

# Refined technique and newer generation device improves TRIVEX outcomes

Refined techniques in combination with additions and improvements to transilluminated powered phlebectomy (TRIVEX) instruments have resulted in improved outcomes and a decrease in potential complications following treatment, whilst reducing the trauma for the patient, according to Dr Marc Passman, Associate Professor Surgery, University of Alabama at Birmingham, AL.

In his presentation at the 2011 VEITH conference in New York entitled, 'Which One: Phlebectomy, TRIVEX or sclerotherapy for bulging varicose vein tributaries?' Passman stated that recent trends toward less invasive procedures for treating bulging varicose veins have led to expanding interest in ambulatory phlebectomy, sclerotherapy and transilluminated powered phlebectomy; each of which have certain advantages and disadvantages.

## Ambulatory phlebectomy techniques

Numerous ambulatory phlebectomy techniques (e.g., excisional phlebectomy, stab avulsion phlebectomy, hook phlebectomy and micro-puncture phlebectomy), all have the same basic technique, which involves multiple small incisions for direct removal of varicosities. With advances in tumescence anaesthesia, these outpatient techniques have become safe and effective methods for varicose vein removal with low complication rates, high patient satisfaction and excellent cosmesis. "However, there are also limitations including the need for multiple incisions, poor visualisation, incomplete resection, and technical challenges for patients with extensive varicosities," said Passman.

## Sclerotherapy

Although sclerotherapy avoids the need for incisions, limitations include the need for higher concentration of sclerosant, decreased effectiveness for larger veins, and the potential for leakage of sclerosant into the deep venous system. "Although foam sclerotherapy may hold future promise, foam reconstitution of sclerosant agents is not currently FDA approved with evidence-based outcomes lacking and limited published reports suggesting some problems especially with venous thrombophlebitis and generalised somatic complaints," he added.

## Transilluminated Powered Phlebectomy

The FDA approved transilluminated powered phlebectomy (TRIVEX) in 1999, which was originally brought to the market by Smith & Nephew. TRIVEX is now marketed by InaVein. Passman commented that the clinical benefits of TRIVEX are best realised in cases of extensive varicose veins where the direct visualisation allows for complete resection with fewer incisions. However, for patients with relatively minor varicosities the margin of

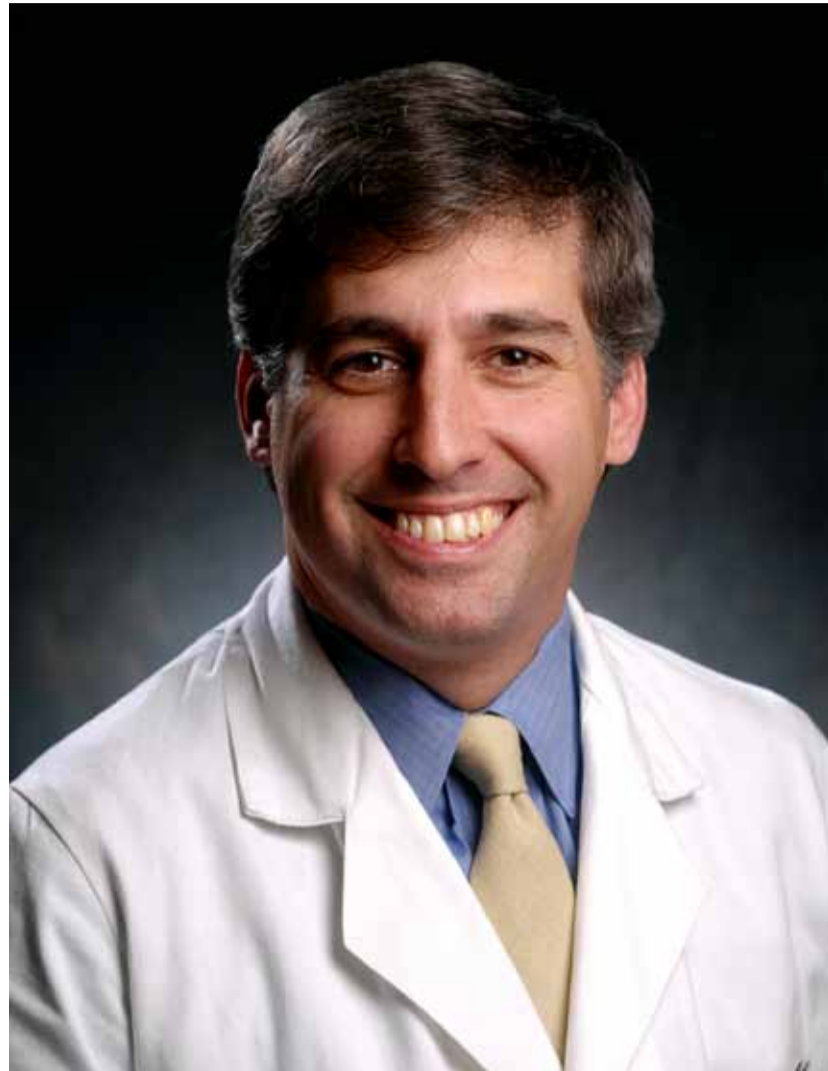
benefit provided by TRIVEX decreases when compared to traditional ambulatory phlebectomy. He added that although the initial experience with TRIVEX after its introduction was variable, more recent publications using the improved technique have demonstrated consistently good outcomes with high patient satisfaction.

## TRIVEX System – changes and technique modifications

The second generation TRIVEX System, designed to address limitations seen in the first version, was introduced in late 2004. The technical changes included a fully integrated system that incorporates dual infusion pumps, a light source for the irrigating illuminator, and a modified resector. The modifications in technique include lower oscillation frequency (300-500 rpm), high pressure suction, refined positioning of the resector blade while targeting the specific varicosities, dermal punch drainage, secondary tumescence with extensive flushing of residual haematoma and residual venous tissue fragments, and a tertiary stage of tumescence in the subdermal plane. "The combination of a newer generation system together with modifications in the technique has eliminated most of the earlier problems," Passman confirmed.

## Clinical studies

There have been four studies from 6-12 years ago, according to Passman, directly comparing TRIVEX to conventional varicose vein surgery: two prospective nonrandomized studies and two randomized controlled trials (Spitz GA, Braxton JM, Bergan JJ. Outpatient varicose vein surgery with transilluminated powered phlebectomy. *Vascular Surgery* 2000; 34(6):547-55; Scavee, Lesceu O, Theys S et al. Hook phlebectomy versus transilluminated powered phlebectomy for varicose vein surgery: Early results. *Eur J Vasc Endovasc Surg* 2003; 25:473-5.; Aremu MA, Mahendran B, Butcher W, et al. Prospective randomized controlled trial: conventional versus powered phlebectomy. *J Vasc Surg* 2004; 39(1):88-94; Chetter IC, Mylankal KJ, Hughes H, Fitridge R. Randomized clinical trial comparing multiple stab incision phlebectomy and transilluminated powered



Marc Passman



Pre-operation (left) and six weeks post-operation

phlebectomy for varicose veins. *Br J Surg.* 2006; 93(2):169-74; and several other prospective single-arm observational studies.

In these four early studies, the overall reported outcomes following TRIVEX varied considerably and consisted primarily of ecchymosis and/or haematoma formation (4.9–95%), paresthesias or nerve injury (9.5–39%), skin perforation (1.2–5%), superficial phlebitis (2.4–13%), swelling (5–17.5%), hyperpigmentation (1.2–3.3%), and deep venous thrombosis (<1%) (Scavee V. Transilluminated powered phlebectomy: not enough advantages? Review of the literature. *Eur J Vasc Endovasc Surg.* 2006;31(3):316-9). Although most studies reported fewer incisions for TRIVEX compared to conventional surgery, differences in operating time varied. With regard to cosmetic scores, outcomes were similar for both groups; although, some authors

reported more favourable results with conventional surgery. Residual or recurrent varicose veins varied between 9.1 and 21.2%. While overall patient satisfaction scores were not statistically significant, the scores had a tendency to be lower for TRIVEX compared to conventional surgery.

Passman added that the problem with most of the published literature is that operative technique included the early generation TRIVEX system and/or initial technical recommendations for higher oscillation frequencies (800-1200rpm), lower pressure suction, and primary – secondary tumescence stages only.

In Passman's own published experience documenting the evolution in his TRIVEX technique (Passman MA, Dattilo JB, Guzman RJ, Naslund TC. Combined endovenous ablation and transilluminated powered phlebectomy: is less invasive better? *Vasc Endo-*

*vascular Surg* 2007; 41(1):41-7), over an eight-year period, 72 limbs in 59 patients were treated with combined stripping-phlebectomy [Strip-Phleb], 92 limbs in 81 patients with combined stripping – TRIVEX [Strip-Tpp], and 99 limbs in 76 patients with combined endovenous ablation – TRIVEX [Evab-Tpp]). Overall distribution of complications remained unchanged between the early (STRIP-PHLEB) and later (Evab-Tpp) portions of the study, although there was an increase in complications during the transition phase (Strip-Tpp) related mostly to the increased haematomas with the earlier transilluminated powered phlebectomy techniques. With the above described modifications of transilluminated powered phlebectomy, problems with haematoma after endovenous ablation decreased to levels comparable to stripping – phlebectomy (Strip-Phleb 5.6%, Strip-Tpp 16.3%, Evab-Tpp 6.9%;  $p < 0.05$ ). Furthermore, when the individual techniques of endovenous ablation and transilluminated powered phlebectomy were evaluated separately, the outcomes reported were not different for those published individually for each technique, respectively, he added.

Two more recently-published studies include Franz, RW. and Knapp, ED. Transilluminated Powered Phlebectomy Surgery for Varicose Veins: A Review of 339 Consecutive Patients *Ann Vasc Surg* 2009; 23: 303-309; and Spitz, GA. Transilluminated Powered Phlebectomy in an Office Setting: Procedural Considerations and Clinical Outcomes. *J Endo Vasc Ther* 2011; 18:734-738.

In the 2009 Franz study, complications following TRIVEX were reported in 12 (3.5%) patients and included one (0.3%) patient with a tibial vein DVT that resolved with anticoagulation therapy after six months, eight (2.3%) patients with discoloration of skin due to hemosiderin staining, and excessive or hypertrophic scarring in two patients (0.6%) that corresponded to areas of extensive varicosities where large (>5mm in diameter) varicose vein removal was required. One patient (0.3%) experienced cellulitis. One patient (0.3%) with excessive scarring was unsatisfied with the outcome of the procedure. The remaining 338 (99.7%) patients were satisfied with TIPP and reported a good outcome. The mean procedure time was 19.7 minutes.

## In-Office, Tumescence-only TIPP study

The most recent publication is Spitz, GA. Transilluminated Powered Phlebectomy in an Office Setting: Procedural Considerations and Clinical Outcomes. *Journal of Endovascular Therapy*: October 2011, Vol. 18, No. 5, pp. 734-738, in which he reported on a series of non-sedated patients treated with transilluminated powered phlebectomy (TIPP) under tumescent anaesthesia in an office setting.

In the study, 36 patients (31 women; mean age  $54.8 \pm 11.8$  years) with a mean body mass index of  $25 \text{ kg/m}^2$  were selected for the in-office TIPP procedure between January 2009 and September 2010. Medical conditions included hypertension, asthma, hypothyroidism, and gastrointestinal problems. Twenty-eight had prior surgical procedures, ten of which were for vascular abnormalities. Symptom duration was a mean of 19 years. Twenty-five had a family history of venous



First generation TRIVEX



Second generation TRIVEX

disease. The CEAP classification ranged from 2 to 4, but the majority were class 2. Seven patients had conditions that made the TIPP procedure more challenging. Medical data, preoperative venous status, post-operative findings, and patient-reported satisfaction were reviewed.

The results showed that all TRIVEX procedures were completed as planned and without complications. The mean TIPP procedure time was  $13.5 \pm 3.7$  minutes. Thirty-three patients underwent concurrent endovenous ablation. A mean procedure time of 13.5 minutes ( $\pm 3.7$  min) was reported. Patient satisfaction measured on a scale from 0 to 10 ranged from a mean of 8.8 at 48 hours to 9.6 at three months. At the three-month follow-up, there were no reports of haematoma, deep venous thrombosis, or extended paresthesia.

The study concluded that appropriately selected patients with a variety of clinical presentations can safely undergo the TIPP procedure in an office setting utilising only local tumescent anaesthesia. "More recent cases have confirmed that when patients are prepared for an in-office procedure and treated by a physician well versed in the TIPP procedure and tumescent anaesthesia, the outcomes are mutually satisfying," said Spitz. "There should also be an economic benefit, with reduced cost to the healthcare system, as has been realized in other clinical situations."

#### Technical Components

The TRIVEX System Control Unit is the central power unit with controls for the xenon light source, irrigation pumps, and resection oscillation speeds. The TRIVEX Illuminator connects to the control unit with a fibre optic cable and provides high intensity light for transillumination. Tumescent irrigation is with footswitch control through a channel in the Illuminator Handpiece. The TRIVEX Resector Handpiece has both 4.5mm and 5.5mm resector blade options, control of oscillation direction and rpm speed, and a connection port for suction tubing.

#### TRIVEX Technique

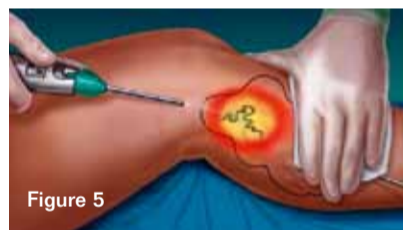
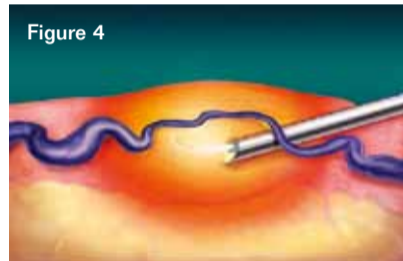
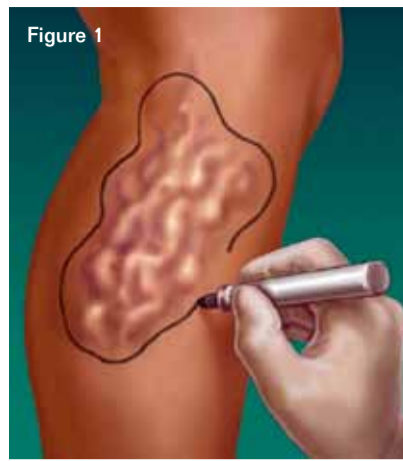
Preoperative marking is performed with the patient standing to maximise varicose vein dilation. Unlike standard phlebectomy that requires direct marking over the varicosity, an outline is

made around the area of varicosities to avoid obscuring the vein with the skin mark (Figure 1). General, epidural, spinal or light conscious sedation anaesthesia can be used depending on patient preference. In Spitz' most recent article (discussed above), local tumescent anaesthesia was used exclusively.

The patient is positioned supine with the lower extremity elevated 30° degrees. Standard sterile prep and drape is performed with care to avoid removal of preoperative marks. If other procedures like endovenous ablation or saphenous stripping are required, these are performed first, he explained. Incisions used for these other procedures can be subsequently used for TRIVEX when appropriate based on preoperative marking.

Incisions should be strategically placed to minimise the number of incisions, and to use maximum length of the TRIVEX Resector Handpiece. Incisions (Figure 2) can also be interchanged between instruments to allow extension of the resection range. Position of the incisions should also be oriented so the instruments approach the intended area of resection near 180° degrees, if possible, to maximize the area of resection; although, at times, the angle of instrumentation will decrease in order to accommodate the best position and to avoid limitations while approaching knee or ankle varicosities. Incisions, 2-3mm in length, are vertically oriented in the thigh and calf and transversely at the knee level following natural Langer's skin lines for most cosmetically appealing results. Resection of varicosities across the foot is avoided.

Tumescent solution is prepared with 40ml of 2% Lidocaine and 2ml of 1:1000 epinephrine diluted in 1000 ml 0.9% normal saline. The irrigation pump is incorporated into the TRIVEX System Control Unit. Adjustment can be made in the intensity of pump pressure generated although the default flow rate of 450ml/min is appropriate for most cases. The TRIVEX Illuminator is placed initially and first stage tumescence is administered (Figure 3). The Illuminator is placed a few millimeters deeper than the target varicosity and tumescence solution is infiltrated into the area along the course of the vein. With adequate infiltration, visualization with transillumination effect will improve, but over infiltration should be avoided to prevent compression of the vein and loss of visualisa-



TRIVEX Technique, figures 1-6

tion, Passman warned. Tumescence also allows for hydro-dissection of the varicosities which will assist with resection (Figure 4).

Through the counter incision, the TRIVEX Resector Handpiece is placed and the distal tip is directed to just underneath and next to the target varicosity. Resection along the longitudinal axis of the vein is preferred when possible to maximize the amount of vein resected with a single pass. As the angle to the vein becomes more acute, additional passes to reposition the tip of the resector may be required for complete removal. While the earlier technique included higher oscillation frequencies (800-1,200 rpm), modification with the newer generation system allows for lower oscillation frequency (300-500 rpm). With the lower speed and a rapid on-off pulsing, limited dissection with the resector results in gently loosening the vein from supporting tissue, with most of the resection then accomplished by the high suction.

During resection (Figure 5), the skin is held taught to facilitate resection and prevent skin penetration. As resection proceeds, additional tumescence is infiltrated to flush any residual vein tissue and blood into the suction, and to increase pressure along the resected vein to provide a tamponade effect (Figure 6). Successful resection of the vein will be confirmed with blanching along the vein tract. The TRIVEX Illuminator and TRIVEX Resector Handpieces are then exchanged through respective incisions. After completing resection in one area, attention is then directed to the next segment of the leg.

#### Additional Technique Improvements

Modification of technique with the newer generation system also includes a more extensive secondary tumescence phase through additional drainage incisions made using a 1.5-2.0mm dermal punch biopsy. Punch holes can be made either before resection along the course of the vein, or after resection in areas where blood pools subcutaneously as visualized with transillumination. Evacuation of any haematoma is facilitated with manual compression along the vein tract. Copious irrigation is performed through the dermal punch incisions using the TRIVEX Illuminator until drainage is clear. After resection is completed, ter-

tiary tumescence is performed in the subdermal plane using a spinal needle connected to the pressure tubing to create a "peau de orange" effect in the skin. This allows for additional irrigation and drainage, provides increased subdermal - subcutaneous pressure to decrease potential for delayed haematoma, and extends the anaesthetic effect of the tumescence.

Only passive drainage of irrigation fluid is recommended at this stage. Incisions are too small for suture closure and post-procedure drainage is beneficial to prevent bruising and decrease the potential for haematoma formation. A three-layered compression dressing (ABD pads/Webril for absorbency, Kerlix/Coban for mild compression and ace wrap) is applied from base of the toes to high up on the thigh. Some delayed passive drainage and staining of the dressing should be expected. Ambulation is encouraged; although, elevation of the extremity should be recommended during periods of rest in the initial few post-operative days. Non-steroidal anti-inflammatory type medications are generally not required, and should be discouraged in the first week to avoid increased bruising and bleeding risk. Compression is continued for 24-48 hours post-procedure with transition to graduated compression stockings. Compression is continued for an additional 1-2 months. Post-operative visits are usually within 48 hours to one week and, then, between 4-8 weeks.

#### Conclusion

"In conclusion, although there is no published data clearly showing any significant statistical advantage of TRIVEX over conventional treatment except for the number of incisions, most of the published literature represents the earlier generation system and techniques," Passman surmised. "With a newer generation device, smaller instrumentation, and modification of technique that allows for slower oscillation speed, higher suction, and extensive tumescence irrigation and drainage, the technique of TRIVEX has become less traumatic, which imparts decreased potential for complications and improved outcomes over those reported previously. Until additional randomised trials evaluating these newer techniques are published, any additional potential benefits of the procedure have yet to be determined."

## Venous fellowships in vascular training

Continued from page 8

dependent residents, they graded venous procedure training to be excellent/good at the 66.6% and 76.1% level, respectively. A second question, coming from a slightly different perspective, asked the resident to estimate the appropriateness of venous training (need more, just right, not important). Just right was the opinion of 71.9% and 67.6% of the integrated and independent residents, respectively. The residents were further asked to rate the didactic instruction as excellent, good, fair or non-existent. The integrated residents responded with an excellent/good rating of 68% while the independent residents gave it a 72% rating.

Residents were then asked whether the hands-on venous operative experience provided by their program would allow them to confidently perform all venous procedures, the integrated response was yes in 77% with the independent residents rating it higher at 81%. Finally, when grading the (anticipated) level of competence and comfort level in venous procedures 81% of the integrated and 81% of the independent residents thought that they would be competent or even very competent to do this work when training was completed.

There are over 100 Accredited Vascular Surgery training programs, the survey to the Program Directors realized less than a 20% re-

sponse. Five programs responded that they would use an outside venous rotation with the desire that a wide range (acute and chronic) of experiences being included and directed to the PGY 4-7 resident. If the parent training program was responsible for the cost then only 40% could utilise the opportunity. From the verbal responses obtained at the APDVS meeting, it is Dr Dalsing's impression, that there would only be a few more programs interested in such an opportunity.

Therefore, from the perspective of the vascular surgery resident; 20-30% feel that the training in venous disorders is less than good or excellent and, therefore, might view an out-of-program experience a desired option, said Dalsing. Since there are approximately 150 residency positions available per year in the US, one could estimate that at most 45 mini-venous rotations could address the perceived need. Ultimately, however, 81% of both the integrated and independent residents feel that they will be competent and comfortable in performing venous interventions when training is complete.

"Therefore, in reality, only 19% of residents feel a real deficiency in training so 28 mini-rotations provided either during residency or as post-graduate venous specific fellowships would meet any perceived need," he commented. "Although I have no specific data to prove this the-

ory, I would postulate that most completing trainees might need more experience in venous thrombolysis, venous stenting, or deep venous interventions rather than in the care of superficial disease. Whether the practicing surgeon will take the time to improve skills or simply refer such cases would also be a factor in the need for venous specific training for which I have no relevant information."

Data obtained from perspective Program Directors showed that it was likely that venous rotations during a dedicated vascular surgery residency has limited need since at most ten programmes (<0%) would see any need. In addition, there are practical issues which must be considered. The Accreditation Council for Graduate Medical Education has restrictions on rotations outside of the parent training institution aimed at maintaining the proper educational and work environment for the trainees. Dalsing also added that issues of licensure for out-of-state rotations, malpractice, room and board logistics, and other costs will add additional barriers to such rotations. "Within state rotations might be more plausible by eliminating some of these challenges. Regardless, the apparent lack of demand from the perspective of the Program Directors in addition to the effort which would be required to provide such experiences may limit such experiences," he explained.

Dalsing commented that many other specialties which have begun to provide treatment for superficial venous disease. The core training pro-

vided by the parent training paradigm is extremely variable from essentially no training to a more robust experience. International consensus panels have hoped to define a phlebology curriculum and there has been a push to provide board certification, without membership in the American Board of Medical Specialties (ABMS), to budding phlebologists within the US. Nevertheless, the pathways in training and education required to be eligible for this specific board testing are quite diverse. Such diversity in education brings into question the final meaning of certification since, in reality, experience and training is the essence of medical practice in the US. Some fellowships aimed at addressing deficiencies in training specifically for those individuals who have had little prior training or desire a concentrated experience are available, but limited in number.

"Phlebology as a specialty is gaining some support in the US driven by several factors. Outside of existing ABMS training programs, determining competent providers who have credentials the public can trust is an issue still in flux," concluded Dalsing. "Resolution of this issue may well drive the need or lack thereof for standalone venous fellowships."

Part of this research was presented at the Peripheral Vascular Surgery Society 2011 meeting in July, and has been submitted to the *Journal of Vascular Surgery* (Dalsing MC, et al. APDVS Survey of Program Selection, Knowledge Acquisition and Education Provided As Viewed by Vascular Trainees from Two Different Training Paradigms).