Taking a Step in the Right Direction

Your Guide to Misaligned Feet

Overview

The stability and alignment of your feet is very important, just like the alignment of the tires on a car. The average person takes nearly 6,000 steps a day. These steps quickly add up to over 90 million by the age of 50. Due to the sheer number of steps taken year after year, you can now understand why the health of your feet and the integrity of their physical structure are significant.

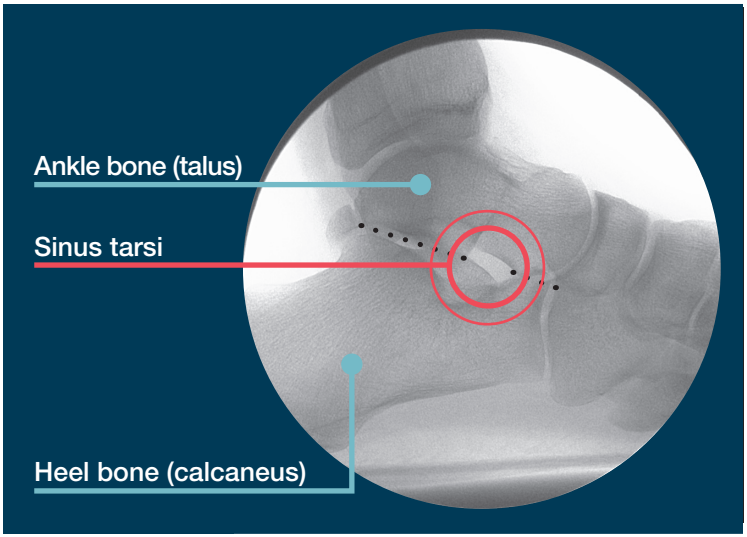
Misaligned feet are very common but often ignored. That's because most people with misaligned feet don't experience foot problems, rather the pain shows up to other parts of the body such as the knees, hips, or back. Medical attention is mainly directed to pain-relief and little importance is given to solving the underlying problem.

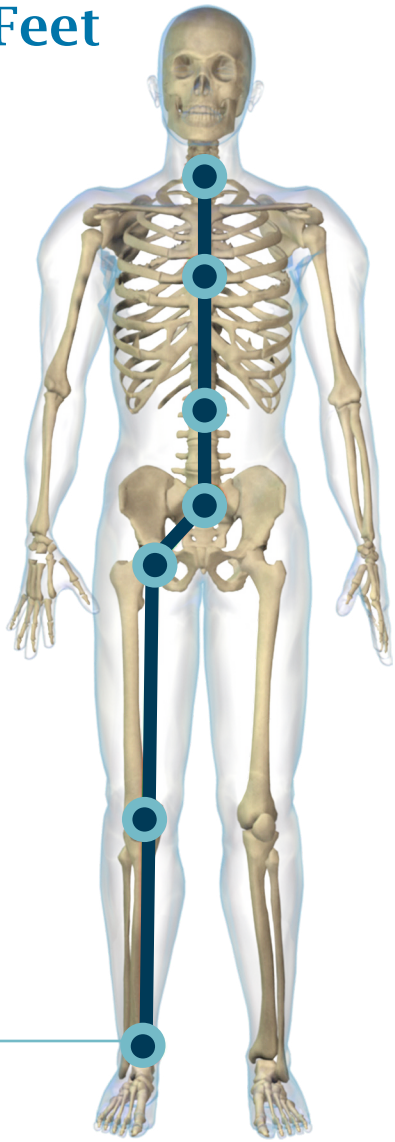
This booklet will provide you with further information about foot alignment and common treatment options.

The Importance of Aligned Feet

When your feet are correctly aligned, so is the rest of your body. Your body and feet work together to efficiently transfer forces from the body's movements to the ground below.

The "foundation joint" of the body is located between the ankle bone and heel bone. There is a natural occurring space in between these bones called the **sinus tarsi**.



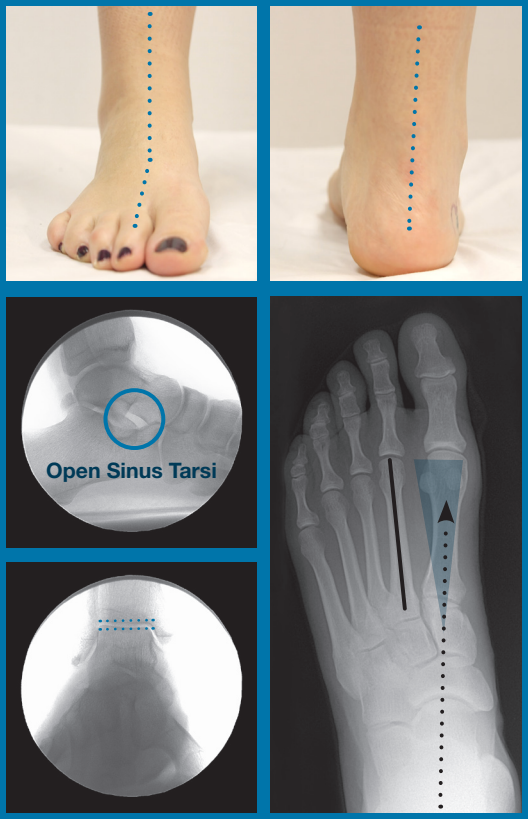


Normal ankle and heel bone alignment provides a stable foundation for the rest of your body.

What Causes Foot Misalignment?

Foot misalignment occurs when the ankle bone loses its normal stability and alignment on the heel bone forcing the sinus tarsi to collapse.

Normal Alignment



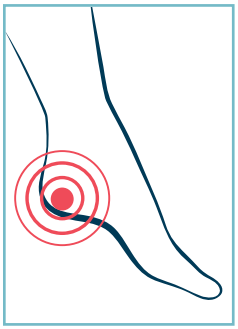
Notice the dotted arrow is within the shaded area. This is the normal range of motion.

Abnormal Alignment

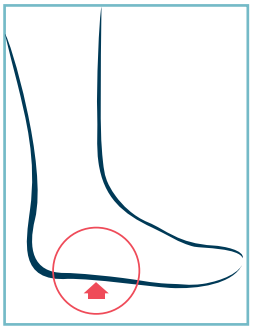
Notice the dotted arrow is turned inward. It should be in the shaded area.

Negative Effects to Your Feet

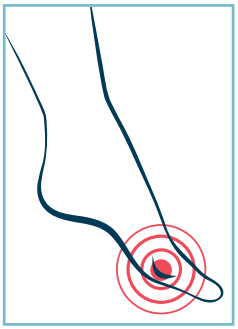
Many common foot problems are directly related to excessive ankle bone motion. These are the “symptoms” or warning signs of an underlying problem. The treatment starting point has to begin with ankle bone realignment & stabilization. Failure to address the cause of these secondary conditions leads to recurrence.



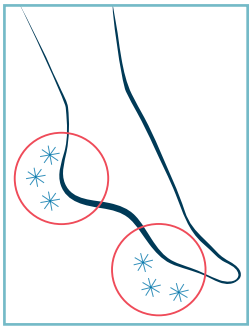
Heel pain/
Plantar fasciitis



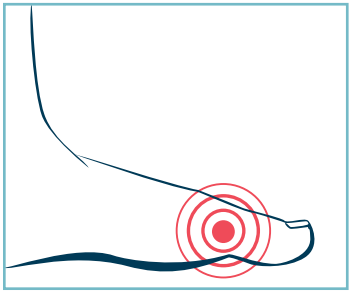
Low-arches



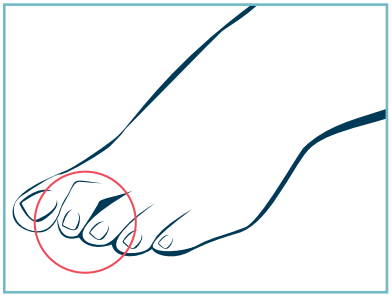
Bunions



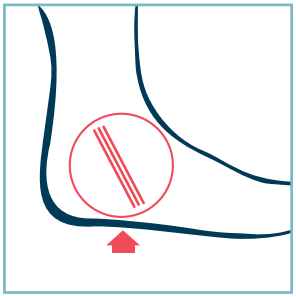
Nerve compression/
Plantar neuropathy



Limited big toe joint motion



Hammertoe(s)



Tendon over-stretching

Negative Effects to Your Body

Misaligned feet can lead to damage to the many parts of the body. When standing, walking or running, abnormal forces twist and pull at your knees, hips and back. Have you noticed that the more active you are, the more pain you suffer?

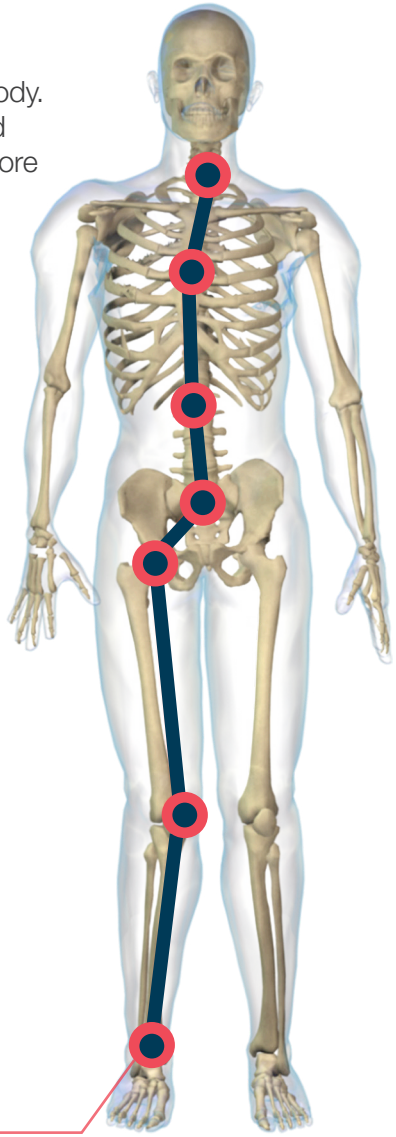
Unfortunately, millions of people experience chronic pain to their feet, knees, hips and back. Even worse are those who have surgery to repair the “wear and tear” damage only to have a recurrence of the same symptoms.

The leading complication of foot, knee, hip and back surgery is recurrence. That’s because no one properly addressed their misaligned feet.

Have you, or are you experiencing any of the following?

- Growing pains/shin splints
- Chronic back pain
- Chronic hip pain/sciatica
- Chronic knee pain
- Heel pain/plantar fasciitis
- Arch pain/posterior tibial tendon dysfunction (PTTD)
- Bunions/Hammertoes
- Numbness on the bottoms of your feet
- Functional symptoms—the more active you are, the more you hurt

A checked box is an indication that a misaligned foot could be affecting your life.



It all starts here.

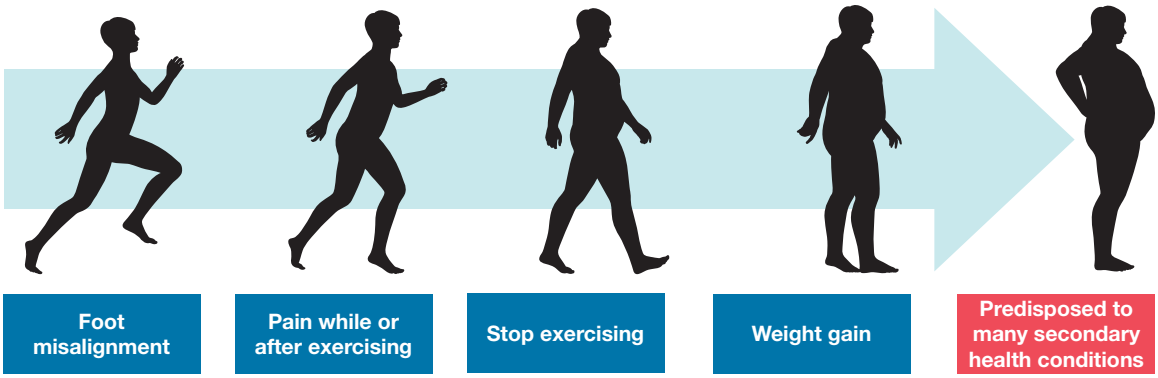
Negative Effects to Your Health

Exercise is essential to good health; it increases your body's metabolism to burn calories and improves your mental well-being. Walking is one of the best forms of exercise: it's easy, inexpensive and doesn't require any special equipment. But if you have misaligned feet, walking can be painful.

If you suffer when you walk or exercise, your body is telling you to stop. However, if you don't exercise, your metabolism drops, you don't burn calories and the next thing you know, your belt size increases. The pain from your misaligned feet has put you at risk for weight gain and its related issues.

Obesity is a major health care problem because it leads to diseases, such as:

- Diabetes
- High blood pressure
- Heart disease
- Certain forms of cancer



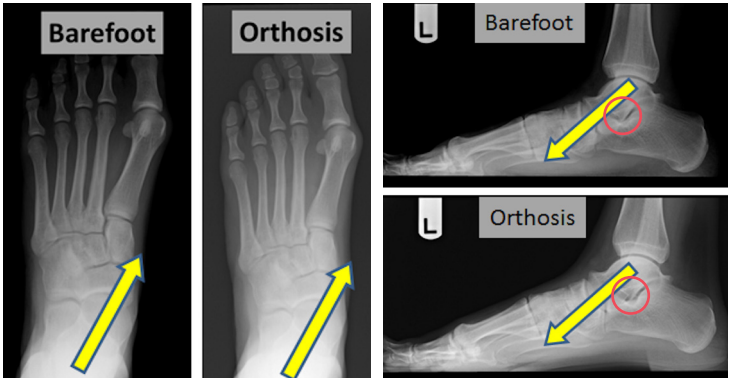
Foot Realignment Treatment Options

Observation

This represents “supervised neglect”. Foot misalignment is not a condition you can “outgrow”. It will continue to get worse as you age. It’s typically only a matter of time until a part of your body starts to hurt. If you wait too long, your treatment options will be limited.

Arch Supports/Orthotics

While they may play a role in your treatment, these devices are supportive, not corrective. As you can see in the x-rays, the sinus tarsi remains closed even with the orthotic. In fact, there is no evidence that an insert placed in your shoe will realign and stabilize the ankle bone. They provide a “false-sense” of correction.



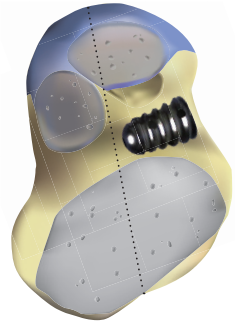
Reconstructive Surgery

Unfortunately, for many, this is the only option offered. These procedures have a long recovery, and will require additional surgery to remove painful screws and plates. There are several risks and potential complications. Many times other joints of the foot will need to be fused. This is an irreversible treatment option.

Subtalar Arthroereisis

Arthroereisis is a **joint blocking procedure** where an implant is placed into the outer portion of the sinus tarsi.

Due to repeated forces acting on the implant, there is a high likelihood that it will become dislodged and therefore need to be removed. Depending on the design, these implants have removal rates of up to 100%.



Arthroereisis devices are placed into the outer area of the sinus tarsi.

This x-ray shows an arthroereisis device that has been partially drilled into the heel bone.

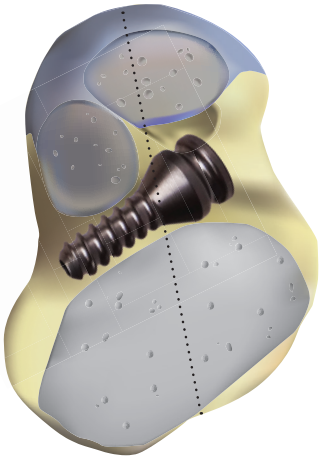
The EOTTS with HyProCure® Solution

The HyProCure titanium stent acts differently from the joint blocking arthroereisis devices. **It is not a joint blocking device.** It stabilizes the ankle bone, yet allows **normal joint range of motion.** It has the greatest success rate compared to other "similar" devices because of it's anatomic fit and improved biomechanic function. Published removal rates are less than 10%.

HyProCure is used in both pediatric and adult patients. While it is often the only form of treatment required, some patients may require the use of an arch support or additional surgical procedures to address other parts of the foot.

HyProCure is scientifically proven to:

- Internally realign & stabilize the ankle bone
- Have the highest success rate (> 90%)
- Positively affect tendons and nerves
- Normalize misaligned hindfoot bones
- Reduce high pressure areas to the bottom of the foot
- Improve arch height



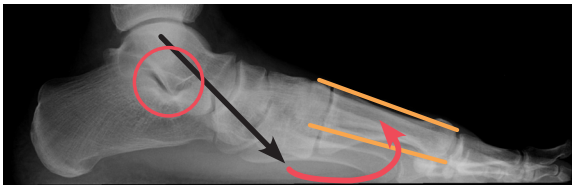
Positive Effects

- Offers a long term solution for misaligned feet
- FDA cleared since 2004
- Stent of choice by leading orthopedic and podiatric surgeons around the world
- Permanent yet reversible solution that is routinely used in both children and adults
- Most patients experience minimal pain and are allowed to bear weight on their feet the same day

The actual size of HyProCure is about .75 inches, which is smaller than your average paperclip.

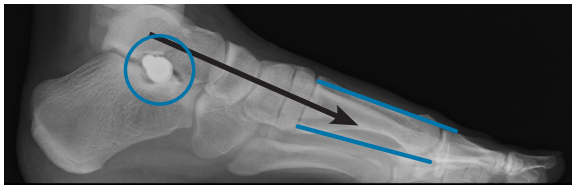
Before

Notice the abnormal ankle bone alignment. The dotted arrow is pointing outside of the normal range (shaded area) and the sinus tarsi is closed.



After

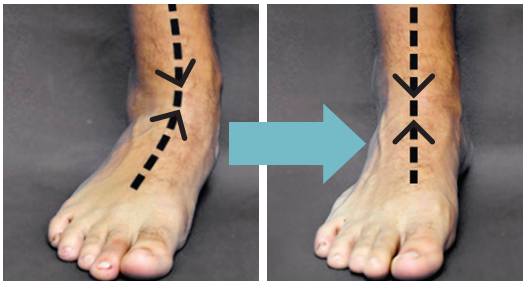
You can see how HyProCure corrects and maintains the ankle bone alignment and still allows a normal range of motion.



Are You an EOTTS with HyProCure Candidate?

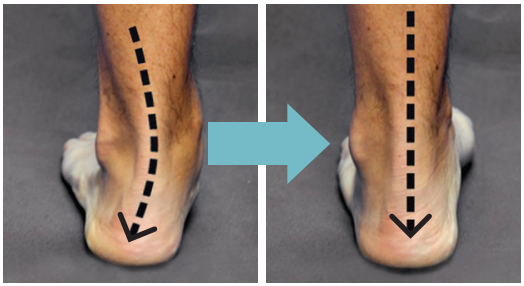
To be considered as a candidate for the EOTTS with HyProCure procedure you need to have a flexible, reducible condition and be 3 years of age or older. While there are many other factors that must be taken into consideration, being able to reposition your ankle bone back onto the heel bone is the starting point.

1



If your ankle bone turns inward, can you straighten it?

2



If your heel turns outward, can you straighten it?

3

If you have a low arch, can you recreate it?

Note: Not all patients with ankle bone displacement develop a lower than normal arch.

HyProCure Advantage Facts

- FDA cleared in 2004, CE marked in 2006
- Available for use in over 60 countries
- Used by leading orthopedic and podiatric surgeons
- Performed on tens of thousands of patients–both pediatric and adult
- Used as a stand-alone or in combination with other treatment options
- Proven to have the highest success rate (> 90%)
- Backed by extensive, evidence-based scientific papers

Frequently Asked 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.

After the EOTTS with HyProCure procedure, will I need to be pre-medicated prior to dental treatment or other future surgical procedures?
The HyProCure stent is not embedded into the bone, so you should not need to pre-medicate prior to dental or other surgical procedures, unless there are pre-existing reasons. Check with your health care provider.

Will this implant get rid of all of the pains in my body?
This solution should help improve your body's alignment. Therefore, pain caused by the foot imbalance will also be reduced or eliminated. However, it is possible that some joints and soft tissues may have already suffered irreversible damage and other procedures may be necessary. In either case, correcting the root of the problem is still essential to stopping any further damage and allowing for any additional therapies to be long lasting.

Will I still have to wear my arch supports after the procedure?
Orthotics may still be required after the procedure. Orthotics can be used to support other parts of the foot.

Do both feet need to be realigned for EOTTS with HyProCure to be effective?
Yes, if both feet need to be stabilized. Compare it to the tires on your car. If you only balance the tires on one side, it would have a negative impact on the alignment. The same goes for your feet. However, it is generally recommended to correct one foot at a time, when possible.

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 below the outer ankle bone and the stent simply slides into place. The threads on the stent are only there to allow the tissue to anchor it in place during the healing process.

Are there any limitations after this procedure?
Once the tissues surrounding the stent are healed, there should be no limitation.

If this procedure is performed on a child, does it have to be replaced later in life?
If the most common adult size is placed into a child's foot, then it is unlikely it will have to be replaced upon maturity.

What are the chances of having an allergic reaction to this implant?
HyProCure is made of medical grade titanium, which is the least reactive in the human body. 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?
HyProCure takes a minimum of 4-6 weeks to become anchored within the sinus tarsi. Displacement rarely occurs after 6 weeks. Running or jogging should not be attempted until 6 weeks after the procedure. Ultimately, the final clearance comes from the foot surgeon.

Published Studies

- Subtalar Joint Arthroereisis in the Management of Pediatric Flexible Flatfoot: A Critical Review of Literature. Foot & Ankle International, Volume 32, 12:1127-1139, 2011.
- Stabilization of Joint Forces of the Subtalar Complex via HyProCure. Journal American Podiatric Medical Association, Volume 101, No. 5, Pages 390–399, 2011.
- Radiographic Evaluation of Navicular Position in the Sagittal Plane – Correction Following an Extra-Osseous TaloTarsal Stabilization Procedure. Journal of Foot & Ankle Surgery, Volume 50, Issue 5, Pages 551–557, 2011.
- Effect of Extra-Osseous Talotarsal Stabilization on Posterior Tibial Nerve Strain in Hyperpronating Feet: A Cadaveric Evaluation. Journal of Foot & Ankle Surgery, Volume 50, Issue 6, Pages 672–675, 2011.
- Effect of Extra-Osseous Talotarsal Stabilization on Posterior Tibial Tendon Strain in Hyperpronating Feet. Journal of Foot & Ankle Surgery, Volume 50, Issue 6, Pages 676–681, 2011.
- The Effect of HyProCure on Tarsal Tunnel Compartment Pressures in Hyperpronating Feet. Journal of Foot & Ankle Surgery, Volume 50, Issue 1, Pages 44–49, 2011.
- Evaluating Plantar Fascia Strain in Hyperpronating Cadaveric Feet Following an Extra-Osseous Talotarsal Stabilization Procedure. Journal of Foot & Ankle Surgery, Volume 50, Issue 6, Pages 682–686, 2011.
- Talotarsal Joint Displacement–Diagnosis & Stabilization Options. Foot & Ankle Quarterly, Volume 23, Issue 4, Pages 165–179, 2012.
- Extra-Osseous Stabilization Devices: A New Classification System. Journal of Foot & Ankle Surgery, Volume 51, Issue 5, Pages 613–619, 2012.
- Extra-Osseous Talotarsal Stabilization Using HyProCure in Adults: A 5-Year Retrospective Follow-Up. Journal of Foot & Ankle Surgery, Volume 51, Issue 1, Pages 23–29, 2012.
- Extra-Osseous TaloTarsal Stabilization Using HyProCure: Preliminary Clinical Outcomes of a Prospective Case Series. Journal of Foot & Ankle Surgery, Volume 52, Issue 2, Pages 195–202, 2013.
- Plantar Pressure Distribution in a Hyperpronated Foot Before & After Intervention with an Extra-Osseous Talotarsal Stabilization Device – A Retrospective Study. The Journal of Foot & Ankle Surgery, Volume 52, Pages 432–443, 2013.
- Congenital Talotarsal Joint Displacement & Pes Planovalgus. Clinics Podiatric Medicine & Surgery, Issue 30, Pages 567–581, 2013.
- Ligament Structures in the Tarsal Sinus and Canal. Foot & Ankle International Volume 34: 1729-1736, 2013.
- The Effect of Subtalar Joint Position on Dorsiflexion of the Ankle/Rearfoot Versus Midfoot/Forefoot During Gastrocnemius Stretching. Foot & Ankle International Volume 35: 63-70, 2014.

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