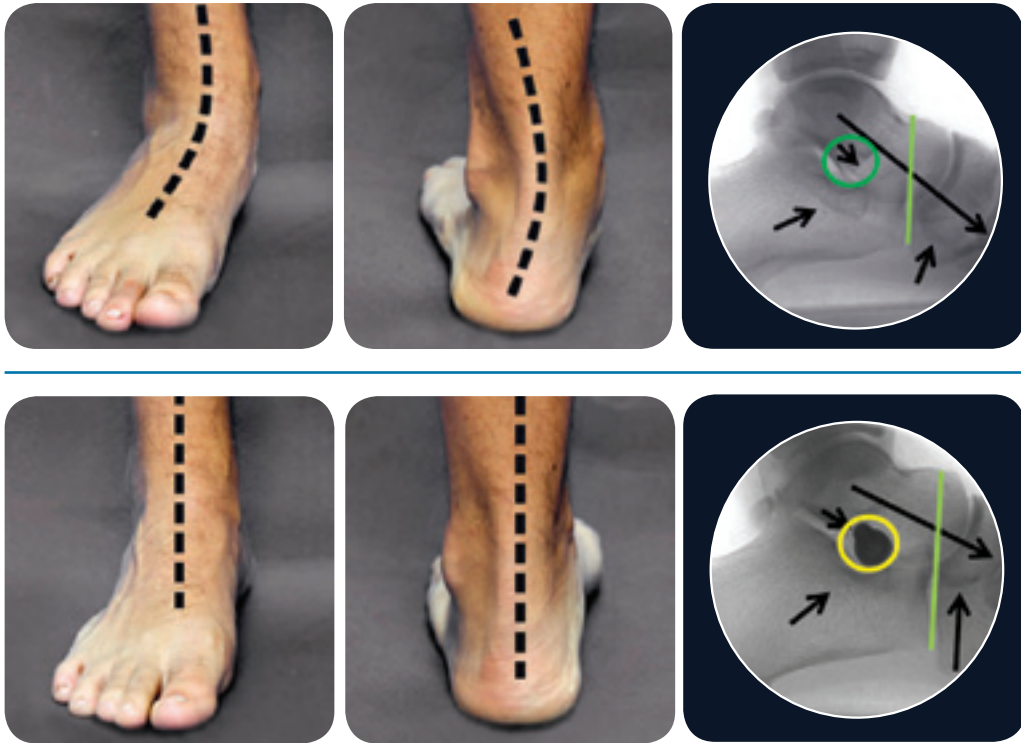


HyProCure[®]



EOTTS with **HyProCure[®]** Surgical Guide

Together We Can Change Lives, One Step at a Time[®]

There is a perception that Extra-Osseous TaloTarsal Stabilization (EOTTS) with HyProCure is a simple procedure that any surgeon could perform. The reality is that the nuances of this procedure are actually quite complex.

This guide has been created as a reference training tool to shorten the time it takes to become a “Master” HyProCure surgeon, not just in terms of the number of procedures performed, but in terms of patient satisfaction or success.

Challenges of the EOTTS with HyProCure Procedure

- No two feet are alike and every sinus tarsi has unique characteristics.
- No two stent placements will be exactly alike. Sometimes the device placement will not be “pretty” or ideal, yet the stent still functions to stabilize a recurrent talotarsal displacement (RTTD).

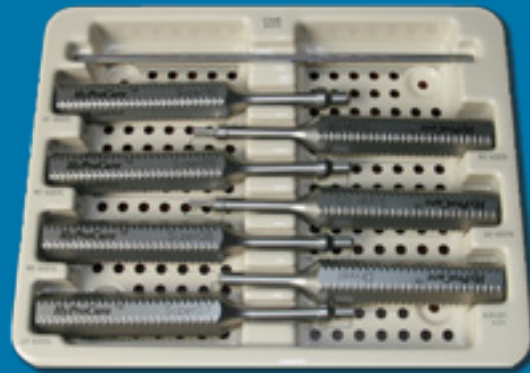
There are guidelines that help determine “acceptable” vs. “less than ideal” positioning. This can vary too at different phases of the treatment and recovery, for example, intra-op vs. three weeks post-op. The device is not anchored into bone, but simply held in place by a combination of soft-tissue adherence and the walls of the chamber forming the sinus tarsi. Therefore, getting the initial placement as close to ideal as possible is of extreme importance.

First Things First—Using the Correct Tools

HyProCure Instrument Set

The instrument set includes trial sizers, a driver and guide wires. Trial sizers determine the size of stent that will best stabilize the talotarsal joint while still allowing for natural range of motion.

The instruments are made of surgical stainless steel.



Sinus Tarsi Decompression Scissors

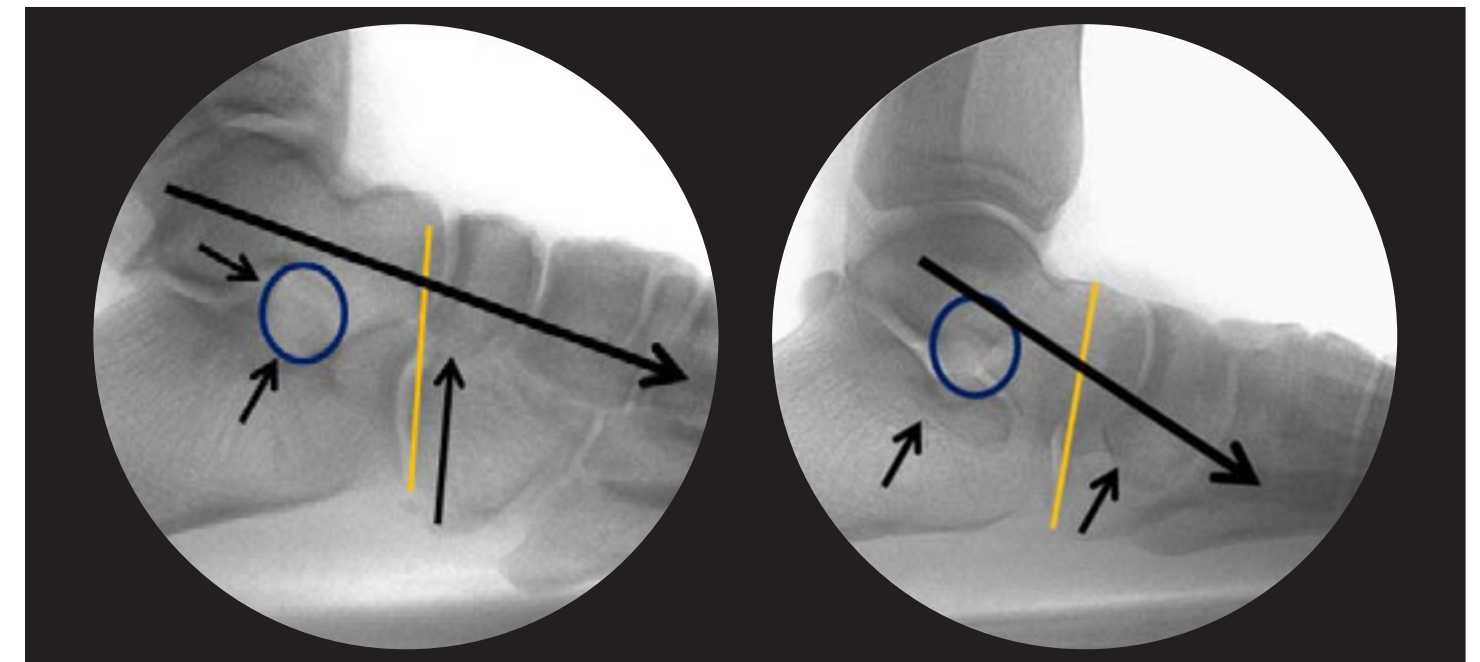
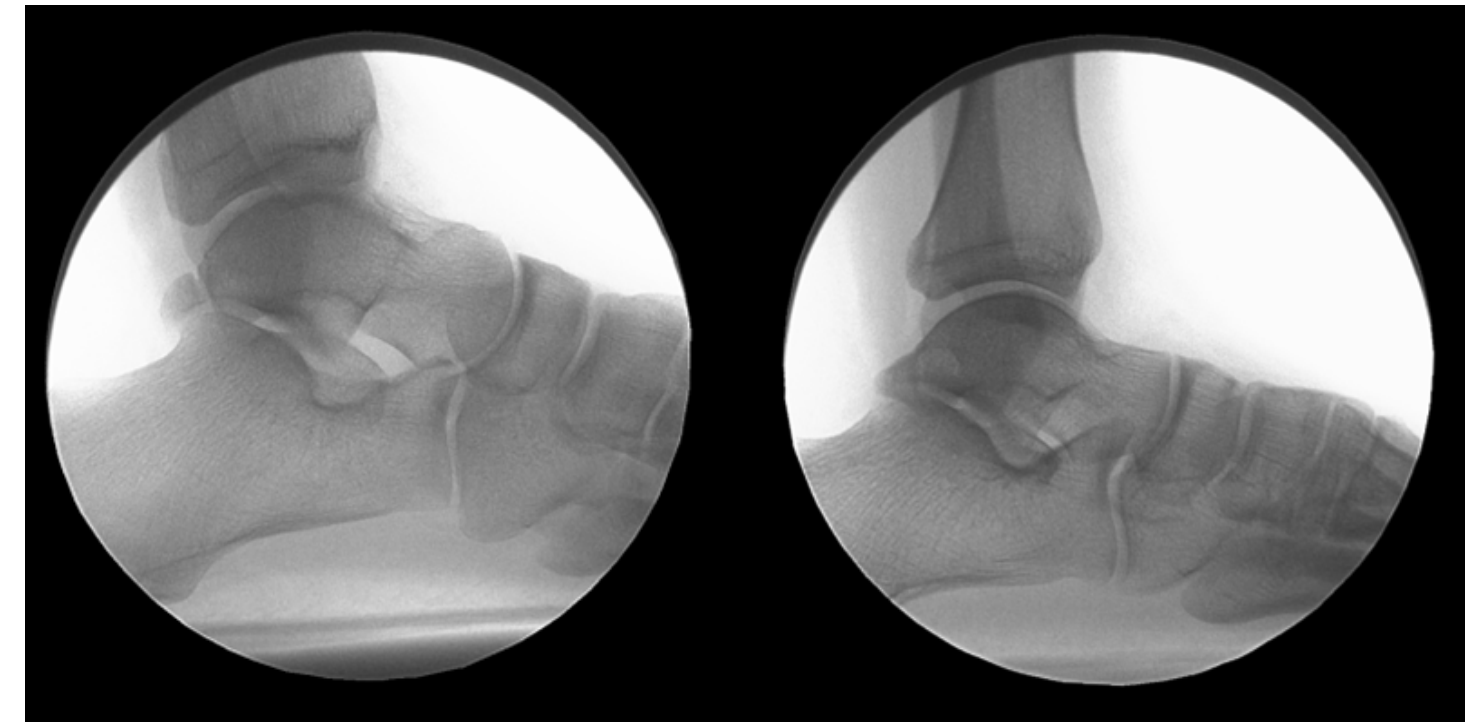
The Sinus Tarsi Decompression/Stevens tenotomy scissors are blunt tipped and curved to allow for better decompression of the interosseous ligament. They are made of premium German stainless steel.



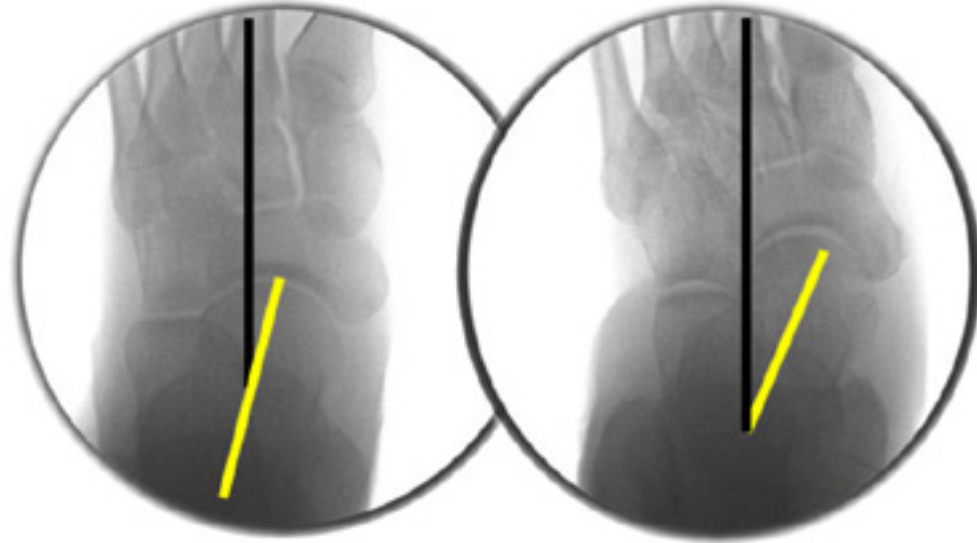
Selecting the Right Patient

Patient selection is the first consideration. Inappropriate patient selection will lead to less than ideal, or compromised results. The patient must have a flexible talotarsal joint. This means that the talus can be repositioned back onto the tarsal mechanism when the patient is not placing weight on the foot. This realignment transforms the “closed” or obliterated sinus tarsi and “re-opens” it back to its normal shape.

Neutral Stance (NSP) Position compared to Relaxed Stance Position (RSP). Observe the open vs. closed sinus tarsi, navicular drop, increased talar declination angle and slight drop of the sustentaculum tali.



Comparison of DP x-rays with the talar second metatarsal (T2M) angle drawn.



NSP has a $< 16^\circ$ angle whereas the RSP T2M angle is $> 16^\circ$.

Notice the anterior/medial displacement of the talus.

If the talus cannot be repositioned onto the tarsal bones (calcaneus/navicular) then it is possible there is a tarsal coalition, severe arthritic changes or an end-stage deformity. If the sinus tarsi cannot be “re-opened”, then EOTTS with HyProCure should not be performed.

Example of a rigid, non-reducible talotarsal displacement deformity.



If the talus cannot be repositioned on the calcaneus and/or navicular, HyProCure should not be used.

HyProCure alone cannot “fix” a lower than normal calcaneal inclination angle.

Surgeons Tip



It is recommended that the surgeon not perform the EOTTS with HyProCure procedure unless the comparison of RSP and NSP x-rays has been made to document the presence of reducibility. This also helps to rule out the presence of a tarsal coalition. If there is any suspicion of a coalition, other imaging studies should be ordered. This comparison can be used as part of the presentation to the patient, demonstrating the ideal talar position compared to how the talus is displacing on the tarsal mechanism when the patient applies weight to their foot.

Once the surgeon has identified that the patient is a candidate for the EOTTS with HyProCure procedure, it is important to make sure the surgical technique is performed correctly. Also, it is important to identify coexisting foot pathologies and address them conservatively or surgically.

Surgical Prep

As a stand-alone procedure, HyProCure is generally performed under local anesthesia and/or twilight sedation. An ankle tourniquet is not necessary. There will be very little bleeding and the tourniquet will limit range of motion testing. If EOTTS with HyProCure will be performed in conjunction with other procedures, an ankle tourniquet can be used, but it should be left deflated for the HyProCure portion.

Lateral view of a right foot with skin markings.



The fibular malleolus is marked with two parallel lines extending, indicating the dorsal and plantar margins of the sinus tarsi. The distal circle (dorsal calcaneus process) indicates the distal boundary. The dotted lines indicate peripheral cutaneous nerves that must be avoided. The incision is usually one index finger anterior to the fibular malleolus.

Injection

Injection/incision placement must be in the correct location. The procedure requires the introduction of long-lasting anesthetic to the skin and to the sinus and canalis portions of sinus tarsi. It is strongly recommended to add a short acting steroid to local anesthesia.



Inject superficially to the area of incision and slowly aim toward the posterior aspect of the medial malleolus.

Surgeons Tip



Combine the anesthetic with a short-acting steroid (0.5–1.0 cc) to minimize inflammatory reaction. Inject the anesthetic to this area prior to performing the procedure as this usually leads to a dramatic decrease in post-op pain and speeds recovery.

The skin incision should be approximately 1.5–2.0cm in length, utilizing a #15 blade-scalpel. It should start at the anterior/distal border and extend posteriorly/plantarly following the relaxed skin tension lines. **Only incise the skin/dermis.**



Mark the ankle in preparation for making the incision.



Start the incision on the anterior border and extend it posteriorly.



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

The sinus tarsi is decompressed using the curved Stevens Tenotomy Scissors. **The tips of the scissors must be angled posteriorly, aiming towards the posterior end of the medial malleolus.** If the curve/tip is angled anteriorly, the structures within the canalis tarsi will not be transected which will result in failure of the procedure.



The artery, nerve and vein to the sinus tarsi are directly under the talus, however, the blunt upper end of the scissor will prevent transection of these tissues.



Failure to adequately decompress the entire sinus tarsi, especially the tissues within the canalis tarsi, could result in mal-position of the stent.



Surgeons Tip

It is important to document the presence, or absence of the interosseous ligament being decompressed. Occasionally there are situations where the ligament has atrophied due to chronic deformity. This means there is little to no anchoring mechanism that could lead to device displacement. Document and inform your patient.

Sinus Tarsi Decompression

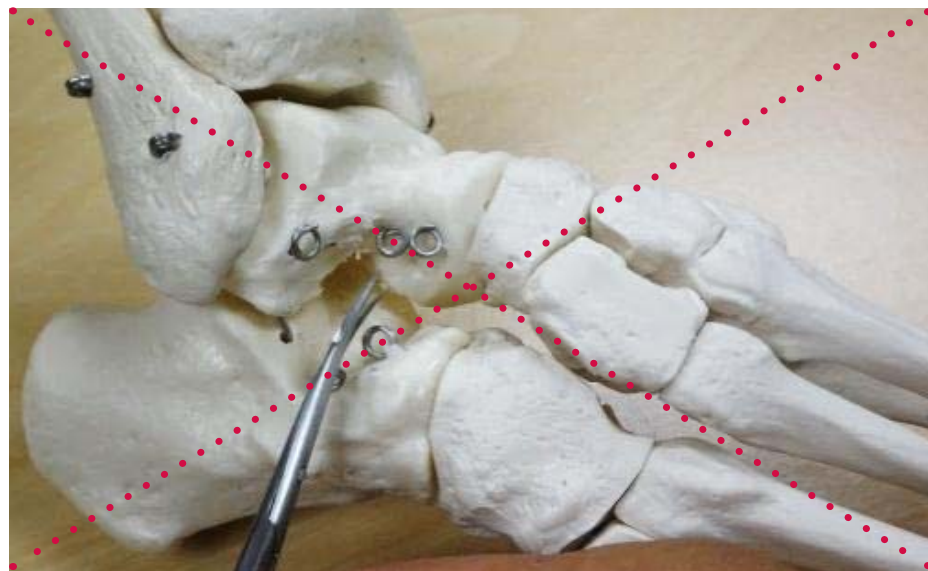
(Continued)

The talocalcaneal interosseous ligament (TCIL) within the canalis and sinus portions of the sinus tarsi is one of many talar stabilizers. There are additional ligaments around the periphery of the subtalar joint that serve to prevent excessive talar motion. Unfortunately, the interosseous ligaments along with the other supporting ligaments are incapable of preventing the excessive mobility of the talus in patients who are candidates for the EOTTTS with HyProCure procedure.

It should be emphasized that the surgeon should not remove the ligament, rather simply decompress it. The cut ends of the TCIL will undergo a “healing” process that stimulates fibroblastic activity to repair the cut ligament. This leads to adherence and reattachment around the threaded portion of HyProCure anchoring it into the most stable portion of the sinus tarsi.

Incorrect Decompression of the Sinus Tarsi

The tips of the scissors are pointing anteriorly, rather than posteriorly. The structures within the canalis are left intact and therefore will prevent the deep insertion of the threaded portion of HyProCure into the canalis tarsi.



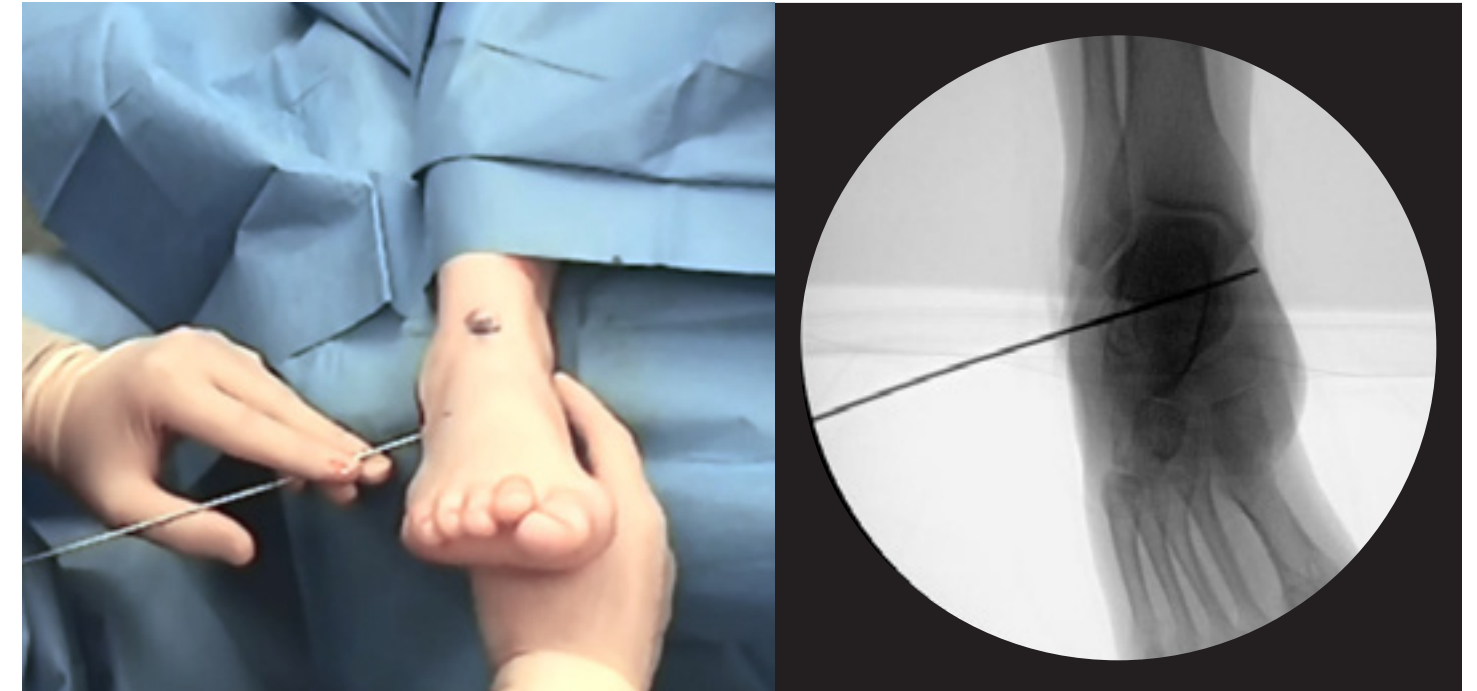
Step 3

Guide Wire Placement

Step 4

Place the Guide Wire along the oblique orientation of the sinus and canalis tarsi. There should not be a struggle inserting it. A struggle indicates inadequate decompression.

Make sure that the guidewire is placed into the canalis portion of the sinus tarsi. There should be an obliquity to the placement. Angle the medial tip towards the posterior aspect of the medial malleolus.



Incorrect Guide Wire Placement

The guidewire is not placed within the canalis tarsi. This will result in an over-sizing and mal-position of the HyProCure stent.



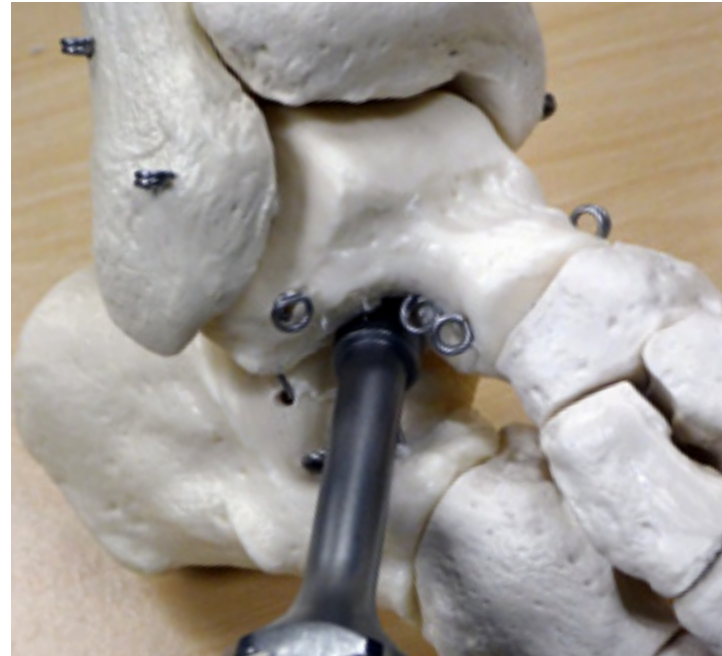
Once the tissues within the canalis tarsi are decompressed and guidewire is in place, insert a trial sizer over the guide wire. The goal is to achieve 3-4 degrees of talotarsal joint pronation.



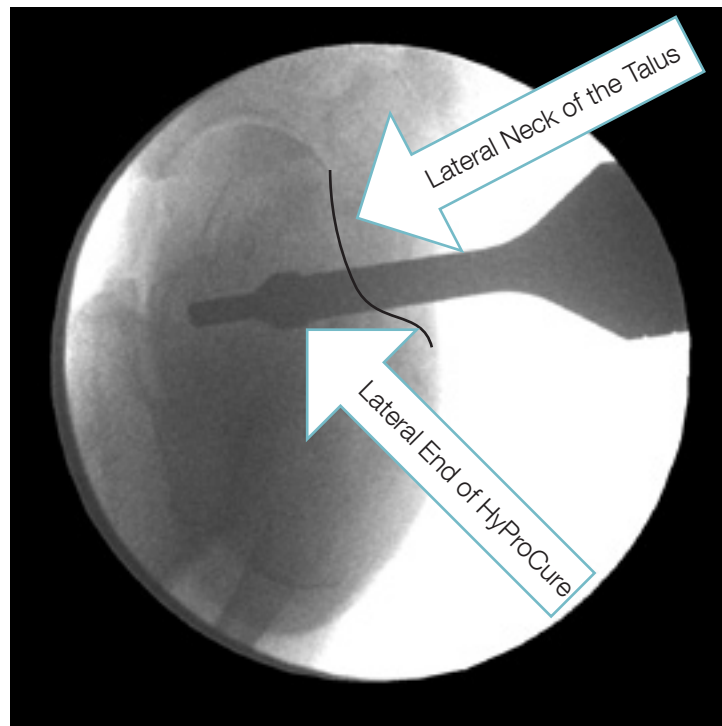
Surgeons Tip

It is recommended to start with size 6, the most common size, and work up or down from there based on the results.

Step 1 Ensure that the tip of the sizer is entering into the canalis tarsi and not abutting the lateral neck of the talus. Notice the horizontal alignment of the sizer in relation to the orientation of the sinus tarsi.



Step 2 Check placement under fluoroscopy. Notice that the lateral end of HyProCure is deeper than the lateral neck of the talus.



Surgeons Tip

If two sizes appear to give similar results, the smaller size is usually the preferred choice. It is better to under- rather than over-correct.

How to Check TTJ Pronation

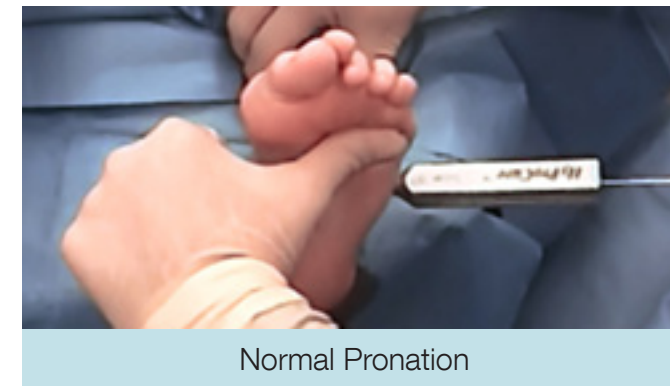
Maximally load the lateral column of the foot pressing on the necks of the 4th and 5th metatarsals and applying a dorsal-lateral force. The goal is to allow 3-4° of pronation.



Trial Sizer Final Position



Excessive Pronation



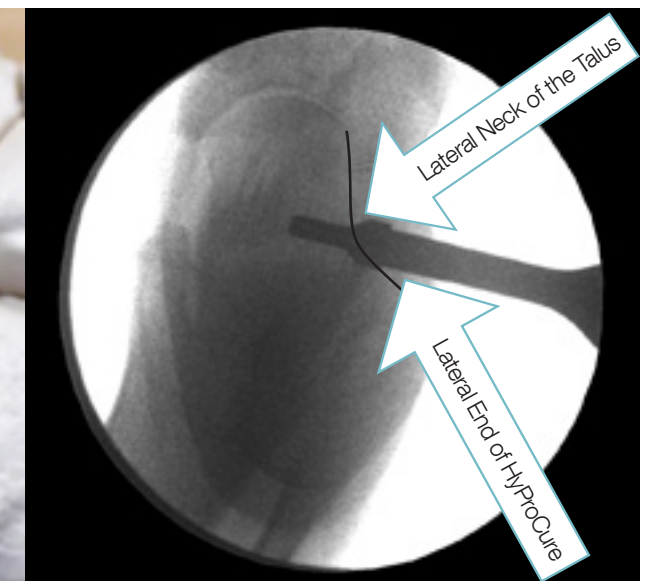
Normal Pronation



Over Corrected

Incorrect Trial Sizing

Common mistakes are to either insert the sizer so that the tip hits against the lateral neck of the talus, or the floor of the sinus tarsi instead of entering into the canalis tarsi. Both will result in over-sizing and ultimately to likely failure of the procedure.



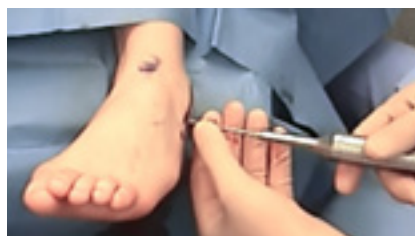
Notice that the tip of the sizer is hitting against the lateral neck of the talus and not entering into the canalis tarsi.

The ideal location to stabilize the talotarsal mechanism is at the cruciate pivot point. This is where the tapered portion of HyProCure functions to stabilize the talus on the calcaneus while still allowing for normal TTJ motion.

Step 1 Place the desired HyProCure stent onto the guidewire.



Step 2 Engage the tip of the driver onto the lateral end of the HyProCure stent and advance the stent into the sinus tarsi. Once the lateral end of the stent passes into the skin incision, remove the guide wire from the back end of the driver. This prevents bending of the medial end of the guide wire when checking final correction.



Note: HyProCure is not a screw and will not “tighten”.

Step 3 Check final DP view position under fluoroscopy. Lateral view does not give accurate stent position under the talus. The lateral end of the stent should be deeper than the lateral neck of the talus.

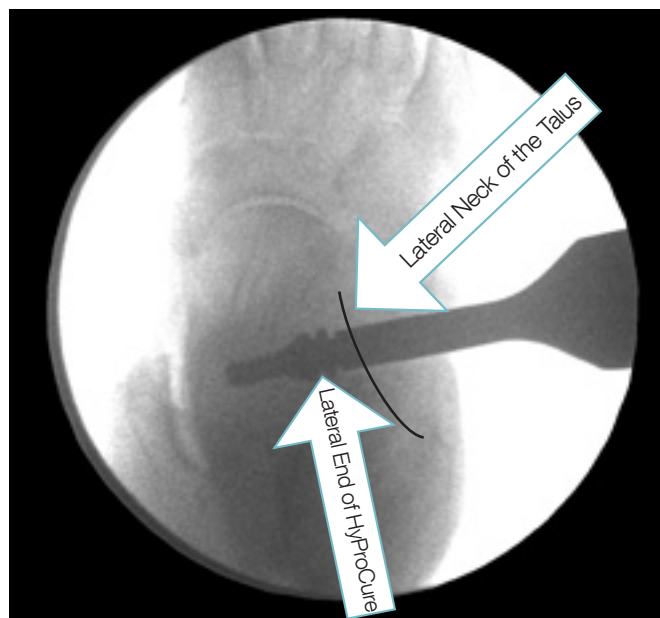


Surgeons Tip



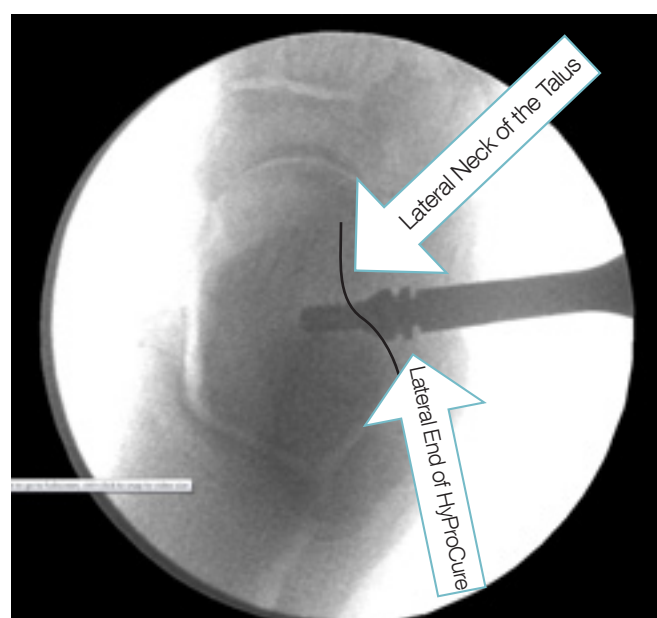
It is better to use a slightly smaller device and have it inserted deeper than to have a superficially placed device that has a higher risk of displacing post-procedure.

Ideal Placement



HyProCure is aligned along with the sinus tarsi. The lateral end of HyProCure is deeper than the lateral neck of the talus.

Incorrect Placement

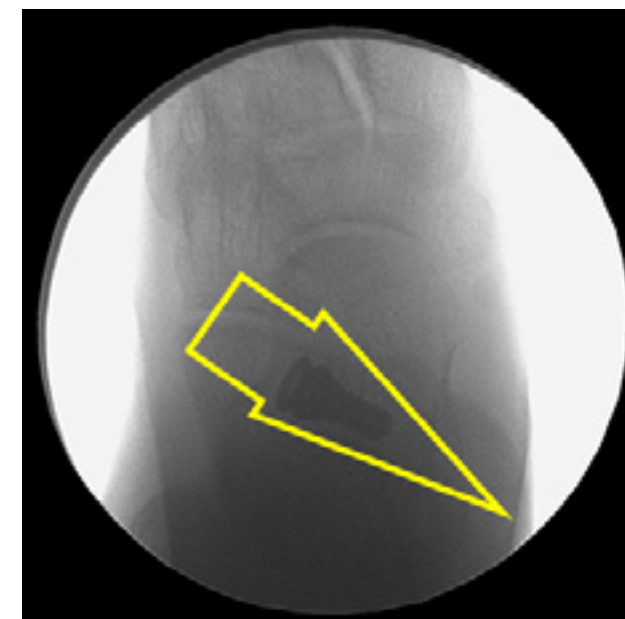


HyProCure is placed in a lateral to medial fashion instead of obliquely along the natural orientation of the sinus tarsi. The tip of HyProCure is abutting the lateral neck instead of entering into the canalis tarsi.

Examining Ideal Placement vs. Less than Ideal Placement

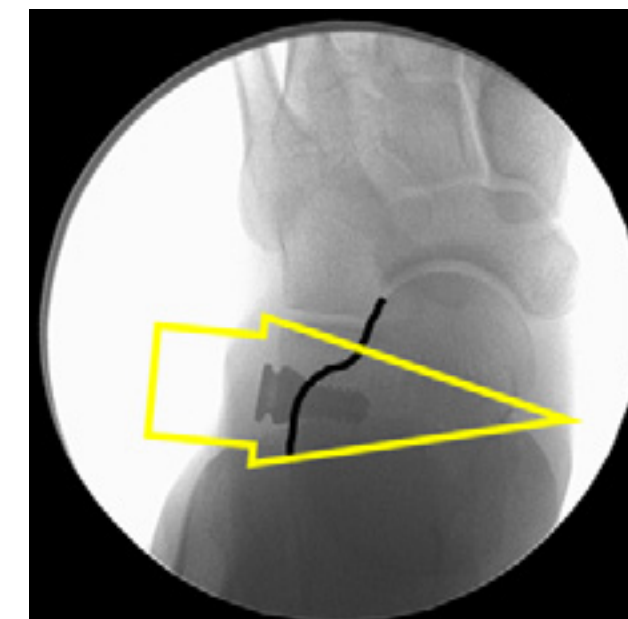
There is “anatomic ideal” placement, which is what we are trying to achieve and then there is “functional-ideal” placement– this is when the device “seeks its own level.”

Ideal Intra-Op Placement



The lateral end of the device is deeper than the lateral neck of the talus.

Less than Ideal Intra-Op Placement



Placed lateral to medial, the end of the device is not deep enough.

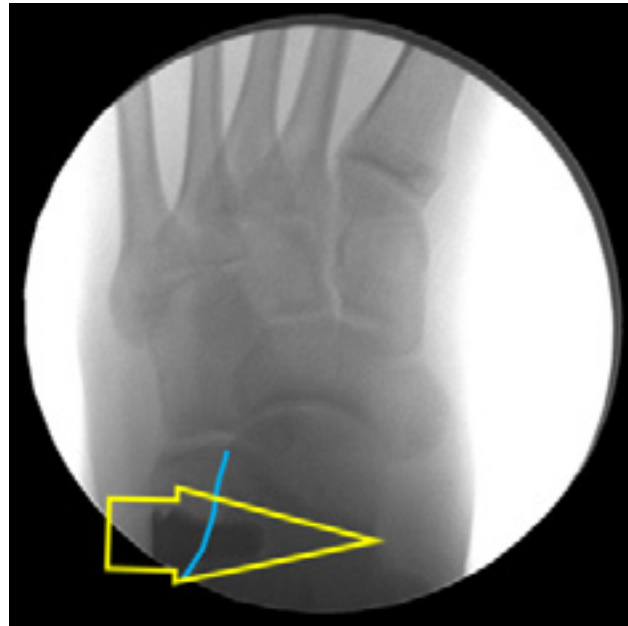


The lateral end of HyProCure is deeper than the lateral neck of the talus. Notice the anterior-distal-lateral to posterior-proximal-medial orientation. This device is functioning with the talotarsal joint, not against it.



The lateral end of the device is too superficial. Make sure that the deep structures within the canalis are decompressed/cut and that the tip of the device is entering into the canalis tarsi. This is an oversized stent.

Less than Ideal Placement



If this position is seen intra-op

Remove the device, ensure proper decompression of the sinus tarsi and re-trial size.

If this position is seen post-op

If the correction is maintained, the patient is not experiencing pain and there is stabilization of the talotarsal joint, there is no immediate need for revision. This device is acting as an arthroerisis implant and will have a higher likelihood of failure than a device that has been placed deeper.



Another DP radiograph showing too superficial placement. The lateral end of HyProCure is not deeper than the lateral neck of the talus.

If this position is seen intra-op

DO NOT BE SATISFIED! It is possible that this patient has a very narrow canal. It is better to use a smaller size that can be inserted deeper than to use too large a size that cannot be inserted deep enough.

If this position is seen post-op

If the talus is stabilized on the tarsal mechanism and there is normalization of the radiographic angles, this placement may be acceptable.



Surgeons Tip

HyProCure will seek the ultimate position where it will best function to stabilize the talotarsal joint mechanism. Ultimately, as long as the talotarsal joint dislocation is stabilized and there is improvement of the radiographic angles, then mission accomplished.

Ideal Post-Op Placement



A lateral view showing the desired placement of HyProCure. Notice that the threaded portion is posterior and slightly dorsal. That is the natural orientation of the sinus tarsi.



Again, notice the posterior alignment of the threaded portion of HyProCure. Every foot will be slightly different and some may be more horizontal while others may be slightly more dorsal.



Surgeons Tip

It is possible that even with ideal initial placement there could be a failure of HyProCure to maintain its position within the sinus tarsi and lateral displacement. It is also possible that, due to anatomical variability, EOTTS with HyProCure just cannot work and another form of treatment will be necessary.

Less than Ideal Post-Op Placement



Notice there are no dorsal/posterior threads. The threads are slightly plantar which is concerning. This device is aimed more lateral to medial. Confirm placement with DP image.



The device is placed lateral to medial and the tip of HyProCure is not entering into the canalis tarsi.

Less than Ideal Post-Op Placement



The lateral view shows a dorsal-plantar position instead of plantar-dorsal. The tip of the device is hitting against the floor of the sinus tarsi and is “over-stuffed”/over-sized. The lateral end of the device is not deeper than the lateral neck of the talus. The tip of the device has not been placed into the canalis tarsi.



Surgeons Tip

Make sure to look for the tell-tale signs that the device is placed correctly. Remember that the orientation of every sinus tarsi is different. No two are alike. Some will be oriented more lateral to medial whereas others are very oblique (anterior-lateral-distal to posterior-medial-proximal).



Notice that the threads are directed anteriorly rather than posteriorly.

Closure is per surgeon's choice. It is not necessary to close deep tissue, only the skin. Using a bioabsorbable suture is generally preferred. A running subcuticular combined with a continuous simple suture is recommended.



Patient Recovery Tips

The following recommendations apply only when performing HyProCure as a stand-alone procedure. If there are additional procedures performed, the post-op protocol should follow that of the procedure with the most restrictive course.

Early weightbearing is recommended.

There will be a period of adjustment while the soft tissues adapt to the new foot position. The sooner this adjustment begins, the sooner the patient will feel comfortable with their HyProCured foot.

The patient should stay off their foot as much as possible in the first few days following surgery.

Weightbearing to tolerance is recommended. Most patients can wear a new, supportive shoe once the dressings are removed. A surgical shoe can also be used. Make sure the collar of the shoe does not rub against the incision.

The patient should begin taking a NSAID immediately.

They will likely need a 2–3 month prescription.

Encourage patients to discard all older, worn-out shoes.

Worn shoes place a strain on the soft tissues of the foot and ankle and this can lead to device displacement or increased pain due to over-supination.

Lots of ice/elevation (15–20 min/hr) is strongly suggested.

The patient should wrap a bag of frozen peas or corn in a moist dish towel and apply it to the area for 10-15 minutes several times a day.

Remove the post-op bandage at 2–3 days.

Replace with normal Band-Aid type of product.

Full Recovery Could take up to a year.

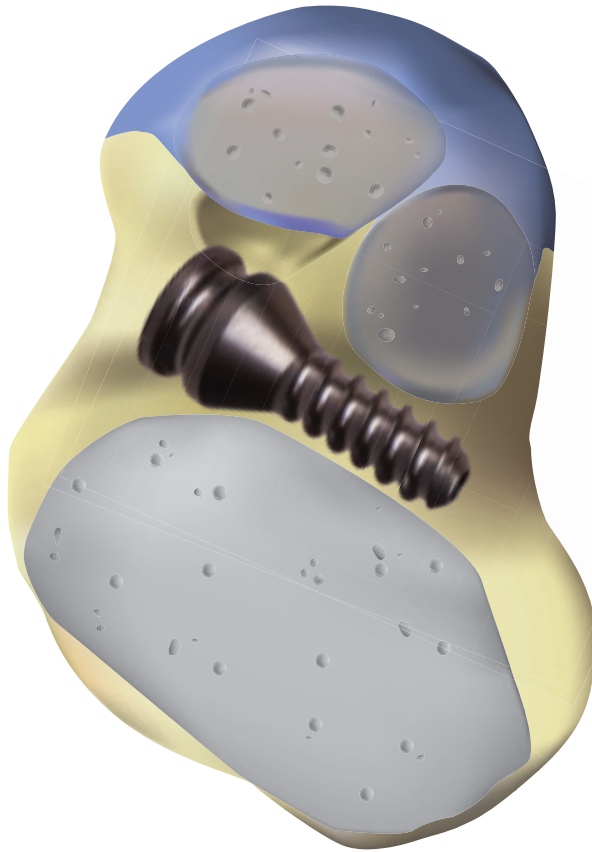
EOTTS with HyProCure is a time-tested procedure backed by years of scientific literature, which is why it has become the preferred sinus tarsi implant by foot surgeons globally. While there isn't a surgical procedure without potential complications, it is clear that the benefits of EOTTS with HyProCure far outweigh the possible risks. There also isn't a single comparative treatment option that outshines the HyProCure Advantage, when indicated.

We urge you to send potential candidates to www.HyProCure.com so that they can become informed on the advantages and potential risks associated with this life-changing procedure.

HyProCure is Scientifically Proven to:

- ◆ Stabilize and realign the TTJ (*J Am Podiat Med Assoc. 2011;101(5);390–399.*)
- ◆ Decrease anterior forces acting on the medial column of the foot (*J Am Podiat Med Assoc. 2011;101(5);390–399.*)
- ◆ Decrease strain on the medial band of the plantar fascia by 33% (*J Foot Ankle Surg. 2011;50(6) 682–686.*)
- ◆ Decrease strain on the posterior tibial tendon by 51% (*J Foot Ankle Surg. 2011;50(6);676–681.*)
- ◆ Decrease pressures within the porta pedis and tarsal tunnel (*J Foot Ankle Surg. 2011;50(1); 44–49.*)
- ◆ Decrease strain/elongation of the posterior tibial nerve (*J Foot Ankle Surg. 2011;5(6); 672–675.*)
- ◆ Normalize sagittal plane TTJ dislocation deformity (*J Foot Ankle Surg. 2011;50 (5);551–557.*)
- ◆ Normalize transverse plane TTJ dislocation deformity (*J Foot Ankle Surg. 2011;50 (5);551–557.*)
- ◆ Normalize plantar foot forces (*J Foot Ankle Surg.2013; 52(4); 432–443.*)
- ◆ Removal rate < 7% after five years (*J Foot Ankle Surg. 2012;51(1);23–29.*)
- ◆ Shown to increase quality of life (*J Foot Ankle Surg. 2013;52(2);195–202. J Foot Ankle Surg. 2012;51(1);23–29.*)
- ◆ Positive functional out-come SCORES (*J Foot Ankle Surg. 2013;52(2);195–202. J Foot Ankle Surg. 2012;51(1);23–29.*)

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