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INDUSTRY PARTNER ISSUE

American Venous Forum
Promoting venous and lymphatic health

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AND NOW A FEW WORDS FROM OUR SPONSORS

–Edgar Guzman, MD
Guest Editor

The field of venous intervention has had tremendous growth in the last decade. We have seen the emergence of non-thermal methods to treat superficial reflux, the advent of dedicated venous stents and vein-specific thrombus management systems. All the while, our understanding of venous pathology at hemodynamic and molecular levels continues to grow. It is no longer the case that one has to think about adapting arterial devices to the venous circulation, but rather about what venous device to use.

Industry has played a key role in helping develop therapeutic concepts into widely available treatment systems. The present issue of Vein Specialist acknowledges that contribution and offers the perspective of our industry partners on their devices.

Boston Scientific and BD discuss the strengths of their venous stents. Both offer superior radial force, deployment accuracy and absence of foreshortening; but still, the flexibility and long track record of the Wallstent preserve its relevance. As with endovascular aortic repair devices, tailoring stent selection to different anatomies and underlying pathologies will yield superior results.

It is now widely established COVID-19 constitutes a hypercoagulable state. Current projections suggest we will be treating these patients for the foreseeable future. AngioDynamics and Inari Medical describe their large caliber venous thrombectomy devices. Both offer rapid and thorough thrombus removal while reducing the need of ICU care.

Thrombolex presents the Bashir catheter. This tool enhances and accelerates thrombolysis by increasing flow across the thrombosed area; offering an alternative to thrombus aspiration and ultrasound accelerated thrombolysis.

Tactile Medical challenges two conceptions many of us grew up with. First, the Starling model, in which distal capillary oncotic pressure drives interstitial fluid reabsorption. This effect is actually rather small, with the lymphatic system returning the majority of this fluid to the circulation. Second, and consistent with the above, lymphedema is not an isolated and somewhat rare pathology; on the contrary it is present in combination with many causes of leg swelling including chronic venous insufficiency.

We hope you find this issue informative and look forward to an ever broadening and evolving physician-industry collaboration for the benefit of our patients.

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Vacuum Assisted Novel Thrombectomy for the Venous System

–Yosef Golowa, MD[1] and Venkat Shankarraman, PhD[2]

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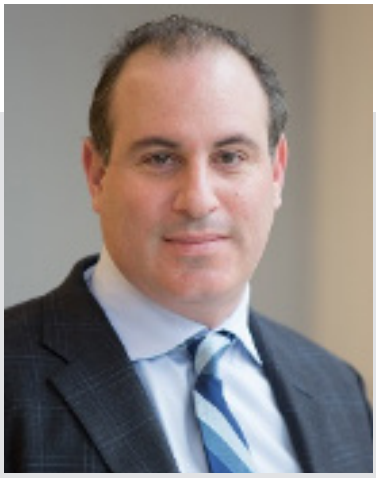
2. AngioDynamics, Inc. Latham, New York



–Yosef S.Golowa, MD

Venous thromboembolism (VTE) including deep vein thrombosis (DVT) and pulmonary embolism (PE) is the third most common cardiovascular disorder in the United States. DVT most commonly occurs in the more central and peripheral venous segments of the lower extremities and has an estimated annual incidence of 80 cases per 100,000.[1, 2] Iliofemoral DVT accounts for 20-25% of lower limb DVTs.[3] Patients with iliofemoral DVT are also at risk of developing inferior vena-cava (IVC) thrombi which constitutes 2.6 – 4% of all the proximal DVT cases. IVC thrombosis, if left untreated, can result in dire complications such as large PE in the acute setting and, severe post-thrombotic sequalae, including disabling venous claudication, and venous ulceration, in the chronic setting.[4]

Several different treatment algorithms are available for patients diagnosed with caval thrombosis. Anticoagulation is considered the first line of treatment; however, many patients develop post-thrombotic syndrome despite use of adequate anticoagulation therapy. Catheter based techniques for venous thrombus removal utilizing aspiration, fragmentation or extraction thrombectomy have been described.[4, 5] However, many of the available devices pose limitations for use in the IVC given the considerable thrombus burden and the large diameter of the vena cava.

–Venkat Shankarraman, PhD

The AngioVac System (AngioDynamics, Inc. Latham, New York, USA) has emerged as an effective tool for removal of undesirable intravascular material from the venous system. The AngioVac System pairs a large bore aspiration cannula with a veno-venous bypass circuit run through a filter (Figure 1) to create a suction vortex allowing en-bloc removal of large amounts of thrombus. With a large caliber aspiration catheter in conjunction with a funnel shaped tip and continuous suction, this technology can aspirate large thrombus without necessitating fragmentation or maceration. Overall, the AngioVac System has the potential to minimize blood loss, reduce the risk of embolization and hemolysis (otherwise associated with

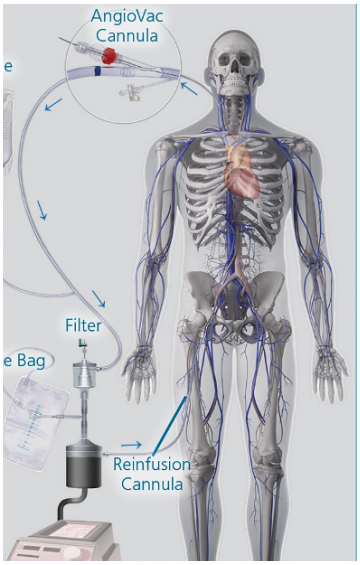
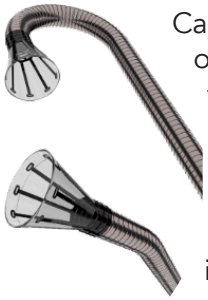


Figure 1. AngioVac system

rheolytic devices), and avoid the use of thrombolytics.[5, 6] The current iteration of the AngioVac Cannula (Generation 3) offers 20-degree and 180-degree angled nitinol funnel shaped tips (Figure 2). These options facilitate improved navigation through the patient's anatomy, helps prevent clogging and allow added steerability.

Numerous studies have shown the use of the AngioVac Cannula to be effective in removing caval thrombi with little to no procedure-associated mortality and a reduction in associated complications.[7, 8] In addition to efficient extraction of venous thrombi, the AngioVac Cannula has shown success in the removal of soft, fresh thrombi, emboli and infected vegetations from the right heart, including tricuspid valves and cardiac leads. Recent studies have articulated the safety and efficacy of the AngioVac System as an alternative to open surgery in tricuspid valve infective endocarditis patients and as an adjunct procedure for aspirating vegetations prior to and during lead extraction procedures.[9,10]

Figure 2



In summation, the next generation AngioVac technology is a promising tool demonstrating its unique versatility, efficacy, and enhanced safety features by providing a minimally invasive alternative for removing venous thrombi and right heart vegetations.

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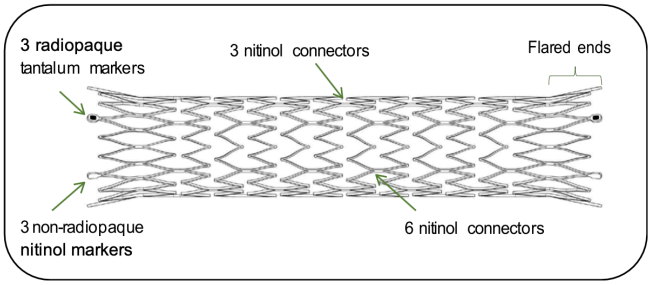
The BD Venovo™ Venous Stent: Addressing Unique Needs

–Stephanie Klocke, V.P of Research & Development, Becton Dickinson Peripheral Intervention

– Stephanie Klocke

According to clinical literature and key venous leaders, physicians cannot apply the same learned arterial techniques to the venous system P1P. Treating iliofemoral venous obstruction presents unique challenges – and these must be taken into consideration when designing a stent for the venous system. To design an effective stent for the treatment of iliofemoral venous obstruction, BD conducted an in-depth analysis of the venous anatomy and pathophysiology, collaborated with physicians, participated in various case observations, performed human imaging studies, computational modeling, and much more. After careful evaluation, there was a clear need for a dedicated venous stent designed with the right balance between radial force, compression resistance and flexibility, without compromising placement accuracy. Over the course of six years and following our rigorous product development process, BD developed the Venovo™ Venous Stent System, receiving FDA-approval on March 13, 2019, for the treatment of symptomatic iliofemoral venous outflow obstruction.



Stents with high radial force are needed to counteract the less prominent elastic and muscular component of the veins, as well as the intrinsic forces due to thrombotic changes such as Post-Thrombotic Syndrome (PTS). The high radial force from end-to-end of the Venovo™ Venous Stent assists in luminal gain to combat iliofemoral occlusive lesions.

Since the veins are thinner compared to the arteries, they are susceptible to changes in vessel shape, lumen size and/or external compressions. Sufficient compression resistance is necessary for treating non-thrombotic iliac vein lesions (NIVL) and the Venovo™ Venous Stent was designed to accommodate for such extrinsic compression forces.

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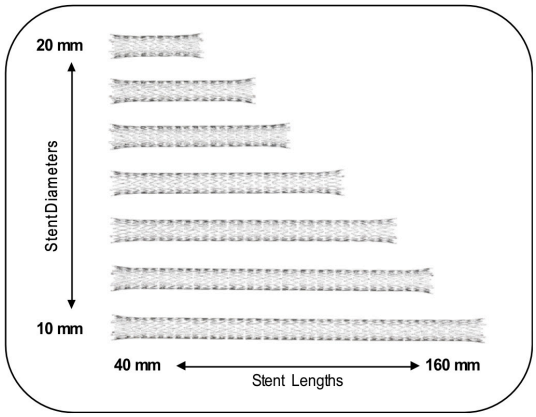


For optimal long-term outcomes, the veins need good inflow to good outflow, even if it means crossing under the inguinal ligament. Due to frequent movement in this area, conformability to vessel curvature is critical for a stent, making flexibility a key desired characteristic of dedicated venous stents. In order to optimize the flexibility and maintain high radial force throughout all stent sizes, the size ranges of the Venovo™ Venous Stent are made from separate nitinol tubes that are micro-polished into an open-cell stent design with alternating strut connectors, which demonstrated 0% stent fractures out to 24-months in the VERNACULAR trial.

Early research also identified a need for stent placement accuracy. With these findings, a tri-axial delivery system was designed to facilitate excellent placement accuracy. In addition, the Venovo™ Venous Stent has 3% stent foreshortening and flared ends to maximize wall apposition and prevent stent migration. Together, the attributes of the Venovo™ Venous Stent demonstrated 100% placement accuracy with 0% stent migration on all 219 stents implanted in the VERNACULAR trial.

The Venovo™ Venous Stent offers a broad range of stent sizes including diameters from 10-20 mm that help address the large caliber vein sizes and lengths from 40-160 mm, which allow for a single-stent solution for long diffuse PTS lesions and/or focal NIVL lesions.

The VERNACULAR trial results are a true testament to the design of the Venovo™ Venous Stent System; demonstrating a 12-month primary patency rate of 96.9% in patients with NIVL and 81.3% in patients with PTS and 24-month primary patency rates of 95.2% and 73.4%, respectively. With the combination of high radial force, crush resistance, flexibility, and excellent placement accuracy, the Venovo™ Venous Stent has been proven to be safe and effective in the treatment of venous outflow obstruction with clinically proven results out to 24-months.

[1]PSchwein A, Yannick G, et.al. Endovascular Treatment for Venous Diseases: Where are the Venous Stents? Methodist Debakey Cardiovasc J. 2018 Jul-Sep; 14(3): 208-213

Foreshortening is calculated as the difference, represented as percentage, between the compressed stent length and expanded stent length at minimum/maximum oversize (1-3 mm). Results shown in bench testing. Average foreshortening = 2.9% (values based on mathematical calculations). Data on file, Bard Peripheral Vascular Inc., Tempe, AZ. Bench tests may not be indicative of clinical performance. Different test methods may yield different results.

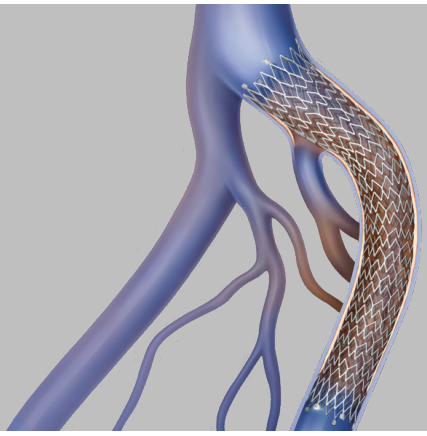
The Venovo™ Venous Stent System was studied in the global VERNACULAR clinical trial, which was a prospective, multi-center, non-randomized, single-arm study of 170 patients. The primary effectiveness endpoint of the study was primary patency (PP) at 12 months post-index procedure. Patients who received a VENOVO® Venous Stent had a weighted PP rate of 88.3%, demonstrating a statistically significant difference from a literature-derived performance goal (PG) of 74%, with an 81.3% PP rate for subjects with post-thrombotic syndrome (n=93) and 96.9% PP rate for subjects with non-thrombotic iliac vein lesions (n=77). The primary safety endpoint was freedom from major adverse events (MAE) through 30 days post-index procedure. Freedom from MAE was 93.5%, demonstrating a statistically significant difference from a literature-derived PG of 89%. N=141. VERNACULAR Clinical Study. Patients who received the Venovo stent had a weighted PP of 83.2% with a 73.4% PP rate for PTS (n=79) and 95.2% PP for NIVL (n=62) at 24-months. 0TSecondary endpoints included acute technical success and stent fractures. Results demonstrated 100% acute technical success, defined as successful deployment of stent(s) to intended target with adequate lesion coverage as assessed by the Investigator at the time of the index procedure. Stents were evaluated at the 24-month follow-up for fracture analysis. An anteroposterior and lateral x-ray for each evaluated stent were sent to an independent core lab for analysis. 128 subjects' x-rays were analyzed, and no stent fractures were reported. Missing x-ray analyses were recorded as protocol deviations. VERNACULAR Clinical Study. Data on File. Bard Peripheral Vascular Inc., Tempe, AZ.

The Venovo™ Venous System is indicated for the treatment of symptomatic iliofemoral venous outflow obstruction. Do not use in patients with a known hypersensitivity to nitinol (nickel-titanium) and tantalum or in patients who cannot receive intraprocedural anti-coagulation therapy. The Venovo™ Venous Stent is not designed for repositioning or recapturing. Please consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions.

Single-stent Solution with **Stent Lengths up to 160mm**

Venovo™

Venous Stent System



Varithena®: The Swiss Army Knife of the CVI Toolbox

–Thomas M. Hughes, PharmD[1] and Michael R. Jaff, DO[2]

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Peripheral Interventions, Boston Scientific Corporation, Maple Grove, MN

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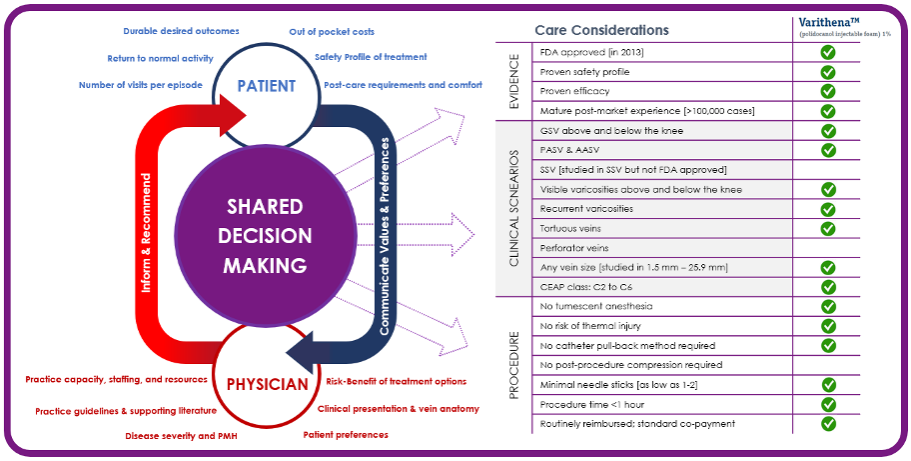
– Thomas M. Hughes, PharmD

– Michael R. Jaff, DO

Recent innovations for the treatment of chronic venous insufficiency (CVI) were developed to be equally efficacious as the current standard, thermal tumescent (TT) ablation, while addressing unmet clinical scenarios and enhancing patient experience. These new procedures, known as Non-Thermal Non-Tumescent (NTNT), do not employ thermal energy, obviating the need for tumescent anesthesia. Without risk of thermal injury, NTNTs are advantageous for patients with epifascial and below-the-knee venous incompetence. Supporting evidence demonstrates comparable efficacy for the therapies available in the US: polidocanol 1% endovenous microfoam (PEM), mechanochemical ablation, and cyanoacrylate embolization; however, each mechanism of action varies, conferring distinct risk-benefit profiles.[1,2]

With an expanding CVI 'toolbox', physicians balance clinical assessment and recommendations with their patient's goals for therapy to determine the right treatment. A survey had patients rank their preferences related to TT and NTNT procedures, and a majority of respondents favored attribute combinations that coincide with NTNT over TT procedures.[3] PEM has not only demonstrated comparable efficacy to TT ablation but also improved patient experience with fewer needle sticks, minor post-procedure pain, quicker return-to-normal activity, and a retreatment rate of only 3.4% (Figure 1).[1,4-8] PEM, available as FDA approved Varithena®,

Figure 1. CVI Care Considerations



is a proprietary canister generating a low-nitrogen microfoam uniform in bubble size and stability that fills the vein lumen for enhanced circumferential contact and duration of action.[9-10] A recent observational study demonstrated a closure rate of 93% (n=55) at six months with only one DVT.5 Although a valuable benchmark in research, assessing occlusion of the treated vein(s) has fallen out of favor as the definition for treatment success.[1,2] Also, physician performance and reimbursement is in transition to emphasize quality and value over fee-for-service.[11,12] As a scientific leader, the manufacturer of Varithena developed, validated, and utilized VVSymQ®, a patient-reported outcome tool measuring varicose vein symptoms, as the primary endpoint for the pivotal Phase III randomized controlled trials (RCT). In these RCTs, Varithena resulted in a two-fold greater improvement in VVSymQ® and two-and-half fold improvement in VEINES-QOL scores over placebo,[6,8] which continued to improve out to one year.[13]

Varithena also serves an important tool in challenging anatomies and pathologies. A key advantage is the technique is not reliant on catheter pull-back rate, so it is effective in varied vein anatomies including large, small, tortuous, and scarred (Figure 2).[6,8,14] In a retrospective review, Varithena was the treatment of choice for complex clinical scenarios including patients with a history of severe lipodermatosclerosis and failed TT. Patients improved in pain and VCSS scores at short term and one-year follow up.[14] Varithena is also being evaluated in patients with venous leg ulcers (VLU); the interim analysis was promising. Nearly half of patients with a mean VLU perimeter of 10.86 cm experienced wound closure within three months.[15] Varithena is a proven effective first line option for GSV incompetence but also addresses multiple populations of unmet needs.

Figure 2: Versatility of Varithena

Due to the durable efficacy, patient-friendly procedure, and clinical versatility; Varithena is the "Swiss Army Knife" of CVI treatment. While it may not replace all other superficial vein treatments, it may enable physicians to carry a smaller and more specialized toolbox.

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Venous Stenting: Dedicated Stent Designs Showing Encouraging Clinical Results

–Nick Johnson, Product Manager, Boston Scientific Corporation, Peripheral Interventions

–Nick Johnson

The treatment of iliofemoral venous obstruction poses unique challenges. Physicians must tackle the disease state itself but also account for the chronic obstruction and compression that these deep veins can be subjected to. Recent data shows the large number of the U.S. population that suffers from venous disease. Venous disorders affect nearly 40% of the U.S. population[1] and the incidence of deep vein thrombosis (DVT) in the U.S. is 350,000 to 650,000 people annually[2]. Of those with DVT, 50% will develop Post Thrombotic Syndrome (PTS)[3].

When choosing a stent for the treatment of non-thrombotic iliac vein lesions (NIVL) or PTS several key characteristics of stent performance should be considered: crush resistance, radial strength, flexibility, scaffolding, and deployment accuracy. The VICI Venous Stent™ System from Boston Scientific, currently the only nitinol, closed-cell stent available for venous stenting, was specifically engineered to withstand the crushing forces of these challenging scenarios.

Studies have demonstrated that closed-cell stents provide better scaffolding and crush-resistance compared to open-cell stents[4]. Closed-cell stents are characterized by small free cell areas between the struts, whereas open-cell stents have larger uncovered gaps. The Vici stent's closed-cell design creates a circular lumen that reduces turbulence and restores flow, which is critical for patients with deep venous disease. Vici Stent users have also reported positive experiences with predictable and consistent deployment and say that crush resistance and flexibility performance align with the internal bench test comparisons of Vici compared to other competitive venous stents. That data shows Vici with a 20% higher crush resistance and similar system flexibility to other commercially available venous stents.[7]

The VIRTUS trial evaluated the Vici stent in patients with clinically significant obstructions in the iliofemoral venous outflow tract resulting from NIVL and PTS. These conditions can cause decreased outflow of blood in the legs, resulting in pain, swelling and ulceration. In the VIRTUS trial, the Vici stent met its primary effectiveness endpoint with a primary patency rate of 84.0 percent at 12 months[5], which was greater than the pre-defined performance goal (PGE) of 72.1 percent (p-value=<0.0001). Nearly all the patients treated with the Vici stent, 98.8 percent, were free from major adverse events at 30 days post-procedure, which surpassed the pre-defined safety performance goal (PGS) of 94 percent (Refer to MAE chart below). In addition, 2-year results highlighted exceptional 79.4% patency and 88.7% freedom from target vessel revascularization (TVR). This is exceptional data considering the challenging patient population studied, including severely diseased patients with 75% suffering from chronic PTS, 66% with VCSS ≥ 8 and 25.3% with CEAP clinical severity C5 and C6. Lesion complexities included 31.2% total occlusions and 31.8% involving the entire iliofemoral segment. Additional real-world clinical evidence can be found in the Arnsberg Venous Registry which shows 92% 1-year patency.[6]

Engineered to withstand the crushing forces often observed in venous disease, the Vici stent offers an exceptional option for patients with iliofemoral venous obstruction and

compression. The VIRTUS trial demonstrated strong clinical efficacy, even in the most challenging patients. Boston Scientific continues to develop its portfolio of durable venous therapies and is committed to partnering with the physician community to improve patient outcomes and expand treatment options.

VIRTUS Clinical Trial MAE

Major Adverse Events (through 30 days)	n/N
Arterial or venous injury at the target vessel segment and/or target lesion location or at the access site requiring surgical or endovascular intervention	2/169 (1.2%)
Device or procedure-related death	0/169
Bleeding at the target vessel and/or target lession or at the access site requiring surgical or endovascular intervention or blood transfusion	0/169
Acute DVT outside the target vein segment	0/169
Clinically significant pulmonary embolism	0/169
Embolization of the stent	0/169

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6. Presented at LINC 2018 by Michael Lichtenberg, MD, Arnsberg Registry

7. Bench testing performed by Boston Scientific. Data on file. N = 3 VICI and Wallstent and N = 2 Venovo stents tested: 14 x 60 mm. Bench test results may not necessarily be indicative of clinical performance.2:1

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Purpose-built DVT thrombectomy via the ClotTriever System

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– Michael Patel, MD

– Brandon Olivieri, MD

The venous system is inherently different than the arterial system. While the high-pressure arterial system is made up of narrow vessels that taper in the direction of flow, the low-pressure venous system consists of large vessels that get larger and generally flow against gravity. Furthermore, while arterial vessel blockage leads to dramatic symptoms such as myocardial infarction or stroke, venous blockage can lead to no or minor initial symptomology. Consequently, venous thrombus is inherently different than arterial thrombus, often being large, wall-adherent, and more chronic in nature. All these factors contribute to the clinical challenge in repurposing tools developed for extraction of arterial thrombus in treating deep vein thrombosis (DVT).

To this end, Inari Medical developed a purpose-built DVT treatment option called the ClotTriever® System. The ClotTriever System, FDA-cleared for removal of thrombus from the peripheral vasculature, comprises a specialty sheath and catheter with a nitinol coring element and integrated collection bag for effective thrombus removal (Figure 1). The mechanism of action lies in the atraumatic coring element which extracts acute, subacute, and chronic thrombus from the vessel wall, collects it in the integrated bag, and returns it to the ClotTriever sheath for removal from the body. The catheter

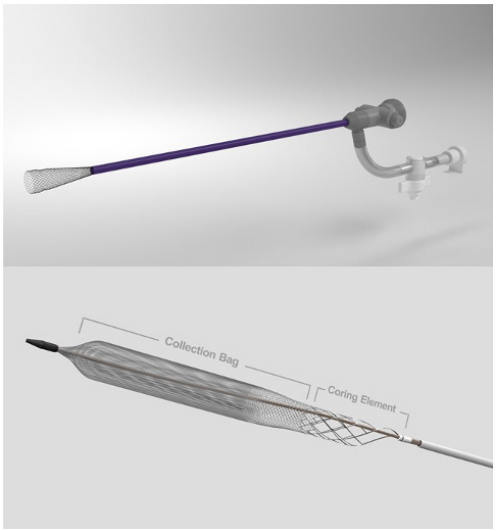

Figure 1. ClotTriever sheath (top) with specialty funnel for maximal thrombus capture and ClotTriever catheter (bottom) with coring element and integrated nitinol collection bag.

can then be reinserted for multiple passes until the vessel is free from residual thrombus.

The ClotTriever System doesn't require capital equipment and was designed to avoid the need for thrombolytics and their associated bleeding risks.[1] Furthermore, DVT patients can be treated in a single session, avoid the ICU, and be discharged home quickly. Data from the first 105 DVT patients enrolled in the CLOUT registry shows that 99% of patients were treated in a single session, none required thrombolytic drugs, only 4% of patients were sent to the ICU, and the median hospital stay was two days.[2] Furthermore, a multi-center study showed that all 12 patients treated with the ClotTriever System avoided the ICU and had an average hospital stay of two days.[3]

The coring element is specifically designed to safely and effectively treat the often chronic and wall-adherent thrombus present in DVT (Figure 2). Initial CLOUT data showed that 70% of patients had complete or near-complete thrombus removal as determined by core lab-assessed Marder scores. Furthermore, the ClotTriever thrombectomy procedure was shown to be extremely safe with a 2.9% MAE rate at 30 days, none of which were device-related, and a median blood loss of 40 cc. In over 5,000 patients treated, there are no reports of vessel or valvular damage via the MAUDE database and similarly no reports of such injury in the CLOUT study. The CLOUT study will follow patients out to two years, and it will be interesting to determine whether the effective thrombus removal associated with the ClotTriever System will result in lower occurrence of the post-thrombotic syndrome and its significant impact on patients' quality of life.

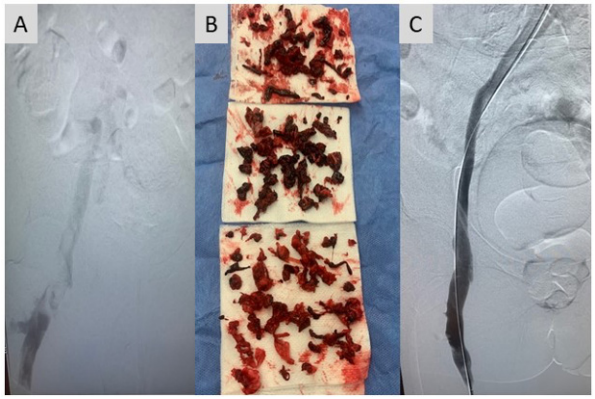

Figure 2. (A) Pre-thrombectomy venogram showing lack of flow in the iliofemoral segment. (B) Extensive subacute and chronic thrombus extracted in five passes with the ClotTriever System. (C) Post-thrombectomy venogram showing restored blood flow and no residual thrombus.

– Adam Zybulewski, MD

– Micheal Ayad, MD

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New Impact Factor Confirms JVS-VL Top Vein Journal

–Peter Gloviczki, MD and Peter F. Lawrence, MD

On June 30th, 2020, ClarivateR released the 2019 Impact Factors, one of the most influential annual metrics of quality and impact of a scientific journal. The Journal of Vascular Surgery – Venous and Lymphatic Disorders (JVS-VL), the Official Publication of the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF), has now a recorded Impact Factor of 3.137, an increase of 0.441 from the Impact Factor of 2.696 the journal received in 2018 (Fig.1.) The 2019 Impact Factor reflects the

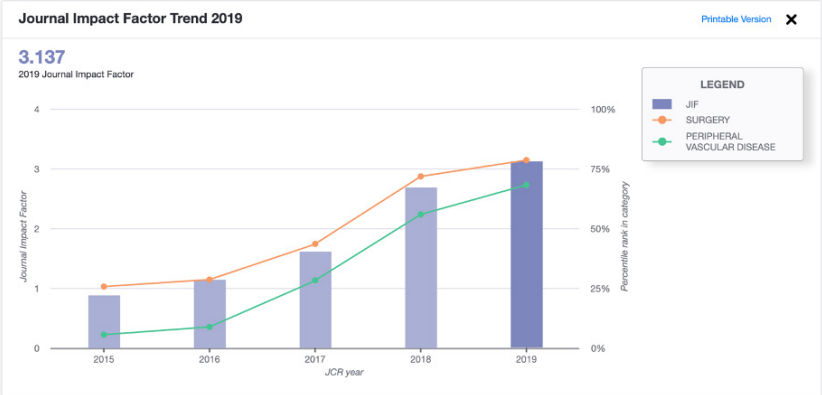


Figure 1. Impact Factors of the Journal of Vascular Surgery- Venous and Lymphatic Disorders (2015-2019). Source: https://clarivate.com (Accessed on July 1st, 2020)

average number of citations that articles published in the journal in the last two years (2017, 2018) received (Fig. 2.)

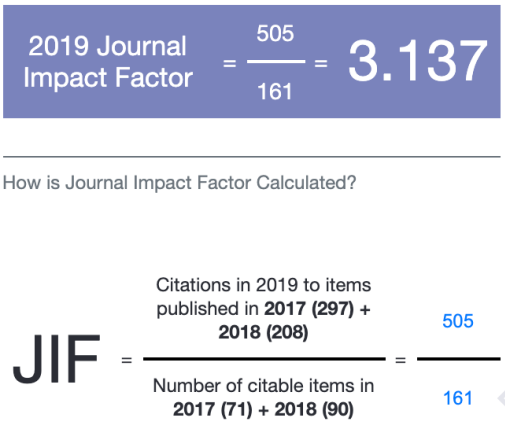


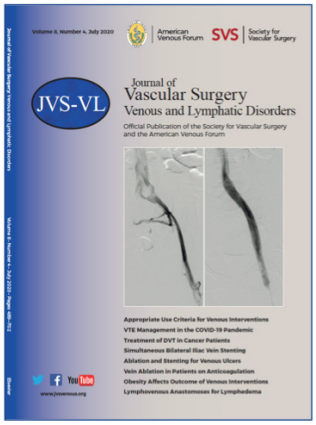
Figure 2. Calculation of the 2019 Impact Factor of Journal of Vascular Surgery- Venous and Lymphatic. Source: https://clarivate.com Accessed on July 1st, 2020)

JVS-VL continues to be the top journal dedicated solely to venous and lymphatic disease, ahead of Phlebology, a United Kingdom publication that received an Impact Factor of 1.914. JVS-VL now ranks 45th among 210 journals in the category "Surgery" and 21st among 65 journals in the category "Peripheral Vascular Disease".

–Peter Gloviczki, MD

–Peter F. Lawrence, MD

JVS-VL is a bimonthly publication, available in print or on-line at https://www.jvsvenous.org/. We are an international journal, with an increasing number of submissions from around the world, with the top five countries including the United States, followed by China, the United Kingdom, India and Turkey. In 2019 we enlarged our editorial board and invited more international experts of venous and lymphatic disease (Fig.3). The current manuscript acceptance rate is 40%.



Launched in 2013, JVS-VL received its first Impact Factor of 0.882 in 2015, and then it rose rapidly to above 3.000; it is listed now among the top 20% of the more than 12,000 scientific journals. Progress would not have been possible without a competent and enthusiastic staff and a superb editorial board. We are grateful to our expert reviewers and truly indebted to our authors who have selected our journal because of its high quality and impact on clinicians and researchers alike. The recently released Impact Factor of 3.137 is a reflection of excellence that we are fully committed to preserve.

Clinical Challenges & Your Tool Box

– Patrick E. Muck, MD, Chief of Vascular Surgery,
Program Director, Vascular Fellowship and Integrated Residency,
Good Samaritan Hospital, Cincinnati, Ohio
Disclosures: Consultant for Penumbra, Inc.

—Patrick E. Muck, MD

Acute and chronic venous thromboembolism are limb-threatening and potentially life-threatening conditions. Acute lower extremity deep vein thrombosis (DVT) is a common condition described by the three factors of Virchow's triad, stasis, vessel damage, and hypercoagulability. DVT can cause significant disability to the affected population, with the most fatal being thrombus embolizing to the pulmonary artery (PA) causing pulmonary embolism (PE) in almost 50% of cases.[1]

For the ideal treatment of PE, there are certain goals to take into consideration. Treatment should attempt to minimize or eliminate the need for thrombolytics to reduce bleeding complications and provide treatment options to patients contraindicated to systemic tPA. For catheter directed embolectomy, aspiration catheters should be as atraumatic and trackable as possible to reduce additional stress on the RV. Treatment goals should include normalization of pulmonary artery pressure and RV/LV ratio without further trauma to the RV or increased bleeding risk.

The Indigo Aspiration System with Penumbra ENGINE and Indigo CAT8 provides an option for the treatment of pulmonary embolism with a possible reduced need for lytics. The sustained aspiration provided by the Penumbra ENGINE facilitates full vacuum throughout the duration of the procedure, differing from the diminished aspiration from syringe aka manual aspiration. The CAT8's large inner lumen paired with the SEP8's mechanical separation is designed to allow for more efficient thrombus removal in the treatment of PE and possibly help to reduce the risk of further distal embolization. The advanced trackability and torqueability in the CAT8 are designed to allow the physician to establish inflow and outflow in the pulmonary arteries.

The latest in the Indigo System line is Lightning™ (Penumbra, Inc.). It is an intelligent aspiration system powered by the Penumbra ENGINE™ (Figure 1). Indigo, now with Lightning, utilizes a unique mechanism of action to help optimize thrombus removal procedures by differentiating between thrombus and blood. Lightning enables clot detection, so the physician knows when the catheter is in thrombus and when it is in patent flow. Lightning has also demonstrated an 18:1 potential fluid loss savings during bench top testing when used versus the Dynamic Aspiration Tubing.[3]

Penumbra's EXTRACT-PE trial took place in 22 centers with 119 patients studying the Indigo System CAT8.[2] The Indigo system met its efficacy and safety endpoint by reducing RV/LV ratio by 27.3% at 48 hours and maintaining a low MAE rate of 1.7%. The device time, 37 minutes, is the shortest seen so far in an IDE trial on patients with PE. EXTRACT-PE also demonstrated a statistically significant on-table reduction in systolic pressure. The trial demonstrated that the Indigo System can provide immediate mechanical relief using sustained aspiration. This established the safety and efficacy of the Indigo System for the treatment of PE and has become our frontline option for managing intermediate risk and high-risk PE.

Disclaimer: The opinions and clinical experiences presented herein are for informational purposes only. The results may vary depending on a variety of patient specific attributes. For indications, contraindications, warnings precautions & potential adverse events see: https://bit.ly/2W4ZggM.

Figure 1. Lightning™ Intelligent Aspiration on the Penumbra ENGINE™

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3. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance.

Phlebolymphedema: CVI's Inseparable Twin

–Tom O'Donnell, MD[1], Darren Wennen[2] and Dan Carlson[2]

1. Cardiovascular Center at Tufts Medical Center; Chief Medical Officer-Tactile Medical
2. Tactile Medical

–Tom O'Donnell, MD

–Darren Wennen

–Dan Carlson

Veins and lymphatics are embryologically and anatomically interrelated, functioning as complementary drainage systems.[1] They also share a common disease: phlebolymphedema (PLE); extremity swelling caused by combined venous and lymphatic insufficiency.[2] Indeed, PLE is likely to be more frequent than an oncologic cause, and the most common cause of lymphedema in the Western world.[1,2,3] Like viewing an iceberg, clinicians recognize the venous component of PLE but may fail to see the lymphatic component below the surface.

Venous outflow obstruction and/or reflux produces venous hypertension, which initiates the clinical spectrum of PLE. The pathophysiological consequences of increased capillary filtration results in accumulation of protein-rich fluid within the interstitial space (ISP) and overwhelms lymphatic capacity, so that edema ensues. Chronic edema can permanently damage the lymphatic capillaries causing lymphedema. Our revised understanding of interstitial fluid dynamics dictates that this fluid load be drained by the lymphatics rather than by the disproven concept of venous reabsorption[4] (Fig. 1). When the lymphatics become damaged, this initiates a vicious spiral[4] of chronic inflammation, fibrosis, adipose deposition, and cellulitis.[6-9]

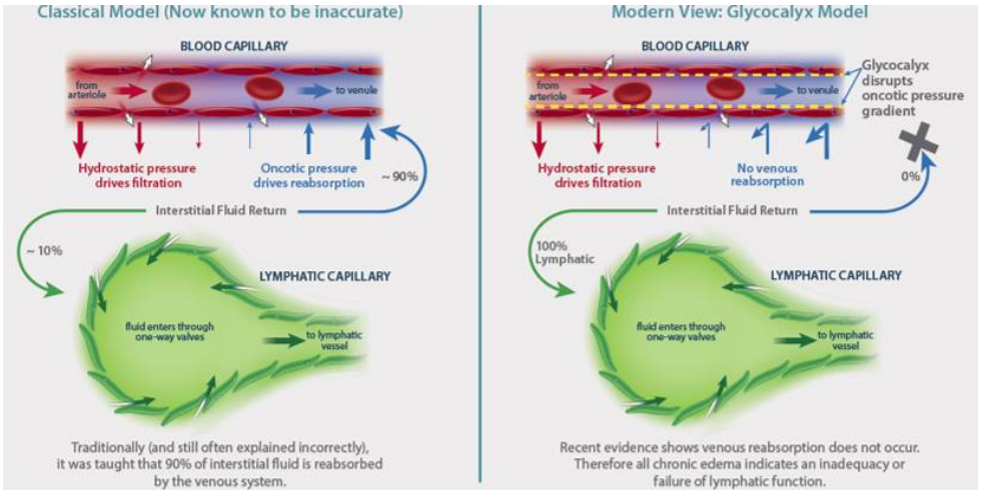

Figure 1. The Revised Starling Principle[4,10]

Traditionally therapy in advanced CVI (C3 – C6) is directed toward reducing chronic venous hypertension by ablating reflux in superficial veins, or relieving obstruction in the

ilio-caval system, under the belief that reducing venous hypertension alone should resolve edema. Though fundamental to effective healing, the lymphatic component of PLE is often overlooked by clinicians.[2,8] To avoid PLE's vicious spiral, active promotion of lymphatic flow is essential to removing static fluid, even at the early stages of swelling.

The goal of focused PLE treatment should be to reduce the fluid load by promoting increased lymphatic flow and subsequently reducing limb volume.[12] As lymphedema currently is incurable, long term and continued treatment involves at-home self-maintenance. Unfortunately, self-manual lymphatic drainage (MLD) is difficult to perform, particularly in older patients, compliance is generally poor[13] and may produce limited clinical benefit.[15]

At-home pneumatic compression devices, particularly Advanced Pneumatic Compression Devices (APCDs, HCPCS E0652) can improve lymphatic circulation,[16] reduce limb volume,[17,18] improve patient-reported symptoms and quality of life,[18] and lower healthcare expenditure.[19,20] In patients with PLE we have specifically assessed both the physiologic and economic impact of the Flexitouch (FLX) APCD (Tactile Medical, Minneapolis, MN.), designed to automate at-home self-MLD, and have found that, unlike manual self-MLD, FLX therapy is associated with high patient satisfaction and compliance.[18] Additionally, near-infra-red fluorescence lymphatic imaging (NIRFLI) validated physiologically improved lymphatic function in most patients with a single 60 min. session of FLX treatment, as determined by (1) the presence of newly recruited lymphatics, (2) the emptying of fluorescence from lymphatic vessels and/or (3) the change in contractile function in each of 12 subjects.

In a longitudinal matched case control analysis of de-identified private insurance claims from a dataset of 165 million people, use of FLX in a PLE population was associated with statistically significant reductions in PLE and sequelae-related medical resource utilization (MRU) and costs compared to conservative care, simple PCDs (SPCDs), and other APCDs (Fig. 2).[21]

PLE is widespread, underrecognized and can be devastating to health. Accordingly, vascular specialists should ensure that all PLE patients undergo early, effective, and ongoing effective lymphatic treatment with a clinically proven PCD.

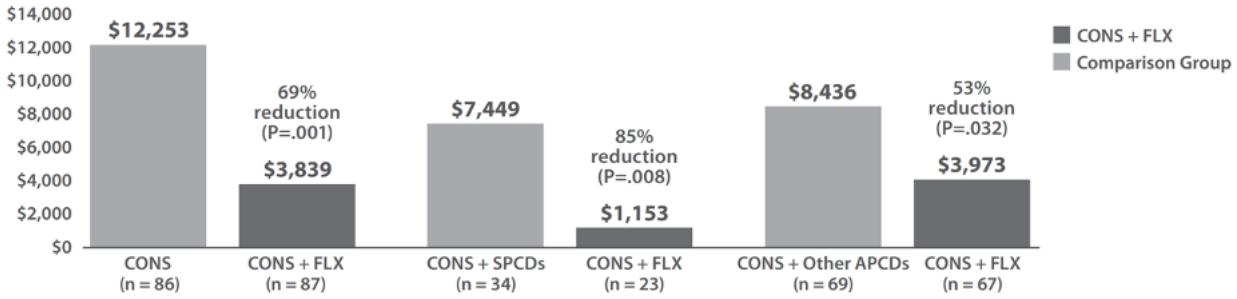

Figure 2 Total PLE-Related Cost Comparing FLX vs. Alternative Treatment Modalities[21]

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Benefits of Achieving Robust Clot Resolution In VTE Patients While Balancing Lower Risk of Adverse Events

–Brian Tweddale, MD, Doylestown Hospital

—Brian Tweddale, MD

The majority of VTE patients have traditionally been treated with anticoagulation alone. However, up to 50% of patients who present with lower extremity DVT develop post-thrombotic syndrome (PTS), despite being treated with anticoagulation therapy and compression therapy, while 35-50% of patients with PE who are treated with anticoagulation therapy go on to develop some form of functional limitation (Post PE syndrome).[1]

This has led to a quest to identify treatments that carry a much better risk-benefit ratio while reducing adverse event complications. Two interventional approaches have evolved: localized CDT, and mechanical thrombectomy. Beyond solving for the acute episode, the next challenge is how to achieve the greatest degree of clot burden reduction while optimizing perfusion and lowering adverse event risk.

While mechanical thrombectomy helps to reduce the risk of systemic bleeding, there are other risks related to the use of these devices that should be considered. There is a potential to damage to the vessel wall, damage to the valves, risk of hemolysis and the consequent damage to the kidneys. Prolonged aspiration can also lead to a high volume of blood loss, requiring blood transfusion.

A recent addition to the percutaneous devices is a catheter-directed thrombolysis device developed by Thrombolex. A good example of the effectiveness of this device is a recent patient I treated, who presented with a massive PE. He was a 79-year-old man, previously healthy, who presented in acute respiratory distress. The venography showed a massive saddle embolism and large bilateral pulmonary emboli and a 5.3:1 RV/LV ratio, (figure 5A&6).

The patient underwent thrombolysis using the Bashir Endovascular Catheter (BEC) (Figure 1). Boluses of 2.0 mg of r-tPA were injected into each pulmonary artery, followed by bilateral infusions at a rate of 0.65 mg/h, for a total dose of 14.0 mg. Follow-up, performed 16 hours after admission, revealed a decrease in pulmonary artery pressures to 43/12 mmHg (mean = 23), and a marked increase in the pulmonary arterial perfusion bilaterally compared to pre-procedure (figures 7 and 8A&B). The patient was discharged from the hospital 48 hours post procedure. A two-month follow-up showed resolution of all emboli (figure 5B).

This novel device provides us with rapid results that we have not found with any other catheter-directed device. There were no bleeding complications or adverse events of any kind related to this massive PE patient. Alternative devices I have used in the past have not been adequate for quick resolution of such a large thrombus burden. Using the BEC, we have been able to get results that we have been unable to achieve with other devices.

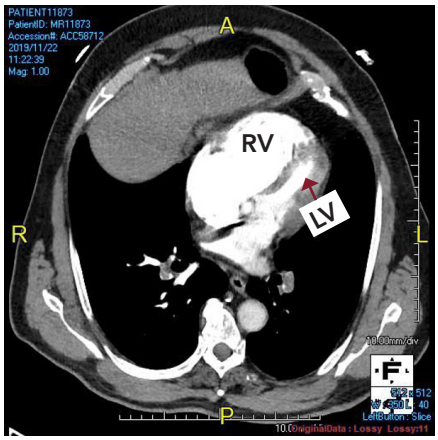
Figure 1. Bashir Endovascular Catheter (BEC)

A.

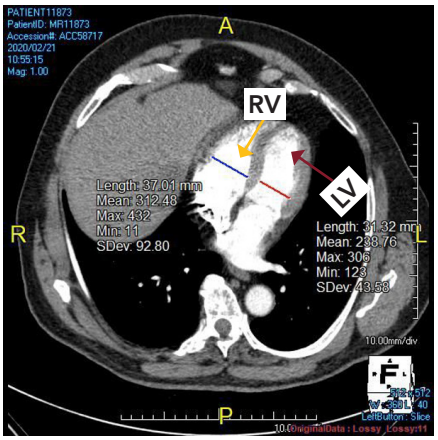
B.

C.

Figure 5. Pre- And Post-Procedural Thoracic Computed Tomographic Venography Cross-Sectional Views

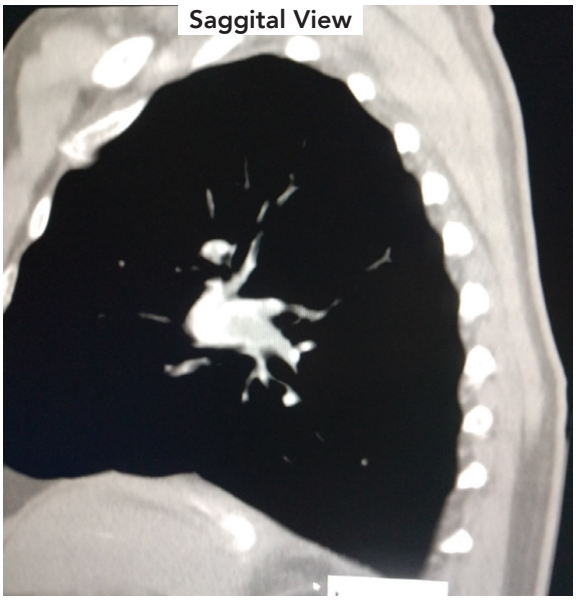


A. Initial presentation



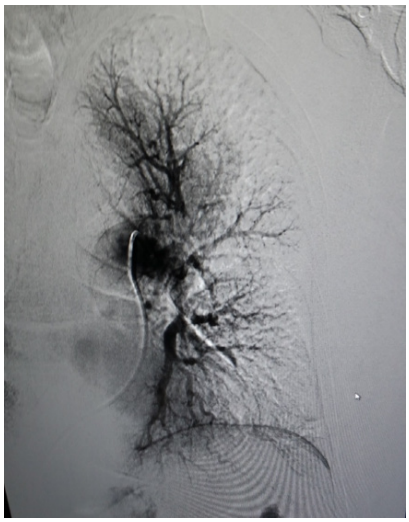
B. Two months post pharmaco-mechanical thrombolysis

Figure 6. Pre-Procedural Computed Tomographic Angiography

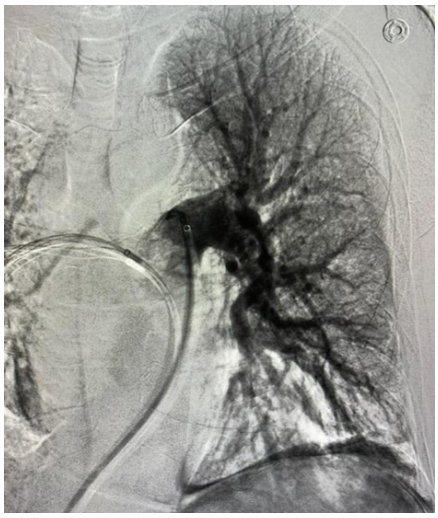


Marked Pulmonary Hypoperfusion

Figure 7. Left Pulmonary Angiography

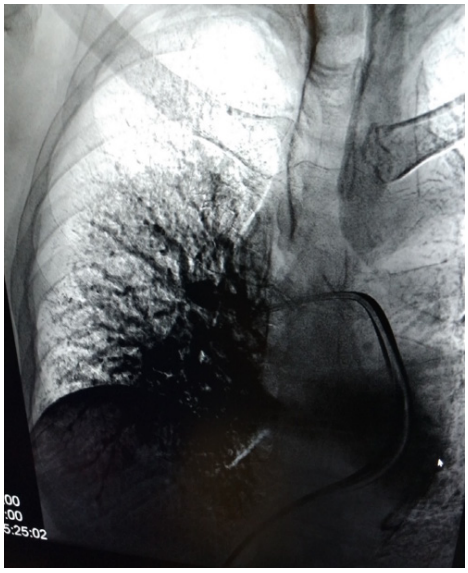


A. Pre-Procedure

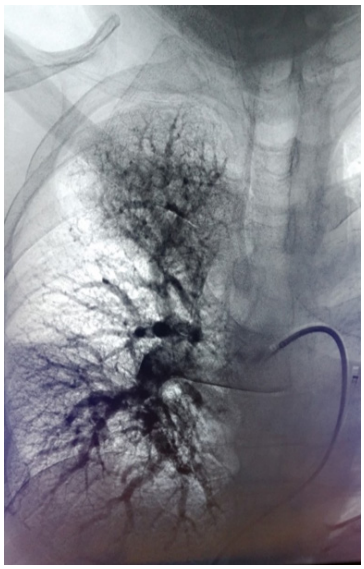


B. 16 Hours Post-Procedure

Figure 8. Right Pulmonary Angiography



A. Pre-Procedure



B. 16 Hours Post-Procedure

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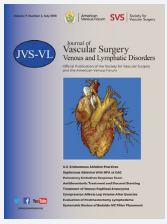

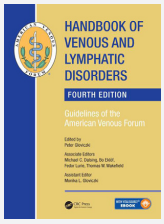

NIH National Heart, Lung, and Blood Institute

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President's Message – Survey 1 Results

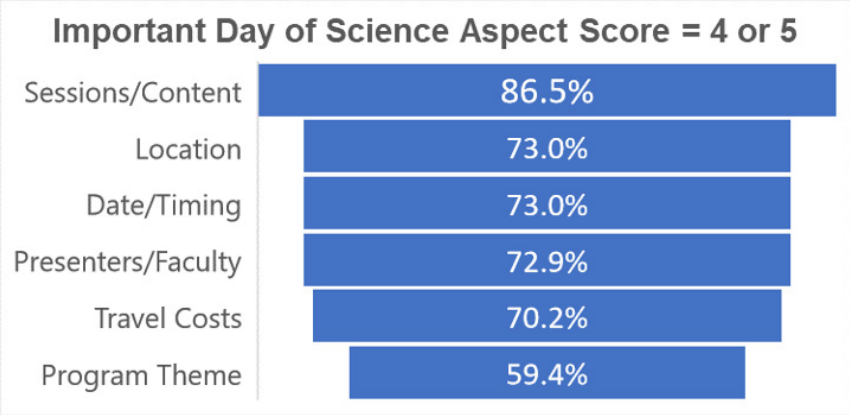
–Harold J. Welch, MD

Dear Fellow AVF Members,

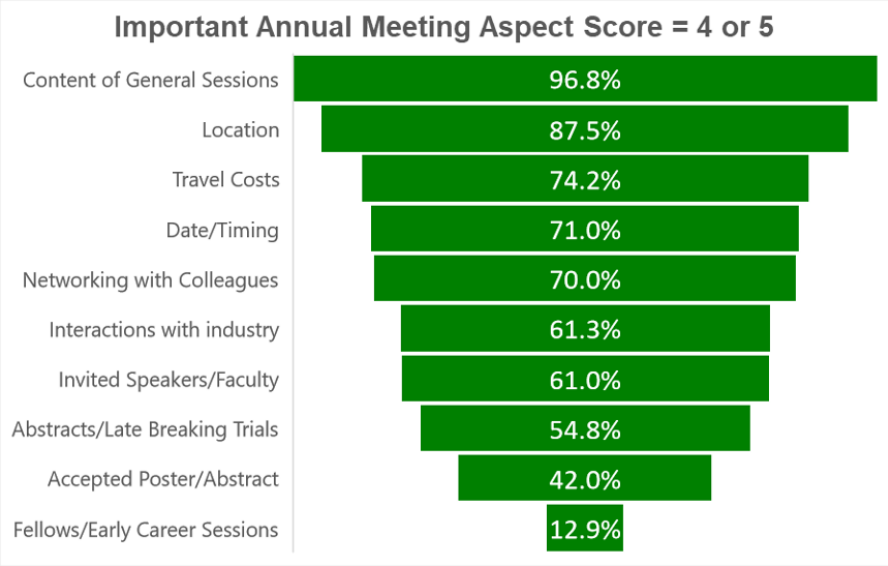
As promised, I would like to share with you the results of our recent survey concerning the VENOUS2020 meeting. Two different surveys were sent out by the AVF administration, one to attendees of the meeting and one to members who did not attend the meeting.

Of members who did NOT attend VENOUS2020 (n=37 respondents), concerning the Day of Science, members were asked to rate important aspects, on a scale of 1-5, with 5 = extremely important, 3 = somewhat important, and 1 = not important. The following were rated either 4 or 5.

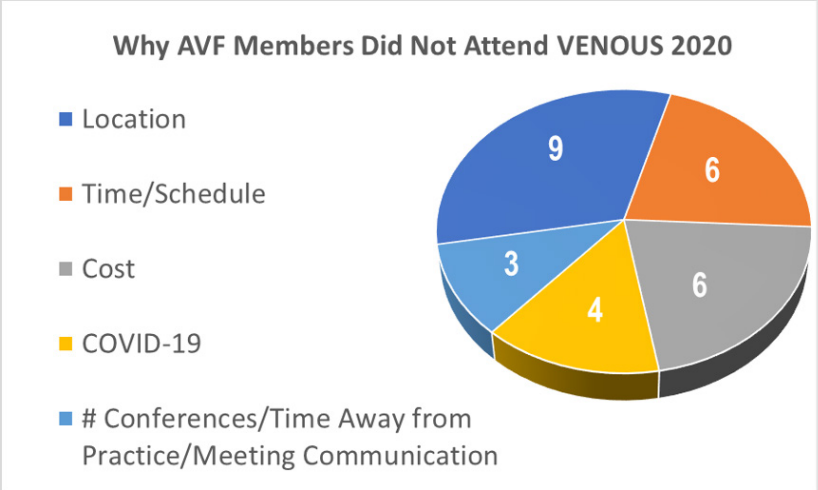
—Harold J. Welch, MD



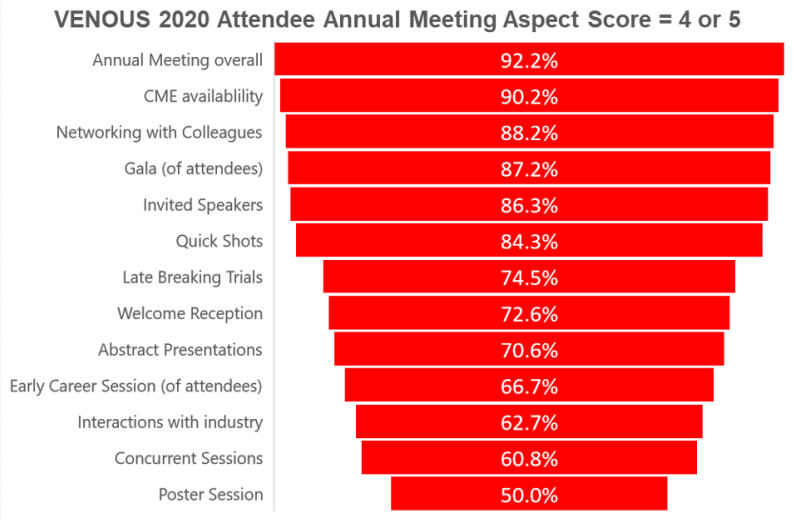
Similar responses for aspects of the Annual Meeting:



As for comments on why members did NOT attend the meeting, the reponses fell into an number of categories:



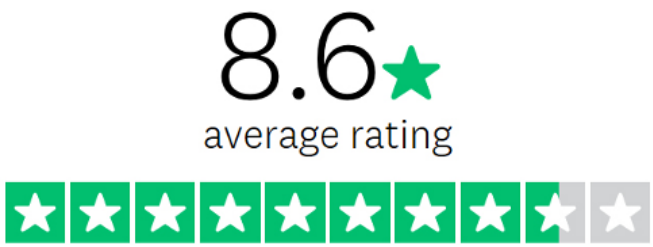
Of those respondents (n = 52) who DID attend the meeting, they were asked how valuable/informative were the following, with percentages answering 4-5 on the the 1-5 scale, with 5 = extremely valuable.



Value of the meeting related to the cost of registration:

Equal To / Greater Than / Far Greater Than = 70%

Likely to recommend the AVF Annual Meeting to a colleague: 8.6/10



There were many constructive comments that we will try to use to improve the meeting. At VENOUS2021, there will not be any invited discussants for papers, to allow for more discussion from the audience. The moderators will be instructed to run on time. And of course, there will be an option for virtual attendance (hopefully not the only option).

I would like to address the issue of concurrent sessions, such as those from the Society of Vascular Medicine (SVM) and the American Venous and Lymphatic Society (AVLS). These are our sister societies and colleagues, and the AVF is invited to present a session at their meetings. Having their experts present at our annual meeting provides insight and opinions that can only enhance the educational experience of our meeting. Additionally, we have many renowned international members from around the globe. Our International Session allows us to learn from the worldwide experience in the treatment of venous disease, and improves the quality of our meeting.

A second questionaire was sent out in July concerning your membership in the AVF and what is important and valuable to you. I will share the results with you in an upcoming newsletter.

To conclude on a light note, I thought I would share these two comments from the Annual Meeting survey. "Athletic things are a waste of time." "A daily round of golf." Thank you for being a valued member of the AVF, and if not a member, please consider joining the pre-eminent venous society, the AVF. Hope to see you in San Antonio, either in person, or on the screen.

Warm Regards,

Harold Welch, MD

President, American Venous Forum

New AVF Members – Welcome to the Community!

Eric Goldschmidt	*Member-In-Training, Ohio*
Michael Levy, MD	*Physician Membership - National, Massachusetts*
Kristin Schafer	*Member-In-Training, Ohio*
Edvard Skripochnik	*Member-In-Training, New York*
Giancarlo Speranza	*Medical Student Member, Pennsylvania*
Minhaj Khaja	*Physician Membership - National, Virginia*

VEIN SPECIALIST PUBLICATION

EDITOR-IN-CHIEF: Steve Elias, MD
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Please send all comments to info@avfmail.org.

American Venous Forum
Promoting venous and lymphatic health

**Disclaimer: The information featured in this newsletter selected by AVF, which offers educational materials, are not intended to be representative of patients with venous disease generally and should not be considered medical advice. Patients should consult their doctor to determine the best treatment decision for their individual disease.*

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