Acquired Cardiac Disease Session 2 Imaging/Robotics/CABG Rooms 115/117 **10:40-13:15**

Live video box presentation: External mesh for vein grafting

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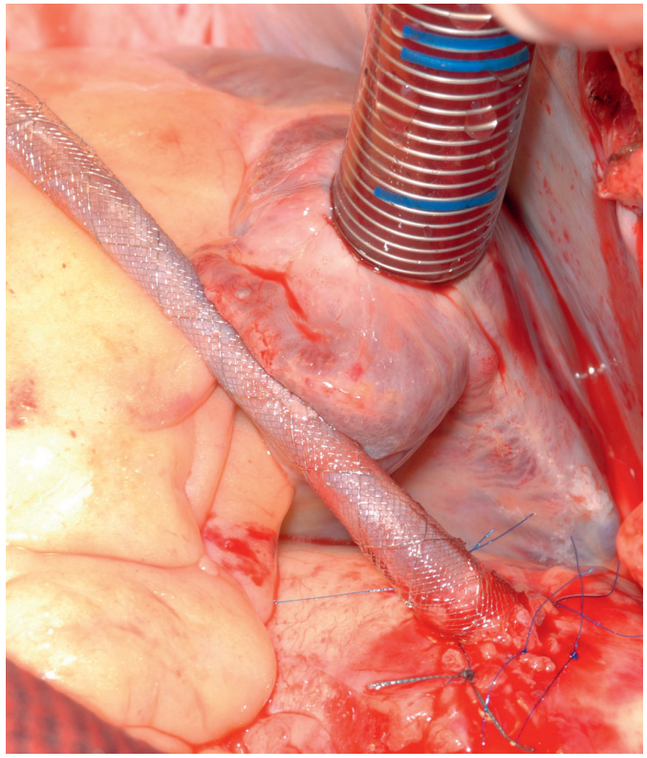
Coronary artery disease (CAD) is the leading cause of death in the U.S and Europe and recent studies (eg SYNTAX) have confirmed that CABG remains the treatment of choice for severe CAD. While most patients receive a single internal mammary artery (IMA) only around 5-10% receive two IMAs or additional arterial grafts. Most conduits are still Saphenous Vein Grafts (SVGs) because of their abundance and ease of harvest and use. However their main disadvantage is relatively poor long term patency compared to IMA grafts with graft failure in as many as 20% of veins within the first year and in as many as 50% at 10 years and with further significant disease in half of the remaining patent grafts. SVG failure carries important adverse clinical sequelae (including myocardial infarction, re-interventions and death).

Vein graft disease begins with diffuse neo-intimal tissue proliferation which develops in 75% of grafts within one year of implantation. Subjected to the arterial circulation, the vein graft is exposed to a "new" mechanical environment with relatively high pressures and shear stress. In the first few weeks, shear induced remodeling occurs which leads to luminal enlargement. This is followed by a later phase characterized by wall tension induced remodeling which results in wall thickening (intimal hyperplasia) and stiffening. In addition to the diffuse intimal hyperplasia, the luminal irregularities of the native vein and its valves are the main triggers for aggressive focal intimal hyperplasia which carries higher risk for vein graft failure.

Preventing vein graft dilation and reducing its luminal irregularities and wall tension by using an external stent therefore has the potential to mitigate intimal hyperplasia and to reduce high failure rates in vein grafts. However, previous attempts at external support of vein grafts have been unsuccessful for a variety of reasons. VGS FLUENT, a novel external support device for SVG's, is a cobalt chrome braid, with a unique combination of different types of wires which provide it with axial plasticity and radial elasticity. The axial plasticity allows the surgeon to fixate the FLUENT in situ at the desired length and diameter and to cover the entire SVG, without using glue, sutures or other changes which may compromise graft patency. The radial elasticity of the FLUENT makes it crush and kink resistant and provides the SVG with beneficial biomechanical properties by reducing wall tension and the diameter mismatch with the host artery and preventing non uniform dilation and the formation of lumen irregularities.

A CABG study in sheep demonstrated the FLUENT's safety along with outstanding efficacy in reducing intimal hyperplasia, preventing vein graft dilation/deformation and eliminating thrombus formation. Following these successful animal studies the FLUENT has been evaluated in a randomized controlled study (Venous External Support Trial) in the UK which recruited 30 patients in Oxford and Brompton/Harefield who in addition to an IMA graft to the LAD, required grafts to the Right Coronary Artery and the Circumflex Artery. Patients were randomized for one vein graft to receive the stent and the other to act as a control. Patients will now undergo 12 months angiography, IVUS and OCT to compare the experimental and control grafts' patency, lumen uniformity and plaque volume (intimal and medial hyperplasia). If the external stent successfully reproduces the findings in the sheep model it will have major implications for clinical practice.



Vein graft to right coronary artery covered with the Fluent Stent

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