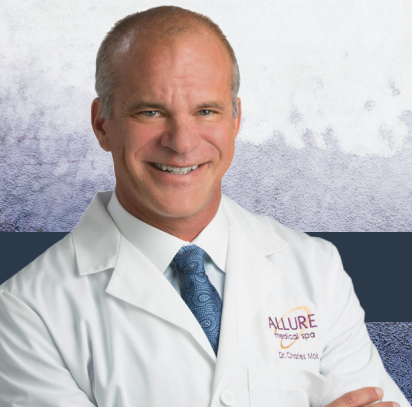
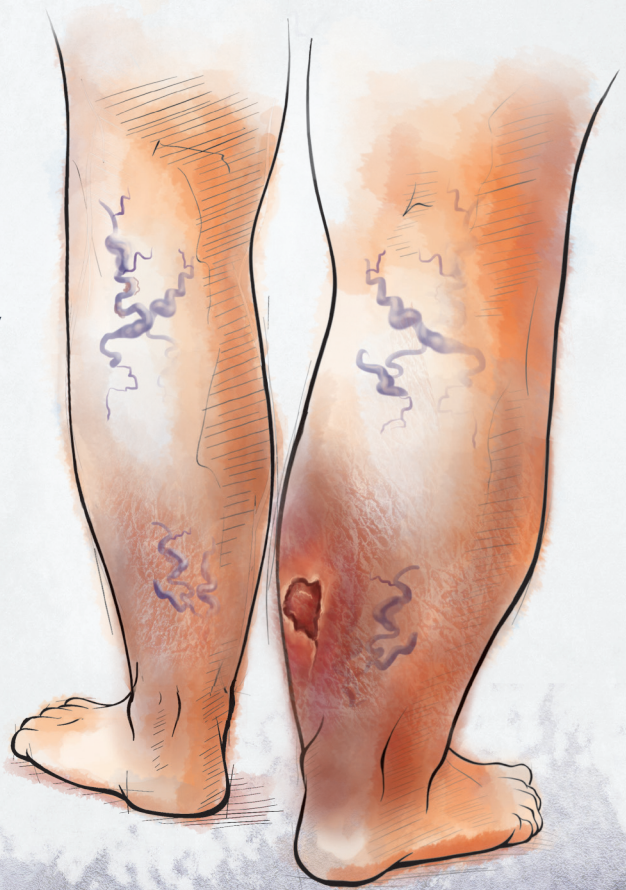


Cure Your Leg Pain For Good

The truth about varicose veins, venous insufficiency & options for curing vein disease.



DR. CHARLES MOK



“We believe in curing vein disease, not just managing its symptoms. Old treatment methods are putting a huge burden on our nation’s economy and causing patients unnecessary suffering. It’s time we make a much needed shift in healthcare.”

Dr. Charles Mok,
Founder of Allure Medical

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INTRODUCTION

To give a very brief overview of how the practice of managing varicose veins in venous insufficiency has evolved, I'll tell you a story.

I first started treating varicose veins with ultrasound-guided sclerotherapy. This is something that came over from Europe as a solution for or an alternative to the conventional surgical stripping of saphenous veins and varicosities. French and other European doctors had noted that if they treated the saphenous reflux with liquid sclerotherapy, it wasn't as effective as surgical stripping. If these sclerotherapy solutions are turned into a foam, however, they were about as effective as surgery for long-term resolution of saphenous reflux. Numerous papers (that I won't review here as this has evolved so much) showed almost even effectiveness; in some cases, these European methods were superior as far as patient satisfaction went.

I then decided to start treating patients with venous insufficiency. In 2004, when I started this practice, lasers and radiofrequency weren't approved for insurance coverage, so I did pretty extensive research and became an expert at foam sclerotherapy for the treatment of varicose veins. I had the only practice in the Midwest that offered this novel alternative to surgery.

We grew rapidly because we had no competition. Yes, at the time, there were certainly surgeons who were cutting out veins, but we were standing alone saying "we're different!" When

people can see that you're doing something different, they get an opportunity to investigate what exactly you're doing and find out that you're offering a better service. Anyone can say they are better, but different is something that gets noticed. It is a secret to our success. We can deliver better by being different.

I started attending various venous disease meetings where the new lasers and radiofrequency devices were being presented. At that point, the manufacturers had gotten FDA approval; then, insurers started paying for the procedure since the laser- and radiofrequency-based methods were found to be superior to surgery. Interestingly, I treated 10 patients who had bilateral venous insufficiency by using foam on one leg with a catheter and tumescent—in other words, it was chemical ablation but treated the same way as we do now with the laser. In the other leg, I treated those ten patients with a 1320 nm CoolTouch laser, which was the best laser available at the time.

At the one-year mark, both the laser-treated leg and the foam-treated leg had the same outcome. The foam was much less expensive, but Blue Cross and other carriers had approved paying for the laser treatments—which were expensive and cost insurers a lot of money—and then decided that foam sclerotherapy was “experimental” and that they, therefore, wouldn't cover foam treatments for saphenous reflux. They still cover for foam treatments for varicose veins, but not for saphenous reflux.

We switched over to CoolTouch for ablation of the saphenous reflux and did sclerotherapy for associated varicosities. At that time, I never did any microphlebectomies, because I was differentiating us as a nonsurgical vein practice, and although

the surgical removal of the varicosities is a reasonable option, my patients were coming to me because they did not want to be cut.

I did a study comparing the radiofrequency device to the laser device: I treated one hundred patients with bilateral disease using laser on one leg and radiofrequency on the other. The outcomes were pretty much the same. They had the same postoperative comfort or discomfort and the same procedural comfort or discomfort. Neither leg had any significant complications. In the end, performing the procedure with the laser was a little easier—plus I already had the laser machine, whereas I had to purchase/rent the radiofrequency generators—so I stuck with laser.

About two or three years ago, the radiofrequency device company came to me and offered us the radiofrequency generators too. Since there was no ethical concern because I knew that scientifically, the two procedures had the same outcome, I decided to start using the radiofrequency devices so that I didn't have to buy more generators as we grew our offices.

What we observed years after our first study was that radiofrequency patients had less postoperative pain than our laser patients typically did. Both were very minimal, but in that regard, the radiofrequency is superior. And after doing the radiofrequency procedures consistently, we've been able to see that the outcomes are identical, so from time to time, we may change between laser treatments and radiofrequency treatments. I consider them to be equally highly effective. Certainly, either is superior to traditional old-fashioned surgery.

Early on, we were a “varicose vein” practice. We saw some



Jerry 2006



Jerry 2016

patients with significant disease, as in the case of Jerry.

Jerry had extensive blood clots with some outflow obstructions and extremely ugly legs: one of his legs was about two times or three times as big as the other leg, and he had ulcerations and skin changes. He was pretty much incapacitated and got around in a wheelchair or with a walker. He had had prior stripping of the saphenous system in 2006. Over a period of about a year, I treated 16 of his perforators. He brought his daughter in to see me in 2016, and while he was in my office with her, I took a look at his legs. They're now both the same size and free of ulcerations. He has no more pain. His wife was telling me that now he can walk around the yard, do chores, and is very active, none of which he never thought he would be able to do again.

Jerry's case led me to hyperfocus on "ugly legs." This group of "ugly leg" patients is a group of patients that nobody in our market

is paying any attention to. They are left to suffer from venous insufficiency, and because their legs are ugly and they have comorbidities, doctors are telling them to “just live with it” so that the doctors can focus on patients with “pretty legs”—that is, patients who have a normal appearance and some varicose veins.

Our business is a business. It is a medical practice, yes, but we have to run it like a business to stay in business. So instead of offering “everything to everybody.” We are focusing in on the group of patients that are being ignored or mistreated.

“The cost of “ugly legs” is \$14.9 billion annually in the form of wound care. \$6 billion alone on dressings.”

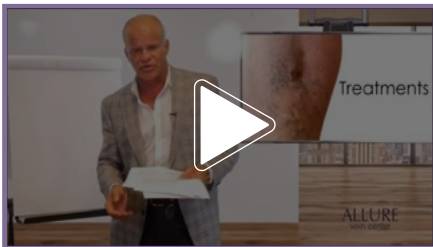
I'll review this in a later chapter, but right now, the cost of “ugly legs” is \$14.9 billion annually in the form of wound care. \$6 billion alone on dressings. And wound care is a band aid. Venous ulcers account for 50% of all wound care visits, and they recur in a couple of years in the majority of case. The American Society of Vascular Surgery, and the American Venous forum have published clinical guidelines spelling out that the proper management of “ugly legs” is treated venous reflux with endovenous ablation, and that conservative management is inappropriate. Far less than 1% of venous ulcer patients are even offered this.

Let me emphasize this. Management of “ugly Legs” with wound care costs the US \$14.9 billion a year and climbing. Wound care of ulcers takes about seven months to resolve the wounds, and about 80% return in a few years. Whereas identifying and curing

the cause leads to the wounds healing in about 2-3 months, with less than a 5% recurrence rate. And last year we spent about \$50 million on treating the cause of vein ulcers, and almost \$15 billion managing this chronic disease.

The vast majority (about 95%) of vein care is for “pretty legs” without skin breakdown. That was about \$2 billion last year in US health care expenditures. This is ultimately a good investment because of more minor venous disease such as individuals with varicose veins and minor symptoms such as heaviness progress at about 4% a year. With public awareness, physician education updates, we will see fewer venous stasis ulcers in decades to come, but right now, based on how we are currently treating vein disease, it is a growing problem. It is estimated that the wound care management of venous ulcers will top \$20 billion in about eight years.

Since everybody else is treating all cases of venous disease, we have chosen to focus on treating people with more advanced disease—although it’s a smaller segment of the market, they have no alternatives. We are their beacon of hope. Again, a classic example of this is Jerry. He told me he had been to several vascular surgeons and that they all turned him away because his legs were so bad. He said, “They all told me they could do nothing for me.” And he was sent to wound care.



Click to watch video

Dr. Charles Mok explains the economic impact vein treatment has on our nation.

SECTION 1

CLASSIFICATION OF VENOUS DISEASE

CEAP is the classification used by most specialists who treat venous insufficiency. While it is not universal, about 60% of practitioners use this classification, and more and more third-party payers will be adopting this language. The CEAP is a classification of chronic venous disorders, not varicose veins.

This section will primarily review the “C” of CEAP. The other components are covered in different sections.

C: Clinical

- C0: No signs of clinical disease
- C1: Telangiectasia or reticular veins
- C2: Varicose veins
- C3: Edema or swelling
- C4: Skin changes without ulceration
- C5: Healed ulceration
- C6: Active ulceration

E: Etiology

- Ec: Congenital
- Ep: Primary (typical)
- Es: Secondary, typically prior DVT

A: Anatomy

- As: Superficial
- Ad: Deep
- Ap: Perforator

P: Pathophysiology

- Pr: Reflux
- Po: Obstruction

STAGES OF VEIN DISEASE

C1 - Spider Veins



Spider veins are a dilated group of veins that appear close to the surface of the skin.

C2 - Varicose Veins



Varicose veins are enlarged and twisted. When they leak, swelling can occur and settle in the ankles.

C3 - Swelling



Reticular varices can cause more discoloration over time and more significant swelling.

C4 - Skin Changes



Chronic venous insufficiency can cause more extreme skin discoloration and texture.

C5 - Healed Ulcer



The active ulcer has healed, but symptoms of chronic venous insufficiency are still present.

C6 - Venous Stasis Ulcer



Open ulcers can be painful and do not heal without proper treatment.

The C4 to C6 patients are the most underserved; they are our primary focus. We use the term “ugly legs” to describe these individuals because our peers in healthcare are not aware of the CEAP classification and are largely unaware of the scope of chronic venous insufficiency. This is evidenced by the fact that almost \$15 billion is spent annually in treating wounds associated with venous insufficiency. This is also in the face of the fact that most ulcers treated with conservative management will recur, while ablation of saphenous and perforator reflux reduces recurrence to below 5%. In 2016, US healthcare expenditures on treating perforator veins (which are responsible for venous ulceration) amounted to only \$51 million. Again, we have a national problem that costs \$15 billion to chronically manage...But only \$51 million was spent to cure the underlying disorder.

This section will clarify some misunderstandings about the “C” in the CEAP classification. We will also review some of the characteristics that may be not fully understood when the CEAP classification was

“We use the term “ugly legs” to describe these individuals because our peers in healthcare are not aware of the CEAP classification and are largely unaware of the scope of chronic venous insufficiency.”

“Almost \$15 billion is spent annually in treating wounds associated with venous insufficiency.”

developed in 1994, so we can better predict who will benefit from early intervention, vs. waiting for wounds to develop and treating them with wound care.

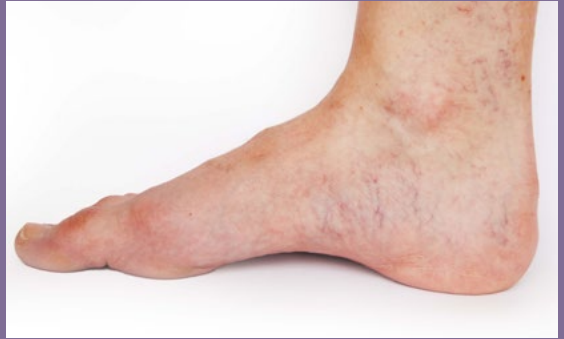
C1 is patients with spider veins and small reticular veins. These are purely cosmetic. We don't typically attract this type of patient, and this is not our core business, so that I won't discuss the C1 classification here.

C2 would be patients with varicose veins that are either asymptomatic or only cosmetic. A big part of the market in the varicose vein industry is managing these patients. Probably very few people with just varicose veins have no symptoms—when we talk to them, we find that they do indeed have symptoms such as heaviness and fatigue. But in reality, patients with heaviness and fatigue generally have those symptoms as a result of edema, which makes them a C3. In some cases, the C3 classification is not evident during the physical exam, particularly if you examine them in the morning. It would be reasonable, therefore, to have them come back in the evening; however, this is impractical. That being the case, we can rely on the patient history instead: if they have symptoms of swelling, they are a C3.

C4 refers to skin changes without evidence of ulceration. There are various types of skin changes. A common one would be eczema of venous stasis (or a dermatitis, more or less). There is also discoloration and brown spots, and then there is a condition called corona phlebectatica.

Corona phlebectatica refers to tiny blue or red veins located near the ankle and in a specific type of pattern.

**Mild
Symptoms**



**Moderate
Symptoms**



**Advanced
Symptoms**



The CEAP classification system was developed over 20 years ago. Since that time, there have been attempts to more clearly define what types of corona phlebectatica belong in which C classification.

These are clearly skin changes, but different types of corona phlebectatica and even different colors represent the extent of venous disease differently.

“Clinical and Hemodynamic Significance of Corona Phlebectatica in Chronic Venous Disorders” in the 2005 edition of the *Journal of Vascular Surgery* evaluated the hemodynamic nature associated with corona phlebectatica. They found that patients who had corona phlebectatica regardless of location had features seen in C3 disease. They recommended classifying patients with corona phlebectatica—even as a sole finding in conjunction with leg symptoms—as a C3 at a minimum. The authors of the paper noted that individuals with corona phlebectatica had more severe venous disease, that they were very likely to have perforator reflux, and that they all had significant saphenous reflux.

In April 2017 in *Phlebology, The Journal of Venous Disease*, they noticed that when blue corona phlebectatica was present, hyperpigmentation was frequently missed by the naked eye when looking at the ankles. They used digital photography to examine skin features and found that when blue corona phlebectatica is present, the brown skin discoloration can be identified with magnification.

In “Clinical Analysis of the Corona Phlebectatica” published in the *Journal of Vascular Surgery* in 2012, the authors analyzed

different characteristics of corona phlebectatica. They found that individuals with blue-colored corona phlebectatica and “stasis spots” (little spots of slightly beige or brown skin in the region of the blue vessels) was a very specific condition and useful for identifying more advanced venous insufficiency. This was opposed to red-colored corona phlebectatica, which was related to venous insufficiency but not as advanced.

This led to the conclusion that red-colored corona phlebectatica would be a C3 classification and blue-colored corona phlebectatica would be a C4 classification. They also noted that blue-colored corona phlebectatica was generally associated with “light brown spots” or hyperpigmentation that might not be noticed without close inspection. This is because blue-colored corona phlebectatica leads to inflammation that causes the skin to change color in spots; this condition will progress if left untreated.

In an article titled “Risk Factors for Chronic Ulceration in Patients with Varicose Veins: A Case Control Study” published in the *Journal of Vascular Surgery* in 2009, the authors detailed the features seen upon clinical examination that predict ulceration. They found that individuals with corona phlebectatica, hyperpigmentation, or eczema were far more likely to develop ulceration compared to patients who lacked those findings. There's a closer correlation between actual skin changes and the development of ulceration than the severity of the varicose veins upon examination or the degree of reflux found upon ultrasound examination.

The authors also found an association between deep venous insufficiency—particularly in the popliteal vein—and the eventual

“Conservative management neither effectively treats nor prevents venous ulceration and its recurrence.”

development of ulceration of venous stasis. As we discuss in another section, when deep and superficial reflux is present, and the superficial reflux is treated, the deep reflux will typically predictably improve. Additionally, deep venous

insufficiency is by no means a contraindication to superficial vein ablation. The presence of deep venous insufficiency in conjunction with superficial venous insufficiency is essentially a “sicker leg.” It is all the more important that we treat these patients.

In the same paper, they also found that obesity, smoking, and limited mobility are all minor risk factors for the development of ulceration. Again, none of these are contraindications to treating venous insufficiency. Interestingly, some of the things we associate with varicose vein risk were not risk factors for venous ulceration: for example, neither prolonged standing, nor the lack of use of compression, nor a lack of exercise was risk factors for venous ulceration. Conservative management neither effectively treats nor prevents venous ulceration and its recurrence. The perforator veins must be found, the superficial saphenous reflux must be identified, and all points must be treated.

These studies emphasize the ever-expanding understanding of venous disease. There are obvious situations where a person has minor spider veins (C1), ropey varicose veins without leg symptoms (C2), varicose veins with edema or symptoms of edema (C3), varicose veins with skin changes (C4), varicose veins with healed

ulceration (C5), and varicose veins with active ulceration (C6).

But now that we can see that evidence-based medicine has allowed us to gain a better understanding and that there is more to venous disease than just varicose veins. It is not uncommon to see a person with a healed or active ulceration with no visible varicose veins—they might be hidden by swelling or by obesity, or they might just be deep in the skin. Many insurers use the diagnosis code of “varicose vein” in conjunction with edema, ulceration, or bleeding, for example, but that does not mean that this represents the full scope of venous insufficiency.

Even the term “varicose vein” can be misleading. The public might think of a varicose vein as a large, dilated, bulging vein on the surface of the skin, but that's not the real definition. A varicose vein is a vein that has become enlarged and twisted. Obviously, you don't know what size the vein was previously, so you can't guarantee that it has become enlarged unless the patient has noticed the growth of the vein. And unless it's on the surface of the skin, you can't see if the vein is straight or twisting. This is why we look for venous insufficiency as a hemodynamic feature as well as recording clinical symptoms and doing a physical exam. But typically, you still have to use the varicose vein diagnostic code for reimbursement even though the varicose vein is not the main problem. The main problem may be an ulcer, so it is a “varicose vein with ulceration.”

Another classification system that has been around since 1976 (thus predating the CEAP classification of varicose veins) was the classification of venous insufficiency. Widmer's classification system broke venous insufficiency into three stages:

Stage I: Corona phlebectatica

Stage II: Trophic lesions, including lipodermatosclerosis, atrophie blanche, and dermatitis

Stage III: Active or healed ulceration

This predated the CEAP, but we can see the logic. Note there was no mention of varicose veins—this classification system was all about venous insufficiency. When the new classifications were developed, the system included etiology, anatomy, and pathophysiology.

At the 16th annual conference held in New Orleans in 2015 titled “New Cardiovascular Horizons,” the presenters spent a lot of time talking about the evolution of the disease in people with untreated venous insufficiency. It's not just varicose veins; it's the corona phlebectatica—the skin changes—that predict eventual ulceration. They also noted that the medical management of venous insufficiency consumes about 2% of the US healthcare budget. An absurd amount for something that is so treatable.

The next thing to review is the significance of skin changes beyond corona phlebectatica. As mentioned earlier, blue corona phlebectatica is generally accompanied by “light brown spots” and is a C4 classification because of the skin changes as well as the hemodynamic characteristics that accompany the skin findings. Red-colored corona phlebectatica is a C3 unless accompanied by other skin changes.

Let's break down some confusion surrounding the C4, C5, and C6 classifications. C6 is an active ulceration—you can see the wound. C5 is generally thought to be patients who remember having had a wound that has since healed. Frequently, the



ATROPHIE BLANCHE

Atrophie blanche is a dermatologic finding characterized by white- or light-colored patches of skin in regions with darker discoloration.

patient history is used to determine if the patient is a C5.

So what is C4? It's generally thought to be skin changes, but skin changes can also be an ulceration or a healed ulceration.

ATROPHIE BLANCHE:

Atrophie blanche is a dermatologic finding characterized by white- or light-colored patches of skin in regions with darker discoloration. This is a result of necrosis and the replacement of necrotic tissue with fibrin deposits and collagen. This is known as C4b on the CEAP classification, with C4a being devoid of any evidence of tissue necrosis. But from a diagnostic coding standpoint, it is "varicose vein with ulceration." Insurers do not use the CEAP classification system at this time, although there may be some expectation of a minimal amount of disease. From the standpoint of coding as well as the standpoint of proper management, an ulcer is an ulcer is an ulcer. It doesn't matter if they had it before or they have it now or they didn't even know they had it (as in the case of atrophie blanche). The treatment is the same: we find the perforator vein and the other points of reflux and we ablate them.

When circling the CEAP on the history or the physical exam, the patient is a C4, but for diagnostic coding, it doesn't matter if the

ulcer is active, inactive, or not known to the patient—it is on the spectrum of venous insufficiency with ulceration. It is dead tissue that has been replaced by scar tissue.

Venous insufficiency is a progressive disease. In a paper titled “Progression and Venous Pathology” in *Phlebology, The Journal of Venous Disease*, the authors found that 58% of all patients with venous insufficiency had progression over time, worsening at a rate of about 4.3% per year over 13 years of observation. The authors found that the most significant predictors of the progression of varicose veins toward leg ulcers were corona phlebectatica, skin changes, popliteal reflux, and obesity.

In summary, we treat not only varicose veins, but we also treat “ugly legs.” These “ugly legs” may range from corona phlebectatica to minor skin changes to atrophie blanche, and “ugly leg” patients may have active or healed known ulcerations. These patients typically will have more diseases and comorbidities, are more likely to be overweight, and/or have less ambulation ability. Patients who have had a DVT in the past are more likely to develop superficial and deep venous insufficiency as well as go on to develop leg ulceration. Also, patients C4 and above are very likely to have had prior blood clots in the lower extremities even though they might not have known it (this is discussed in a different chapter). In fact, when examined closely, over 40% of these patients show evidence of having had a prior DVT. These patients are more likely to have deep venous insufficiency and various other comorbidities. However, none of these factors are contraindications to appropriate ablative treatment. Ablation of reflux is paramount to improve their quality of life and to reduce their overall lifelong risk of living with diseased legs.

SECTION 2

COMPRESSION THERAPY

Compression therapy has been a mainstay of the treatment of venous insufficiency for decades. Before 2005, insurance companies did not reimburse for venous ablation as it was too new. Then, however, insurance carriers started taking notice, realized the reduced costs compared to surgery, and began covering this procedure. Now reimbursement is pretty much universal.

Initially, insurers were recommending that conservative management is tried before initiating therapy. Some insurance carriers were vague and recommended the use of some form of conservative therapy, including stockings, walking, weight loss, narcotics, and other chronic management interventions. Other carriers were very specific and required patients to wear a specific type of compression for a finite amount of time even though there was absolutely no evidence to support this recommendation.

In addition to the legacy of having patients wear stockings when they do not resolve chronic disease, physicians are making patients wear stockings after the procedures. Sometimes for months! When I started going to the phlebology meetings, there were two different groups. Group 1 was the surgical section, and group 2 was the nonsurgical section (which was of course ablations). The groups were split about 50/50, with the traditionalists balking at a new effective and noninvasive procedure that

would undermine everything they been doing for decades and the people who had open minds interested in learning about advances in healthcare. That was in 2004. Now if you go to the same meeting, there is only one section: the nonsurgical group. Nobody's lecturing about or doing studies on surgical stripping, high ligation, or SEPS procedures anymore. There is even a procedure called TRIVEX that arrived on the scene around the same time as venous ablation. This was a procedure that made stripping easier, but was very expensive. Also, although it was a very effective procedure, it had the same issues as surgical stripping did: it's a surgery, the patient needs be knocked out, there's a lot of recurrences, and there's a convalescence period.

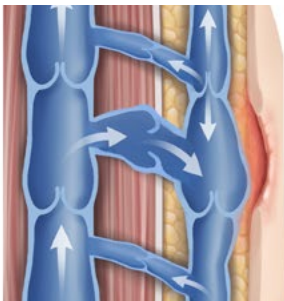
Still, even though we differentiated between surgical and nonsurgical approaches, we applied the same logic to venous ablation as we did to surgical stripping: we made patients wear stockings. I heard some guys talking about having the patients wear stockings for two weeks and others saying three months.

When I started doing the procedure, I told some patients to wear stockings for about a week and some for about two weeks. I observed there was no difference in outcomes, so I changed my recommendation to a week. I started asking patients "Did you wear the stockings?" In reality, only about half of them actually wore the stockings for a week. I noticed that the week-long-wearers and the non-weeklong-wearers had no difference in outcomes. The latter would typically wear them for about two days, get sick of them, and take them off. They had the same outcomes as people who wore the stockings for a whole week, so I changed my recommendation to two days. We did that for about ten years.

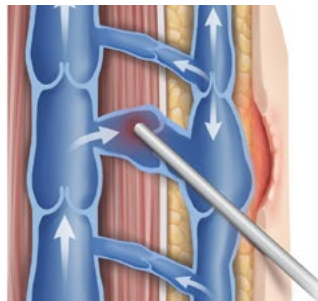
Let's review the science and a little bit of history. The first endovenous laser ablation procedure used a laser that had a wavelength of 810 nm. It worked by attacking the red color in the red blood cells, hemoglobin. Because the laser heated up the red blood cells and caused little holes in the saphenous vein, however, this led to considerable bruising and discomfort. Then came the laser with a wavelength of 980 nm, which caused less pain and discomfort. And then came the 1320 and 1470 nm lasers we use today. These attack the water in the blood vessel wall and are not fraught with the kind of discomfort caused by 810 nm lasers. **There's also radiofrequency (FIGURE below), which heats up the vein wall. There is far less discomfort with the newer lasers and with radiofrequency than what the original 810 nm laser caused.**

That being said, a paper was written that evaluated the use of compression therapy after vein ablation with an 810 nm laser. The study was in 400 patients. Half of them used compression stockings, and the other half did not use compression after an

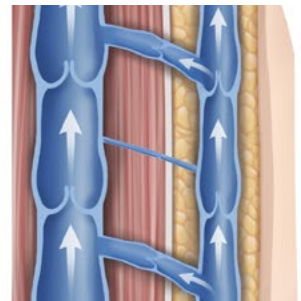
Radiofrequency Ablation Procedure



Abnormal blood flow from a failed perforator valve, leading to skin discoloration and eventually a venous ulceration.



The diseased perforator vein is identified with an ultrasound, then a heat probe is inserted under local anesthetic.



The diseased perforator vein is reabsorbed, normal blood flow is restored, and the ulcer is healed permanently.

ablation. The authors found no difference in outcomes, but they did note a decrease in patient discomfort in the week following the ablation for the patients that wore stockings.

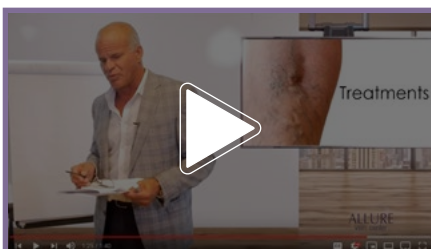
But let's talk about ablation done with more modern devices (i.e., radiofrequency and newer lasers). "Compression Versus No Compression After End of Venous Ablation of the Great Saphenous Vein: A Randomized Controlled Trial" was published in 2017 in the *Annals of Vascular Surgery*. The authors studied compression stockings after radiofrequency, the device we most commonly use. There were 80 patients in the study, with half of them using compression stockings for week and the other half not using compression. The authors found no differences between the groups regarding success or postoperative symptoms.

A paper published in the *British Journal of Surgery* in 2015 titled "Systematic Review of Compression Following Treatment for Varicose Veins" pulled together seven randomized controlled trials evaluating the use of stockings or the lack of compression after endovenous ablation. The results were interesting. The studies that looked at compliance found it wasn't that good. We can probably suspect that our patients are not following directions exactly, especially in regards to something as inconvenient as wearing compression stockings (particularly when we're talking about working adults). But the authors found that in some cases, the use of compression stockings led to slightly longer recovery time compared to not using compression. Other studies showed a slight decrease in postoperative symptoms with compression stockings. In summary, they found no evidence to support or detract from the use compression stockings after endovenous ablation. We can surely offer stockings to our patients, but using them is not

mandatory, and there is no scientific reason to use them.

Concerning sclerotherapy, there have been longstanding recommendations to use grid compression stockings after the procedure. There's plenty of evidence showing that patient may have some decreased pain or discomfort or discoloration if they wear compression stockings from anywhere from one to three weeks. But the data for this is not very strong. A few papers looked at the amount of compression, the length of compression, and other factors, and there is some correlation that using high-grade compression for a long time may give a slight benefit to people with spider veins or varicose veins who use sclerotherapy. However, statistically, you would have to treat several post-sclerotherapy patients with long-term compression stockings to see a single person derive any benefit from them. We recommend that patients may choose to wear compression stockings but that the stockings don't have to be very high-compression, nor do they have to be worn at night. If patients can do this, there may be some potential for an improved cosmetic outcome, but not much. Patients can weigh their options.

“We recommend that patients may choose to wear compression stockings but that the stockings don't have to be very high-compression, nor do they have to be worn at night.”

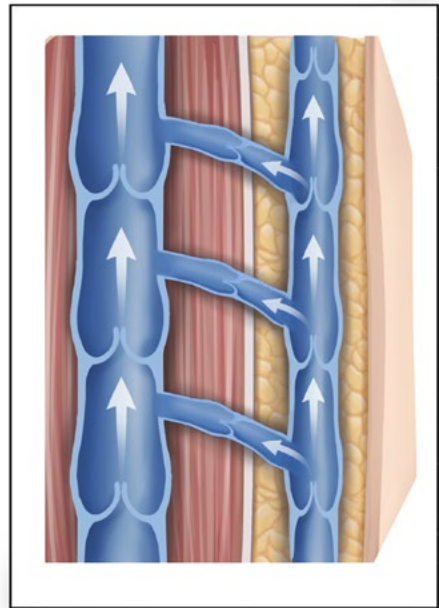


Click to watch video

Dr. Charles Mok talks about the treatment methods for vein disease.



Normal blood flow



SECTION 3

COMPRESSION THERAPY AND CONSERVATIVE MANAGEMENT

There has been a tradition of requiring patients to use compression stockings for a period before surgically treating varicose veins. The surgery had inherent significant risks. In the modern era of vein care, the nonsurgical management is an awake, out patient ambulatory procedure. Some carriers have brought the old school management of venous disease and applied it to newer, simpler, less invasive management.

Just to use an example, Humana in January 2017 updated its policy on management of venous disease. "Documentation of a failed trial of at least three months of conservative, nonoperative treatment consisting of compliance with compressive stockings providing 20 to 30 mm Hg pressure." Here was their reference:

"Gloviczki P, Comerota AJ, Dalsing MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2011; 53:2S-48S."

Ok, let's look at what the document that they referenced stated.

Guideline 9.2 "We recommend against compression therapy as

“the recommendation made up by the insurance companies requiring some patients to wear compression before treatment was supported by little or no evidence.”

the primary treatment of symptomatic varicose veins in patients who are candidates for saphenous vein ablation.” This is a 1A guideline which means they strongly support this guideline and there is extensive evidence to back it up.

The insurance company cited the guidelines by the American Society of Vascular Surgery as a reference and decided that “we recommend against compression therapy as the primary treatment of symptomatic varicose veins in patients who are candidates for saphenous vein ablation” means “we at insurance company recognize that the expert consensus is to avoid delaying treatment with compression stockings, yet we require you to use them anyway.”

The Society went on to say that the recommendation made up by the insurance companies requiring some patients to wear compression before treatment was supported by little or no evidence.

They reviewed the literature and found numerous studies showing that stockings did absolutely nothing to halt the progression of venous disease. They go on to note that the 20 to 30 mmHg pressure stockings were no better than standard stockings even though using this higher compression is a common practice. This particular insurance company recommends an inappropriate

treatment with excessive force that is uncomfortable and can lead to skin necrosis.

They agreed with the REACTIV trial, which was an evaluation of the cost-effectiveness of managing varicose veins, the intervention was cost-effective compared to compression therapy. The insurance company saving no money, in fact wasting money by making this inappropriate recommendation.

To make this requirement by this and other insurance companies stand out for what it really is (an attempt by insurance companies to discourage the payment of benefits), another study showed that only 15% of people, of the group who most commonly suffer from the most significant venous disease, could actually put on the 20 to 30 mmHg compression stockings. So this would mean that we would be required to prescribe home healthcare for three months to put on stockings that don't work, are uncomfortable, and recommended as totally inappropriate by the American Academy of Vascular Surgery and the American Venous Forum.

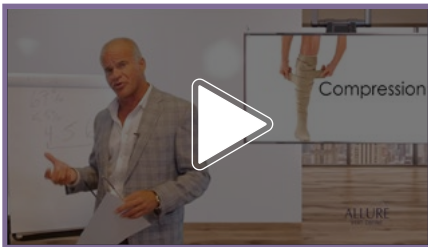
It is astounding that when they were rewriting their policies of denial, they cited an expert consensus panel, but put in the wrong recommendations.

There are other insurance companies, such as Medicare who

“I want to work with the insurance companies to help them understand that the individuals who wrote the guidelines completely misrepresented the literature...”

recommend conservative therapy where appropriate. This makes more sense. For an individual with minor symptoms, such as aching, simply walking around a few times a day may result from it. But people with real venous insufficiency progress at the rate of about 4% per year, and many go on to develop venous stasis ulcers which are a \$15 billion year problem.

I want to work with the insurance companies to help them understand that the individuals who wrote the guidelines completely misrepresented the literature that they cited. I think the most amazing thing, is that they cited a position paper that pointed out that compression stockings were not cost-effective, and were inappropriate. And they are contributing to the escalation into venous ulceration; this is why it is suspected that the \$15 billion year problem will grow to \$23 billion a year in short order.



Click to watch video

Learn how compression effects vein disease with Dr. Charles Mok.

SECTION 4

UGLY LEGS AND VENOUS ULCERATION

Chronic venous insufficiency is commonly associated with ulcers. The diagnosis of venous insufficiency with ulceration is based on a patient's history or physical exam. For example, a person who has a healed ulceration may be CEAP Class 5, but for diagnosis coding, the CEAP classification system is not used.

This is simply for the history. In this case, the diagnosis would be "venous insufficiency or varicose veins with ulceration." For our practice, it is important to understand this distinction between CEAP class and CPT coding. For CEAP classification aC6 is an active ulcer. For CPT coding, and the ulcer is an ulcer is an ulcer.

"The diagnosis of venous insufficiency with ulceration is based on a patient's history or physical exam."

A C5 is a healed ulcer, so it is an ulcer for CPT purposes. So is atrophie blanche, which is a condition where the superficial layers of the skin became necrotic. However from a CEAP standpoint these would be a C4. C4 is more or less a "pre-ulceration" as is blue corona phlebectatica.

The CPT coding of ulceration is important from a medical

“...numerous studies have shown that where there is any form of an ulcer, healed, active, or even one that the patient didn't know about, there is an underlying incompetent perforating vein.”

necessity standpoint. We'll talk about this in a bit, but numerous studies have shown that where there is any form of an ulcer, healed, active, or even one that the patient didn't know about, there is an underlying incompetent perforating vein. If this underlying perforating vein is not

managed, the ulcer will come back, so it is critical that we treat them. Many insurance carriers deny treating the incompetent perforating veins unless there is an ulceration, so is important that we note it. Amazingly some insurance carriers blatantly will not cover perforator treatment at all. This leads to inappropriate management of patient care. If the perforating vein is not treated, the ulcer will come back. If we do not use ablation on the perforator, the patient must go an unnecessary much higher risk surgery called SEPS (subfascial endoscopic perforator surgery). The American Society of Vascular Surgery guidelines advises us that the riskier surgical procedures should essentially be abandoned in favor of newer, modern, minimally invasive, ambulatory procedures.

From a practical standpoint, it can be recognized that not all patients are alike, and some patients without ulceration will have significant perforator veins that made lead ulceration down the road. In these cases, when the judgment is that the perforator without ulceration should be treated, it can be done as an add-

on procedure using a thin laser fiber which we also use to treat the saphenous vein.

For patients with skin changes that represent current or prior ulceration, we would typically treat the saphenous vein reflux with the radiofrequency device or whatever is appropriate at the time. Then we will bring the patient back and use the special radiofrequency perforator fiber, or the special laser perforator fiber. It is not clear why, but no insurance carrier will pay for both of these procedures to be done simultaneously, so the patient has come back.

“Numerous studies have shown that venous insufficiency with ulceration is a chronic disease with significant public health implications.”

Numerous studies have shown that venous insufficiency with ulceration is a chronic disease with significant public health implications. An article from the *Journal of Medical Economics* titled “Burden of Venous Leg Ulcers in the United States” did a thorough review of almost 100,000 Medicare records. What it found was that the annual US taxpayer burden for untreated venous ulceration is approximate \$14.9 billion. Let me repeat that: \$14.9 billion.

The annual cost of managing leg ulcers is astounding. According to the FDA, numerous bandages, creams, dressings, and sterile solutions are used to treat leg ulcers, and approvals for more and more treatments are being sought every day. Currently, the annual expenditure for these creams, dressings, and bandages

exceeds \$6 billion annually. That is staggering.

On Wall Street, this is a very hot topic because of the potential additional billions of dollars that will likely be consumed as baby boomers age. The majority of people with venous insufficiency and ulceration are a little bit older and typically have Medicare insurance. The costs of treating these conditions are expected to rise from \$14.9 billion a year to over \$20 billion a year. This is getting the attention of pharmaceutical companies and medical supply companies. The beauty of the situation for drug manufacturers and medical supply companies is that typically doctors are not treating the primary source of the venous insufficiency and the ulceration—instead, they're just putting a bandage on it. It seems absurd, but this is what is happening.

I read an interesting position paper titled "Challenges and Current Best Practices" that was in a supplement of the *Journal of Wound Care* in April 2016. The paper came from a major wound care medical society. The authors stated that wounds resulting from venous insufficiency should be treated with various types

"As a group, wound care specialists have a vested interest to maintain the status quo, because again, this is a \$14.9 billion-a-year money-making machine."

of compression. They evaluated different compression methods, the best dressing methods, and the best topical and ointment medications. The authors also stated that this is going to be a lifelong, chronic condition for patients and recommended

considering performing surgical treatments such as subfascial endoscopic perforator surgery (also known as SEPS) along with ligation and surgical stripping. They also acknowledged that many of these patients are little old to undergo these kinds of aggressive procedures and noted that new ablation techniques might be considered. They called these procedures “new” even though the referenced ablation techniques been FDA-approved for over 12 years and are now considered to be standard care in the industry for the management of venous insufficiency. As a group, wound care specialists have a vested interest to maintain the status quo, because again, this is a \$14.9 billion-a-year money-making machine.

I want to put this in perspective. There were about 683,000 venous ablations in 2016. That comes to a little over \$2 billion in insurance expenditures for treatment of all venous disease done by nonsurgical techniques (i.e., ablations). Of this \$2 billion in vein ablations, about \$50 million was for venous ulceration patients. We currently spend 300 times more money managing a curable disease than eliminating it. It seems the wound care industry wants to preserve this. We see this and other trends in healthcare where the old school treatments are preserved by the parties that benefit from them, even when newer, more advanced options would improve the patient's quality of life and save billions of dollars.

I want to make it crystal clear that from a purely financial standpoint, the cost-benefit ratio for Americans strongly favors treating venous insufficiency

“Another study found that about 600,000 productive workdays are lost per year because of venous insufficiency.”



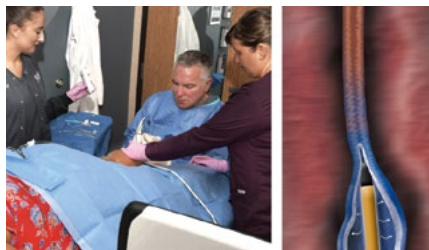
UNNA BOOT WITH DRESSING

1910 - PRESENT

FEEL BETTER IN 4-7 MONTHS

80% RECURRENCE

\$14.9 BILLION BY TAXPAYER



ABLATION

2004 - PRESENT

FEEL BETTER IN 2-8 WEEKS

LESS THAN 5% RECURRENCE

\$2 BILLION BY HEALTH CARE

with methods that result in permanent resolution. I'll talk more about this later. Then there are also the significant quality-of-life interruptions that leg ulcers cause.

Another study found that about 600,000 productive workdays are lost per year because of venous insufficiency. If you add that to the healthcare costs, the overall cost of untreated leg ulcers is quite staggering. If we want to fix healthcare, maybe we should be treating the cause of the ulceration and not just putting a bandage on it.

In a six month period of 2017, there were 437,814 Unna Boots applied in American wound care centers. So we can estimate that would be just under a million in the period of the year. Let's put this in perspective: Unna Boots were developed by a German dermatologist, Dr. Paul Gerson Unna, in 1910. That's over 100 years ago.

In a study published in 2014, "A Comparative Clinical Study of Five Types of Compression Therapy in Patients with Venous Leg Ulcers," the authors evaluated the use of Unna Boots and compared them to different types of compression. The Unna Boots were the least likely to be effective in healing leg ulceration. The most effective are the inelastic compression that has been around the last 20 or so years. Should we still be using something that worked great in 1910 but by today's standards doesn't come close to modern compression? Note that inelastic compression is 400% more effective than the Unna Boots. No, we obviously should not be using Unna Boots.

So not only are wound care centers consuming about \$15 billion years in healthcare expenditures, for a condition that can be eliminated with an ablation procedure, they are also still using about a million dressings a year that was invented over hundred years ago, and have been proven to be far less effective than much less expensive compression devices.

What about the timing of treatment for venous ulceration patients? I've heard that some providers want their patients to heal their leg ulcers before treatment with endovenous ablation and that to achieve this, the providers were telling their patients to use Unna Boots or some other form of compression. Numerous studies (again listed in the reference section) show that this is an inappropriate practice of medicine—using Unna Boots leads to a very low-resolution rate or takes a very long time to achieve resolution of ulceration.

Even the best type of compression, regardless of how modern or expensive pales in comparison to treating the actual cause, and also leads to a very high recurrence rate.

Contemporaneous treatment of axial venous reflux (i.e., a great or lesser saphenous vein and its major tributaries along with associated perforator veins, which are virtually always present in the face of ulceration) rapidly speed up resolution of venous ulcers. More importantly, traditional wound care treatment of venous ulcers has a very high rate of recurrence: about 50% at the two-year mark. Only 50% after two years using standard but old-fashioned treatments for venous ulceration! Whereas studies following patients over long periods of time found that when patients were treated with any type of compression as well as ablation when appropriate, the recurrence rates were less than 5%. So with traditional wound care, the condition is ten times less likely to reoccur, and this is a condition that costs billions of dollars a year in healthcare costs and interrupts hundreds of thousands of workdays! Not to mention puts obvious stress on patients when they have unhealthy legs and a poor quality of life.

"The Impact of Ablation of Incompetent Superficial and Perforator Veins on Ulcer Healing Rates" published by the *Society of Vascular Surgery* cited a study involving people who had venous ulceration for an average of five years who were treated with ablation of the saphenous reflux as well as the perforators. Over 75% of them were completely healed in six months...and again, that's after having had nonhealing ulcerations for over five years. And keep in mind people who have open ulcerations for five years are relatively sick people with very ugly legs. If the majority of them healed in as few as six months (most healed in three months or fewer), there is no reason to withhold this treatment from people regardless of comorbid conditions. Not even if they live in a nursing home.

A paper titled "Endovenous Laser Ablation of the Great

Saphenous Vein and Perforator Veins Improves Venous Stasis Ulcer Healing" in the *Annals of Vascular Surgery* in 2013 retrospectively looked at charts of patients who had venous ulceration and underwent ablation. What the authors found was that when perforator veins were identified, they were ablated along with the great saphenous vein (and of course, when perforator veins were not identified, they were not treated). Again, this was a retrospective review of what they observed: that the patients who had both great saphenous veins (and their tributaries of veins) treated along with perforator veins had a significantly greater degree of complete resolution of ulceration. The highlight of this paper was to look for perforator veins when venous stasis signs are present. If your technician does not find perforator veins, do the procedure again—perhaps with a more experienced technician—or take a look yourself and perhaps have the patient stand for a longer period. If there are significant findings of venous stasis, the perforator veins are there.

A paper titled "Endovenous Ablation of Incompetent Perforating Veins is Effective Treatment for Recalcitrant Venous Ulcers" published in the *Journal of Vascular Surgery* in September 2011 evaluated patients with venous ulcers who were treated with ablation of their perforators along with any actual reflux. At about three months, the authors found that 90% of ulcers healed when at least one perforating vein was closed and that no ulcer healed unless at least one perforator vein was closed. There is a clear pattern here: if you don't close the perforating veins, the procedure doesn't work. That means that if you evaluate a patient who has ulceration that's either current or remote, they're going to require an ablation of the perforating vein. If the technician doesn't find one, the patient hasn't been adequately evaluated.

“After having done over 60,000 vein procedures, I cannot recall a single infection.”

We are treating the patient, not the technician's findings.

There's no reason to wait until the ulcers have resolved to treat

the reflux. Don't put a bandage on it and “wait and see”—solve the problem. This is we are meant to do. Our patients come to us from other doctors' offices or on their own because they have a problem that nobody will deal with. They are not to be turned away because we do not want to practice old-fashioned medicine.

There are no absolute contraindications to venous ablation. (I'll get to that in another section.) Many patients have concomitant low-grade cellulitis. If patients appear to have chronic cellulitis, still treat the problem—it won't go away on its own. When getting venous access requires penetrating the skin in the face of chronic cellulitic appearance or through an ulceration we use antiseptic on the skin and a little clear covering as we might use on an IV. This way, we pierce only a very small area of the skin. After having done over 60,000 vein procedures, I cannot recall a single infection. However, I guarantee you these patients were turned away by other providers simply because they had ugly legs. These patients would have wound up eventually developing recurrent and chronic infections. If there is an acute infection, then it is appropriate to wait till the patient is on an antibiotic for a few days. This is very rare.

Another study published in US Pharmacist, February 16, 2017,

reviewed the significant incidents of ulceration in the US population. About 1 or 2% of US population and is more common in elderly less common in younger people. Venous insufficiency was a significant cause of all extremity ulcerations, with over 80% of all ulcerations being related to venous insufficiency. The authors also note that little over 2% of patients admitted to long-term care facilities have ulcerations related to chronic venous insufficiency. Their angle was how to offer these patients various drugs or dressings or topicals to manage these conditions, of course benefitting in the process. They talk about different types of dressings and different kinds of agents, and they keep noting that these ulcers do not go away and that the patient will be on them long-term or forever. In the same paper, the authors identify a subgroup with severe ulcerations for whom surgery may be warranted. They note that surgery of perforator veins markedly improves healing and results in reduced recurrence, but the authors recommend this only when the patients are severe cases, and for this subgroup, the authors recommend doing standard endoscopic perforator surgery and stripping. The article didn't take into consideration that in the past 12 years, management of vein ulceration has experienced tremendous breakthroughs: there is now a very low-cost, safe, outpatient, well-tolerated, extremely effective, and permanent solution.

I have an article from 2002 before we were using ablation for reflux. The authors were addressing the fact that insurance companies would pay for compression stockings in many cases, pointing out that if stockings were used by people with chronic venous stasis, insurance companies would save \$17,000 during the patient's lifetime even after paying for the stockings. (Keep in mind this was before ablation procedures were FDA-approved.) The authors

“More contemporaneous evidence suggests that if we treat reflux with ablation, the cost savings during the patient's lifetime would be upwards of \$100,000 per individual.”

acknowledged that patients would still have chronic ulceration, but they figured that even while paying tens of thousands of dollars to manage these chronic conditions, insurance companies would save about \$17,000 per patient by paying for stockings.

More contemporaneous evidence suggests that if we treat reflux with ablation, the cost savings during the patient's lifetime would be upwards of \$100,000 per individual. You may not be aware of how much money is being paid to wound care centers. It's about 5% of the national healthcare budget. Not just wound care centers—that's the most obvious—but wound care in general. And venous ulcerations account for about 50% of chronic wound care in the US (which is about \$30 billion a year). Again, the annual cost to manage chronic venous ulcers is \$14.9 billion. It'll keep growing if we don't take action.

It's long been known that using traditional surgical methods such as SEPS and surgical stripping to treat saphenous reflux and its tributaries (as well as perforating veins) improves outcomes in patients with venous insufficiency and ulceration. Those methods have been approved to treat and manage this condition for years. But that was then, and this is now.

Surgical management of venous disease in the face of

ulceration hasn't really caught a lot of traction because the surgical procedures that were historically used before 2005 involved general anesthesia, potentially prolonged immobility that increased the risk of DVT, and significant morbidity. Additionally, these procedures involved managing ulceration while simultaneously managing a fresh surgical wound that could become infected. Also note that compared to age-matched controls, studies show that patients with venous insufficiency and associated ulcerations are typically sicker people. They have higher rates of heart failure, peripheral vascular disease, lung disease, obesity, hypertension, diabetes, and other comorbid conditions.

Currently, however, we have an extremely safe and minimally invasive outpatient procedure to treat venous insufficiency. Endovenous ablation involves local anesthesia only, patients can immediately return to normal mobility, and patients do not experience any negative impact on their immediate quality of life. It doesn't matter if they have other comorbid diseases—none of those diseases are contraindications. Patients with comorbidities can be treated. There may be some rare circumstances—and those circumstances are extremely rare—where patients cannot be immediately treated because of an impending problem such as acute arterial occlusion. In such a case, the inflow should be managed before the outflow. But cases of peripheral vascular disease that are otherwise stable and are not intended for surgery do provide certain indications, so if a patient has comorbidities such as diabetic neuropathy, intermittent claudication that is not surgical at the time, intermittent cellulitis, or other conditions that may be comorbid to venous insufficiency, it is appropriate to tell the patient that they will still have some other symptoms. However, once you release them from having venous insufficiency, their

will leg will start to heal, and they will feel better. They will have a better quality of life and less recurrence of their leg ulcer.

The paper “The Care of Patients with Varicose Veins and Associated Chronic Venous Disease: Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum” published in 2011 made specific recommendations for most all aspects of care of the venous insufficiency patient. In the guidelines, the authors recommend ablation of the saphenous reflux and its tributaries as well as perforator veins in the face of ulceration. They recommended using compression as an adjuvant treatment. They also recommend against using surgery and instead recommend endovenous ablation because of the substantial reduction in complications, pain, and convalescence. They also specifically recommend against conservative management in patients with venous insufficiency, from insufficiency that is associated with symptomatic varicose veins all the way to venous ulcerations. This may conflict with certain insurers' guidelines that conservative management should be considered where appropriate. Keep in mind that you are an advocate of the patient, not the insurance companies, and that there are guidelines in place that recommend against conservative management. This means that conservative management is inappropriate. So you are following certain insurance carriers' recommendations if you do not recommend conservative therapy. An expert panel has said that conservative therapy is inappropriate. “Three months of conservative therapy where appropriate” is the proper documentation. If you feel it is appropriate for the patient to pursue conservative therapy in spite of the recommendations made by the society, you can recommend it, and if you feel that it is inappropriate because

there is no evidence of any benefit to the patient, just document that they had conservative therapy where appropriate. That may have been just simple walking, or perhaps the patient used compression

stockings. The point is that patient pursued conservative therapy, and it didn't work. That's good enough. It is absurd to treat symptomatically venous insufficiency with additional nonbeneficial conservative therapy, particularly when venous insufficiency also involves something as severe as ulceration.

In summary, venous ulceration is a significant public health threat. It is an enormous economic burden on the US healthcare system, and for the most part, it is currently being mismanaged. Drug companies, bandage manufacturers, and large wound care management groups would prefer we keep the status quo—they only briefly mention that there is an intervention available that essentially cures what has become a huge money-making chronic disease.

The cost of venous ulceration to the US healthcare system is almost \$15 billion annually and is expected to increase as baby boomers continue to age. We will see more cases of venous ulceration and more unnecessary expenditures for a treatable disease. Hundreds of thousands of workdays are interrupted in the name of managing this chronic disease every year. This is on top of the

“The cost of venous ulceration to the US healthcare system is almost \$15 billion annually and is expected to increase as baby boomers continue to age.”

economic burden of direct healthcare expenses. Also, these numbers don't take into consideration the cost of the patient losing their quality of life.

Traditional therapies invented over hundred years ago (i.e., Unna Boots) have no role in the management of venous insufficiency or venous ulceration today. Compression therapy—particularly inelastic compression devices—can be used along with our management of the incompetent reflux. However, given the complexity of modern medical devices, the rapid resolution after ablation of perforating veins, and the simplicity of standard compression, this may be overkill. Again, no more Unna Boots. They don't work, and they are outdated.

SECTION 5

DVT, DEEP VENOUS INSUFFICIENCY, AND OUTFLOW OBSTRUCTION

I am writing this to clarify what is evolved in the management of chronic venous insufficiency for the past 10 or 15 years. We will continually be adding providers to our team who arrive with various experiences. Some providers will have been trained in traditional vascular surgery or will have had general surgery residencies and fellowships, where their mentors were training them to carry out classic management methods of chronic venous insufficiency in their patients. That meant either leaving them alone, doing long-term conservative management, or doing surgery. With the advent of modern vein treatments, this type of classic management is no longer the proper standard of care. The public health costs associated with not treating venous insufficiency are enormous.

“The public health costs associated with not treating venous insufficiency are enormous.”

One of the concerns I have heard from providers is that some patients may be at increased risk of developing DVT. They may

even have had DVT in the past. The reality is that because we are treating more CEAP classifications 4 through 6, we will see more people who had DVT in the past or who are at increased risk. Studies have shown that not only does venous insufficiency lead to a significant risk factor for developing a DVT, but patients who have more advanced venous insufficiency are found to have evidence of a prior blood clot in about 40% of the cases. A prior DVT is not a contraindication for management of venous insufficiency. Just the opposite. Avoiding treatment of these patients for fear of causing a blood clot jeopardizes their future health.

In the paper “Primary Venous Insufficiency Increases Risk of Deep Vein Thrombosis” published in April 2016 in the *Journal of Vascular*

“Patients diagnosed with acute DVT were about five times more likely to have venous insufficiency compared to controls.”

Surgery, the authors evaluated this risk factor. They found that patients diagnosed with acute DVT were about five times more likely to have venous insufficiency compared to controls. This was primary venous insufficiency, not that

which may be caused by a blood clot. Five times as likely. So yes, we are going to encounter patients who have had DVT or who may be at risk. However, when we treat the venous reflux as well as varicosities, we have just neutralized that risk factor.

In the *Journal of Vascular Surgery* in 2008, a paper was published that evaluated patients with concomitant deep and superficial venous insufficiency. Before that time, there had been some

degree of bias towards not treating superficial insufficiency when deep venous insufficiency was present, particularly with surgical stripping. However, physicians observed that when patients with mild to moderate venous insufficiency were treated for their superficial symptoms and disease, their deep venous insufficiency improved or resolved entirely. In the paper, the authors sought to evaluate the factors that would lead to predictability of resolution reflux of the deep venous system after treatment of the superficial venous system.

What they found was that regardless of the duration of the reflux of the deep venous system, treatment of the superficial venous system tended to improve the deep venous reflux. In patients with more severe deep venous insufficiency who had a relatively high velocity of reflux, they were less likely to see improvements. This is in no way a contraindication—it means discussing with the patient who has severe deep venous insufficiency as well as superficial venous insufficiency about the fact that the patient may benefit from compression stockings long-term and that they might have some degree of persistent symptoms. But this is in no way to be considered an “outflow obstruction” or contraindication for treatment. The majority of patients with both deep and superficial insufficiency, who had their superficial system treated will have ultra sonographic and clinical evidence of improvement of their deep venous system.

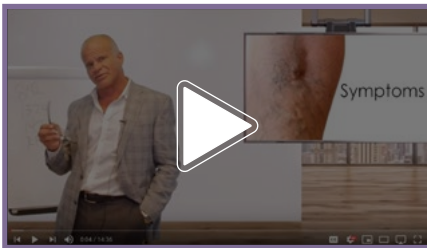
The clinical practice guidelines from the Society for Vascular Surgery and the American Venous Forum that were published in 2011 in the *Journal of Vascular Surgery* are still intact today. Once again, these guidelines identify that there are no absolute contraindications to venous ablation. Patients with extensive

venous occlusion and outflow obstruction can be treated with superficial ablation, however selectively. Here's a case I heard about that illustrates this point. The patient had outflow obstruction mechanical from prior DVT. Had some flow-through various tributaries of the femoral vein, but did have some degree of outflow obstruction. The patient was treated with saphenous ablation and had persistence of venous ulcers at the ankles. They were perforating veins associated with the ankle ulcerations, and the doctor was reluctant to treat them because the doctor felt that perhaps the perforator veins were required for collateral flow. This is not the case. Perforating veins do not account for significant blood flow in patients. When they are pathologic—that is, greater than 3.5 millimeters and greater than 500 ms of reflux—and associated with ulcerations, the society of experts recommends that they are treated.

What about patients who have had prior DVT and the DVT is still visible? If it's fenestrated and there's flow, there's no need for unusual caution. You should indeed tell the patient that they are at an increased risk for blood clots since they had them in the past, and mobility is appropriate as recommended. This may be an area where you consider medical prevention therapy; however, this is not elucidated in the literature.

Prophylaxis for DVT in the face of venous ablation is something that is practiced with various protocols, but there are no accepted criteria. In the clinical practice guidelines, the Society for Vascular Surgery and the American Venous Forum acknowledge that there is no data available but that it is reasonable, however, to treat such patients with a single dose of low-molecular-weight heparin before or at the beginning of the procedure. The societies also note

that since this is performed as an outpatient procedure with early ambulation, the overall risk is not substantial, making this purely a clinical judgment—there is no standard of care.



Click to watch video

Know the symptoms of vein disease and the progression of vein disease from Dr. Charles Mok.

SECTION 6

PERIPHERAL ARTERIAL DISEASE

Peripheral arterial disease is an inflow problem and venous insufficiency is an outflow problem. Both conditions may concur concomitantly. There may be considerations for withholding venous insufficiency treatment until the peripheral vascular disease is managed. Patients with an ABI of less than 0.7 should have a defined relationship with a vascular surgeon to determine if the inflow obstruction should be managed before pursuing treatment of the outflow problem. Patients with known peripheral vascular disease and no intent of or plan for surgery are not contraindicated for venous ablation. In the cases where it is not clear, the patient's prior records should be obtained. If they did not have a vascular evaluation in some time, an evaluation should be done before initiating venous insufficiency. Again, this applies to patients with the severe peripheral vascular disease who may have an impending problem. After over ten years and tens of thousands of procedures, I've seen very, very few of these cases. Typically, they come in thinking they have leg pain from their veins, and they are trying to see somebody for their leg pain...and then it turns out they have previously undiagnosed arterial disease. This is going to happen, yes, but it is uncommon in our practice.

Patients with peripheral arterial disease have a relative counter indication for compression therapy. I talk about this in the compression therapy section, but in general, patients with mild

“The use of compression after treating veins with ablation is based on the legacy of using compression after surgical stripping. What was valid then is not valid now.”

to moderate peripheral artery disease should be treated with minimal or no compression after ablation. There's very little evidence to support the routine use of compression after ablation other than “That's how we've always done it.” The use of compression after treating

veins with ablation is based on the legacy of using compression after surgical stripping. What was valid then is not valid now.

SECTION 7

RESTLESS LEG SYNDROME

This is a condition first diagnosed in 1944 where patients have unexplained leg symptoms (most commonly at night) and an urge to move them, sometimes uncontrollably. The cause was unknown. Until now.

Physicians like me started noticing that the patients we treated for varicose veins with reflux by venous ablation who also had restless leg syndrome started reporting elimination of their restless leg syndrome. At the American College of Phlebology, a few papers had been orally presented by doctors who explained that their restless legs patients had experienced resolution of their restless legs after ablation. The theory is that the continued stasis and inflammation leads to injury to the neural circulatory system in the skin.

Early studies were done in the 90s specifically reported improvement of restless leg syndrome after patients had sclerotherapy for varicose veins. (Sclerotherapy had been an option for treatment of saphenous reflux for decades before the advent of venous ablation with radiofrequency or laser.) In "The Effect of Sclerotherapy on Restless Leg Syndrome" in *Dermatologic Surgery* in 1995, the authors recommended screening patients who presented for restless leg syndrome for venous insufficiency. They found that 98% of the patients had at least some degree of improvement of the restless leg syndrome, with the majority of them seeing significant improvement.

“After treatment, the average discomfort score decreased by 80% in very short order.”

A study published in 2008 in *Phlebology* evaluated the International Restless Leg Score (IRLS) for 35 patients who were diagnosed with venous insufficiency and then

underwent ablation of venous insufficiency. After treatment, the average discomfort score decreased by 80% in very short order. Fifty percent of the patients had absolutely no symptoms of restless leg syndrome after treatment. Virtually all patients had at least some improvement, and about 90% had a near complete resolution. In this study, the authors also recommend screening patients with restless leg syndrome for venous insufficiency because of the substantial benefit that is received using a noninvasive procedure that is safer than the long-term use of drugs currently being prescribed for restless leg syndrome.

SECTION 8

SPECIAL CIRCUMSTANCES

Patients may be on medications that give us concern, such as aspirin, Plavix, Coumadin, or the newer all-oral alternatives to low-molecular-weight heparin. For certain surgeries, there's resistance or reluctance to perform the procedure in patients taking these blood thinners. However, like other physicians with large-scale vein practices, I have observed in my practice that when it comes to side effects and outcomes, we see no difference in results between patients who are on blood thinners and those who are not.

A paper in the *Annals of Vascular Surgery* in 2012 titled "Success of Endovenous Saphenous and Perforator Ablation in Patients with Symptomatic Venous Insufficiency Receiving Long-Term

Warfarin Therapy" reported an observational study where patients on Coumadin had the same outcomes, side effects, and consequences after ablation as compared to those who were not on Coumadin. The fact that a patient is on blood thinners is no reason to withhold treatment.

"...we see no difference in results between patients who are on blood thinners and those who are not."

Some patients have numerous medical conditions—they may be

immobile, be of advanced age, and be under care for multiple different conditions. There are no absolute contraindications to venous ablation in the face of chronic venous insufficiency. If patients have quality-of-life issues, there is no reason withhold treatment. Since the vast majority of symptom improvement will occur from ablation alone—whereas microfoam sclerotherapy results in more of a cosmetic improvement—then patients with other comorbidities and/or immobility should be treated with ablation alone. The addition of microfoam sclerotherapy does give them an inherent increased risk of developing a complication of DVT, making the therapy unnecessary.

In patients with ulceration related to venous insufficiency, is not necessary to wait for the ulceration to be treated, managed, or resolved. Even if you put the patient in some type of aggressive compression for six months and the ulcer resolves, the majority of the time, they will come back, so it is inappropriate to wait.

The Society for Vascular Surgery and the American Venous Forum recommend against the use of compression therapy for the primary treatment of symptomatic varicose veins in patients who are candidates for saphenous vein ablation. While compression stockings cause a great deal confusion because they don't really work when compared to ablation of reflux, some doctors still require their patients to wear them. The societies that issue the guidelines as well as their own clinical practices recommend against this. It is inappropriate.

As we treat more and more patients who have advanced diseased “ugly legs,” we are going to see more complicated cases. A natural response is to want to have the good old days

back, the time when we were the only ones treating varicose veins in the region, and we could stick to patients with “pretty legs.” But our strategy has changed.

We are adapting a new strategy. We are the leading provider for venous disease in our region, and we are probably the largest non-chain provider

in America who treats varicose veins. Therefore, we can intercommunicate and collectively have more experience in treating this condition than anyone else in America.

That means we should be treating more complicated cases,

because with our thorough base of experience, we can give our patients the best outcomes with the lowest risk.

“We are the leading provider for venous disease in our region, and we are probably the largest non-chain provider in America who treats varicose veins.”

There are no absolute contraindications to venous ablation. There may be circumstances where another medical condition is more pressing and is easily managed, but in over ten years of performing tens of thousands of vein procedures, I have rarely encountered a type of condition that precluded proper management of venous insufficiency.

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The U.S. pays a staggering \$14.9 billion a year to manage the symptoms of chronic venous insufficiency or “ugly legs”. That’s just to manage, not to fully heal them. On the contrary, the U.S. spends only \$50 million on treating and healing the root of vein disease with ablation procedures.

Getting to the underlying cause of venous disease leads to the healing of ulcers and wounds in about 2-3 months with less than 5% recurrence rate. With outdated disease management methods taking up to 7-8 months to see improvement, the recurrence rate is a scary 80%.

Surprisingly, fewer than 1% of venous ulcer patients are offered ablation procedures as an option for treatment.

At Allure, we believe in curing vein disease, not just managing symptoms. Old treatment methods are putting a huge burden on our nation’s economy and causing patients unnecessary suffering. We have the power to make an incredible shift in care and that is exactly what we are going to do.

In This Booklet, We Cover:

- The economic burden of wound care
- The history & failures of treating venous disease
- The progressive stages of vein disease
- How to cure vein disease with minimally invasive procedures
- Restless leg syndrome & other symptoms that benefit from treatment
- The best treatment options for curing venous disease for good

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