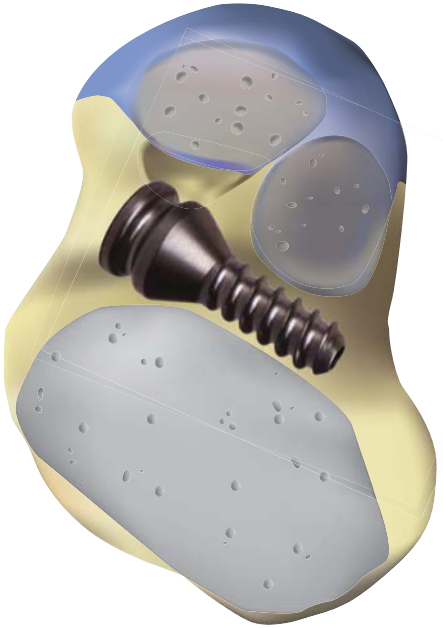
4.1 EOTTS with HyProCure

What is it

EOTTS (Extra-Osseous TaloTarsal Stabilization) is a conservative surgical option to internally realign and stabilize the talus without limiting or blocking normal TTJ ROM. HyProCure is a small titanium stent that is placed into a naturally-occurring space in between the ankle bone and heel bone through a small incision below the outer ankle bone. FDA cleared since 2004, HyProCure has been used by foot and ankle specialists (D.P.M./M.D.) in nearly 60 countries.

Why it's effective

Unlike orthotics, EOTTS with HyProCure is an internal permanent solution and functions with or without shoes. As opposed to reconstructive surgery, there are no pins, screws, or drills required. Post-op recovery time is significantly less. EOTTS with HyProCure is also reversible. Because of its positioning in the sinus tarsi, it has a significantly lower displacement rate than arthroereisis devices. As it is not a joint blocking device, it allows for full range of motion.



Key Points

- Minimally invasive, soft tissue procedure that realigns and stabilizes the talus on the tarsal mechanism
- This is a joint sparing procedure, therefore talotarsal joint ROM is preserved and/or restored
- Offers a conservative surgical approach that is proven to be a superior option to orthosis*
- Extensive evidence-based procedure that is time-tested and used by leading foot & ankle surgeons globally
- Used in both pediatric and adult patients, when indicated
- Unlike traditional osseous reconstructive surgery, the EOTTS with HyProCure procedure can be reversed
- Internal solution for an internal deformity
- Functions regardless of whether or not the patient is wearing shoes or going barefoot, unlike arch supports
- Can be used in conjunction with arch supports, or in combination with other foot & ankle procedures

HyProCure measures approximately 3/4s of an inch in length, which makes it smaller than your average paperclip.

* Superior correction over arch supports/orthosis (J Minim Invasive Orthop, 2015, 2(1): e8).

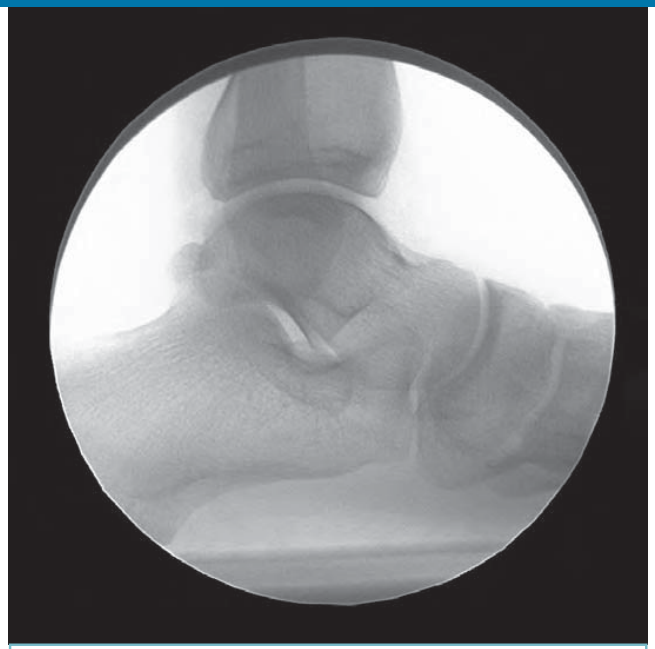
4.2 Positive Effects of EOTTS with HyProCure

EOTTS with HyProCure Benefits:

- Sinus tarsi is restored to its open position
- Joint facets are restored to constant congruent contact
- There are decreased forces acting on the medial column of the foot
- Decreased strain to the:
  - Medial band of the plantar fascia
  - Posterior tibial tendon
  - Posterior tibial nerve
- Normalized plantar foot forces
- Restores navicular position
- Normalized talar declination angle–sagittal plane correction
- Normalized talar second metatarsal angle–transverse plane correction
- Positive effect on the 1st ray and 1st MPJ

EOTTS realigns the TTJ and restores the foundation of the body.

Neutral Stance



Resting Stance

Resting Stance—Internally Corrected

4.3 Patient Selection Criteria

Selecting the Right Patient

When selecting a proper candidate for the EOTTS with HyProCure procedure, there are essentially three patient types to consider.

- **Patient Type 1**
  This patient has RTTJD, but is fortunate enough to go though life with little to no symptoms. This patient type stands to benefit from an over-the-counter or custom-made arch support.
- **Patient Type 2**
  This patient's foot structure is misaligned, but isn't so severe that reconstructive surgery is indicated. Their life is adversely affected while standing, walking, or running. Arch supports do not provide enough correction, but reconstructive surgery is often too aggressive and can be detrimental to the patient.
- **Patient Type 3**
  This patient's foot structure is so misaligned that their only option is traditional rearfoot reconstructive surgery.

Type 2 patients are the candidates who should be considered and offered the option of EOTTS with HyProCure.

Asymptomatic Concerned Patients

Should a patient undergo a minimum of 6 months of conservative care prior to initiating a surgical procedure/option?

The answer depends on the likelihood that conservative care will resolve the underlying condition.

Consider This...

If someone steps on a nail and it becomes partially inserted into the bottom of their foot, should they undergo conservative care of pain pills, padding, non-weightbearing treatments, or should they simply pull out the nail?

The same thought process can be applied to the treatment of talotarsal displacement. Is there any proof that observation, arch supports, or bracing will realign and stabilize the talus and therefore eliminate the underlying etiology to their symptom(s)?

Basic Guidelines

1. If the patient can easily realign their TTJ while standing, this is a good indication that they are a candidate.
2. If the patient has a difficult time realigning their TTJ, they may need additional surgical procedures.
3. If the patient cannot realign their TTJ while standing, then they are unlikely to be a candidate for EOTTS with HyProCure.

Physicians Note

The entire structure of the foot must be evaluated to properly diagnose TTJD or RTTJD. This includes non-weightbearing, weight-bearing and gait analysis.

4.3 Patient Selection Criteria

Hands-on Patient Examination

Patient must have a reducible-flexible deformity, so that the TTJ can be realigned. Entire TTJ must be evaluated.

NWB

Slight Supination

TTJ Neutral Position

Over-pronated TTJ = Talar Displacement

WB

Misaligned

Aligned

Misaligned

Aligned

Physicians Note

To be an EOTTS with HyProCure candidate, patients MUST have a flexible-reducible TTJ. Patients with a semi-flexible TTJ have a higher risk of procedure failure and may require additional procedures.

4.3 Patient Selection Criteria

Patient Consideration Checklist

Note: This list is provided for general findings specific to the consideration of EOTTS with HyProCure procedure and is not intended to be all-inclusive. Each foot must be fully examined to rule–in or rule–out other pathologic findings.

TaloTarsal Joint Range of Motion Maximum Pronation

- ☐ < 5° is normal
- ☐ > 5° is abnormal—may require conservative or surgical correction

1st Metatarsal Cuneiform Joint Range of Motion

- ☐ Normal—no further treatment
- ☐ Hypermobile—requires conservative or surgical stabilization
- ☐ Rigid-Dorsiflexed—requires conservative or surgical stabilization

1st Metatarsal Phalangeal Joint Range of Motion

- ☐ Normal—requires no further treatment
- ☐ Limited/Rigid—requires conservative or surgical stabilization

Integrity of the Posterior Tibial Tendon

- ☐ Stage 1/Stage 2A—requires conservative support/decompression
- ☐ Stage 2B/3—requires tendon augmentation

Equinus

- ☐ Heel touches floor during weightbearing and forefoot dorsiflexion during the gait cycle
  - ☐ Yes—normal
  - ☐ No—consider stretching/lengthening procedure
- ☐ Patient can dorsiflex ankle with knee straight
  - ☐ Yes—normal
  - ☐ No—consider stretching/lengthening procedure

Calcaneal Position – Weightbearing

- ☐ Rectus—normal
- ☐ Valgus—abnormal
  - ☐ Does it reduce by placing TTJ in neutral position?
    - ☐ Yes—consider EOTTS with HyProCure
    - ☐ No—consider other conservative surgical options
- ☐ Varus—requires conservative or surgical realignment

Metatarsus Primus Varus/Metatarsus Adductus

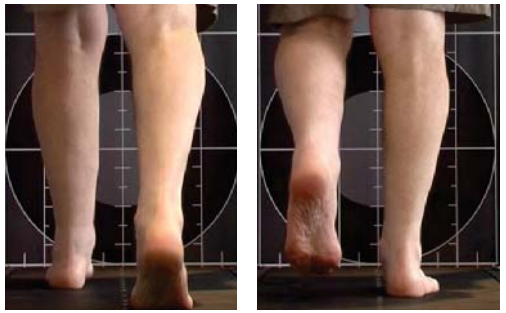
- ☐ Mild and reducible: conservative/surgical options—patient specific
- ☐ Moderate/Severe: surgical correction—patient specific

Hubscher's Maneuver (Jack's Test)—Dorsiflexion of 1st MPJ and Effect to the Medial Arch*

- ☐ Arch is recreated—intact plantar fascia, flexible/reducible TTJ
- ☐ Arch remains flat—compromised plantar fascia, non-reducible TTJ

Gait Analysis

- ☐ Abductory twist
- ☐ "Too many toes" sign
- ☐ Prolonged TTJ pronation



*The value of this test remains uncertain, the main point being is the TTJ reducible/flexible.

4.3 Patient Selection Criteria

Patient Consideration Checklist (continued)

Note: This list is provided for general findings specific to the consideration of EOTTS with HyProCure procedure and is not intended to be all-inclusive. Each foot must be fully examined to rule–in or rule–out other pathologic findings.

DP View

Talar 2nd Metatarsal Angle

- ☐ < 16°—normal
- ☐ 16° ≤ 35° and reducible—ideal candidate for EOTTS
- ☐ 36° ≤ 53° and reducible—less than ideal, but still a possible candidate for EOTTS
- ☐ > 54°—not an ideal candidate for EOTTS

Metatarsus Primus Varus/Metatarsus Adductus

- ☐ No
- ☐ Yes—requires a conservative or surgical option

1st Metatarsal Phalangeal Joint

- ☐ Normal—no treatment
- ☐ Abnormal/Joint disease—requires a conservative or surgical option

Lateral View

Obliterated Sinus Tarsi Re-opens with Neutral TTJ Stance Position

- ☐ Yes—consider EOTTS
- ☐ No—rule out tarsal coalition, may require other surgical option(s)

Talar Declination Angle

- ☐ < 21°—normal
- ☐ > 22°—abnormal
- ☐ < 28° and reducible—ideal candidate for EOTTS
- ☐ 29° ≤ 40°—less than ideal, but still a candidate for EOTTS
- ☐ > 41°—not an ideal candidate for EOTTS

Talar First Metatarsal Angle (Meary's Angle)

- ☐ < 4°—normal
- ☐ 5° to 15°—requires conservative treatment and/or orthosis
- ☐ 16° to 30°—requires conservative treatment and/or surgical option
- ☐ > 30°—requires surgical option, when possible

Calcaneal Inclination Angle

- ☐ > 20°—normal, no further treatment required
- ☐ < 20°—may require TAL/posterior calcaneal osteotomy

Navicular Position

- ☐ Normal—plantar aspect of the navicular is above the horizontal bisection of the cuboid
- ☐ Abnormal—plantar aspect of the navicular falls below the horizontal bisection of the cuboid
  - ☐ Navicular elevates/normalizes with TTJ in neutral—consider EOTTS
  - ☐ Navicular fails to elevate/normalize—may need additional surgical intervention

Rule-out a Tarsal Coalition

- ☐ Does the sinus tarsi re-open with neutral TTJ stance position
  - ☐ No—consider getting a CT to rule-out
  - ☐ Yes—no talocalcaneal coalition

Note: There are other radiographic parameters to be taken into consideration. These findings are in addition to other orthopedic radiograph abnormalities.

4.3 Patient Selection Criteria

EOTTS with HyProCure General Patient Considerations

The patient selection criteria for EOTTS with HyProCure procedure should take into consideration the following criteria:

Indications:

- Patient is 3 years and older
- Clinical and/or radiographic evidence of a flexible/reducible talotarsal joint displacement
- Obliteration of the sinus tarsi

Contra-Indications

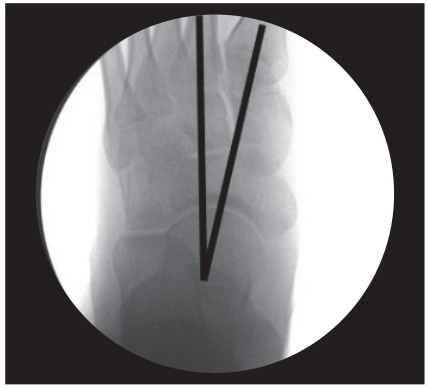
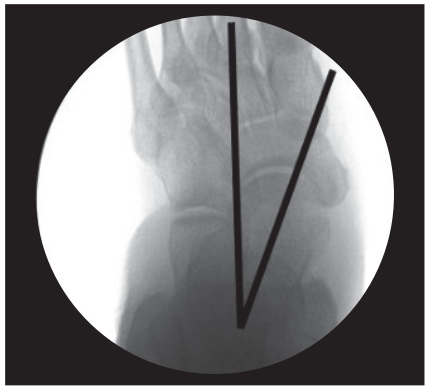
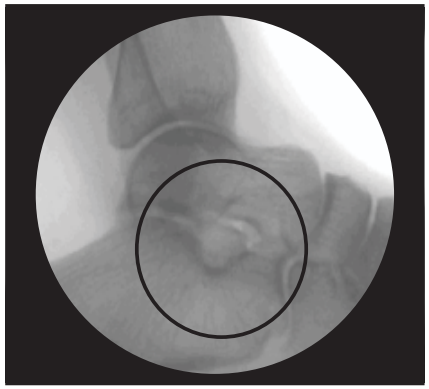
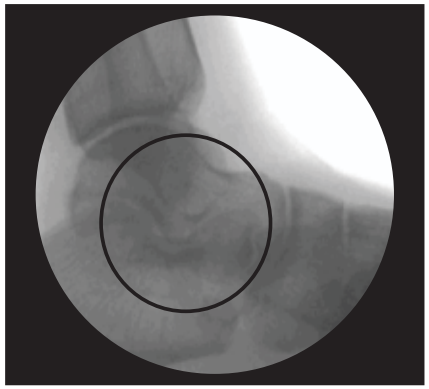
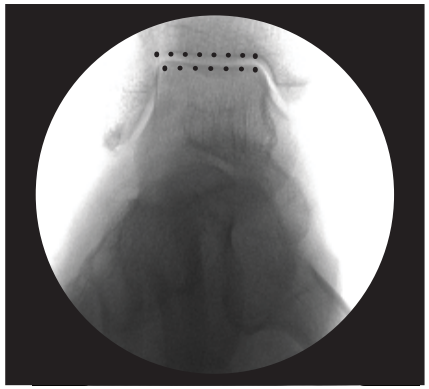
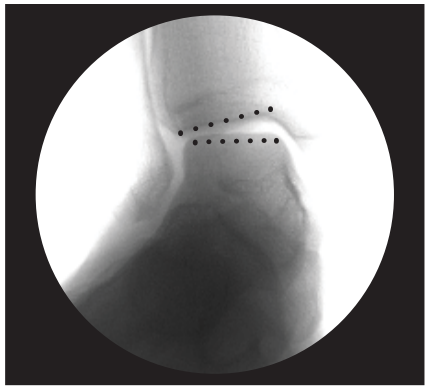
- Patient is less than 3 of age
- Rigid, non-reducible deformity
- Active local infection

Note: Patients may be classified as ideal or less-than-ideal. An ideal candidate would be assumed to have a lower risk of removal than a less-than-ideal candidate. Patient should be forewarned if they are less-than-ideal to keep their expectations realistic.

General Considerations

1. Compare RSP to NSP to document a flexible TTJD deformity. This will also help to rule-out a tarsal coalition.
2. Make sure to rule out a metatarsus adductus, calcaneal varus deformity
3. Evaluate the entire foot structure. Pay especially close attention to the 1st ray. An elevated or hypermobile 1st metatarsal will lead to forefoot valgus. This should be addressed conservatively or surgically
4. Patients may require the use of an arch support following the EOTTS with HyProCure procedure to address other parts of the foot structure.
5. Patients may require additional surgical procedures to address other parts of the foot surgery
6. If RTTJD is present in both feet, than both feet will eventually need to be stabilized and realigned. A unilateral correction can lead to prolonged post-op symptoms until the contra-lateral foot is stabilized

4.4 Radiographic Analysis of RSP vs. NSP

NSP-Aligned TTJ	RSP-Misaligned TTJ	Neutral vs. Relaxed Stance Position
		**Weightbearing Dorsoplantar View** Comparing the talar 2nd metatarsal angle (T2MA). Normal T2MA is < 16°. **Left Image (NSP)** Shows the talus realigned on the calcaneus in neutral stance. T2MA < 16°. **Right Image (RSP)** There is a pathologic anteriomedial displacement of the talus on the calcaneus and T2MA > 16°.
		**Weightbearing Lateral Fluoroscopic Images** Same Patient **Left Image (NSP)** Shows an aligned talus on the calcaneus. Notice the open sinus tarsi. **Right Image (RSP)** Same patient in resting stance position. Notice the obliterated sinus tarsi, as well as the dropped navicular.
		**Anterioposterior Weightbearing Image of the Ankle** **Left Image (NSP)** The talus is aligned on the calcaneus. Notice the ankle joint alignment. **Right Image (RSP)** Notice the valgus ankle joint alignment.

Note: Its is possible to have a single plane deformity. This will still lead to a diagnosis of TTJD. If the deformity is reducible than it is RTTJD.

4.5 Radiographic Analysis Grading

Grade I
Mild TTJD < 10% RR*
Stand Alone Procedure

- T2MA: 16°—28°
- TDA: 21°—27°
- Normal CIA
- No Equinus
- Intact PF/PTT
- Stable 1st Ray
- Normal 1st MPJ ROM

Grade II
Moderate TTJD < 15% RR*
May Require Additional Procedures

- T2MA: 29°—40°
- TDA: 28°—33°
- Decreased CIA
- Slight/Moderate Equinus
- Questionable PF/PTT
- Moderate 1st Ray Instability
- Adequate 1st MPJ ROM

Grade III
Severe TTJD > 15% RR*
Requires Additional Procedures

- T2MA: > 40°
- TDA: > 33°
- Decreased to Negative CIA
- Severe Equinus < 15° PF
- PF Loss/Stage 2B PTTD
- Rigid 1st Ray Deformity
- Limited 1st MPJ ROM

Use these parameters to determine whether EOTTS with HyProCure should be performed as a stand alone procedure, or in combination with other conservative and/or surgical procedures.

Note: There is also a Grade IV, which is complete talotarsal joint disarticulaion. This happens when one or more of the talar articular facets are 100% dislocated.

*RR—Removal Rate. Depending on the severity of their condition, there is an increased possibility that the HyProCure stent may not work. There may also be other areas of the foot that may need to be addressed with an arch support/orthosis or other corrective surgery. These percentages are not evidence based.

Section 5

The EOTTS with HyProCure Procedure

“ The majority of the medical professions are focused on addressing the symptoms of disease, as compared to the few who are addressing the underlying etiology. ”

5.1 Pre-Operative Considerations

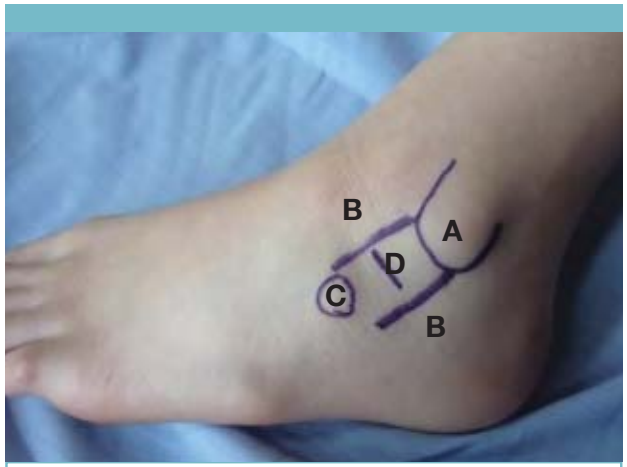
Prior to performing the EOTTS with HyProCure Procedure:

1. Patient should have signed the necessary forms:
    - EOTTS with HyProCure Consent Form
    - General Consent Form
    - Pre-op & Post-op Instructions
2. Patient should be prescribed a pre-op antibiotic and post-op, if indicated.
3. Patient should be made aware that both feet, if indicated, must be internally stabilized or there will be compromised results.

Pre-incision Local Anesthesia Sinus Tarsi Injection

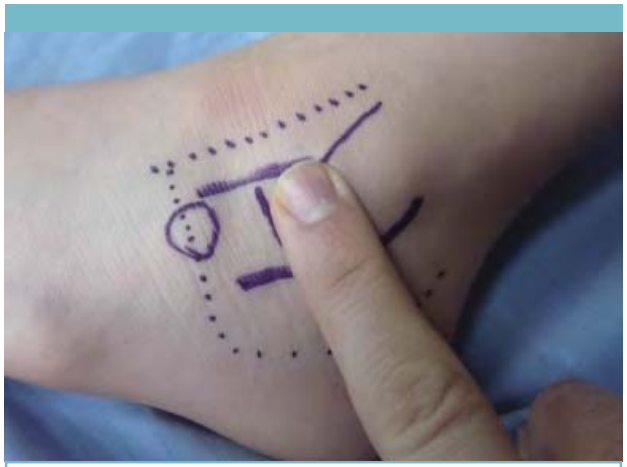
The surgeon must infiltrate the superficial and deep tissues with a combination of long-lasting local anesthesia with approximately 3/4 cc of short-acting steroid prior to making the initial skin incision. This combination provides the patient the best pain relief.

Incision Placement: Landmarks



A Fibular Malleolus
B Anterior/Posterior boundary of the sinus tarsi
C Anterior Calcaneal Eminence
D Incision Placement

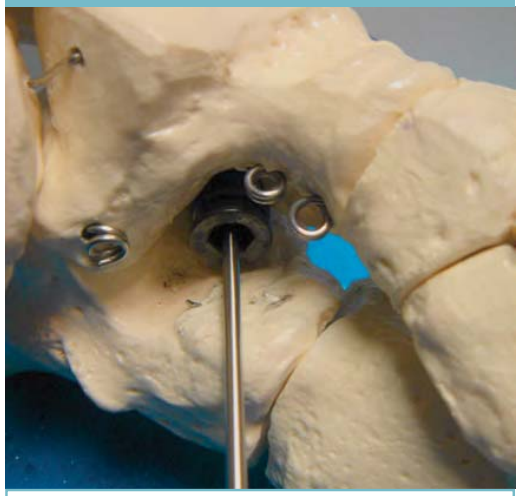
E Intermediate Dorsal Cutaneous Nerve
F Sural Nerve
G Communication Branch



Incision is centered proximally and distally between the tip of the fibula and anterior calcaneus process. Typically, one index finger distal to the fibula.

5.2 Injection, Skin Incision & Blunt Dissection

Step 1: Injection



Insert needle into the center point of the sinus tarsi. Advance and inject to the anterior margin of the:

1. Sinus Tarsi
2. Anterior TaloFibular Ligament
3. Posterior Margin of Sinus Tarsi

Step 2: Skin Incision

Mark the ankle in preparation for making the incision. Start the incision on the anterior-dorsal border and extend it posterior-plantarly.

The incision should not extend beyond the anterior-posterior boundaries of the sinus tarsi.

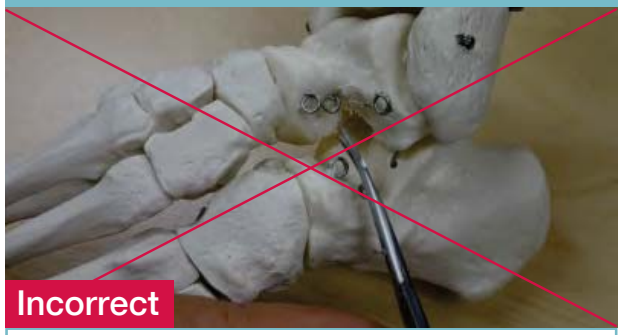
Step 3: Blunt Dissection

Insert curved Stevens Tenotomy Scissors with tips closed. Make sure the tips of the scissors are angled posteriorly. Puncture the tips of the scissors through superficial tissue.

Spread the scissors open. This separates the tissues to create an opening into the sinus tarsi.

5.3 Sinus Tarsi Decompression

Step 4

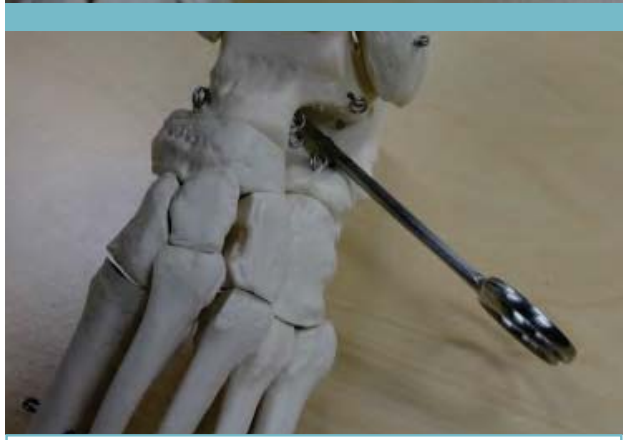


Important: The tip of the scissors **MUST** be angled posteriorly. If the curve/tip is angled anteriorly, the structures within the canalis tarsi will not be transected and this could result in failure of the procedure.

Physicians Note

Make sure the scissors are angled posteriorly.

Step 5

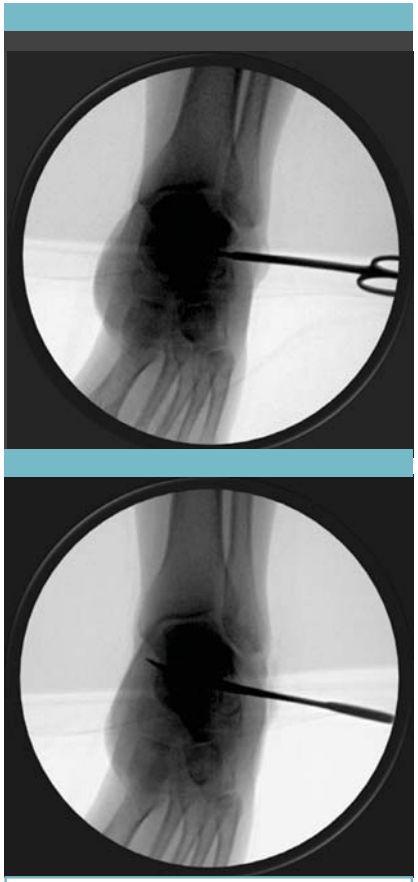


Advance the scissors into the sinus tarsi and cut the mid-substance of soft tissue contents. Make sure the sinus tarsi is in an open position.

Physicians Note

Do NOT remove any of the contents of the sinus tarsi.

Step 6



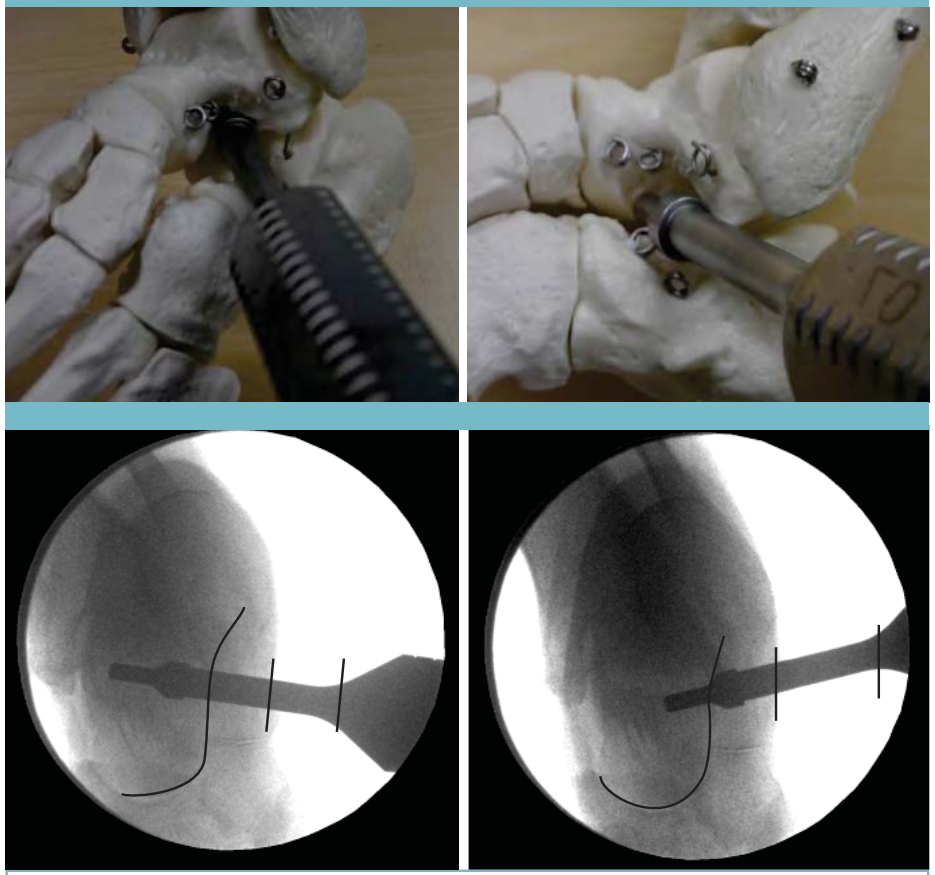
Correct placement of scissors under fluoroscopy.

5.4 Trial Sizer Placement

Step 5

Make sure to insert the guide wire into the canalis tarsi. Aim for the posterior aspect of the medial malleolus.

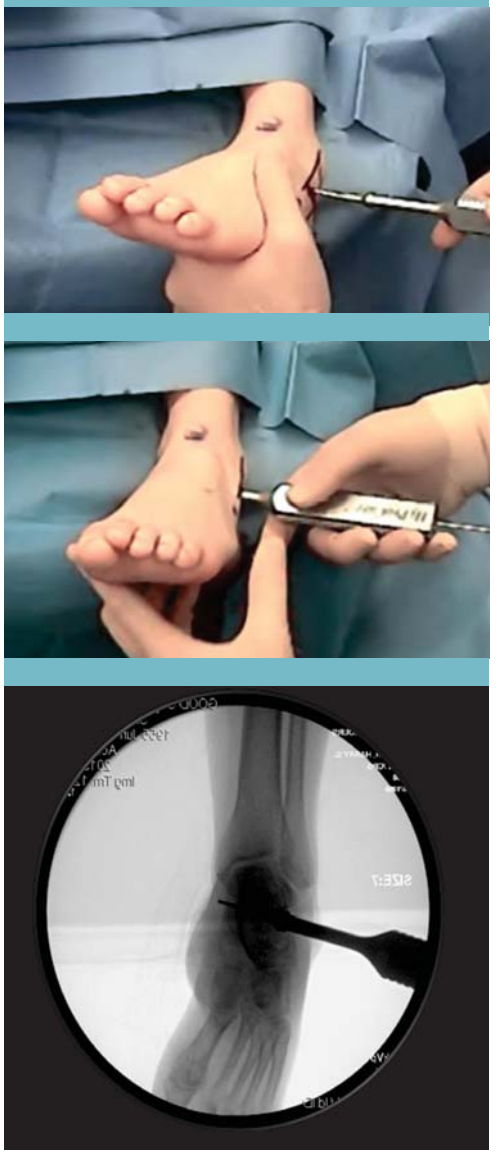
Step 6



Correct Placement **Incorrect Placement**

Supinate the foot to open the sinus tarsi. Use a twisting action and aim to the posterior aspect of the medial malleolus. Notice only an index finger width of the sizer stem remains visible.

Step 7



5.5 Trial Sizing

Step 8

TTJ Neutral Position

TTJ Pronation > 5°

The goal is “some” pronation: 3-4°

If TTJ shows no pronation, insert the next smallest size stent.

This shows supinated over-corrected size.

TTJ pronation is tested by loading the 4th & 5th metatarsal head/neck area. Heel inversion & eversion tests the TC joint ROM, not TTJ ROM.

Physicians Note

It is better to under-correct, rather than over-correct. Initially, most surgeons tend to oversize. The most commonly used sizes are 6 & 7, then the 5 & 8. It is very rare to use a size 9 or 10.

5.6 Intra-Op Placement Guide

Step 9

Place the desired HyProCure stent on the guide wire.

Place the HyProCure driver on the guide wire head/neck area.

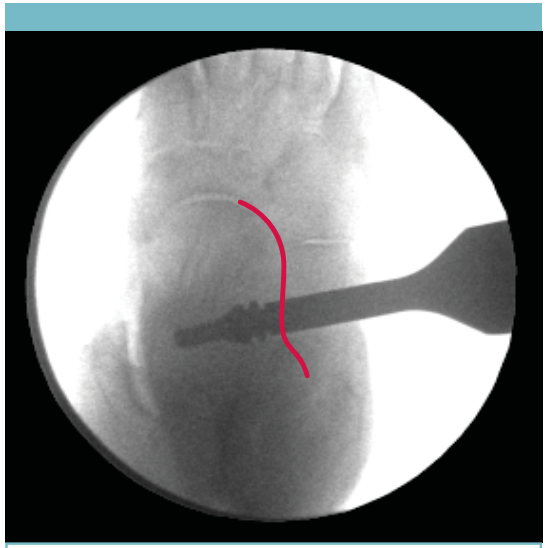
Engage the HyProCure driver into the lateral end. Supinate the talotarsal joint.

Remove the guide wire once the lateral end of HyProCure is no longer visible stent on the guide wire.

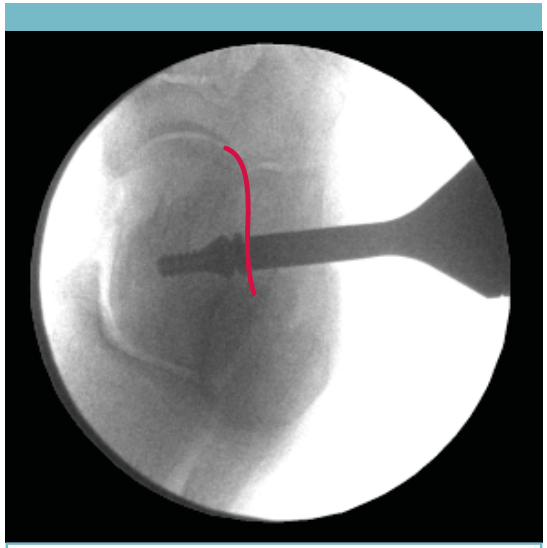
Advance HyProCure deep into the canalis tarsi. Aim to the posterior aspect. Typically, there is only one index finger width of shaft visible.

5.7 Checking Stent Position

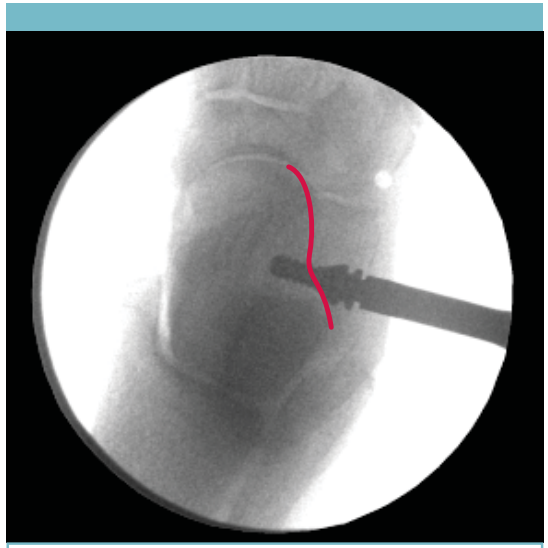
Step 10



Ideal Placement



Ideal Placement



Less-than-ideal Placement

Ideal Placement

Less-than-ideal Placement

Physicians Note

Do not "overstuff" or oversize the HyProCure stent. This is a leading cause of implant removal/revision.

It is better to place HyProCure deeper into the sinus tarsi and lose some correction, than it is to have "more" correction with an over-stuffed stent. If the stent placement is more superficial, there will be a greater chance of removal.

5.8 Post-Operative Considerations

Post-op Protocol

Immediately After EOTTS with HyProCure

- Apply a dry sterile bandage with a semi-elastic outer wrap
- Ice and elevation is recommended
- An oral anti-inflammatory medication is strongly advised

Post-op Weightbearing vs. Non-weightbearing

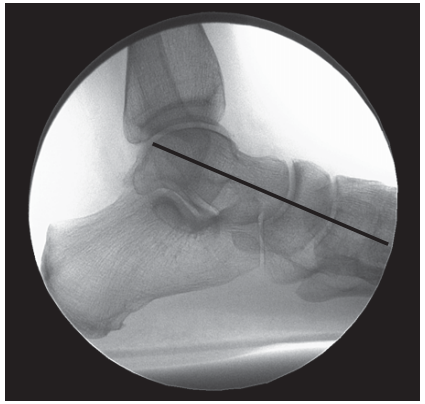
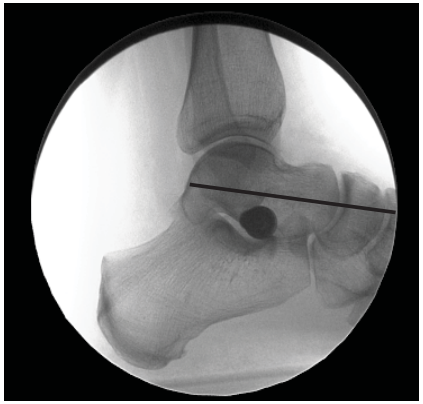
The specific post-op protocol will vary from surgeon to surgeon. Some allow their patient's to bear weight immediately after surgery, however standing and walking should be limited for the first several days. Other more conservative surgeons will not allow a patient to bear weight at all for the first several days and will recommend minimal walking with a removable brace for several weeks after.

While there is no data that supports whether early or delayed weight-bearing will lead to an increased or decreased removal/revision rate, early weight-bearing is typically preferred.

Patients will gradually increase walking naturally as the tissue inflammation subsides. It generally takes 4-6 weeks for the tissues to anchor HyProCure in place. Therefore, patients should limit running or jogging till at least 4-6 weeks after the initial stent placement. Upon activity increase, it is expected that there will be an increase in tissue soreness due to the increased tissue demand.

The patient should wear a new supportive shoe on the operated foot. Make sure the shoe does not rub against the incision and does not over-supinate the hindfoot.

5.8 Post-Operative Considerations

Pre-op	Post EOTTS - HyProCure	Acceptable Placement
		**DP Views** See that there is normalization of the T2MA and the posterior realignment/reduction of the cyma line. Also, the lateral end of HyProCure is at least lined up with the lateral neck of the talus.
		**Lateral Views** This is the same patient as the above DP images. Notice the reduction of the talar declination angle and only slight posterior visualization of the cylindrical portion of HyProCure. Also, see how the navicular bone was elevated. This decreases the strain on the plantar fascia and posterior tibial tendon.
		**DP Views** Note the normalization of the T2MA, decreased anteriorly deviated cyma line, and the position of HyProCure. Every HyProCure placement will be slightly different.

5.9 Results

Normal

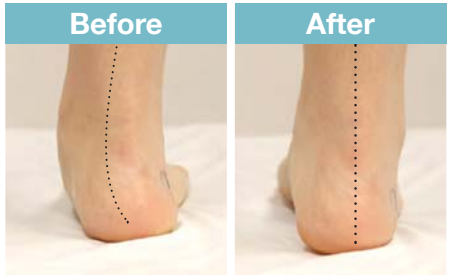
This is what a normal sinus tarsi should look like when standing. Notice the naturally occurring space between the heel bone and ankle bone.

Abnormal

This is an obliterated sinus tarsi. This image shows TTJD. It should be compared to an NSP x-ray to prove a flexible/reducible deformity.

EOTTS with HyProCure

This is what a foot stabilized with HyProCure looks like when standing. HyProCure holds the space open to keep the ankle from rolling inward and the body in its natural alignment.



Note: These patients required EOTTS with HyProCure as a stand-alone procedure only.

Section 6

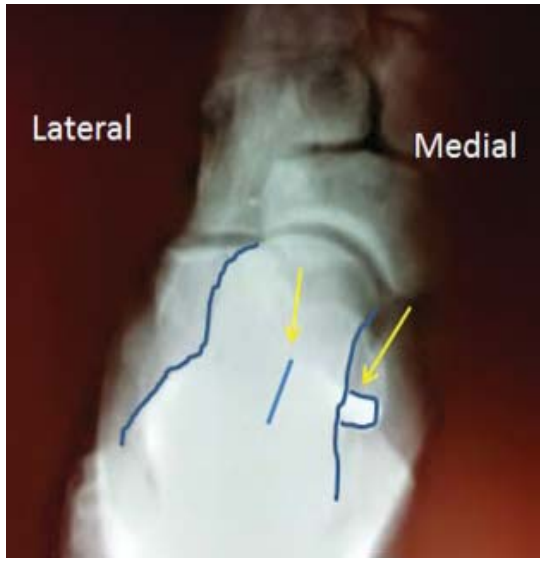
Challenging Situations

“ Skill = Time + Practice ”

6.1-6.2 Challenging Situations

6.1 Too Deep of a HyProCure Placement

This HyProCure stent was inserted too deep into the sinus and canalis portion of the sinus tarsi. The root cause is that too small of a stent was selected. It is possible that the stent will retro-shift laterally.



Solution
The surgeon should have the patient follow up on a regular basis. As long as the patient does not have unusual post-op pain and the correction is acceptable, there is no urgent need to perform a revision.

If there is pain or loss of correction, a revision with a slightly larger stent should be selected. The stent placement should be verified intra-operatively.

6.2 Anterior Rather than Posterior Angulation

The medial end of HyProCure is angulated anteriorly rather than posteriorly. Most likely, the guidewire was placed in between the middle and anterior facets rather than the posterior and middle facets. As long as the patient does not have unusual post-op pain and the correction is acceptable, there is no urgent need to perform a revision procedure.

Solution
The surgeon should have the patient follow up on a regular basis. If there is a loss of correction or unusual pain, a revision procedure should be suggested.

6.3-6.4 Challenging Situations

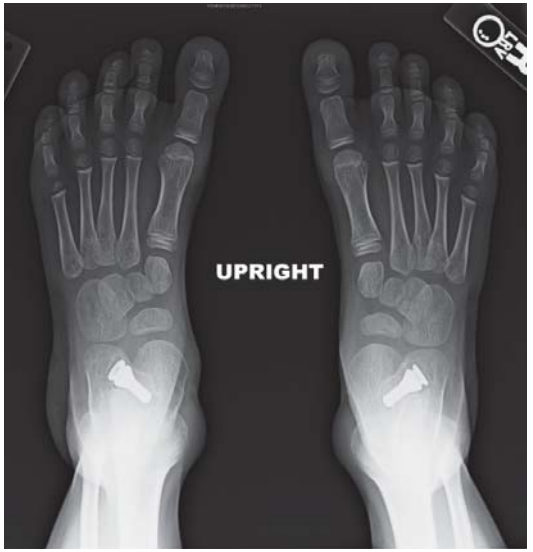
6.3 HyProCure Placed in an Adult's Foot with Metatarsus Adductus

The HyProCure stent is ideally placed and therefore appears to have a normal T2MA. However, the patient has a metatarsus adductus that will be exacerbated by realignment and stabilization of the hindfoot.

Solution
Treat the patient, not the x-ray. As long as the patient is happy with the correction, there is no reason to perform forefoot reconstruction. However, if the patient is having gait issues, metatarsal realignment procedures should be discussed.

6.4 Bilateral Under-Correction with Less-than-Ideally Placed Stents

The T2MA is still increased in both feet. Without pre-op films it's impossible to determine the amount of correction. It could be that this patient had a severe transverse plane deformity and that there is improvement from the pre-op films. The patient could have an abnormally small sinus tarsi preventing the placement of larger stents.



Solution
If larger stents could not be used, then some correction is better than no correction. If symptoms persist, a more aggressive surgical procedure would be recommended.

6.5-6.6 Challenging Situations

6.5 Poor Patient Selection

It appears the HyProCure stent is ideally placed (must be confirmed with the DP view), however there is still a sagittal plane deformity. The calcaneal inclination angle is lower than normal and there is an elevated 1st metatarsal. This patient has a flat foot deformity (pes planovaglus) with multiple “broken” parts. It’s possible that this patient was not a candidate for reconstructive surgery.

Solution

There could be enough correction that the patient is satisfied. Ideally this patient would benefit from a tendoAchilles or gastrocnemius recession procedure combined with a medial column stabilization and plantarflexory 1st metatarsal corrective procedures.

6.6 Poorly Placed HyProCure Stent

This stent is angled from dorsal to plantar, rather than plantar-dorsal (lateral end of the stent to the medial end). Most likely this stent was not placed correctly in the first place. The tip of the stent is hitting the floor of the sinus tarsi, rather than entering the canalis tarsi.

Solution

If there is loss of correction, the stent should be removed and re-inserted. Left as is, this stent is acting as Type I arthroereisis device, which blocks the joint limiting its range of motion.

Section 7

Overcoming Post-op Challenges

“ Every solution has the potential to create a new problem. The difference between a superior over inferior surgeon is how that potential problem is addressed. ”

7.1 Post-op Pain

Etiologic Factors that Contribute to Post-op Pain

- Chronic inflammatory reaction to the surgical procedure
- Hyper-excited nerves within the sinus tarsi due to chronic TTJD deformity
- Inability of the soft tissues to adapt to the corrected position
- Soft tissue irritation due to the stent displacement
- Patient is wearing worn-out shoes that lead to an over-supination of the TTJ and subsequent increase soft tissue strain on the outer sinus tarsi
- Patient had 1st ray/1st MPJ surgery in combination with the EOTTS with HyProCure procedure
- Over-correction of the TTJD deformity
- Only one foot was stabilized and the contra-lateral limb remains uncorrected

Worn out footwear is the leading etiology for prolonged post-op symptoms. **Patients must wear new and supportive shoes.**

Solution

Take an x-ray to check stent placement and verify if there is loss of correction.

If the stent is in good position and there are no other significant findings, try the following options:

1. **Check the shoes the patient wears**
   Make sure the outer heel isn't worn out; check the inside of the shoe; should be a supportive shoe.
2. **Prescribe an anti-inflammatory**
   Suggest limited weightbearing and apply ice to the area.
3. **Consider an injection of local anesthesia**
   (long lasting) combined with a ½ to ¾ cc of short/intermediate acting steroid (dexamethasone) given into the superficial area of the sinus tarsi. Give up to 2 or 3 injections.
4. **Find out if the patient only corrected one of their two feet**
   The patient will continue to have persistent soreness/pain until the contra-lateral limb is internally corrected. This must be explained to the patient prior to the EOTTS with HyProCure procedure.
5. **If both feet have been corrected,** note that one foot will always have more soreness than the other foot and will take longer to heal.
6. **Patient may require a foot orthotic**
   This will help to support other areas of the foot.

If the Stent is displaced and there is a loss of correction, consider revision or removal.

If the pain persists and all conservative options have been taken into consideration and addressed properly, the alternatives are:

- Downsize the size of the stent, some correction is better than none
- Use radiofrequency to "reboot" the nerves
- Permanently remove HyProCure and consider other options

7.2 Device Displacement—Complete vs. Incomplete

One of the known issues with the use of extra-osseous sinus tarsi implants is that there is the potential for displacement. There is no exception to HyProCure. However, a better understanding of the most common causes could help to reduce the displacement rate.

Common Causes of Device Displacement:

- Failure to properly transect the talocalcaneal interosseous ligament (TCIL) within the sinus & canalis tarsi
- Atrophy of the TCIL from a chronic RTTJD condition will lead to loss of the soft-tissue anchoring within the sinus tarsi
- Improper stent selection, too small or too large
- Improper stent placement—tip did not enter into the canalis tarsi
- Poor patient compliance—too active, too soon, improper shoe gear or trauma
- Anatomic variance—defect in the osseous chamber of the sinus tarsi

Bilateral HyProCure placement at the same surgical setting could increase the chance one stent would displace, however there is no scientific evidence to verify this assumption.

There will be an expected shifting of the stent from intra-op imaging due to the final seating of the device upon weightbearing. Each stent will "seek" its final placement upon initial weightbearing.

Solution

If there is loss of correction or unrelenting pain perform a revision or remove the stent

1. Check to make sure the TCIL is completely transected—use curved Stevens tenotomy scissors.
2. If there is little to no soft tissue within the sinus tarsi consider the use of an amniotic tissue supplement insertion prior to the re-implantation of the stent.
3. Re-trial size to make sure the correct size was selected. It is better to under-correct and have a deeper placed stent than it is to over-correct and have a more laterally placed stent.
4. Insert the correct stent and check under fluoroscopy. You may want to consider putting the foot through aggressive range of motion (pronation and supination) to check if the stent displaces.
5. Consider immobilizing the patient during the initial recovery process to ensure soft tissue adherence to the stent.

Displacement rarely occurs after 4-6 weeks (< 2% estimated chance)

7.3 Over/Under Correction

The EOTTS with HyProCure procedure is performed while the patient is non-weightbearing. The best size is a judgment call made by the surgeon.

It is better to under-correct than it is to over-correct; some correction is better than no correction. A surgeon new to the procedure will tend to over-size, however, there are more potential risks of over-sizing than under-sizing. Depending on the situation, a revision may be required. While the idea would be to limit the need for revision, the EOTTS with HyProCure procedure is easily revised, unlike a traditional rearfoot reconstructive surgery.

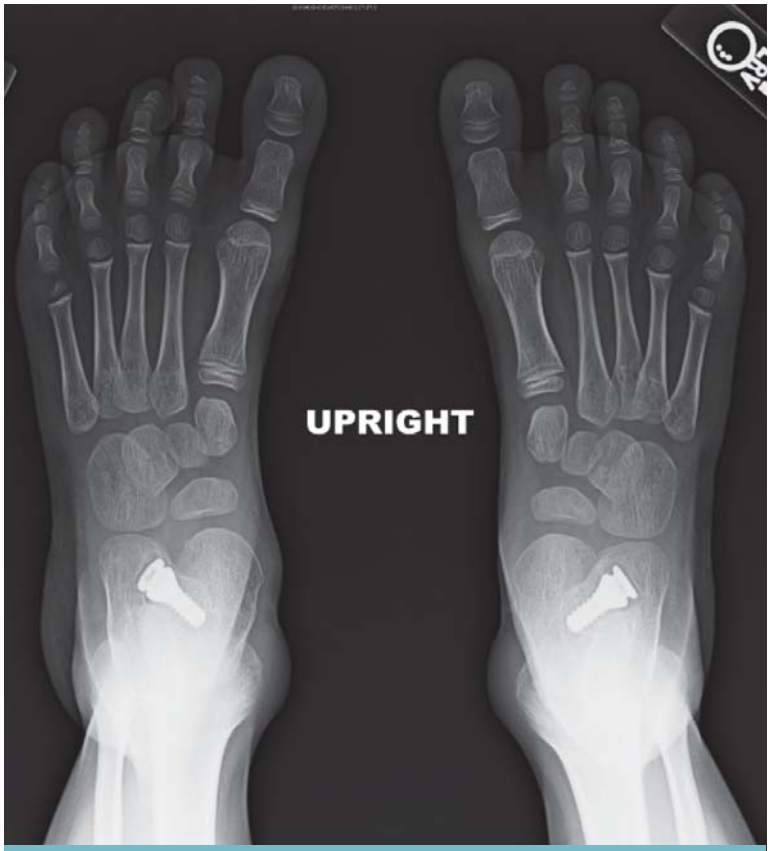
Solution

How do you know if the foot has been under-corrected or over-corrected?

Many times the patient will guard any range of motion testing, so the best way is via weightbearing radiographs.

- DP view—talar 2nd metatarsal angle of < 3° will indicate an over-correction and pain in/around the sinus tarsi will lead to a supination compensation
- Lateral view—significantly increased talar declination angle (< 10°)

Another consideration is the stability of the 1st metatarsal. An elevated or hypermobile 1st metatarsal will lead to forefoot valgus. This can be addressed conservatively or surgically.



Example of an Under-correction

7.4 Abnormal Gait Pattern

Short Term Solution

Patients are expected to develop a temporary abnormal gait pattern during the recovery process. This is due to the natural guarding mechanism after foot surgery. Initially the patient will walk with what appears to be an over-supinated gait.

Over the course of several weeks to months, a gradual normalized gait cycle will occur. This will differ from patient-to-patient and foot-to-foot. The surgeon and/or patient may be concerned about an over-correction so this must be taken into consideration.

DP weightbearing x-rays should be taken to measure the T2MA to rule-out an over-correction. A negative T2MA would suggest an over-correction, but the clinical situation must be taken into consideration. If the patient is experiencing pain in and/or around the sinus tarsi, this could be a false-positive over-correction finding.

Long Term

Another factor that has to be taken into consideration is if multiple surgical procedures were performed on the same foot. The combination of 1st ray surgery will cause a supinatory guarding of the forefoot and can have a negative impact on the hindfoot.

Gradual Normalized Gait Cycle

7.5 Wound Draining/Incision Healing

Depending on their age, patients may develop a chronic inflammatory reaction in response to the talotarsal joint dislocation deformity. Sinus tarsi surgery leads to an opening where this joint “fluid” or synovium will drain from the incision site.

The synovium fluid is somewhat viscus or gelatinous-like. Many patients or surgeons may mistake this for an infection. Others thought they were having an allergic reaction to the titanium. Titanium is one of the best and least reactive biomaterials.

Most surgeons find only the skin needs to be reapproximated, rather than placing deep absorbable stitches. Patients could develop a chronic inflammatory reaction while the deep stitches are being "absorbed". Additionally, scar tissue could be increased due to a foreign body reaction to the deep sutures.

This may appear to be an infection, when in reality it was an allergic reaction to superficial antibiotic ointment. The redness resolved within a few days.

Solution

The need to remove the stent during this situation is very rare.

The surgeon should take an x-ray to make sure there aren’t any other issues.

- The patient should apply povidone-iodine to the superficial aspect of the incision. This solution is rarely recommended, especially when it comes to wounds, but this is an exception.
- The incision should be covered with a dry adhesive bandage and changed frequently. We suggest that the patient “read” the dressing. If there is a lot of drainage on the dressing, it should be changed more frequently. If there is minimal drainage, the frequency can be decreased.
- Make sure to verify that the collar of their shoe is not rubbing against the area.
- It is also possible that the patient applied a cream or gel over the incision. Many times, patients could develop a reaction to various ingredients in over-the-counter topical ointment.
- The adhesive bandage covering the incision could be a factor. Some patients develop a skin reaction to the adhesive or even the latex contained in the bandage.

7.6 Senses or Feels a Clicking

Patients may experience a “clicking” sensation early in the recovery process. This is not a very common patient observation. Typically when this is experienced, it is only a matter of time before it resolves. Of course it would be wise to take weightbearing x-rays to ensure the stent has not displaced. Once the stent is fully anchored by the soft tissues, this will resolve.

Solution

The shoes a patient is wearing should be examined.
It is possible that a worn out heel over-supinated the TTJ, which could be a contributing factor to the clicking sensation.

Revision
If this becomes persistent and begins to bother the patient, a revision procedure may be indicated. The insertion of amniotic tissue into the sinus tarsi may help adhere the soft tissues to the stent.

7.7 Loss of Correction

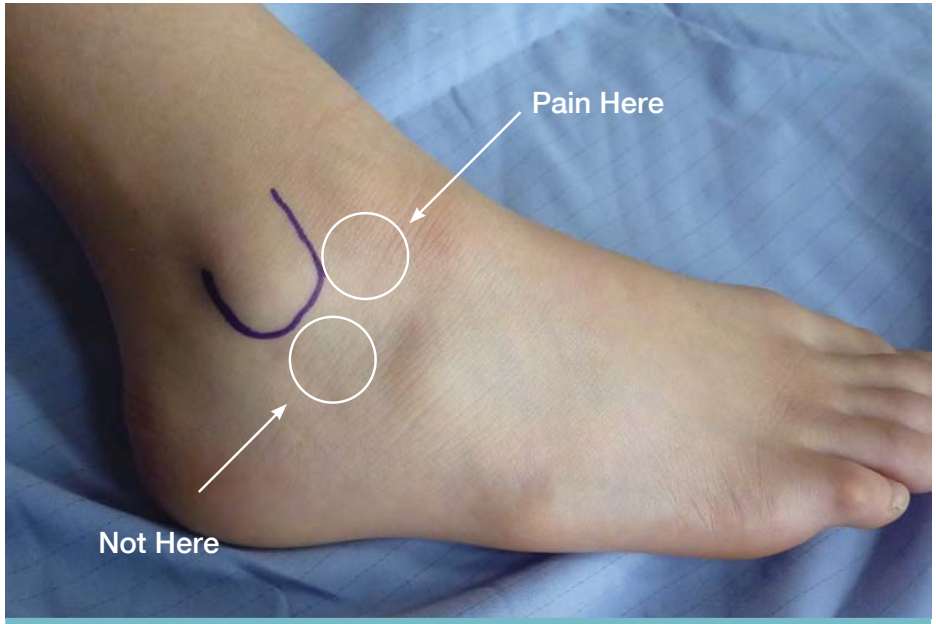
This could be real or perceived. Initially, the foot will feel over-corrected due to swelling and inflammation. As the swelling and inflammation subsides, there will be more ROM and the patient may perceive of a loss of correction. In reality, the foot is where the surgeon “sized” it and it will have the ROM that was found when HyProCure was initially inserted.

Solution

Take radiographs to make sure HyProCure hasn’t displaced.

7.8 “Sprained Ankle” Feeling

Occasionally, a patient will experience soreness to the anterior fibular malleolus over the anterior talofibular ligament (ATFL). The cause of this discomfort is related to the repositioning of the talus and subsequent altered forces acting on the ATFL. There is a higher likelihood of this occurring in patients who have suffered chronic ankle sprains. Scar tissue will be less resilient to the new force and therefore, will need a longer recovery time.



Clinical Lateral View

Solution

1. Always make sure the patient is wearing shoes that aren’t over-supinating the hindfoot.
2. Take an x-ray to ensure the stent hasn’t shifted.
3. If there are no other positive findings, inject the ATFL superficially with a mix of long-lasting anesthesia and a short- to intermediate-acting steroid.

It should only be a matter of time for this to resolve. If conservative therapy does not reduce the symptoms, the surgeon may need to consider downsizing or permanent stent removal.

Anterior Talofibular Ligament

7.9 Psychogenic Reaction

This is a relatively unknown phenomenon where a patient has a mental issue with the fact that there is a device implanted into their body. They have no pain and the correction is more than adequate, yet they are constantly thinking or obsessing about it, until they simply want the sinus tarsi implant taken out. This is rather rare, but still a potential possibility.

Solution

If the patient cannot overcome the fact that they need the stent in their foot and they demand to have it removed, then remove it.

7.10 Patient Feels the Stent

Patient's may feel the superficial area over their incision and become concerned that the stent displaced.

Solution

Order weightbearing x-rays to make sure it did not displace laterally.

Very Likely

Likely

No, this is superficial scar tissue

7.11 Infection

The chance of a post-EOTTS with HyProCure infection is extremely rare, but possible.

The EOTTS with HyProCure procedure is a soft tissue procedure, but there is the insertion of a titanium device and pre-op antibiotic protocol should be followed, and is generally recommended for patients with:

- A history of previous orthopedic infection
- High risk potential of infection (diabetes & certain meds)

Solution

It is better for a patient to take a pre-op antibiotic and not need it, over a patient not receiving a pre-op antibiotic and developing an infection. If the patient happens to develop an infection, it is generally recommended that the device stay in place while they take the antibiotics.

While there is little supportive evidence that the use of antibiotics may or may not reduce post-op infection, they do not lead to adverse complications. It is ultimately up to the surgeon and hospital system.*

*J Foot Ank Surg. 2015, 54(2):273-279

7.12 Allergic to Titanium

Titanium allergy is very rare.

Obviously, patients with a history of metal allergies may be at greater risk of titanium hypersensitivity.* There is a MELISA test that may be helpful if there is a suspected allergy to the stent.

Solution

Obviously, if an allergy exists, remove the stent.

* Indian J Dermatol. 2014, 59 (6) 630.

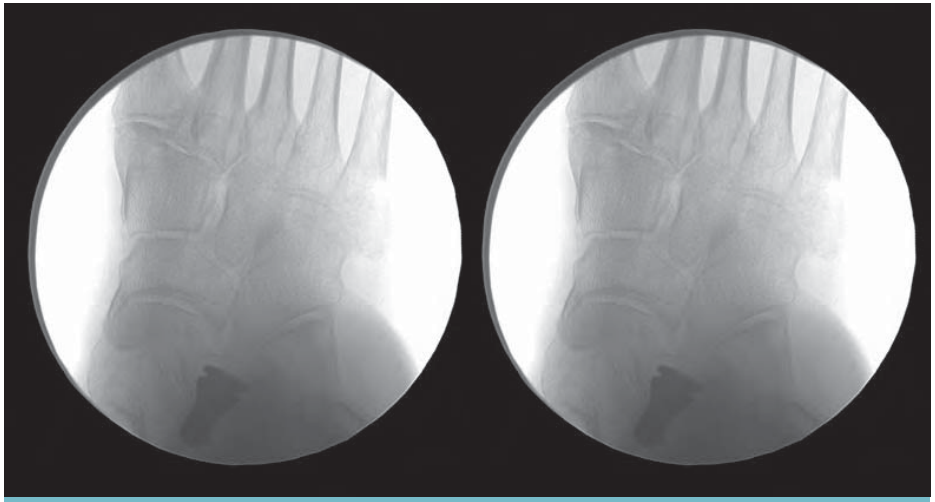
* Inflammation and Allergy, 2008, 7:1-18

7.13 Failure to Achieve Desired Result

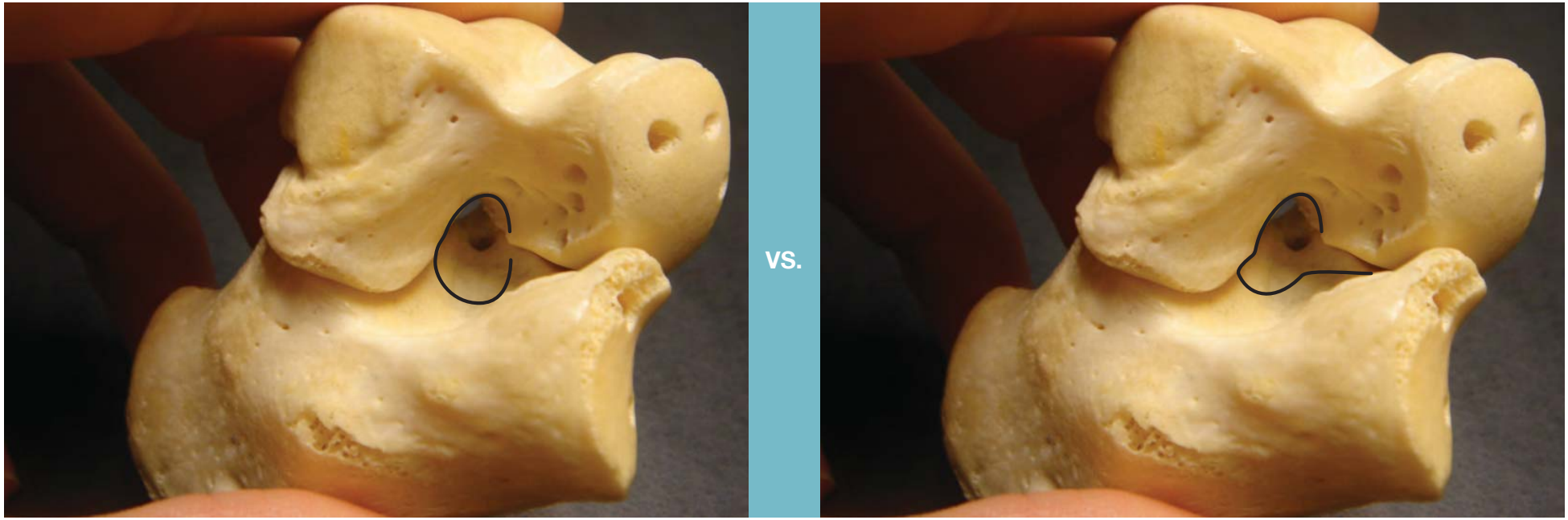
There have been rare occurrences where the HyProCure stent was properly placed, but the talus still displaced on the calcaneus. This is due to a rare anatomic variance where the anterior/distal portion of the calcaneus has been flattened due to years of recurrent talotarsal joint displacement. The talus pushes the stent forward and the distal/anterior end of HyProCure does not come into contact with the proximal portion of the anterio-distal chamber of the sinus because it doesn't exist.

Solution

Unfortunately, EOTTS is simply not an option for this patient and the stent should be removed.



X-rays show the idea placement of a size 10 stent. However, the T2MA and talar declination angle are still pathologic. Unfortunately, this patient will require a triple arthrodesis.



7.14 Poor Patient Selection

Solution

It is highly recommended to take comparison weightbearing x-rays with the TTJ in a neutral–aligned position compared to relaxed stance position.

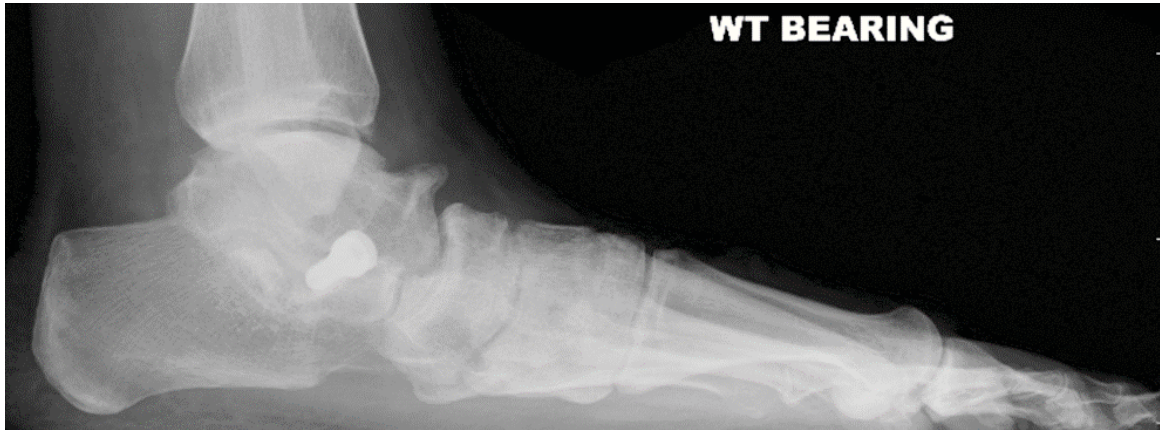
This will confirm the reducibility of the talar displacement deformity and help to rule out a tarsal coalition. Of course, there are many other areas of the foot that must be taken into consideration such as:

- Lower than normal calcaneal inclination angle
- Metatarsus adductus
- 1st MPJ pathology
- Elevated 1st ray

There will be situations where the patient may not be an ideal candidate, but still a candidate for the EOTTS with HyProCure procedure.

It could be an attempt to give some correction prior to a triple arthrodesis, or other situation where the patient simply cannot have traditional reconstructive surgery. **Patients must be warned that there is a high likelihood the procedure won't work.**

HyProCure Placed = Tarsal Coalition



7.15 Revision/Removal

Removal

Use the same incision approach as in the original surgery.

1. Use curved Stevens tenotomy scissors for tissue dissection (use the tips of the scissors to spread the tissues; do not cut the tissues, simply open the tips of the scissors to dissect the tissues).
2. Identify the lateral end of the device.
3. Use the Dupont forceps to remove the stent.
4. Insert one jaw of the instrument into the center of the device and clamp the second jaw on the lateral end of the device.
5. Apply pressure on the instrument to clamp onto the head of the implant.
6. Rotate the implant 360° counterclockwise. This releases the soft tissue adherence on the device, allowing you to then take out/pull the device from the sinus tarsi.
7. Irrigate the sinus tarsi with additional local anesthetic to ensure that the deeper tissues are anesthetized.

Revision

If a revision is necessary, follow the steps specified in the previous section for removal, then:

1. Use the curved Stevens tenotomy scissors to decompress the tissues within the canalis tarsi.
2. Insert the various trial sizers to re-establish the correct size stent to stabilize the talotarsal joint.
3. Insert the proper stent. Verify position under fluoroscopic imaging.
4. Suture the skin and apply dry sterile bandage.

In the rare circumstances that a revision/removal is necessary, use the Dupont forceps to remove the stent.

Section 8

Published Studies

8.1 Published Studies

Extra-Osseous TaloTarsal Stabilization Devices: A New Classification System.
Published: The Journal of Foot & Ankle Surgery, Volume 52, 2012, Pages 613-619.

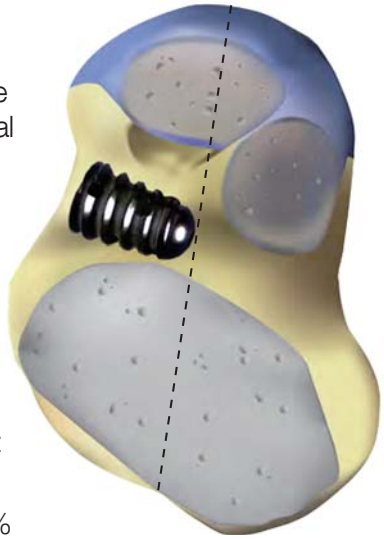
Key Points

- Stabilization of the talotarsal joint is a primary consideration to the treatment of many lower extremity pathologies.

There are 2 main types of extra-osseous implants (not inserted into bones):

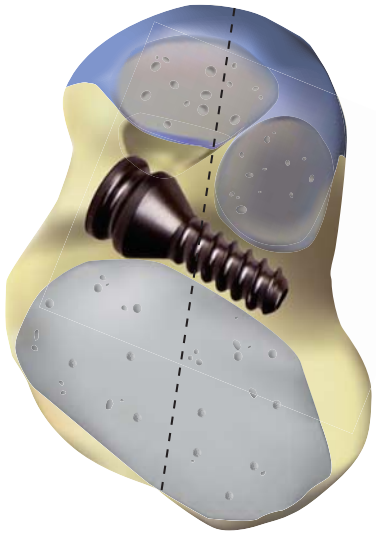
Type I – Arthroereisis devices

- Cylindrical or conically shaped
- Inserted lateral to medial so that the medial tip is aligned with the horizontal bisection of the talus
- Laterally anchored by soft tissues within the sinus portion of the sinus tarsi
- Functions via impingement of the lateral process of the talus to block talar motion
- Works against normal talotarsal joint motion
- Reported removal rate 38% to 100%



Type II – Non-Arthroereisis device

- Combination of conical and cylindral shapes
- Inserted along the normal orientation of the sinus and canalis tarsi. Medial tip is inserted beyond the horizontal bisection of the talus.
- Stabilizes the talus and restores the normal axis point of the subtalar joint
- Medially anchored.
- Allows normal helicoidal motion of the talotarsal joint
- Reported removal rate 4 to 6%



Conclusion

- Sinus tarsi implants are not all the same.
- Type II (HyProCure) is a superior design and function when compared to Type I arthroereisis devices.
- Surgeons & patients must understand the differences between the 2 types.
- Type II (HyProCure) has a proven superior success rate over Type I arthroereisis devices.

8.2 Published Studies

Computed Tomography Review of Tarsal Canal Anatomy with Reference to the Fitting of Sinus Tarsi Implants in the Tarsal Canal. Published: The Journal of Foot & Ankle Surgery, Volume 52, 2013, Pages 714-716.

Key Points

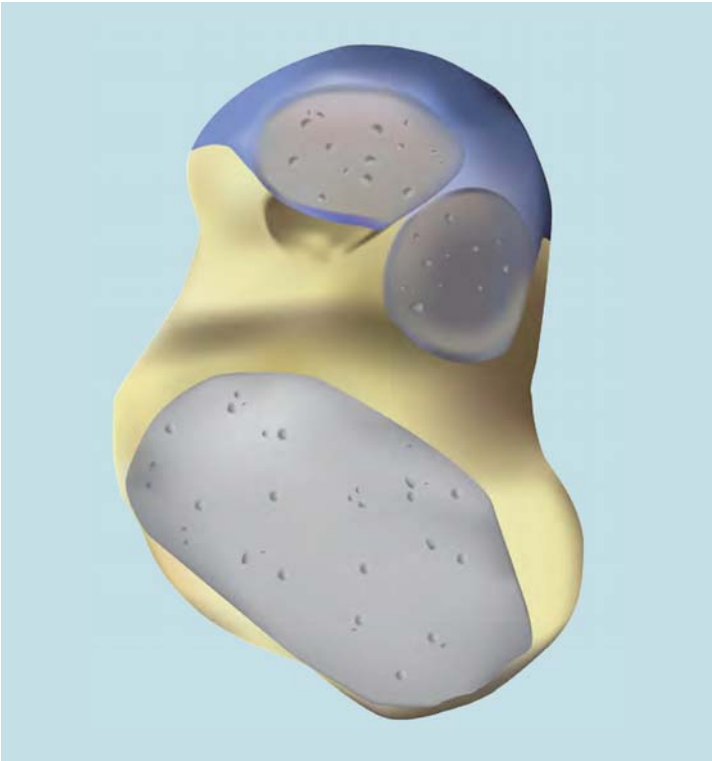
- Pediatric CT analysis of sinus tarsi
- Effect of the anchoring stem into the canalis tarsi and weightbearing factors

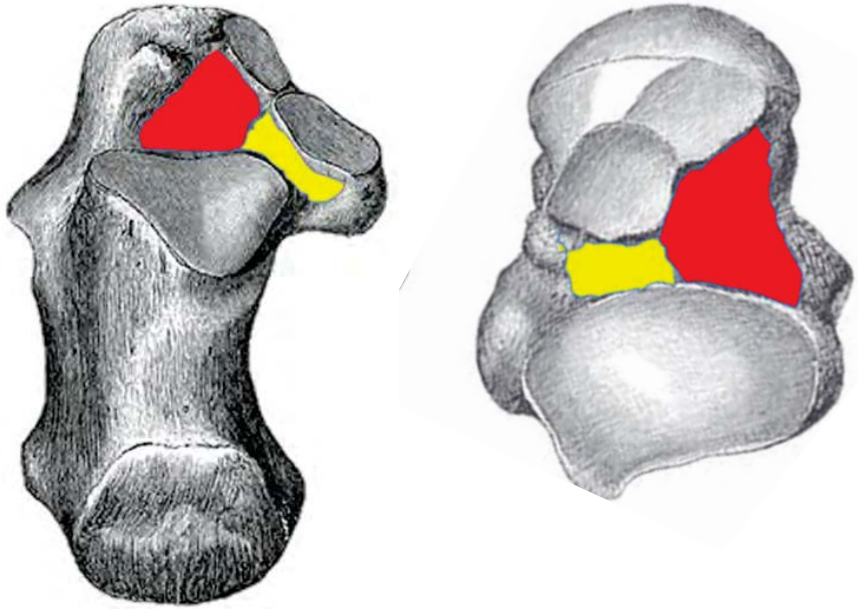
Results

- Narrowest canalis tarsi: 7 mm (5–10 mm) x 9 mm (6–13 mm)

Conclusion

The anchoring stem of the HyProCure sinus tarsi implant extending into the canalis tarsi is unlikely to bear any weight. It anatomically fits into the canalis portion of the sinus tarsi.





8.3 Published Studies

Stabilization of Joint Forces of the Subtalar Complex via HyProCure Sinus Tarsi Stent.

Published: The Journal of American Podiatric Medical Association Volume 101, 2011 Pages 390-399

Key Points

- Recurrent talotarsal joint instability leads to an anteriomedial displacement of the talus on the calcaneus.
- Excessive forces are acting anteriomedially rather than posteriolateral.

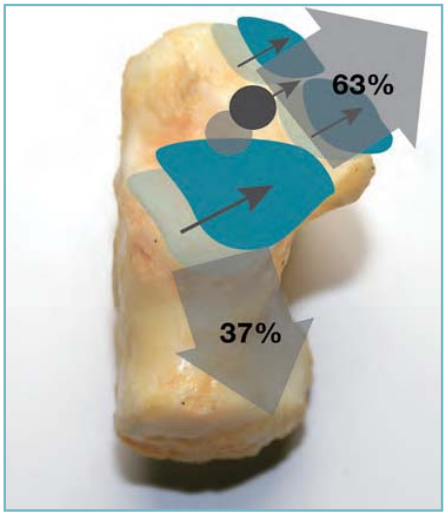
Results

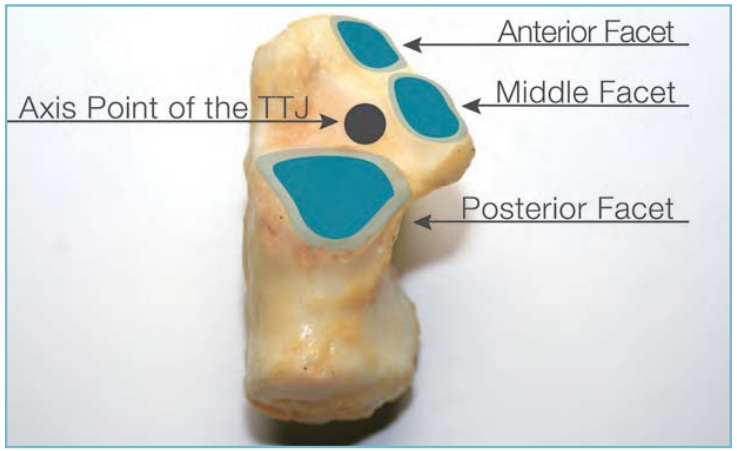
- **There was a reduction of anteriorly acting forces by an average of 24%.**
- RTTJD directly increases the forces acting on the medial structures of the foot.
- HyProCure stabilized the talus on the calcaneus (subtalar joints).
- There was an increase of posterior forces by 21%.

Conclusion

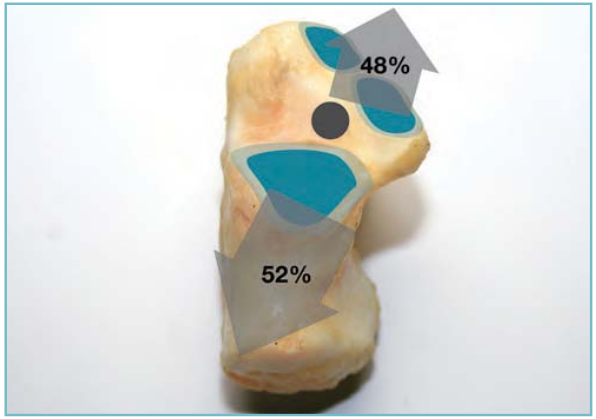
- Subtalar joint instability leads to increased forces acting anteriomedially.
- HyProCure stabilized the talus on the calcaneus keeping the joints in constant congruent contact.
- Forces acting on the medial column of the foot are reduced with HyProCure.
- Patients who have symptoms to medial column related tissues/structures should be evaluated for subtalar joint instability and HyProCure has been proven to stabilize the joint and normalize joint forces.

TTJD — Force Displacement





Normal TTJ Alignment—Force Distribution



Stabilized = HyProCure

8.4 Published Studies

Effect of Extra-Osseous TaloTarsal Stabilization on Posterior Tibial Tendon Strain in Hyperpronating Feet.

Published: The Journal of Foot & Ankle Surgery, Volume 50, 2011, Pages 676-681.

Key Points

- Etiology of posterior tibial tendon dysfunction (PTTD) is controversial.
- PTTD is a very destructive foot pathology that is expensive to treat and it severely limits patients quality of life.

Results

HyProCure stabilized the subtalar joint and decreased the strain on the posterior tibial tendon by 51%.

- Subtalar joint instability leads to increased strain on the posterior tibial tendon specifically to the typical watershed area of the tendon .
- Patients who have symptoms associated with their posterior tibial tendon should be evaluated for talotarsal joint displacement and HyProCure should be considered as part of treatment.

Conclusion

- RTTJD leads to increased strain on the posterior tibial tendon and it can be named as an underlying etiologic factor to the development of PTTD.
- HyProCure is proven to stabilize the talotarsal joint.
- HyProCure can reduce the pathologic strain on the posterior tibial tendon by 51%.
- Patients who have symptoms associated with their posterior tibial tendon should be evaluated for talotarsal joint displacement and HyProCure should be considered to be a part of the treatment solution.

8.5 Published Studies

Evaluating Plantar Fascia Strain in Hyperpronating Cadaveric Feet Following an Extra-Osseous TaloTarsal Stabilization Procedure.
Published: The Journal of Foot & Ankle Surgery, Volume 50, 2011, Pages 682-686.

Key Points

- Plantar fasciopathy or “fasciitis” is a very painful chronic condition that is expensive to treat and it severely limits the quality of life.
- Leading etiology is mechanical over-loading, yet the majority of healthcare providers treat it as an inflammatory condition.

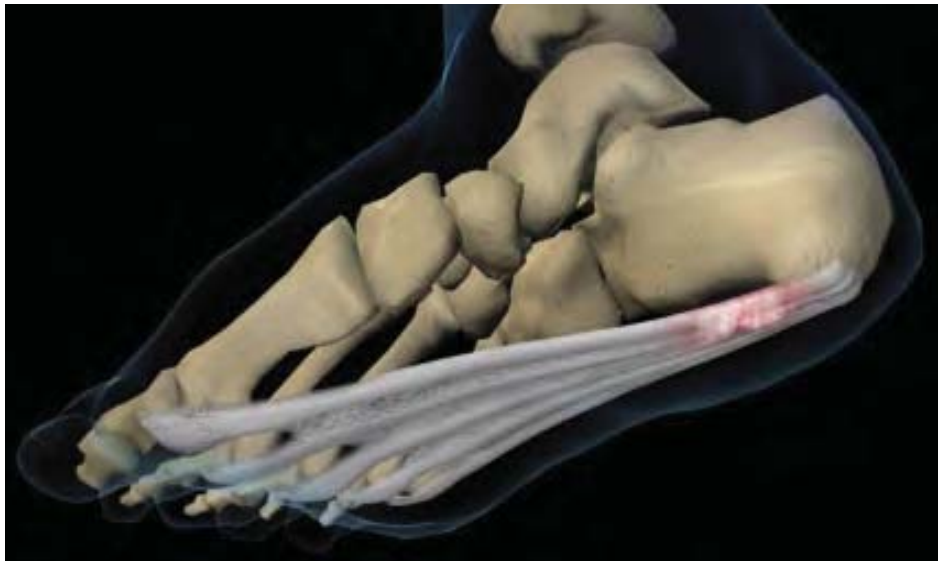
Results

HyProCure stabilizes the talotarsal joint and decreases the strain on the plantar fascia by an average of 33%.

- TaloTarsal joint displacement leads to elongation of the medial band of the plantar fascia.
- TaloTarsal joint displacement leads to increased strain to the medial band of the plantar fascia.

Conclusion

- The Primary factor to the underlying etiology of plantar fasciopathy is mechanical overloading of the plantar fascia.
- TaloTarsal joint displacement directly increases the strain to the medial band of the plantar fascia.
- Patients with chronic heel pain must be evaluated for talotarsal joint instability.
- HyProCure is a proven solution to address the underlying etiology to plantar fasciopathy.

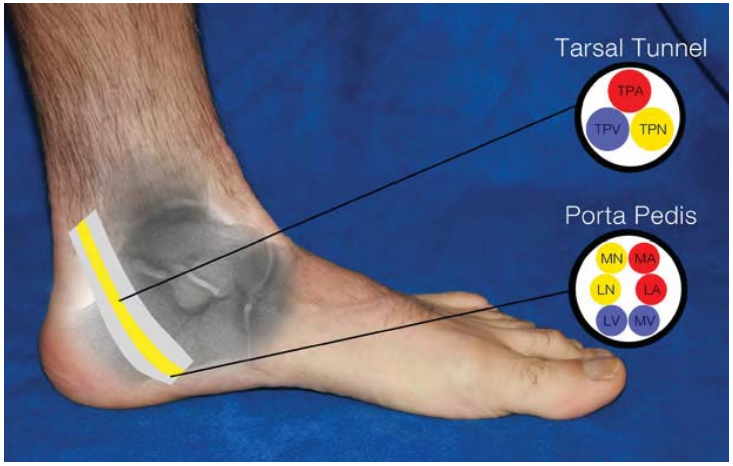


8.6 Published Studies

The Effect of HyProCure on Tarsal Tunnel Compartment Pressures in Hyperpronating Feet.
Published: The Journal of Foot & Ankle Surgery, Volume 50, 2011, Pages 44-49.

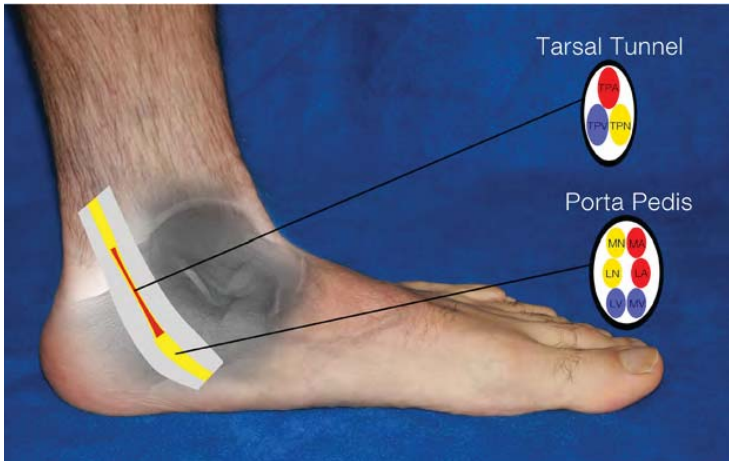
Key Points

- Recurrent talotarsal dislocation leads to a prolonged period of pronation.
- Hyperpronation is a leading etiology of tarsal tunnel syndrome.
- Traditional tarsal tunnel surgery has a recurrence rate of 60%, possibly due to the fact the underlying etiology was not adequately reduced or eliminated.
- Pressures within the tarsal tunnel and porta pedis of cadaver feet were examined.



Results

- **Tarsal Tunnel**
  - TTJ in neutral position was 3 mmHg
  - TTJ maximally pronated jumped to 32 mmHg (9–72 mmHg)
  - After insertion of HyProCure maximum pronation was 21 mmHg (10–53 mmHg)
  - Reduction by 34%
- **Porta Pedis**
  - TTJ in neutral position was 2 mmHg
  - TTJ maximally pronated jumped to 29 mmHg (10–73 mmHg)
  - After insertion of HyProCure maximum pronation was 18 mmHg (5–51 mmHg)
  - Reduction by 38%



Clinical Significance:

- Pressures of 20–30 mmHg
- Inhibits intra-neural blood flow
- Alters nerve conduction
- Leads to neural ischemia
- Impairs axonal flow
- Leads to demyelination
- Hyperpronation/RTTJD leads to neuropathic changes to the posterior tibial nerve resulting in pain and numbness to the plantar aspect of the foot

Conclusion

EOTTS with HyProCure stabilizes the talotarsal joint, decreasing the pressures within both the tarsal tunnel and porta pedis. This could help to reduce the symptoms associated with posterior tibial neuropathy and tarsal tunnel syndrome. EOTTS with HyProCure could be performed as a primary intervention or in combination with tarsal tunnel/porta pedis decompression surgery.

8.7 Published Studies

Effect of Extra-Osseous TaloTarsal Stabilization on Posterior Tibial Nerve Strain in Hyperpronating Feet: A Cadaveric Evaluation. Published: The Journal Foot & Ankle Surgery, Volume 50, 2011, Pages 672-675.

Key Points

- Posterior tibial nerve neuropathy leads to numbness and pain to the plantar aspect of the foot.
- Pressures within the tarsal tunnel and porta pedis can adversely affect nerve function and health.
- Elongation of posterior tibial nerve is rarely taken into consideration.
- TaloTarsal joint instability could lead to increased elongation of the posterior tibial nerve.
- Since HyProCure is a proven solution to stabilize the talotarsal joint, there could be a benefit to the decrease of the elongation of the nerve.

Results

- Maximum pronation of the talotarsal joint instability leads to 6mm elongation of the nerve (range: 3–7mm).
- Upon insertion of HyProCure, the maximum elongation was reduced to 3mm (range: 1–5mm).
- Nerve strain with no intervention had a mean of 27% (range: 13–34%).
- Nerve strain after placement of HyProCure was reduced to a mean of 15% (range: 5–24%).

Clinical significance:

- 6% nerve stain leads to decreased action potential.
- 8% strain leads to impaired venular flow.
- 12% strain leads to complete nerve block.
- 15% strain leads to impaired arterial flow and can lead to an irreversible functional deficit.

Conclusion

- RTTJD leads to pathologic increased pressures on the posterior tibial nerve within the tarsal tunnel and porta pedis.
- RTTJD also leads to an elongation and increased strain on the posterior tibial nerve.
- Stabilization of the TTJ with HyProCure has proven to significantly decrease/normalize both elongation and strain on the nerve.
- EOTTS with HyProCure offers a proven rational in the treatment of plantar foot neuropathy.

8.8 Published Studies

Plantar Pressure Distribution in a Hyperpronated Foot Before & After Intervention with an Extra-Osseous TaloTarsal Stabilization Device – A Retrospective Study.

Published: The Journal of Foot Ankle Surgery, Volume 52, 2013, Pages 432-443.

Key Points

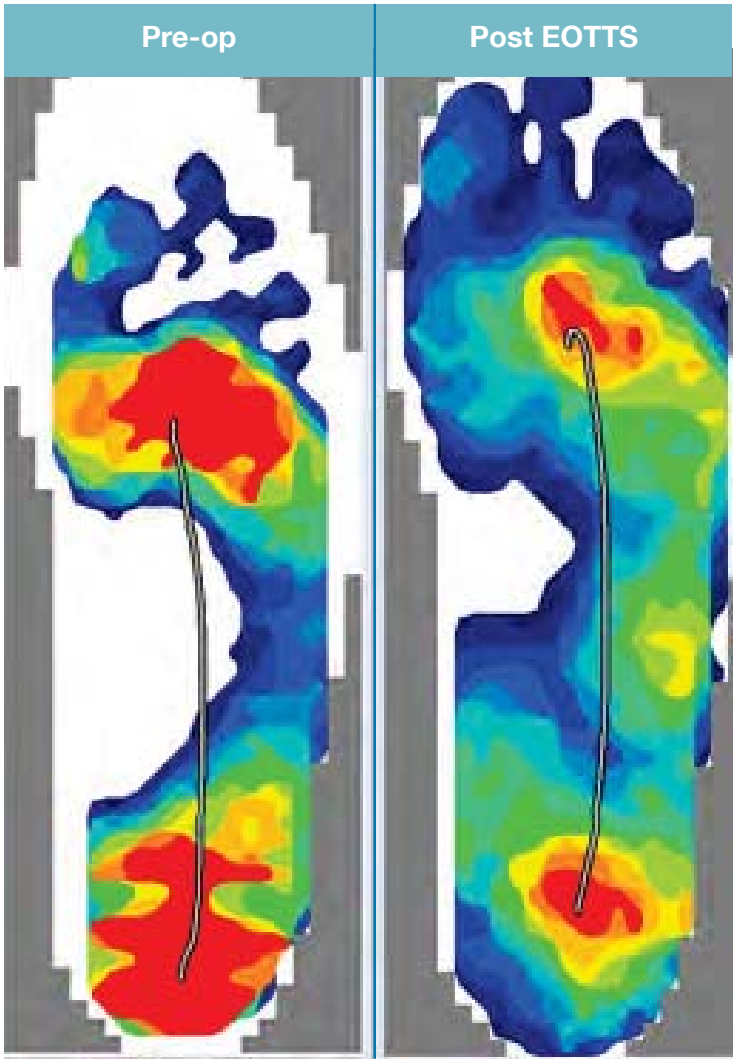
- Weightbearing plantar force measurements before and after EOTTS with HyProCure.
- Increased forces could lead to callus formation or tissue destruction in a sensory compromised patient, i.e. neuropathy.

Results

- Significant reduction of peak pressures by 42% over the entire plantar foot.
- Significant increase in contact area by 20% between the foot and weightbearing surface.

Conclusion

- There is a direct link between RTTJD and pathology plantar foot forces.
- EOTTS with HyProCure has been proven to normalize pathologic plantar foot forces.
- Patients with plantar skin pathology should be evaluated for RTTJD and HyProCure should be considered a part of the treatment solution.



8.9 Published Studies

Extra-Osseous TaloTarsal Stabilization Using HyProCure in Adults: A 5-year Retrospective Follow-up.
Published: The Journal of Foot & Ankle Surgery, Volume 51, 2012, Pages 23-29.

Statistics

1st review of EOTTS as a stand-alone procedure in adults.

- 83 adults ,18 or older at time of surgery
- 117 feet
- Mean age 58 (22–85)
- Average follow up is 51 months

Results

- **Removal rate was 6%** (compared to 38% or greater with Type I arthroereisis devices).
- Patient satisfaction score showed excellent long-term results.

Conclusion

HyProCure has been proven to have the highest success rate over any other EOTTS device.

- HyProCure has the lowest removal rate over any EOTTS device (6% compared to 38–100% of arthroereisis devices).
- Even though there were removals and/or revisions, there were no long-term complications.
- Not a single patient developed chronic pain post-HyProCure removal.
- Patients who required a revision went on to a successful outcome.
- HyProCure is a safe and effective option for adult patients with recurrent talotarsal dislocation, when indicated.

8.10 Published Studies

Extra-Osseous TaloTarsal Stabilization Using HyProCure: Preliminary Clinical Outcomes of a Prospective Case Series. Published: The Journal of Foot & Ankle Surgery, Volume 52, 2013, Pages 195-202.

Statistics

Prospective, multicenter study

- Pediatric and Adult patients
- Mean age 41 (8–72)
- 35 patients (46 feet)

Results

- Foot pain decreased by 37%
- Improved functional activities by 14%
- Improved foot appearance by 29%
- Removal rate of 4%
- No unresolved complications
- Improvement of secondary conditions
- Greatest magnitude of recovery occurred at 4 weeks post-procedure period

Conclusion

- HyProCure is safe and effective in both pediatric and adult patients.
- There was a 96% success rate.
- HyProCure removal rate was 4%.
- Shows that HyProCure has the highest success rate over any other EOTTS stent.
- Not a single patient developed an unresolved complication.

8.11 Published Studies

Surgical Treatment of Hyperpronation Using an Extra-Osseous TaloTarsal Stabilization Device: Radiographic Outcomes in Adult Patients.

Published: The Journal of Foot & Ankle Surgery, Volume 51, 2012, Pages 548-555.

Key Points

- The use of HyProCure has been well tolerated and shown to decrease strain and forces to many areas of the foot.
- This study reviewed DP/lateral weightbearing x-rays of 95 feet (70 patients) who underwent EOTTS with HyProCure as a stand-alone procedure.
- Mean age was 58 (22–85).
- X-rays were taken once patient had no pain or guarding from standing/walking that could compromise the findings.

Results

- All 95 feet had a transverse plane component.
- 65 of the 95 feet also had a sagittal plane component.
- All patients had normalization/reduction of the transverse plane component.
- All patients had normalization/reduction of the sagittal plane component.
- No patient had normalization of one plane component where another plane became pathologic.
- There was no significant effect to calcaneal inclination angle.

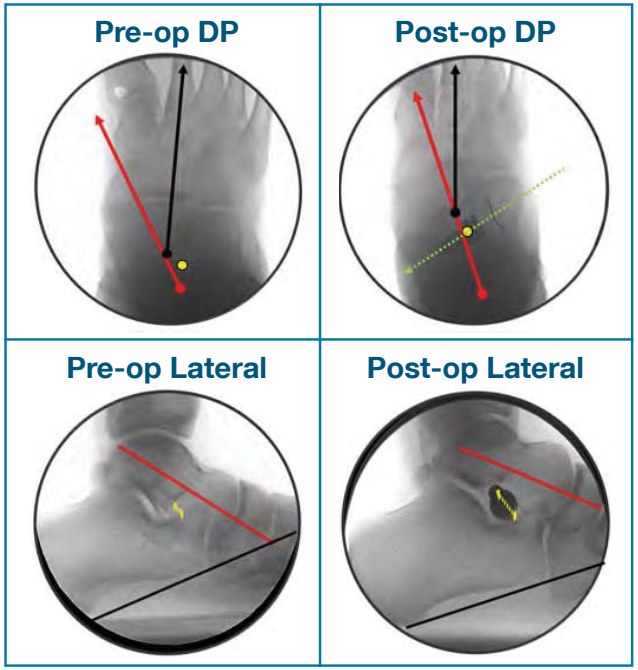
Transverse plane correction via talar 2nd metatarsal angle via DP x-ray

- Pre-op = 25° (normal < 16°)
- Post EOTTS with HyProCure = 6°
- Mean normalization = 19° (77%)
- Maximum correction = 37°

Sagittal Plane correction via talar declination angle via lateral x-ray

- Pre-op = 25° (normal < 21°)
- Post EOTTS with HyProCure = 19°
- Mean normalization = 6° (23%)
- Maximum correction = 19°

Not a single measurement showed an over-correction



Conclusion

- Transverse and sagittal plane normalization with HyProCure as a stand alone procedure is proven via weightbearing radiographic evidence in adult patients.
- Average and maximum guidelines on the amount of expected correction is provided.

8.12 Published Studies

Radiographic Evaluation of Navicular Position in the Sagittal Plane–Correction Following an Extra-Osseous TaloTarsal Stabilization Procedure.

Published: The Journal of Foot & Ankle Surgery, Volume 50, 2011, Pages 551-557.

Key Points

- TaloTarsal displacement leads to navicular sag.
- Navicular sag leads to increased strain on the spring ligament, plantar fascia, posterior tibial tendon and a lowering of the arch.
- Efforts to prevent navicular sag are attempted via various modalities, such as arch supports and extra-osseous talotarsal stabilization devices.

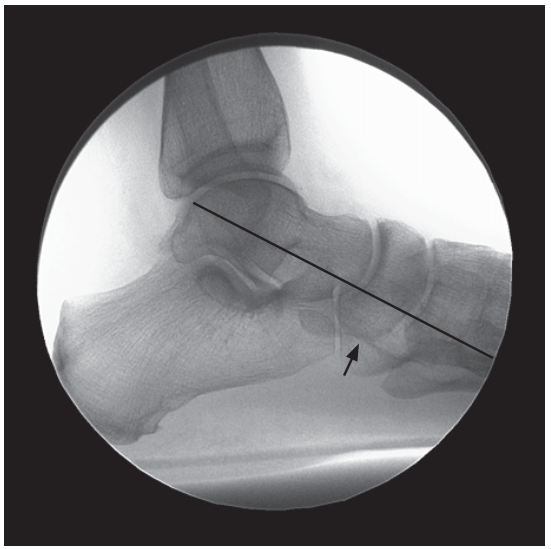
Results

- HyProCure was placed into 86 adult feet (61 patients) as a stand alone procedure.
- HyProCure stabilized navicular sag by 26%.

Conclusion

This is very significant as there is not a single case study showing a similar or greater finding with the use of an arch support (over-the-counter or custom made). This data plays a critical role in the treatment of medial column instability and shows that HyProCure is an excellent option in the treatment of arch instability, when indicated.

Note: A navicular sag leads to a lowering of the medial arch of the foot. While there can be a cosmetic issue, the lowering of the arch serves as a sign of a biomechanical imbalance that could potentially contribute to other lower extremity pathologies.



8.13 Published Studies

Pediatric Congenital TaloTarsal Joint Displacement and Pes Planovalgus Evaluation, Conservative Management, and Surgical Management.

Published: Clinics of Podiatric Medicine and Surgery, Volume 30, 2013, Pages 567-581.

Key Points

- Recurrent Talotarsal joint displacement is a pathologic deformity that does not improve with age.
- RTTJD does not get better, it gets worse.
- RTTJD leads to many secondary pathologies to the lower extremity and can adversely affect health in general.

Results

- RTTJD is diagnosed via physical examination (non-weightbearing/ weightbearing) and confirmed by weightbearing radiographs.
- RTTJD does not present an immediate life-threatening disease, yet it slowly leads to destructive effects to the musculoskeletal chain and to the body/health in general.

Conclusion

- RTTJD is a deformity that must be diagnosed and explained to patients.
- Observation is a poor-treatment choice due to the fact that further destruction occurs to the lower extremity.
- Arch supports are not capable of realigning and/or stabilizing the talotarsal joint.
- Traditional reconstructive surgery is too aggressive for most patients.
- HyProCure is a safe and effective device that is capable of realigning and stabilizing the talotarsal joint without long-term complications.

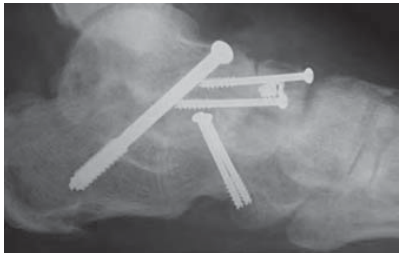
There is no scientific evidence that a pediatric patient with RTTJD will outgrow this orthopedic pathologic finding. It doesn't get better, it gets worse. Early intervention is preferred.

Pediatric Pre-op Lateral

Non-Surgical Treatment

EOTTS with HyProCure

Rearfoot Reconstructive



8.14 Published Studies

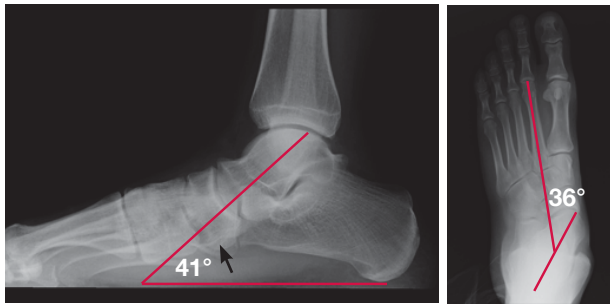
Analysis of Radiographic Outcomes Comparing Foot Orthosis to Extra-Osseous TaloTarsal Stabilization in the Treatment of Recurrent TaloTarsal Joint Dislocation.

Published: The Journal of Minimally Invasive Orthopedics, January 2015 issue

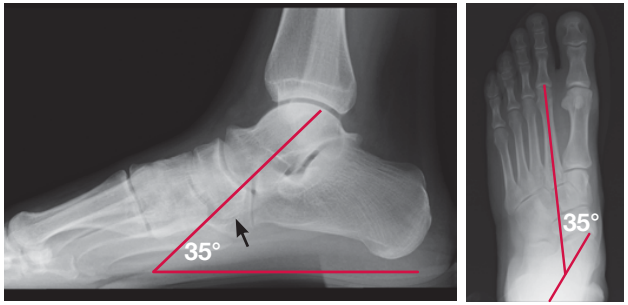
Key Points

Multicenter Prospective Study—Compared weightbearing radiographs

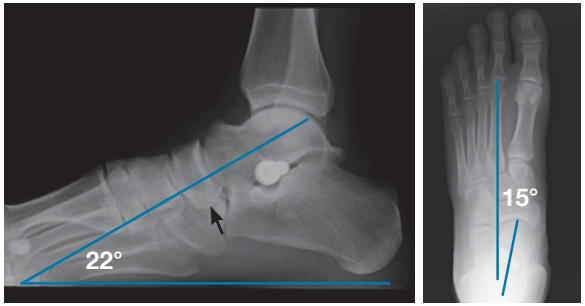
Barefoot—No intervention



Barefoot—Orthosis



Barefoot—EOTTS with HyProCure



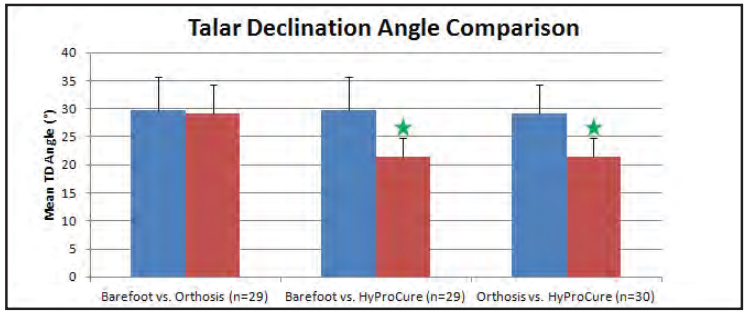
Results

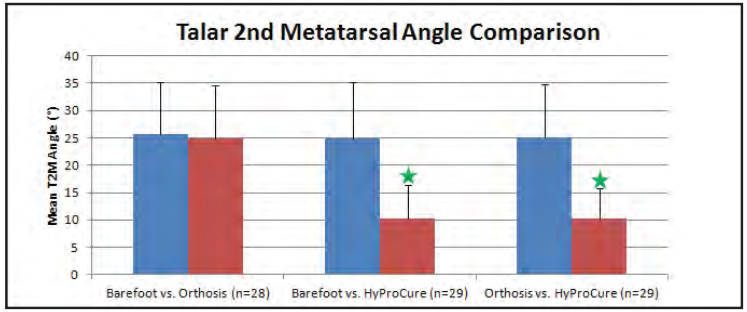
Transverse Plane Improvement

- Orthosis = 3.2% average change
- EOTTS = 58.9% average change

Sagittal Plane Improvement

- Orthosis = 2.2 % average change
- EOTTS = 28.3% average change





Conclusion

- EOTTS with HyProCure is the more effective form of treatment to realign and stabilize RTTJD.
- Orthosis is ineffective in the realignment and stabilization of RTTJD.
- EOTTS with HyProCure is a superior option over arch supports in realigning and stabilizing the TTJ.

Section 9

Quick Facts & Common Patient Questions

“Because Answers Exist Only in Questions.”

~ Mungara Tarou Krishnamurti

9.1 Quick Facts

	EOTTS with HyProCure is an evidence-based procedure that has been used by foot & ankle surgeons in 60 countries in **pediatric and adult** individuals of all activity levels.
	HyProCure is made of titanium and won't set off metal detectors. Recipients can still undergo MRI and CT scans.
	Minimal pressure is put on the HyProCure stent itself. Once it is placed, the bones realign and the majority of the body's weight will be rebalanced on the bones surrounding it.
	HyProCure is centrally placed into a naturally-occurring space in between the ankle and heel bones allowing for natural movement. Other similar devices are designed to block the joint which restricts natural movement.
	Most patients are able to walk again within a few days after the procedure is performed. (Note: this depends on whether the HyProCure procedure is the only one performed).
	Though cause for removal is rare (6% vs. over 40% in other devices), the procedure is reversible.
	HyProCure is domestically and internationally patented.
	HyProCure is FDA cleared since 2004 and CE marked in 2006.

9.2 Common Patient Questions

Will I feel the implant in my foot?

As long as the implant does not displace, you should not be able to feel HyProCure after the procedure. Sometimes for the first few months a hard substance may be felt in the area of the surgery. This is scar tissue and should dissipate after several months, if present at all.

Will there be a visible scar?

The incision is less than an inch long and located below the outer ankle bone. With time, the scar will continue to fade. Results vary for each patient.

Will this implant get rid of all of the pains in my body?

No one can completely predict the outcome of any surgical procedure, but this solution should help improve the entire body's alignment. Therefore, reduction and relief of pain caused by the foot imbalance will also be reduced or eliminated. However, it is possible that some of the joints and soft tissues in the body may have already suffered irreversible wear and tear, and in those cases other treatments or procedures might be necessary. In either case, correcting the root of the problem is still essential to stopping any further damage and to allowing for any additional therapies (if necessary) to be long lasting.

Will I still have to wear my orthotics after the procedure?

There are other reasons for orthotics to be worn. Orthotics can be used to off-weight prominent areas to the bottom of the foot. If those areas are not surgically addressed, then orthotics may still be required after the procedure.

Are there limitations to this procedure?

Yes, every surgical procedure has its limitations. In very severe cases of talotarsal displacement, other surgical procedures may be necessary to achieve optimum correction. There are no guarantees with any surgical procedure. It is possible that even an ideal HyProCure candidate will have to have the stent removed. Weight or BMI is not a factor in patient selection.

Do both feet need to be realigned for EOTTS with HyProCure to be effective?

Yes, both feet need to be stabilized. You can compare it to the tires on your car. You wouldn't balance the tires on only one side of your car. This would have a negative impact on your alignment. It is the same as stabilizing only one foot. However, it is generally recommended to correct one foot at a time, when possible.

9.2 Common Patient Questions

Is there drilling or screwing involved in the procedure?

There is no drilling or screwing involved with the EOTTS with HyProCure procedure. A small incision is made in the skin over the sinus tarsi. The stent simply slides into the natural space inside the foot. The threads on the stent are only to allow the scar tissue to form around the grooves and lock the device in place during the normal healing process.

As far as sports and physical activity go, are there limitations after the procedure?

Once the tissues surrounding the stent are healed, there should be no limitation. The abnormal motion is no longer present. Usually, there is a significant improvement in running, jumping—any activity involving propulsion from the foot.

Can I still get MRIs, CT scans, etc. with HyProCure in my foot?

Yes. HyProCure is made from medical grade titanium. However, as with any procedural implant, you should inform your doctors of the implant and follow their recommendation.

If this procedure is performed on a child, does it have to be replaced later in life?

The short answer is likely no, but this is not a guarantee. Normally, once the stent is inserted into the foot, it rarely has to be changed. The bones will continue to grow peripherally around the HyProCure stent. Time has shown that if the most common adult size is placed into a child's foot then it is unlikely it will have to be replaced upon osseous maturity.

What are the chances of having an allergic reaction to this implant?

Titanium is the choice material used in the body since it is the least reactive. HyProCure is made entirely of medical grade titanium. Some patients develop what appears to be an allergic reaction, but this could be the result of a pre-existing chronic inflammation of the foot (synovitis).

How soon can a HyProCure recipient return to sports, running or jogging?

It will take a minimum of 4-6 weeks for the HyProCure stent to become anchored within the sinus tarsi. Displacement rarely occurs after 6 weeks, therefore running or jogging should not be attempted until 6 weeks after the procedure. Ultimately, the final clearance comes from the foot surgeon.

After the EOTTS with HyProCure procedure, will I need to be pre-medicated prior to dental treatment or other future surgical procedures?

You should not need to pre-medicate prior to dental or other surgical procedures because the HyProCure stent is not embedded into the bone. Of course there are other reasons to require pre-medication. Check with your healthcare provider.

Appendix

“ Always present, always active disease demands prompt treatment and cannot wait until modern research has settled absolutely, which is the best remedy for it. ”

~ F.L.J. Valleix, MD

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Removal Rates for Arthroereisis Devices—Section 3.3

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A1 References

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About Us

About the Author

Dr. Michael E. Graham, a board certified podiatric surgeon, knew he wanted to be a foot specialist since the age of seven. He was granted early acceptance to Temple University of Podiatric Medicine in 1994 and began his private practice in 1996, after completing a two-year surgical residency at Kern Hospital for Special Surgery in Warren, Michigan.

During his private practice years, he became unsatisfied with the ineffectiveness of foot orthotics, but found traditional reconstructive surgery too aggressive for a large subset of patients.

He began using arthroereisis devices in 1999, but became frustrated with the high removal rates he was seeing in his patients. In search of a better, more effective option, he used his expertise in biomechanics and foot anatomy to design the HyProCure stent in May 2003. Since receiving FDA clearance in September 2004, the implant has been used globally in patients ranging between the ages of 3 and 95.

He currently spends his time publishing, lecturing and traveling the world to train orthopedic and podiatric surgeons on this game-changing device.

About GraMedica

Incorporated in 2003, GraMedica is a global foot care solutions company passionate about creating innovative foot and ankle products that improve patient options and outcomes. With a primary focus on Extra-Osseous TaloTarsal Stabilization, GraMedica is globally recognized as a leader in sinus tarsi implantology. It's HyProCure stent is used by leading orthopedic and podiatric surgeons in 60 countries world-wide.

Along with an elite set of orthopedic and podiatric surgeons, GraMedica is "Changing Lives, One step at a Time®".

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16137 Leone Drive, Macomb, MI 48042
586-677-9600 I www.GraMedica.com