OPTIMIZING CONDUIT QUALITY IN CABG SURGERY HELPS IMPROVE PATIENT OUTCOMES

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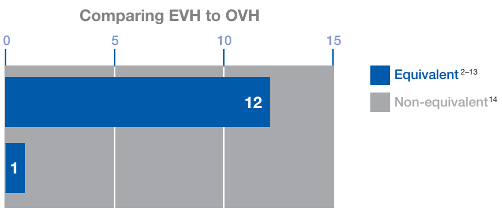
OPTIMIZING CONDUIT QUALITY

The quality of the conduit and how it is handled during the vessel harvest and preparation steps are significant factors in the success of coronary artery bypass graft (CABG) surgery. Success of CABG surgery is measured by patient outcome data regarding morbidity, mortality and the need for repeat revascularization to treat a new blockage. Poor conduit quality is associated with risks, including adverse effects on graft occlusion. Good conduit quality is obtained by vessel harvesting techniques that maintain the integrity of the harvested blood vessel and protect it from damage, which helps to ensure long-term graft patency and optimal patient outcomes.[1]

THE PREPONDERANCE OF STUDIES SHOW PRESERVED ENDOTHELIAL INTEGRITY WITH EVH



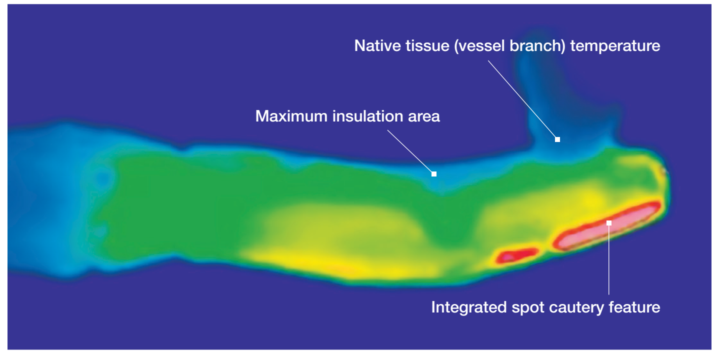
Study Type	Investigator(s)
Macroscopic Inspection	Morris RJ, et al. *Ann Thorac Surg*. 1998;66:1026-1028 Patel AN, et al. *Am J Surg*. 2001;182:716-719 Aziz O, et al. *Ann Thorac Surg*. 2005;80:2407-2414
Histology	Crouch JD, et al. *Ann Thorac Surg*. 1999;68:1513-1516 Griffith GL, et al. *Ann Thorac Surg*. 2000;69:520-523 Meyer DM, et al. *Ann Thorac Surg*. 2000;70:487-491 Kiaii B, et al. *J Thorac Cardiovasc Surg*. 2002;123:204-212
Functional Assessment	Alrawi, et al. *Heart Surg Forum*. 2000;3:241-245 Alrawi, et al. *Heart Surg Forum*. 2001;4:47-52 Alrawi, et al. *Heart Surg Forum*. 2001;4:120-127 Alrawi, et al. *JSLS*. 2002;6:5-9 Alrawi, et al. *JSLS*. 2001;5:37-45 Nowicki, et al. *Eur J Vasc Endovasc Surg*. 2004;27:244-250 Rousou LJ, et al. *Ann Thorac Surg*. 2009;87:62

Graph 1. EVH studies on endothelial integrity

As clinicians shift to more minimally invasive techniques such as endoscopic vein harvesting (EVH), investigators are studying patient data to verify that EVH does not compromise conduit quality and long-term patient outcomes. In fact, data across a dozen studies demonstrate that endothelial integrity is preserved when EVH techniques are used (Graph 1). Additionally, results from three recent studies published in 2010 and 2011, tracking more than 16,000 patients, provide strong evidence that EVH is a safe and viable technique that can be used to obtain a saphenous vein conduit for CABG surgery.[15,16,17] The studies demonstrated that EVH did not compromise subsequent event-free survival and reaffirmed the significant benefits of EVH in reducing wound complications.

Several procedural factors play a critical role in ensuring that vessel integrity is maintained and conduit quality and long-term patient outcomes are optimized. These include the use of EVH technologies to protect the conduit from the risk of thermal injury, a careful approach to vessel handling and preparation, comprehensive harvester training and the adoption of protective harvesting practices.[18]

PROTECTING AGAINST THERMAL INJURY



Thermal imagery of direct current device *Adapted from LT900926*

All EVH systems use some form of energy to ligate branch vessels and cauterize the adjacent tissues in order to seal the branch vessel. If the energy used during the EVH procedure is not properly controlled, unintended thermal damage to the surrounding cells, including the endothelium of the main vessel or conduit, can result.

Three forms of energy are used to cut and seal branch vessels during EVH procedures: electrocautery (direct current), bipolar radiofrequency (alternating current) and harmonic energy (ultrasound dissection).

ELECTROCAUTERY (DIRECT CURRENT)

Direct current device for cutting and sealing vessels

Electrocautery devices use direct current that passes through a resistive element in the device tip. This element heats up and is used to seal and cut branch vessels. The electrical current does not enter the tissue and is contained entirely within a circuit consisting of the generator, device and electrical cord. With certain devices, when used according to the Instructions for Use, thermal spread is completely eliminated so there is no risk of injury to the surrounding tissue, and the procedure of cutting and sealing can take place immediately adjacent to the main conduit. Devices that use direct current technology include MAQUET Cardiovascular's VASOVIEW HEMOPRO 2 and VASOVIEW

HEMOPRO Endoscopic Vessel Harvesting Systems, which use cut-and-seal technology that virtually eliminates thermal spread beyond the insulated jaws of the electrocautery device.[19,20]

BIPOLAR RADIOFREQUENCY (ALTERNATING CURRENT)

Bipolar devices use alternating electrical current to cut and seal tissue. The alternating current is passed through the tissue—in this case, the branch vessel—located between two electrodes.

To prevent the risk of heat damage to the main vessel conduit, industry best practices recommend keeping device energy settings as low as possible and minimizing the length of time spent cauterizing—bursts of 1.0 to 1.5 seconds are usually adequate. Additionally, maximizing the distance between the location at which the side branch is cauterized with respect to the main conduit is critical with bipolar radiofrequency devices in order to minimize thermal injury to the main vessel during dissection. EVH systems that use bipolar energy include MAQUET Cardiovascular's VASOVIEW 6 PRO, VASOVIEW 6, VASOVIEW 7 BiSECTOR and VASOVIEW 7 Scissors. All of these devices also have built-in safeguards, such as a mechanical "C-Ring" feature, to physically distance the main conduit from the cautery device.[21]

ULTRASOUND DISSECTION (HARMONIC ENERGY)

Ultrasound dissection uses vibration in the range of 55,500 Hz to cut through and seal tissue. Vibration cuts through the tissue and seals it using protein denaturization rather than heat. Advantages of ultrasound dissection include minimization of thermal tissue damage[22] and reduced vessel spasm compared with electrocautery.[23] Disadvantages of this technology include difficult maneuverability and cost.[24]

ENSURING CAREFUL VESSEL HANDLING AND PREPARATION

AVOIDING MANIPULATION OF THE MAIN CONDUIT

Overhandling of the vessel both during and after the harvesting procedure may damage or stretch the internal endothelial layer of the conduit. Therefore, it is important to minimize unnecessary stress and manipulation of the vessel.[18] During blunt dissection and tunnel creation, care should be taken to avoid inadvertent movements and over-dissection that can increase risk of conduit injury or trauma. Additionally, careful manipulation of the conduit during harvesting is advised in order to dissect it as gently as possible from its native tissue bed.

The likelihood of damage can be reduced with harvester training, as well as with the use of EVH devices that minimize the amount of torque or stretch to the main conduit during harvesting.

In 2009, a panel of highly experienced harvesters in the United States worked in partnership with MAQUET Cardiovascular to prepare a white paper on best practices to serve as the gold standard for performing EVH.[18] By adopting these recommendations, harvesters can obtain optimal conduit quality.

REDUCING THE RISK OF OVERDISTENSION

Prior to grafting, it is common practice to check the vessel for leaks by manually flushing it with a standard syringe. However, this method is not easily controlled or measured in regard to the amount of pressure exerted on the endothelial lining of the vessel wall. If not controlled, internal pressures have been observed to reach as high as 600 mm Hg, causing overdistension and inadvertently damaging the endothelial layer.[25,26] Damage to the endothelium may increase the likelihood of graft failure.[27,28,29]

AVOIDING UNCONTROLLED DISTENSION IS CRITICAL

	Intact Endothelium
No Distension (Proximal Inflow)	60%
Distension (Saline Flush)	25%

Adapted from Burris et al. J Thorac Cardiovasc Surg. 2007.

Impact of uncontrolled distension on endothelial integrity

Risk of overdistension can be minimized with the use of a device that controls the pressure exerted on the internal vessel wall during preparation. For example, MAQUET Cardiovascular's VASOSHIELD Pressure Controlling Syringe features three pressure settings—150, 250 or 350 mm Hg—to allow harvesters and surgeons the ability to control the maximum pressure delivered during vessel flushing. Starting with the lowest pressure setting, users can adjust pressure in controlled increments to accommodate any situation or vessel type.[30] By limiting the maximum pressure that can be applied when distending the vessel, overdistension and potential endothelial injury can be minimized. Vessels flushed at controlled, lower pressures have been shown to more effectively overcome spasm and maintain the vessel endothelial and medial layers.[18]

VESSEL DISTENSION AND STORAGE SOLUTION

Once the vessel is extracted and prepared, it should be placed in the solution specified by hospital protocol until the surgeon is ready to use it. Studies have shown that endothelium and smooth muscle cells are affected by the storage solution used.[26] Therefore, the type of solution may play a role in long-term graft patency.

PREVENTING FIBRIN CLOTS

To address the potential for clot formation during EVH resulting from temporary blood stasis, clinicians have incorporated routine administration of low-dose heparin prior to insufflation. This approach is based on evidence that heparin limits retained clot in the vessel lumen and is associated with improved EVH graft patency.[31]

IMPORTANCE OF EVH PROCEDURAL TRAINING IN OPTIMIZING CONDUIT QUALITY

CAREFUL ATTENTION DURING HARVEST IS CRITICAL TO MINIMIZE INJURY TO THE VESSEL

Recent studies have shown that vein grafts with four or more injuries had significantly impaired remodeling responses and worse early patency rates (67% vs. 96%, $p<0.05$).[32] Careful harvesting can help avoid inadvertent "nicks" that may occur. User efficiency must not be sacrificed for speed during the harvesting procedure.

EVH conduit quality and patient outcomes can be optimized through improvements to the EVH procedure. This includes emphasizing the importance of EVH procedural training. Data presented at the 2011 Annual Meeting of the Society of Thoracic Surgeons documented that, during EVH procedures, injuries to veins are more frequent with novice harvesters than with experienced harvesters.[33] Because technical errors are more common early in the learning curve with most novel procedures, it is important to be particularly careful during the learning curve for EVH.

EVH: STANDARD OF CARE IN THE UNITED STATES

In many parts of the world, EVH is being recognized as the preferred method for harvesting a conduit to be used in CABG procedures. In the United States, 90% of hospitals perform EVH, and more than 1 million EVH procedures using the MAQUET VASOVIEW technology had been completed worldwide by 2009.[34]

As EVH becomes an increasingly popular procedure to reduce morbidity and improve patient satisfaction, certain factors should be considered to maximize patient outcomes and optimize the quality of the conduit, including selection of the device, reduction of thermal spread/injury, administration of heparin, post-harvest preparation and avoidance of over distension and a focus on training techniques to minimize vessel injury.[18, 31]

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