THE EVOLUTION OF A MINIMAL-TOUCH ENDOSCOPIC VESSEL HARVESTING TECHNIQUE

September, 2018

Eric L. Ping¹, ACNP, Aaron M. Amburgey¹, PA-C, Albert K. Chin², MD

Abstract

Endoscopic vessel harvesting (EVH) is a wellestablished technique performed in conjunction with coronary artery revascularization. More recently, the technique and instrumentation has evolved with two primary objectives:

- Decreasing the mechanical manipulation associated with vessel extraction.
- Curtailing the prolonged learning associated with the present technique.

A preferred surgical technique has been developed to optimize the use of the modified instrumentation. The elements of the technique are presented in detail to guide harvesters interested in applying the new technology to their cardiac surgical practice.

¹Department of Cardiothoracic and Vascular Surgery, St. Mary's Medical Center, Huntington, WV ²Chief Medical Officer, Director, Stockholder, Saphena Medical, Inc., West Bridgewater, MA



"We have been able to compare Saphena's Venapax to the other devices and have found less trauma to the vein during harvesting. I have also seen less bleeding during harvesting as evidenced by less bruising or hematoma formation post-operatively. I am very happy with this system and prefer it for all of my patients requiring EVH."

> Nepal C Chowdhury, MD, Cardiac Surgeon St. Mary's Medical Center Huntington, WV.

Introduction

Limited incision extraction of the greater saphenous vein for application as a bypass conduit in coronary revascularization was initially contemplated as a means to address excessively high rates of postoperative lower extremity wound complications, previously observed to be in the range from 24% to 44% of patients undergoing coronary bypass surgery¹⁻². The earliest attempt at limited incision saphenectomy was reported in 1984³, with the description of a subcutaneous coring device that navigated the thigh segment of the saphenous vein between an incision above the knee and second incision at the groin. Tributaries were not ligated, and the patient's thigh was wrapped immediately following vein removal to achieve hemostasis. Blind passage of the tubular cutter led to an as expected high rate of vein graft trauma, and use of the device was discontinued after only a short while.

The first endoscopically guided limited incision vessel harvesting device was described by Lumsden et al.^{4,5} employing a transparent, spoon-shaped hemispherical hood to dissect along the adventitial plane anterior to the vessel, and to retract the surrounding tissue to allow ligation and transection of venous tributaries. A 3-4 cm long incision is performed over the saphenous vein, and the optical dissector is advanced to dissect the vessel from the surrounding subcutaneous tissue under direct visualization. A single hemostatic clip is placed on each tributary, due to potential branch avulsion upon manipulation in the limited operative environment⁶, and the lower limb is wrapped with a compression dressing upon completion of the bypass procedure. Due to the increased contact surface area of the spoon-shaped dissection hood, isolation of the vein may incur significant force, and the requirement for continuous elevation of the retractor to maintain a subcutaneous visual cavity rendered a lengthy procedure tedious.

Endoscopic vessel harvesting (EVH) developed into a practical, functional procedure with the introduction of the VasoView[®] device (Maquet, Getinge Group, Wayne, NJ), which utilized an enclosed, transparent conical dissection tip for visually guided isolation of the saphenous vein in the subcutaneous space.^{7,8} The small 3 mm radius of the distal rounded tip allowed the harvester to advance along the peri-adventitial plane without incurring venous puncture or laceration, and tributaries were likewise visualized and bluntly dissected. Conical tip dissection is also utilized by the VirtuoSaph[®] Plus Endoscopic Vein Harvesting System (Terumo Cardiovascular Systems Corporation, Ann Arbor, MI).

The axial surface of the conical tip lies in contact with a 15 mm length of vessel, providing an optically clear road map of the greater saphenous vein during the dissection process. Following circumferential exposure of the vein graft, a cannula with a thermal device is introduced into the insufflation supported subcutaneous tunnel to retract, cauterize and transect attached venous tributaries prior to vein removal.

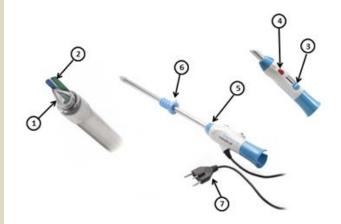
Conical dissection tip endoscopic harvesting devices have become standard of care for less invasive vein harvest procedures. However, during the early stages of device development, it was important to identify the pathophysiologic effects of the technique on the harvested conduit. Although the rounded, transparent polymeric tip was able to dissect out the vein with minimal tributary avulsion, it was recognized that conical tip dissection exerted shear force on the venous adventitia, and the ultimate effect on luminal endothelium was unknown. Therefore, during the initial clinical procedures in the United States, unused harvested segments of vein were submitted for histological examination and immunohistochemical studies.⁹ Submitted specimens demonstrated intact and reactive endothelium, indicative of the atraumatic nature of conical tip dissection in the subcutaneous region.

The VasoView technique of endoscopic blunt dissection of the bypass conduit involves full length anterior and posterior passage of the dissection cone, with skeletonization of all tributaries extending laterally in the gas insufflated tunnel.¹⁰ Following complete blunt dissection, a vein harvesting cannula with a retractable C-ring is used in conjunction with a 5 mm thermal device to mobilize the main vein, provide counter-tension at each individual branch site, cauterize and cut all branches while avoiding direct or collateral injury to the vein wall. The VirtuoSaph[®] Plus technique incorporates а V-keeper appendage to encapsulate the vessel during harvesting, while a V-cutter mechanism is used to coagulate and cut the branches.

Although conventional techniques for EVH are well established, questions arise regarding vessel trauma during the procedure, and its potential effect on graft patency. Vessel trauma that occurs during the course of endoscopic harvest consists of two types; these are thermal and mechanical injuries. These vessel injuries are postulated to result in reduced graft patency. Thermal energy, in particular, has been proposed to cause endothelial injury leading to intimal hyperplasia and graft stenosis. In a study comparing graft patency between EVH and open vein harvest for lower extremity bypass in critical limb ischemia, graft stenosis in EVH was more commonly seen in the body of the bypass graft, likely at the site of cauterization of large branches; whereas in the open vein harvest group, it was generally localized to the anastomosis.¹¹ The requirement for long vein grafts in lower extremity revascularization led to these observations. Short segment graft requirements in coronary revascularization allow exclusion of traumatized regions of vein in EVH, if recognized. Occult thermal or traction injury may still be of substantial clinical significance.

A modified technique for EVH is presented, utilizing simplified, self-contained endoscopic instrumentation designed for reduced manipulation of the bypass conduit during the harvesting process. The modified endovascular vein harvesting device, Venapax[®] (Saphena Medical, Inc., West Bridgewater, MA), is an endoscopic cannula with a conical dissection tip and retractable rotating bipolar electrocautery blades. Tributaries are cauterized and transected as they are encountered during the dissection process. Since the cautery blades form the sole moveable components in the device, procedural manipulation is minimized, facilitating both the harvest technique as well as the initial learning curve.

Components of the Venapax device include: (1) the conical dissection tip; (2) retractable cautery blades, with the rotating, blue colored blade containing a razor-sharp edge; (3) the blade advancement button in the device handle; (4) the rotational blade control knob; (5) the cautery actuation button; (6) the flexible gas insufflation port; and (7) the bipolar generator cord and connector. The generator cord connects to the bipolar outlet in a standard Valleylab® Force FX electrosurgical unit.



Venapax Technique

Exposure of the Greater Saphenous Vein

Ideally, preoperative vein mapping is performed immediately prior to vein harvesting, to delineate the course of the vein, vein caliber, and the presence of any anomalies. If low dose anticoagulation is given, the dose is administered per customary institutional guidelines. A 15 mm long transverse incision is performed at slightly above or slightly below the level of the knee to ensure that access to the sapheno-femoral junction is achieved without difficulty in tall patients.

Following blunt dissection to expose the vein at the incision site, the tip of the harvesting cannula is advanced along the anterior aspect of the vein to dissect a 6 – 8 cm long tunnel for insertion of the soft insufflation port. The port may be backloaded onto the shaft of the cannula and advanced into the incision while the conical dissection tip is in contact with the anterior vein wall. A tiny vein retractor is used to lift the edge of the incision, and the port is advanced into the incision with a back and forth twisting motion; only one or two ridges on the port need to be inserted into the harvesting tunnel. Carbon dioxide gas insufflation is infused via the female luer fitting on the port, at a pressure of approximately 10 mmHg and a low flow rate of between 3 – 5 liters per minute. Establishment of a distended harvesting tunnel without gas leakage is important, as the insufflation pressure tamponades oozing from the vaso vasorum during vein dissection, particularly in anticoagulated patients, and ensures a clear visual field during EVH.

Vein Harvesting Technique

Following port placement and initiation of gas insufflation in the harvesting tunnel, the cannula is pulled back to the port site, and the conical tip used to work its way to the posterior aspect of the vein. Full length dissection is conducted of the posterior greater saphenous vein from the knee to the sapheno-femoral junction. All posterior and lateral tributaries are cauterized and transected as encountered during the Initial dissection of a posterior dissection. posterior tunnel allows any blood oozing during posterior and anterior dissection to collect inferiorly due to gravity, with decreased disturbance to endoscopic visualization.

Upon encountering a tributary, the conical tip is used to perform minimal isolation of the branch, by limiting dissection with the conical tip to a distance 2 cm distal to the tributary, and avoiding significant lateral skeletonization of the tributary. Make a window above and below the branch, and keep the branch in the visual field. Minimal lateral dissection maintains tether support of the tributary on the wall of the harvest tunnel, facilitating the tributary transection process. Following creation of a window on both sides of the tributary, the cannula is pulled back to place the conical tip 1 cm proximal to the tributary, and the slider on the cannula handle advanced forward to extend the cautery blades into view. During this process, the conical tip is placed in the center of the tunnel, adjacent to the main trunk of the vein, to ensure that the extended blades are well visualized and do not protrude into the wall of the harvesting tunnel. One hand of the harvester grips the body of the Venapax cannula, and also controls the slider button to extend the cautery blades; the other hand is used to rotate the blue collar to open and close the blue cautery blade against the stationary green cautery blade. The cautery blades are organized in a specific orientation with respect to the handle. When the handle is in an upright position with the control buttons facing upward, the green and blue cautery blades always extend forward in the 12 o'clock and 1 o'clock positions, respectively. The handle is simply rotated about its central axis to position the blades in angular alignment with the target tributary.

In order to cauterize a tributary, the cannula is pulled 1 cm proximal to the branch, the blades extended distally, opened, and the open blades advanced forward to intersect the branch. As the blue collar is rotated to close the blades. cautery energy is applied using either the red cautery button on the handle, or a foot pedal control connected to the bipolar electrosurgical unit. With the tributary positioned in the distal portion of the blades, cautery energy is initiated upon contact with tissue, and continued as the blades close onto the tributary. A wisp of white mist is observed upon cautery blade application, indicating sealing of the tributary. The cautery blades may be repeatedly opened and closed at the same location on the tributary while continuously maintaining energy delivery. This causes further desiccation of the branch at the ligation region to enhance the transection process.

EXPERT PERSPECTIVE

 (\mathbb{Q})

"When I started my cardiovascular fellowship, we were primarily performing open saphenous vein harvesting. This technique yielded high quality saphenous veins but often times at the expense of a non-healing wound. Particularly, below the knee harvest sites. Near the middle of my fellowship training, we integrated 'bridging' where we would make skip lesions in the skin.

It was in my first year as an attending surgeon at the Charleston Area Medical Center (CAMC) in Charleston, West Virginia when I was introduced to endoscopic saphenous vein harvesting. This technique was revolutionary in conduit harvesting for both saphenous veins and radial arteries. At this time, CAMC first assistants were very early adopters of the new technology and we were a very high-volume center at that time, performing nearly 2000 hearts per year. As a result, we trialed and used every type of endoscopic harvesting system available.

I have been very happy with the quality of the veins that our first assistants have been able to harvest with Saphena's device. We emphasize a 'no touch' technique. It is preferable to leave a small layer of adventitia associated with the vein. We believe that the saphenous harvesting technique developed by Eric Ping, ACNP and Aaron Amburgey PA-C, provides us with quality vein comparable to what we used to see with open vein harvesting."

Geoffrey R Cousins, MD, Cardiac Surgeon at St. Mary's Medical Center in Huntington, WV.

Branch transection is performed by rotating the cannula in the direction of the center of the cone while holding the blades stationary. Both hands maintain their position on the device handle and the blue collar while the device is rotated up or down approximately 45° towards the dot corresponding to the center of the conical tip. This rotational maneuver imparts a shearing action to the tributary at its fixation point to the wall of the harvest tunnel, against the fulcrum formed by the conical tip, resulting in transection of the tributary while minimizing traction on the main trunk of the vein and the ostial region of the tributary. For example, in Figure 2, the dot corresponding to the distal conical tip lies down below the right lateral tributary, and the blade tips are moved down. In Figure 3, the dot corresponding to the distal conical tip lies down below the left lateral tributary. The closed blade tips are moved down. Concomitant with blade movement, a slight distal advancement of the cannula causes the tributary to drape on the enlarged potion of the tapered tip. The fulcrum formed by the conical tip is effectively moved closer to the tributary tether point on the lateral wall of the tunnel, and rotational shearing is increased for enhanced transection. In Figure 4, the dot of the tapered tip lies above the branch, so the blade tips are moved up as the cannula is advanced distally, resulting in effective branch transection.

Following full posterior dissection, cautery ligation and tributary transection, the cannula is withdrawn to the port site, and anterior dissection is performed. Conical tip dissection is performed gently and deliberately, in small increments. The dissection tip is advanced 2 cm, then pulled back 2 cm, allowing the insufflated gas to distend the newly dissected region and further delineate the peri-adventitial plane and potentially occult miniature tributaries. In patients with fibrotic subcutaneous tissue or superficial vein, oscillating rotation of the conical tip is employed during incremental dissection. The dissection tip is also displaced downwards during advancement. This prying motion gently teases the vein away from its fibrous bed and

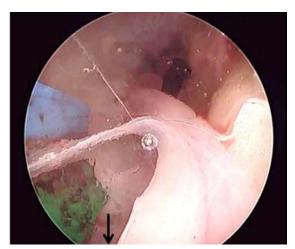


Figure 3 - Dot Down (under branch), Tips Down



Figure 2 - Dot Down (under branch), Tips Down

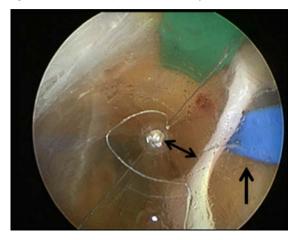


Figure 4 – Advance Cone Slightly Forward, Dot Up (above branch), Tips Up

decreases traction exerted on the vein trunk and tributaries during vein isolation. If the blush of micro-perivascular connections or vaso vasorum are observed as the dissection proceeds, pause to pre-emptively cauterize these plexi to prevent oozing that may impede endoscopic visualization. Extend the blades forward with a 2 mm gap between the respective blades, and use the distal tips of the blades to contact the microvasculature while applying bipolar electrocautery current. Prophylactic spot cautery may often save overall procedural harvest time. Any remaining tissue holding the vein is easily removed by sequentially opening and closing the blades (a "Pac-Man" approach) along the lateral walls while applying continuous bipolar cautery. This should be performed as one proceeds anteriorly, so only two passes are conducted on the vein. This approach decreases potential bleeding and enhances visualization.

Upon completion of the thigh vein harvest, if additional vein length is needed, the cannula tip may be retracted into the insufflation port, and carefully flipped over to point in the inferior direction. Ligation and transection at the sapheno-femoral junction ("stab and grab") is not performed until the entire length of conduit has been harvested, to avoid a period of venous stasis that would occur with a proximally ligated vein. Lower leg vein harvest proceeds in a similar

"I have been extremely pleased with the Venapax from Saphena Medical. I was introduced to Venapax a couple of years ago and the product is producing the highest quality conduit I've seen in my years of cardiothoracic surgery. The Venapax has provided harvesters an opportunity to reduce vascular trauma due to its hybrid 'no touch' single instrument design in reducing venous compression and traction, resulting in less endothelial damage, therefore enhancing graft patency. I'm very pleased with the product and look forward to the future of endoscopic vein harvest and Saphena Medical. "

Aaron Amburgey, PA-C

"Since we first began using the simplified method of vein harvesting with the Saphena Vein Harvest System, I have noticed a significant decrease in the learning curve of our new and inexperienced vein harvesters. In addition, the quality of the vein is more pristine with fewer avulsions and fewer thermal burns as compared to the other systems we have trialed."

Dr. Scott Schubach, Chairman of Cardiac Surgery, NYU Winthrop Hospital

fashion to thigh vein harvest, with a 6-8 cm anterior tunnel dissected initially to allow insufflation port placement, followed by full posterior dissection and transection of tributaries as encountered. During anterior passage in the lower leg, with the superficial nature of the saphenous vein, dissection may be facilitated by the use of external palpation to carry the skin and subcutaneous tissue towards the dissection cone, as well as conventional cannula advancement. If the saphenous nerve is observed crossing over the vein, it is gently dissected away from the vein, to avoid inadvertent injury during tributary cautery and transection. Upon harvest of the desired length of lower leg vein, a distal stab incision is performed to allow distal ligation and transection. The conical dissection tip is placed anterior to the vein to shield it during blade insertion. The knife blade may be inserted directly on the spot of light transilluminating through the skin from the dissection tip. In cutting down directly on the conical tip, the tip acts as a cutting board and backstop for the inserted blade. Following ligation and transection of the distal end of the conduit, the transected vein may be delivered to the port site by turning the cannula upside down and extending the blades forward at the 6 o'clock position, opening the blades, and gently closing them down to grasp the severed vein end, and pulling the harvested vein out of the tunnel.

Discussion

The modified EVH technique, involving minimal lateral blunt dissection at tributary sites and immediate cautery transection of branch vessels as encountered, seeks to minimize manipulation of the bypass conduit. Severing each branch as dissection proceeds avoids back and forth passage of the harvesting cannula over intact tributaries, a maneuver that carries increased risk for tributary avulsion and vessel traction. Traction on a tributary extends the tensile loading to the vein trunk, which may disrupt the endothelium at the ostial regions of the vein graft. Severing each tributary as encountered also enhances visibility during endoscopic dissection, as conical tip dissection occurs in undisturbed subcutaneous tissue, and potential bleeding from avulsed proximal tributaries is avoided.

"The more cases I do the better the vein graft looks. I never have to repair anything, just tie branches."

The novel bipolar cautery system of the Venapax device incorporates a razor-sharp blade that opens and closes on a blunt anvil. The sharpness of the cautery blade serves to concentrate the entire output of the bipolar generator into an exceedingly small contact surface area, resulting in

Eric Ping, ACNP

application of a high-density current to the tributary at the cautery site. The Valleylab generator also contains built-in controls to constantly measure the electrical impedance of the tissue and instantly adjust the generator output to maintain optimal cautery current.¹²⁻¹⁴ This feedback control interrupts energy delivery to tissue as the impedance rises with tributary desiccation, limiting adjacent thermal spread. Active power control is appreciated by the release of a tiny amount of fine white mist during cautery blade usage, rather than the thick smoke typically observed; as well as the minimization of char formation on the treated tributary.

"The Utley et.al paper cited is from my practice. We have long emphasized vein quality and minimizing leg vein harvest morbidity. Since we *historically had great graft patency* rates with open vein harvest I was slow to embrace EVH in my practice. We began EVH in 2000. Gentle dissection of the vein is essential. The ability to dissect with minimal distortion of the vein while providing long branches decreases the risk of unseen intimal damage. Also, utilizing Bipolar technology with long branches should limit the risk of thermal injury. I have observed excellent vein quality and no leg wound issues with the use of Venapax."

Dr. Steven A Leyland, Cardiac Surgeon Spartanburg Regional Hospital

Since the active moving components of the system are limited to extension and rotation of the cautery blades, assimilation of the technique by novice harvesters tends to be expedited. A one hundred case learning curve has been estimated for conventional instrumentation.¹⁵ The movements associated with use of the simplified device occur along the axial plane of the device, whereas manipulation of the conventional devices requires radial positioning of the appendages within a limited tunnel. Manipulation of the appendages and coordination of their position with respect to the vessel, its branches, and the cautery instrument could result in the protracted learning curve of the traditional EVH instrument.

With the simplified harvest cannula, any needed vein retraction is conducted by placing the conical tip against the lateral aspect of the vein.

Based on early immunohistochemical studies,⁹ conical tip vein application has been demonstrated to be gentle and atraumatic. Limitation of applied shear force to venous adventitia should result in graft conduit with decreased spasm, increased distensibility, and enhanced flow rates. Further studies must be conducted to elucidate the favorability of this approach.

Conclusion

A preferred surgical technique has been described for simplified instrumentation for endoscopic vessel harvesting, with the objective of achieving minimal manipulation of the bypass conduit during vessel extraction, and decreasing the learning curve of EVH for novice harvesters. Continued application of the novel device will elucidate its effectiveness in accomplishing both of these goals.

REFERENCES

- 1. Utley JR, Thomason ME, Wallace DJ, Mutch DW, Staton L, Brown V, et al. Preoperative correlates of impaired wound healing after saphenous vein excision. J Thorac Cardiovasc Surg 1989;98(1):147-9.
- 2. Wipke-Tevis DD, Stotts NA, Skov P, Carrieri-Kohlman V. Frequency, manifestations, and correlates of impaired healing of saphenous vein harvest incisions. Heart Lung 1996;25(2):108-116.
- 3. Rashid A, Fabri B, Meade JB. Subcutaneous technique for saphenous vein harvest. Ann Thorac Surg 1984;37:169-170.
- 4. Lumsden A, Eaves F. Subcutaneous, video-assisted saphenous vein harvest. Perspectives in Vascular Surgery 1994;7:43-55.
- 5. Lumsden A, Eaves F, Ofenloch JC et al. Subcutaneous, video-assisted saphenous vein harvest: Report of the first 30 cases. Cardiovasc Surg 1996;4:771-776.
- 6. Lee J, Conant P, Hofer B, et al. Minimally invasive vein harvesting systems What the experts say. Surgical Physician Assistant 1997;3(8):36-47.
- 7. Chin A, Meyer D., Jessen M, Rogers T, Johnson P, Tan S. Endoscopic cardiovascular vessel Harvesting. In Montori A, Lirici MM, Montori J (eds.), 6th World Congress of Endoscopic Surgery, Bologna, Monduzzi Editore, 1998
- Johnson PR, Tan SL, Chin AK. Endoscopic Femoral-popliteal/distal bypass grafting: A preliminary report. J Am Coll Surg 186(3):331-336, 1998
- 9. Meyer DM, Rogers TE, Jessen ME, Estrera AS, Chin AK. Histologic evidence of the safety of endoscopic saphenous vein graft preparation. Ann Thorac Surg 70:487-493, 2000.
- 10. Jiminez JC, Eisenring C. Endoscopic harvesting of the saphenous vein. In Moore WS, Lawrence PF, Odenrich GS, (eds.), Vascular and Endovascular Surgery: A comprehensive review. Amsterdam, Elsevier Health Sciences, 2018.
- 11. Eid RE, Wang L, Kuzman M, Abu-Hamad G, Singh M, Marone LK, et al. Endoscopic versus open saphenous vein graft harvest for lower extremity bypass in critical limb ischemia (CLI). J Vasc Surg 2014;59(1):136-144.
- 12. Klicek MS. Impedance and temperature generator control. U.S. Patent #5,496,312, 1996.
- 13. Smith GC. Automatic bipolar control for an electrosurgical generator. U.S. Patent #5,514,129, 1996.
- 14. Gines DL. Electrosurgical generator with adaptive power control. U.S. Patent #6,033,399, 2000.
- 15. Zenati MA, Gaziano M, Collins JF, Biswas K, Gabany JM, Quin JA, Bitondo JM, et al. Choice of vein-harvest technique for coronary artery bypass grafting: rationale and design of the REGROUP trial. Clin Cardiol;2014;37(6):325-330.