

**A POSITION STATEMENT ON THE POST-HOC ANALYSIS OF ROOBY TRIAL ENDOSCOPIC VEIN HARVEST OUTCOMES PRESENTED AT 90<sup>TH</sup> ANNUAL MEETING OF THE AMERICAN ASSOCIATION OF THORACIC SURGERY**

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Results of a post hoc analysis of endoscopic vein harvest (EVH) versus open vein harvest (OVH) - "Endoscopic Vein Harvest Is Associated with Compromised Patency Outcomes: Results from the Prospective Randomized ROOBY Trial"<sup>1</sup>- were presented on May 3 at the annual meeting of the American Association of Thoracic Surgery (AATS) in Toronto.

According to the results, patients who underwent EVH were reported to have worse graft patency, increased need for revascularization at one year, but no difference in mortality compared to patients who underwent open vein harvest procedures. Similar to the post hoc analysis of PREVENT IV, this study was not randomized nor did it standardize a number of factors that are known to affect the quality of the graft and patency outcomes.

Importantly, these results stand in contrast to recently-published data from a large observational study that followed 5,285 patients who underwent EVH using VASOVIEW for an average of two and a half years and documented reduced wound complications and similar long-term survival outcomes for EVH compared to OVH.<sup>2</sup> This study corroborates the well-documented short-term benefits achieved with EVH while providing evidence that EVH is safe and does not compromise long-term outcomes.

Furthermore, recent studies have underscored the importance of meticulous vein handling, avoidance of distension-related endothelial damage and pre-harvest administration of low-dose heparin to limit retained clot.<sup>3</sup> In order to provide a more contemporary assessment of the quality of conduit obtained with EVH performed according to increasingly-recognized "best practices," MAQUET initiated the OPTION (Optimal Improvement of Vein Graft Patency Long Term by the Implementation of Novel Endoscopic Harvesting Techniques) study to evaluate EVH, specifically using VASOVIEW, performed according to standardized procedure, harvester experience, post-harvest graft handling and medical management. The OPTION study will address the limitations of previous studies evaluating EVH in CABG and will validate the safety and efficacy of EVH, without subjecting patients to complications associated with open harvesting techniques that a randomized study would require.

In addition, on May 3, MAQUET announced the launch of the VASOSHIELD Pressure Controlling Syringe for use during CABG surgery. The VASOSHIELD syringe limits internal "flushing" pressure and controls vessel distension when harvested grafts are irrigated in preparation for use in bypass surgery. Avoiding excessive pressure and limiting distension help maintain internal vessel integrity, which has been shown in clinical studies to be an important factor affecting conduit quality and long-term graft patency.

MAQUET continues to advance cardiac bypass surgery techniques by investing in technologies that help improve patient outcomes and enhance the quality of life. As the leader in EVH, MAQUET has been and will continue to be committed to optimizing EVH technology and the procedure to deliver the best care and outcomes for patients.

References:

1. Zenati et al. "Endoscopic Vein Harvest Is Associated with Compromised Patency Outcomes: Results from the Prospective Randomized ROOBY Trial. Paper presented at the 90<sup>th</sup> annual meeting of the American Association of Thoracic Surgery, Toronto, Ontario, May 2010.
2. Ouzounian M, Hassan A, Buth KJ, MacPherson C, Ali IM, Hirsch GM, Ali IS. Impact of endoscopic versus open saphenous vein harvest techniques on outcomes after coronary artery bypass grafting. *Ann Thorac Surg.* 2010 Feb;89(2):403-8.
3. Poston et al. Heparin Administration Prior to Endoscopic Vein Harvest Limits Clot Retention and Improves Graft Patency. Paper presented at the annual meeting of the International Society for Minimally Invasive Cardiothoracic Surgery, San Francisco, CA, June 2009.