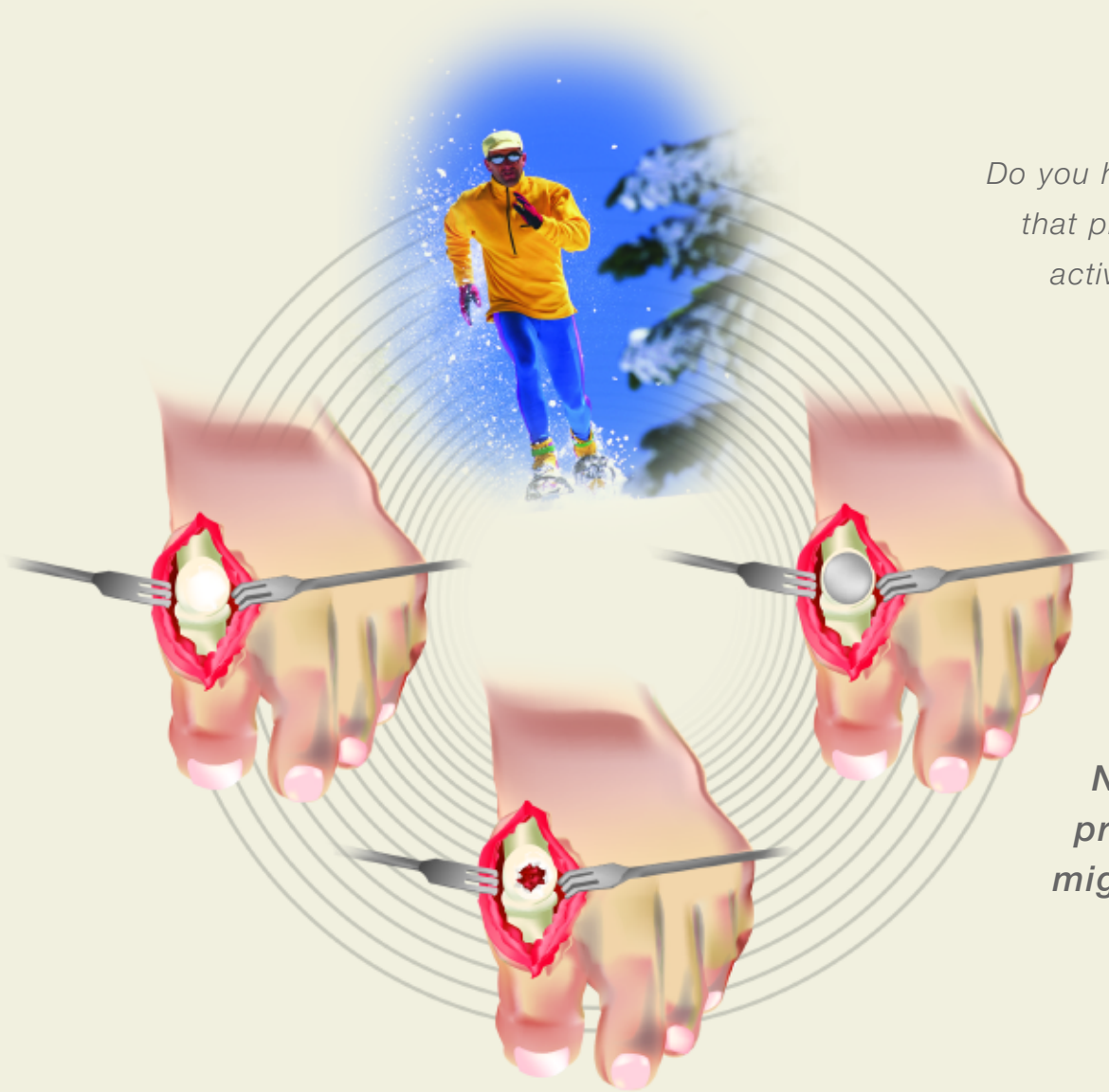
Toe Resurfacing & *Joint Preservation*



Do you have pain in your great toe that prevents you from doing the activities of daily life?

Has your doctor told you that you might need surgery or a fusion?

Now there is a joint preserving solution that might be right for you.

Anatomy

Have you become frustrated because of the limitations of a painful toe?

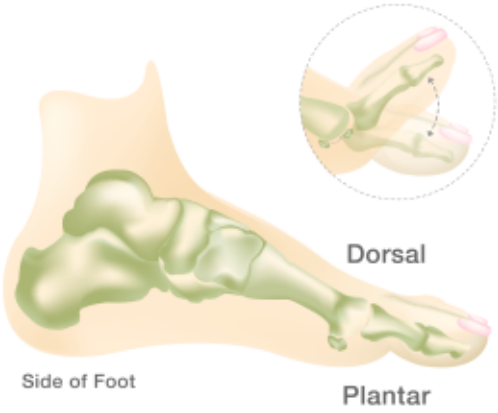
Before we begin to explain a possible solution, it is important to understand the problem.

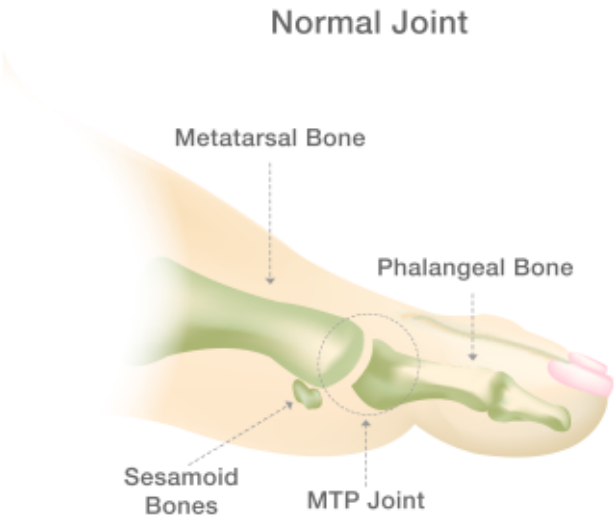
Anatomy of the great toe.

The great or big toe is an important part of how we walk. It needs to bend with every step we take. It has a major joint at its base called the metatarsal-phalangeal joint or MTP joint. The MTP joint is where the metatarsal and phalangeal bones meet and articulate with one another. The ends of these bones are covered with a smooth articular cartilage that helps the bones move together freely.

How does cartilage get injured?

A variety of events can damage cartilage; some include trauma (injury), infection, inflammation, and malalignment. A traumatic injury can cause an isolated defect. Malalignment of the 2 bones can cause more widespread damage to the joint surfaces similar to the way the tires on a car lose their tread if the wheels are not properly aligned.





Can arthritis get worse?

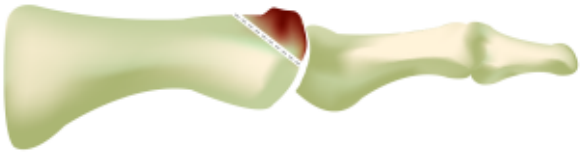
Any event that injures the cartilage may cause joint damage or arthritis. A small cartilage injury with time may become larger and lead to widespread cartilage loss or degenerative joint disease. Typically as the “wear and tear” on the MTP joint progresses there are bone spurs or osteophytes that form on top of the bones. These bone spurs (osteophytes) can impede the motion of the joint which can lead to a painful condition called Hallux Limitus or Hallux Rigidus.

What are treatment options for Hallux Rigidus and injured cartilage?

Depending on the degree of cartilage injury, age and activity level, patients may be candidates for either a cheilectomy, arthrodesis (fusion), total joint replacement or now with the advent of resurfacing technologies, a joint preserving procedure such as the Arthrosurface HemiCAP® system.

What about a Cheilectomy?

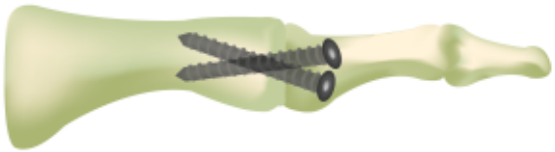
This technique involves making a diagonal resection of the top (dorsal) portion of the metatarsal head to remove the osteophytes as well as up to 40% of the dorsal portion of the joint surface. This is a fast and easy operation to perform but is only good when there is little of the joint surface involved. It has been reported that approximately 30% of patients will progress toward more arthritic changes. X-rays often underestimate the extent of the disease at this stage.



Cheilectomy

What about a Fusion or an Arthrodesis?

A fusion is a procedure where the metatarsal bone and the phalangeal bones are set at a predetermined angle and permanently fixed with 2 metal screws. This procedure does provide pain control and is appropriate when the arthritic changes involve the sesamoid bones. However, it also limits shoe wear especially in women and may limit activities such as running, golf, tennis and certain jobs. It may also increase the stress on the next toe over time. It may be considered an appropriate treatment for the older sedentary (less active) patient.



Arthrodesis (Fusion)

A Patient's Story

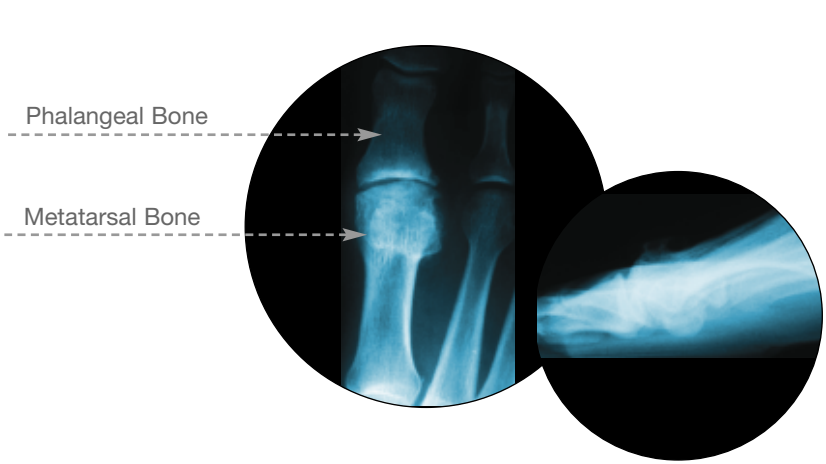
"For the last two years the pain in my foot got progressively worse, so much so, that I started to change the way I walked just so I could avoid walking on my toe. When I started walking on the outside of my foot I ended up getting neck and back pain as well, which just made matters worse. I'm a carpenter and so I spend a lot of time going up ladders, bending, kneeling and reaching into difficult places. The pain got so bad I could no longer do my job and that's when I decided to go see a specialist. When I first saw my surgeon he told me that my only option to get rid of the pain was a fusion. Even though it sounded pretty drastic, I decided to have the surgery. Being a carpenter I am very familiar with the concept of fusing things together and so I knew that I would end up loosing most of the movement in my toe. Not a great option, but at that point there was nothing else that would take care of my pain.

As fate would have it, just days before my surgery, my surgeon advised me that there might be another option. He told me about a product called the HemiCAP® which was an implant that would replace the arthritic part of my joint and give me a new surface. I could avoid getting a fusion, keep the movement of my toe and if it worked as planned I would get pain relief. Even though it was new for the toe, the HemiCAP® implant had already been used successfully in several hundred patients in the hip, shoulder and knee. Deciding to try it wasn't a difficult decision, especially given my other choice, a fusion.

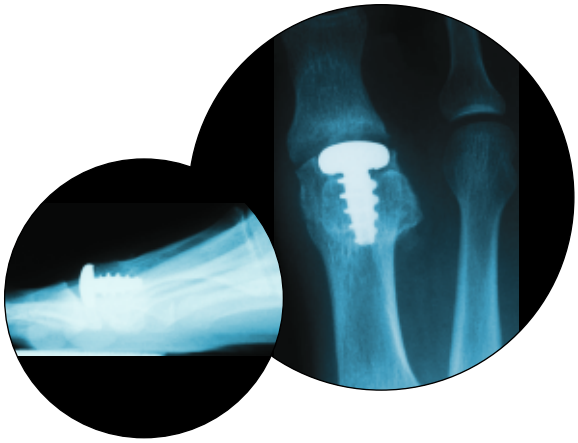
Well it's now been a few months and I couldn't be happier. I can bend, jump, walk up ladders and after 6 weeks I was walking 3 miles a day, 5 days a week! Two weeks after surgery my swelling was down, my pain was virtually gone and I had the movement back in my toe. The strangest thing was that I had to learn how to walk on my toe again. Seven weeks after surgery I was working and doing all those things I hadn't been able to do for years. The best part was that I didn't have any more pain in my neck or back either. When I decided to have surgery I never expected that it would turn out this good. The fact that I have no more pain and still have my movement is just fantastic."

– J.R., Pennsylvania

Many patients treated with the HemiCAP® device experience relief from pain and symptoms, however individual patient results will vary. Consult your physician to see whether this treatment is right for you.



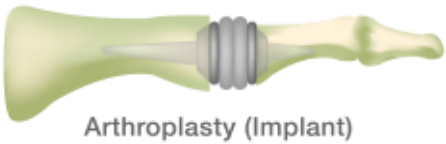
Preoperative X-rays



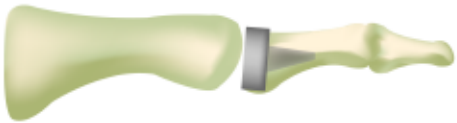
Postoperative X-rays

What about Total Toe Joint Replacement?

This is major surgery designed to relieve the pain of widespread arthritis. The implants can be made of metal and plastic and some have been made of a silastic (silicone) compound. There is a lot more bone and cartilage removed which may make a future salvage operation much more difficult. Clinical studies have shown that the debris caused by the breakdown of the silastic (silicone) and polyethylene parts in these implants may lead to problems in the joint. In addition, it can be difficult to balance the soft tissue/ligaments which can result in partial dislocation of the bones (subluxation).



Arthroplasty (Implant)

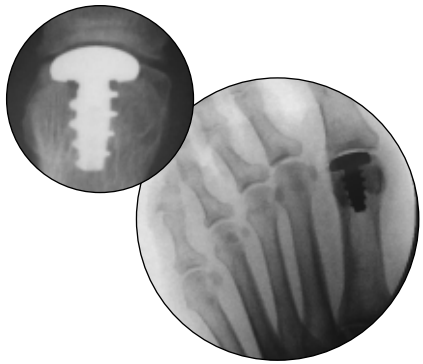


Metal Hemi Toe (Implant)

HemiCAP® Implant

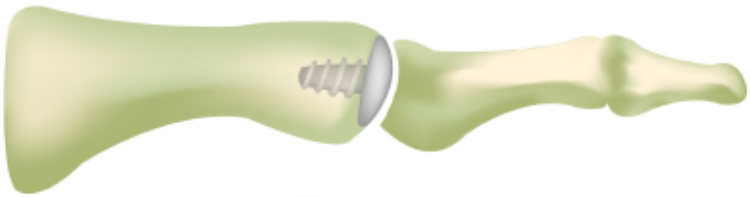
What about the Arthrosurface HemiCAP® implant?

The HemiCAP® implant is a technologically advanced system designed to match the shape and contour of the individual patient's cartilage surface. It is a "contoured CAP" for an area of damaged cartilage designed to protect the remaining, normal cartilage in an attempt to prevent further damage to the joint while maintaining the patient's range of motion. The HemiCAP® system is indicated for use in the treatment of patients with the following clinical conditions: hallux rigidus, hallux limitus, hallux valgus and an unstable or painful MTP joint.



HemiCAP® Implant

The HemiCAP® system matches not only the diameter of the damaged area but also the precise radius of both curvatures of the patient's joint surface (top to bottom) **dorsal** to **plantar** and (inside to outside) **medial** to **lateral.** The technology for mapping the joint curvatures comes from eye surgery where it was used to make products to protect the corneal surface. The mapping is done in the operating room by the surgeon. Once the mapping points are defined, an appropriately sized implant is chosen and then implanted into the patient. Different diameters & curvatures are available to provide a proper fit for each individual patient.



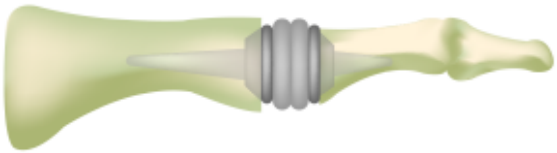
HemiCAP

How is this different than existing devices?

The HemiCAP® implant:

- Is custom matched and fit to a patient's joint size and shape.
- Removes a much smaller amount of cartilage and bone than traditional joint implants.
- Is placed "into" the surface leaving the joint less surgically altered.
- Preserves joint motion versus a toe fusion.

Existing devices

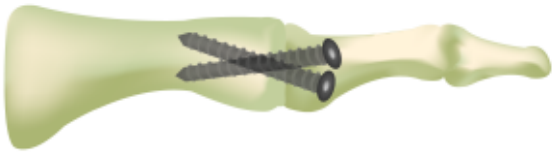


Arthroplasty (Implant)

May lead to future joint problems due to wear debris from plastic or silastic components.

Metal Hemi Toe (Implant)

Does not resurface side of the joint that typically shows arthritic change.

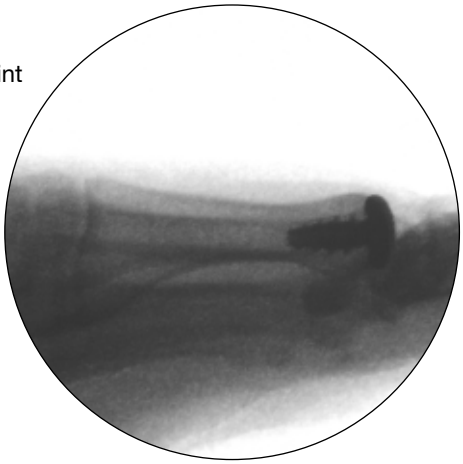


Arthrodesis (Fusion)

Typically provides pain relief but takes away motion of the joint.

Why is the HemiCAP® placed on the metatarsal side?

The HemiCAP® implant is unique in that it is designed for the metatarsal side of the joint where the arthritic changes begin and which generally has more wear and tear on it. Other hemiarthroplasty devices replace only the end of the phalangeal side which may still have good remaining cartilage and do not address wear on the metatarsal side.



HemiCAP® Implant

What happens if it fails?

If it ever fails, it may be replaced with total joint replacement or, if necessary, it may be easily converted to a fusion.

Does it "burn any bridges?"

Compared to existing toe implants there is minimal bone removal with the HemiCAP® implant. With existing joint replacements, the entire bony surface, sometimes even both sides of the joint, are surgically removed to facilitate the implant being placed. This means there is far less of the natural bone to work with if future surgery is required. The HemiCAP® system leaves more bone intact therefore provides more options should future surgery be required.

Will I feel it?

No. The implant is surgically placed using precision instrumentation. Your surgeon will map your joint intraoperatively so that the implant will articulate with the sesamoids and phalangeal bones as they did originally. The bone and the implant become a smooth surface you will not feel.

How long will I be off of work?

This will be dependent on your overall health, range of motion and the type of work you do. Many patients have experienced a rapid return to daily activities. However, as with all medical treatments, your results may vary.

What type of physical therapy will I need to do?

Your doctor and therapist will design a rehabilitation protocol to return strength to your foot so that you can return to your original lifestyle.

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