



Background

Endoscopic Vein Harvesting is the standard of care for patients who require saphenous vein grafts for coronary and lower limb revascularizations. (1)

While a consensus is present that EVH minimizes wound complications, long-term graft patency remains a concern. It has been reported that primary graft patency ranges from 44-68% at 5 years in humans, (2,3) and the extent of thermal injury to the grafts at the ligation of the branches ranges from 1.5-6.3 mm in animals models. (4) Poor graft patency rates are associated with direct trauma and irreversible thermal injury to the vascular endothelium at the time of harvesting (5-7).

In this study, the Terumo® VirtuoSaph™ EVH system was tested in a swine model using an open technique on both arteries and veins in order to assess the extent of thermal spread during ligation of branches.

References:

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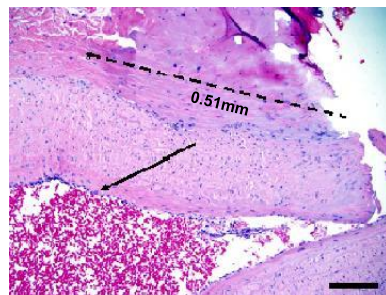


Product and materials for the study were supplied by: Terumo Cardiovascular Systems Corporation, 6200 Jackson Road, Ann Arbor, MI 48103

Methods & Results

Animal Model: Four anesthetized (~35 Kg) swine underwent surgical procedures to expose both superficial epigastric veins (SEV) and superficial saphenous arteries (SSA) to simulate branches of the human saphenous vein and radial artery. All vascular specimens (conduits) were harvested using the VirtuoSaph™ EVH system. A total of 144 conduits (83 from veins and 61 from arteries) approximately 10mm in length were harvested and fixed in 10% neutral buffered formalin for histological analysis. Diameter of SSA were between 1.10-1.25mm and SEV between 0.25-0.63mm.

Histomorphometric Evaluation: Conduits were embedded longitudinally in paraffin, cut, and stained with standard H&E stain. Samples were analyzed by a blinded veterinary pathologist. Histological change attributed to cautery consisted of coagulative necrosis affecting the tunica adventitia, media, and/or endothelium. All visible areas of coagulative necrosis within the vascular wall or in immediate contact (adventitial) with the vascular wall were included and the maximal longitudinal extent of damage was recorded. Maximal extent of damage was assessed as the maximal longitudinal distance, within the section, from the cauterized/cut edge to the boundary of normal/necrotic tissue (Figure 1). Damage was further classified as predominantly adventitial or affecting both tunica adventitia and tunica media.



Measurement of the maximal extent of thermal damage. Maximal longitudinal distance of coagulation necrosis from the cauterized end of the blood vessel was measured (dashed arrow). Damage to the adventitia and tunica media corresponded to extent of endothelial damage (short arrow). H&E stain 200x. Scale bar=100 um.

Figure 1: Measurement of Thermal Spread

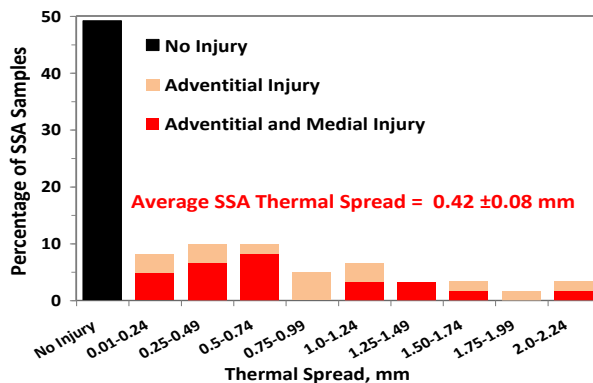


Figure 2: Distribution of SSA Thermal Spread and Injury Type

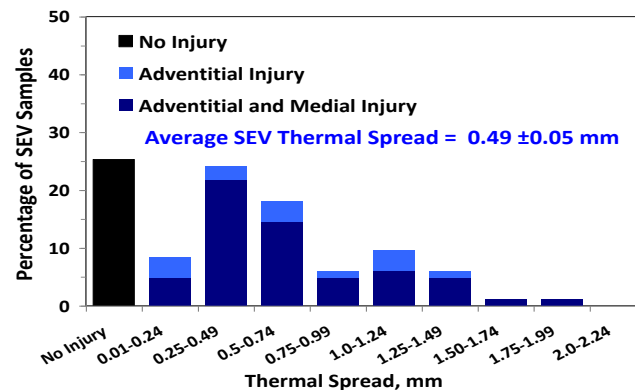


Figure 3: Distribution of SEV Thermal Spread and Injury Type

Conclusions

- 1. The use of Terumo® VirtuoSaph™ system in this animal model resulted in a high percentage of samples with no thermal injury (n=51/144).
2. The extent of thermal spread of the samples that sustained either adventitial injury alone, or adventitial and tunica media injury was lower (<1.5 mm) that the values reported in the literature (1.5-6.3 mm) in similar animal models.
3. A limitation of this study is that the open technique does not mimic the clinical (closed tunnel technique).
4. Clinical studies are needed to correlate the findings in this animal model.