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The Monocusp

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The Monocusp

Pioneering a New Treatment for Chronic Venous Insufficiency Disease

By Dan Walker

Varicose veins affect millions of Americans, both women and men. The condition frequently results in unsightly gnarled, enlarged veins that may cause aggressive leg pain, restless legs syndrome, general leg discomfort, leg swelling and the inability to fit into shoes.

For many, the condition deteriorates to a point where routine daily activities like standing and walking can become difficult if not impossible. As blood continues to pool and exert pressure on the lower extremities, it can cause swelling, discoloration and inflammation of the leg and foot, as well as painful venous stasis ulcers that can be extremely difficult to heal.

Several treatments and therapies exist for relieving the symptoms of superficial varicose veins, but nothing exceptional exists as a permanent cure for deep venous incompetence ... until now.

For the past four years, two noted Scottsdale cardiovascular and thoracic surgeons, John C. Opie, M.D., FRCS, FRCS(C), and Dale N. Payne, M.D., Ph.D., FACS, have developed what they call monocusp surgery for otherwise uncorrectable chronic venous insufficiency (CVI) with aplastic/dysplastic (unusable) valves. The in-hospital operative procedure introduces a novel viable monocusp valve into the vein. So far, 14 patients have received 17 surgeries (three patients had staged bilateral operations) and their progress followed for the past five years. A paper with their findings will soon appear in the *Journal of Phlebology.*

MEDICINE'S AGE-OLD CONUNDRUM

For almost as long as recorded history, humans have suffered from varicose veins. The Ebers papyrus, scribed in Egypt during the days of Pharaoh Amenhotep's rule more than 3,500 years ago, outlines in detail the "serpentine dilations" observed in varicosed lower limbs. A millennium passed before Hippocrates took on the subject — he could arguably be called the first physician to complete an early derivative of minimally invasive endovenous vein ablation surgery, a feat he certainly performed without anesthesia.

More modern thinking about the condition didn't emerge until 1525, when a French physician introduced the use of compression bandages from the foot to the knee for managing weeping skin ulcers of the ankle — a common complication of CVI. This treatment modality is still in use today in the widely prescribed Unna boot, a management therapy now over 150 years old.

In 1860, Dr. Pravaz invented a specialized syringe and gave birth to sclerotherapy, a relatively effective nonsurgical treatment for sealing smaller varicose veins.

Still, medicine seeks cures, not containment. But CVI defeated everyone. In 1904, Dr. Charles H. Mayo began surgically stripping varicose veins using a vein enucleator of his own design — a ¼-inch ring of steel with a long handle. Other techniques included saphenous vein ligations and vein transplants, as well as occasional attempts at repairing venous valves. In 1966, Dr. John Kistner described a surgical technique to repair valves that were repairable. That procedure only works in cases where there are still valves in repairable condition. What if the valves are nonusable or absent? Sympathy, a pat on the back, an Unna boot, failed skin grafting or an amputation may not be enough in an advanced world of I-phones, DVDs and the Internet. Surely, there had to be a solution for a 4,000-year-old unsolved problem.

Current outpatient surgical procedures for varicose veins such as EVLT, VNUS and sclerotherapy successfully manage the common varicose vein issues, but these treatments have no impact on CVI and the aggressive complications that are apt to develop.

"Here in the U.S., 3% or approximately 10 million patients suffer from CVI, and about half of those patients (5 million) will have active venous stasis ulcers," said Dr. Opie, "and we can probably help many of them."

iVena vascular patch (20 mm x 15 mm). Dr. Opie has a patent pending on monocusp/CVI surgery and the specialized, highly compliant vascular patch.

PHOTO BY KING LAWRENCE

FROM CHRONIC TO 'CURABLE?'

Chronic venous insufficiency says it all, really. The veins cannot adequately perform their function to overcome gravity and efficiently return blood to the heart due to failed or absent venous valves. This results in worsening reflux complications over time. Chronic implies that the condition is persistent and usually cannot be cured. That's one

reason why existing present treatment options are generally limited to supportive measures and most previous surgery attempts failed. Surgeons did not know what to do when they encountered no valves, or valves that could not be repaired. Therefore, venous valve reparative surgery was relegated to history's "dustbin." The mantra was, "CVI is an incurable curse, but the leg can always come off."

That mantra might be about to change.

It is likely too soon to start considering eliminating the word "chronic" from the condition's name, but results so far show great promise that the patent-pending monocusp procedure, invented by Dr. Opie and performed by Dr. Payne, can cure CVI once and for all. "I've performed the procedure on 17 patients over the last five years and they all seem to be doing really, really well," said Dr. Payne, who is noted for his work as heart and lung transplant surgeon. "The monocusp is a big breakthrough. We have several ways to take care of varicose veins, especially by way of laser therapy, but many of these patients need more than just taking care of their varicose veins. Those who have combined disease also need treatment of their central venous insufficiency. It's a situation where they need a new venous valve and that's what the monocusp does." The new disease name might become DVI or deep venous insufficiency (amenable to corrective surgery) — it may no longer need the term chronic.

There are a variety of causes for varicose veins and the more serious CVI: Heredity, trauma, leg-vein clots (DVT — deep vein thrombosis, gravitational forces, pregnancy, obesity and advancing age all contribute to the abnormality).

Aggressive in nature, CVI can create serious, life-altering conditions. "It creates a pooling of the blood under high venous pressure in the lower extremities," said Dr. Payne, "because the valve in the upper thigh is insufficient and is not allowing blood to efficiently return to the heart. It just stays trapped in the lower extremity and accumulates." He goes on to outline additional complications. "The pressure pushes the iron out of the red blood cells into the tissues around it, and you get hemosiderin staining, which is an iron-like reddish discoloration around the ankle skin. Once you get the iron staining, collagen also oozes out, forming a 'fibrin collar,' and the tissue starts breaking down and eventually the patient can develop venous stasis ulcers — ulcers that are likely to become chronic. If left untreated, they are painful and can lead to serious bleeding, infection and even amputation.

AMPUTATION AVOIDED

Dr. Opie presented his idea for the monocusp to Dr. Payne several years ago. "Initially, I was thoughtful about doing it," he said. Understandably so, since after more than 3,500 years of working on this problem, no one had found an approach that would work. "But the success rate in several cases he did looked really promising," Dr. Payne continued. "Then, I was presented with a patient who was about to lose his leg. So I told that person all of my doubts and everything else, but his only alternative was amputation, and so he agreed to the procedure and it worked. He went home from the hospital within three days, and everything, including his ulcer, started to heal very

PHOTO BY KING LAWRENCE

Dale N. Payne, M.D., Ph.D., FACS

fast. We checked him with periodic Doppler studies and the monocusp valve has shown no reflux." Years later, he still has his leg and his ulcer has never recurred.

Dr. Payne was so impressed that he continued to do monocusp procedures on a case-by-case basis, informing patients about the investigational nature of the surgery. "All of these patients were very desperate because of the severe nature of their disease," explained Dr. Payne. "And once we did their operations, they've all had very successful outcomes."

"It's almost unbelievable to be able to offer successful outcome surgery for such an ancient incurable disease," added Dr. Opie.

BUILDING A VALVE

In the monocusp procedure, three incisions are made in the anterior wall of the vein, creating a fingernail-shaped "flap" with an intact distal hinge. Two sets of carefully measured sutures are placed on this flap and on the walls of the vein. These sutures effectively act as "mooring lines," precisely limiting the flap's range of movement when subjected to forward or backward venous flow conditions. The opening in the venous wall left by the incision is replaced with a specialized e-PTFE (iVena) vascular patch. "The result is a single valve that is much more robust than the vein's normal valves," said Dr. Opie. "The normal valves are like a piece of cellophane — they're so thin and flimsy — it's amazing they can stand up at all to the wear and tear they receive. The monocusp is the thickness of a piece of vein wall, because it is a piece of vein wall. Due to this fact, only one valve is necessary and it has the potential to last a lifetime." Dr. Opie is currently working on a revolutionary new kind of vascular patch, which might replace the current highly compliant e-PTFE vascular patch. If the science works out correctly, this new patch will be visible on X-rays. That capacity can be important in protein-deficient patient subsets who have coagulation disorders, especially if their future involves X-ray-monitored balloon venoplasties, which must not be

done within the monocusp site. That would fracture the suspension sutures, and CVI would recur.

In addition to its stout build, the monocusp valve's origin from the wall of the vein it serves solves a more difficult problem encountered with venous vascular repairs. The main concern is the potential for the patient to develop a postsurgery DVT or a clot, which could break free and travel to the patient's lungs, a potentially serious complication. "Since the monocusp is autogenous living tissue with an intact blood supply and exposed to the correct bloodborne hormones, it should become fully endothelized, including its outer surface (now within the bloodstream) and therefore NOS (nitric oxide synthase) and thymomodulin capable," Dr. Opie explained. "These are the essential antithrombotic hormones continuously secreted by living endothelium, which together with circulating plasmin, prevent repetitive DVTs (deep vein thromboses) from occurring under normal sluggish venous flow conditions." In addition to postoperative antibiotics following the procedure, patients are put on anticoagulants for six months, followed by aspirin or Plavix for life.

Dr. Opie adds that the procedure can be done even on patients experiencing postphlebitic leg syndrome, and on patients with procoagulation enzyme deficiencies such as protein S or C deficiency, etc., provided there are no concurrent clots actually in the common femoral vein at the time of monocusp surgery. That would likely be a contraindication due to high embolic risk.

Drs. Payne and Opie are currently in the process of setting up a new institute as an international center for training other surgeons in the monocusp procedure, as well as a surgical center for identifying CVI patients who can benefit from the monocusp. "The advantage of the monocusp surgery is that, if you get a 20-mm Gore-Tex tube graft, you can actually make the incisions in the tube graft to practice the technique, and you can do the operation without a patient," explained

John C. Opie, M.D., FRCS, FRCS(C)

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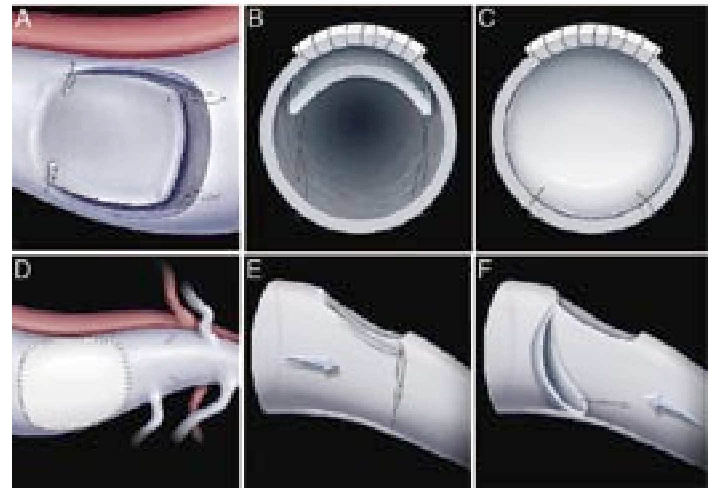

Dr. Opie, with a grin. "So once you've made the cuts, placed and tied the suspension sutures and sewn in a patch on a piece of tube graft, for a board-certified, trained cardiovascular surgeon, it's actually fairly easy to do this operation. You just need to be very careful adjusting the length of the leading-edge suspension sutures. They are key."

The institute will be based alongside their existing Scottsdale practice, which offers several treatment options for all types of venous disorders, including the highly effective endovenous laser treatment (EVLT), an outpatient treatment for certain varicose vein conditions, TCL (transcutaneous laser) and sclerotherapy for spider veins. They also have advanced Triplex Doppler ultrasound technology, which is critical to accurately locating and precisely identifying the severity of the various venous disorders, including CVI.

The institute is already receiving calls from doctors in California and Colorado and Texas, looking to refer their CVI patients for the new monocusp procedure. "Once the paper is published [in the *Journal of Phlebology* — distributed worldwide], we expect to be fielding calls from all over the world," Dr. Opie anticipated.

With the monocusp potentially set to revolutionize CVI surgical treatment somewhat similar to the way that endovascular arterial stents revolutionized arterial surgery, Drs. Payne and Opie are preparing both for the referrals and surgeons that will come to Scottsdale and the Advanced Vein Institute. They believe this is serious treatment for a serious disease. "Somewhere between 20-50% of the world's population suffer from all kinds of venous diseases and 3% suffer CVI," said Dr. Payne. "That's millions of people that may one day benefit from monocusp surgery. It's incredibly exciting to think that what we're doing can help that many people."

Dale N. Payne, M.D., Ph.D., FACS, and
John C. Opie, M.D., FRCS, FRCS(C)
(480) 861-9292
10290 N. 92nd St., Suite 300
Scottsdale, AZ 85258
www.gotveinpain.com ■