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Research Paper

A new design concept for knitted external vein-graft support mesh

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ABSTRACT

Autologous vein-graft failure significantly limits the long-term efficacy of coronary artery bypass procedures. The major cause behind this complication is biomechanical mismatch between the vein and coronary artery. The implanted vein experiences a sudden increase (10–12 fold) in luminal pressures. The resulting vein over-distension or 'ballooning' initiates wall thickening phenomenon and ultimate occlusion. Therefore, a primary goal in improving the longevity of a coronary bypass procedure is to inhibit vein over-distension using mechanical constriction. The idea of using an external vein-graft support mesh has demonstrated sustained benefits and wide acceptance in experimental studies. Nitinol based knitted structures have offered more promising mechanical features than other mesh designs owing to their unique loosely looped construction. However, the conventional plain knit construction still exhibits limitations (radial compliance, deployment ease, flexibility, and bending stresses) which limit this design from proving its real clinical advantage. The new knitted mesh design presented in this study is based on the concept of composite knitting utilising high modulus (nitinol and polyester) and low modulus (polyurethane) material components. The experimental comparison of the new design with a plain knit design demonstrated significant improvement in biomechanical (compliance, flexibility, extensibility, viscoelasticity) and procedural (deployment limit) parameters. The results are indicative of the promising role of new mesh in restoring the lost compliance and pulsatility of vein-graft at high arterial pressures. This way it can assist in controlled vein-graft remodelling and stepwise restoration of vein mechanical homoeostasis. Also, improvement in deployment limit parameter offers more flexibility for a surgeon to use a wide range of vein diameters, which may otherwise be rendered unusable for a plain knit mesh.

Abbreviations: CABG, Coronary artery bypass graft; AVG, Autologous vein graft; IH, Intimal hyperplasia; PET, Polyester; NT, Nitinol; PCU, Polycarbonate urethane; LM, Low modulus; HM, High modulus; DL, Deployment limit

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1. Introduction

Coronary artery bypass graft (CABG) surgery is one of the most frequently performed surgical procedures in the United States, with over 400,000 procedures performed annually (Members et al., 2011). Autologous saphenous vein graft remains the graft of choice for surgeons performing CABG procedures (Vijayan et al., 2002). However, failure of autologous vein grafts (AVG)s still remains a major problem and has been reported as high as 25% within 12–18 months after surgery (Members et al., 2011). A number of factors contribute towards AVG failure namely, early thrombosis, atherosclerosis, intimal hyperplasia (IH), and compliance mismatch (Davies et al., 1992; Harskamp et al., 2013). However, IH has been a major investigative factor for decades owing to its significant contribution towards the failure (20–40% within the first 5 years) (Davies and Hagen, 1995). The initiation of IH is due to an abrupt exposure of AVG to the dynamic environment of arterial circulation (Davies and Hagen, 1995; Harskamp et al., 2013). Post-implantation, the AVG, which has experienced luminal pressures only up to 10 mmHg, is suddenly subjected to high arterial pressures (100–120 mmHg) (Dobrin et al., 1989; Powell and Gosling, 1998). In such conditions, circumferential wall stress in an AVG can increase 140-fold compared to that in a vein under normal circumstances (Liu and Fung, 1998). An uncontrolled wall thickening (or lumen narrowing) initiates as a response mechanism of AVG to return back to normal venous stress levels and normalize tangential wall stress (Dobrin et al., 1989; Vijayan et al., 2002). An AVG can become stiff beyond distending pressures of 75 mmHg owing to elastin fibre degeneration (Ozturk et al., 2013) and thus exhibit low compliance in much higher physiological pressure range of coronary artery. The formation of IH particularly at the heel and toe of the distal anastomosis initiates as a result of compliance mismatch between artery and vein (Kidson, 1983; Tiwari et al., 2003).

An external mesh reinforcement has proven to be a promising technique in preventing over-distension of AVGs and IH development (Desai et al., 2010). Since its first trial in 1963 (Parsonnet et al., 1963), several studies have verified this effect using various mesh constructions (electrospun (El-Kurdi et al., 2008), braided (Ben-Gal et al., 2013; Krejca et al., 2002; Zilla et al., 2008, 2009), woven (Jeremy et al., 2004), knitted (Moodley et al., 2013; Murphy et al., 2007; Schoettler et al., 2011; Zilla et al., 2011)) and different materials (polyurethane (El-Kurdi et al., 2008), polyester (Krejca et al., 2002; Longchamp et al., 2014; Murphy et al., 2007; Trubel et al., 1994), metal alloy (Ben-Gal et al., 2013), polyglactin (Jeremy et al., 2004; Vijayan et al., 2004), polytetrafluoroethylene (Kohler et al., 1989), nitinol (Zilla et al., 2008, 2009, 2011)). However, none of these trial meshes has been successfully included into regular clinical practice except the CE certified eSVS® mesh (Kips Bay Medical, Minneapolis, MN USA), a knitted nitinol mesh (Emery et al., 2012). The device is not yet U.S. Food and Drug Administration (FDA) approved and is currently undergoing clinical feasibility trial (eMESH trial). The manufacturers claim that the eSVS® mesh can restrict diameter of AVG and exhibit pulsatile flows similar to an artery. Till date there are very few studies which have reported the clinical performance of eSVS® mesh in animals (Moodley et al., 2013; Zilla et al., 2011) and humans (Genoni et al., 2013; Schoettler et al., 2011). One of the first studies comparing a knitted nitinol with a braided nitinol mesh as femoral artery graft support was conducted on nonhuman primate models (Chacma baboons) (Zilla et al., 2011). The knitted mesh exhibited significantly better handling and biomechanical (radial compliance, bending stiffness, kink-free radius, radial narrowing) properties than the braided mesh with nearly total suppression of IH and more physiologic remodelling of AVG media.

Knitted structures are inherently flexible constructions and hence a promising design approach for an external support mesh. However, the limitations reported by the short term trials of eSVS® mesh cannot be ignored and can become an early call for further improvisation in its design. The kink-free configuration of knitted mesh allows easy adaptation to anatomic bends and curves (Zilla et al., 2011). However, nitinol wire in a looped knit configuration can undergo hemodynamic strain specifically at anatomical bends, and exhibit breakages (Moodley et al., 2013; Murphy et al., 2007; Zilla et al., 2011). A numerical study by van der Merwe and colleagues has attempted to provide solution to minimise loop breakage by suggesting the use of an even knit loop design and use of thinner nitinol wires (⌀<0.05 mm) (van der Merwe et al., 2008). Longitudinal flexibility of knitted mesh provides high length and diameter stability during implantation procedure (Zilla et al., 2011). On the contrary, this property also makes the deployment stage a traumatising event for the AVG tissue as it involves an uneasy feeding of AVG from one end of an insertion straw and pulling it from other end (Zilla et al., 2011). This problem can be more prominent in longer AVGs and arises due to insufficient circumferential extensibility of the knitted mesh to accommodate a high calibre insertion straw. It was numerically computed that free movement of knitted loops allows diameter extension in a knitted nitinol mesh (⌀=3.34 mm) but only to limited pressure levels (up to 15 mmHg) which is far below the physiological arterial pressure (van der Merwe et al., 2008). As the pressure increases, the loop-loop interlocking jams the knit structure with no further increase in mesh diameter owing to inextensibility of the nitinol wire itself. The compliance of knitted nitinol mesh (⌀=3.37 mm, wire thickness=0.05 mm) was less than half of the artery (Zilla et al., 2011), which may render such plain knit mesh design incapable of producing the required pulsatile flow and hence prone to long-term failure (Abbott et al., 1987; Trubel et al., 1994; Weston et al., 1996). The use of thinner nitinol wires (⌀<0.05 mm) has been suggested to improve compliance in a computational study (van der Merwe et al., 2008) but not yet experimentally proved. A critical issue with a vein-graft is that it shows high compliance in low-pressure range (<10 mmHg) while remains inextensible in the high-pressure range (>50 mmHg) (Stooker et al., 2003). An ideal external support mesh should be capable of enhancing the compliance property of an AVG even while acting as a mechanical constriction to the AVG wall. The combined use of a non-compliant AVG and a stiff mesh can further deteriorate the biomechanics of the treated artery (Trubel et al., 1994). Diameter mismatch in a compliant mesh is not as big an issue as a non-compliant mesh with matched diameter (Trubel et al., 1994). A non-complaint mesh graft with matched diameter will automatically become undersized after implantation as the diameters are generally matched at diastolic pressures (Weston et al., 1996).