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ON THE MECHANICAL FAILURE OF ARTERIAL PROSTHESES

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ABSTRACT

Nowadays, the use of synthetic grafts to bypass occluded arterial sections is common practice in clinics and hospitals. Success has been achieved in cases involving large diameter blood vessels. However, for arteries with a diameter less than 5 mm, the success rates for synthetic grafts have been low mainly due to intimal hyperplasia formation at anastomoses. The postulated reasons affecting graft failure include compliance mismatch, internal radius mismatch, Young's modulus, and impedance phase angle. Development of a graft that is mechanically equivalent with a natural artery requires investigation of the mechanics of arteries and possible grafts. Numerical studies can provide information on how selection within existing prostheses can influence the patency rate. A computational model is used to determine design parameters for patient-specific optimal grafts.

Keywords: modelling, vascular graft, optimization, biomedical technology.

INTRODUCTION

The major causes of prosthetic graft failure have been thrombosis and intimal hyperplasia formation associated with the bypass surgery. Vascular endothelial cell damage triggers intimal hyperplasia (IH) at the anastomosis site, connection between the vascular graft and the host artery, becoming a major cause of low graft patency. IH is often found near the anastomosis suture line and on the floor of the host artery leading to the belief that both hemodynamic factors as well as vessel wall mechanics play an important role in the patency of vascular grafts (Salacinski et al., 2001).

The mechanical behaviour of an artery is complex and the ideal graft would replicate its behaviour. On the other hand, patients with peripheral vascular disease already have increased intima-media thickness, contributing to arterial rigidity and the physical concept of Young's modulus is difficult to adjust. Instead, the term compliance is used, encompassing the changing mechanical properties depending on the hemodynamic pressure within the graft. Compliance is inversely proportional to vessel wall thickness and research on tissue engineering offers materials of natural origin with viscoelastic properties similar to native arteries due to its compliance and favourable biocompatibility. The mechanical requirements for completely biological tissue engineered grafts are not limited to demonstrating physiological burst pressure and compliance (Kannan et al., 2005). It is also important that grafts be resistant to rapid degradation and fatigue-induced aneurysm formation in vivo.

The ideal bypass graft requires a broad range of characteristics including strength, viscoelasticity, biocompatibility, blood compatibility and biostability (Desai et al., 2011). The biomechanical uniformity of a synthetic graft could enable the development of an effective anastomotic device for minimally invasive surgery. When considering bypass grafts, the impedance to flow is drastically increased by reducing graft radius, thereby reducing flow rate and increasing the risk of stasis and promoting IH (Sarkar et al., 2006). This work aims to discuss the critically important roles that mechanical properties play in maintaining patency of bypass grafts.

PROSTHETIC BYPASS GRAFTS AND FAILURE MODES

The main synthetic graft materials used in peripheral vascular reconstructions are expanded polytetrafluoroethylene (ePTFE) and polyethylene terephthalate (PET, commonly known as Dacron).

Dacron is a type of polyester in the form of multiple filaments either woven or knitted into vascular grafts. The manufacturing process makes Dacron grafts resistant to cyclic pulsatile stretching, but it has shown poor patency rates when used in small diameter sizes or in low-flow locations (Van Damme et al., 2005). The total incorporation of the graft by tissue without fibrinous material lining the luminal aspect of the graft is known as complete healing. Man appears to have a limited capacity to completely organize his own fibrin deposit on the luminal aspects of arterial prostheses, except by pannus outgrowth immediately adjacent to anastomoses to the host artery (Berger et al., 1972). The conceptualization of pannus growth as viewed at an anastomosis between the aorta and an impervious graft such as silastic-sealed Dacron velour is shown in Fig. 1. A hyperplastic response takes place from the luminal surface and the divided end of the artery. Simultaneously, tissue grows up through anastomotic line, as well as suture tracks. An advancing wedge of tissue replaces the thrombus overlying the graft, with endothelium frequently in the forefront. With porous grafts, in addition to these mechanisms, tissue would also continue lumen-ward through the interstices.

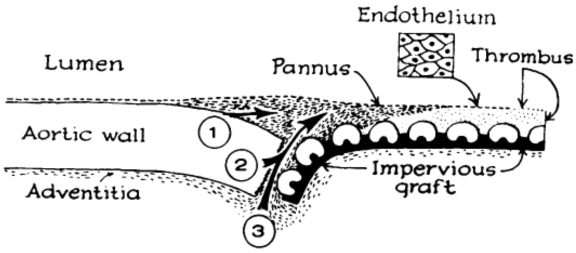

Fig. 1. Pannus growth at an anastomosis between the aorta and an impervious graft: hyperplastic response from the luminal surface and the divided end of the aorta (arrows 1 and 2); tissue grows up through anastomotic line, as well as suture tracks (arrow 3) (Berger et al., 1972).

PTFE is an inert fluorocarbon polymer and subsequently made more microporous by extrusion and sintering to form expanded PTFE (ePTFE) (Kannan et al., 2005). This polymer is non-biodegradable with an electronegative luminal surface that is antithrombotic and is now widely used for lower-limb bypass grafts (7-9 mm) with excellent results. The poor mechanical characteristics (compliance) and the lack of endothelial cells (ECs) lining the lumen of such graft materials are the significant factors contributing to their poor patency (Kapadia et al., 2008).

Structural defects, resulting in graft rupture or false aneurysm formation has been observed after seven years or more of implantation. Occasional structural textile failure is supposed to be multifactorial namely, manufacturing flaws (errors in the production process), erroneous storage conditions, inappropriate surgical handling, material fatiguing and biodegradation.

Failure modes for vascular grafts are detected within less than 30 days from surgical procedure if due to a technical issue namely, marginal conduit, diseased inflow or outflow vessel. Failure observed from 30 days to 2 years is usually due to intimal hyperplasia either in the bypass or at the inflow or outflow conduit. Failure observed after a period greater than 2 years is due to aneurysmal degeneration of the target artery and recurrent atherosclerosis. After surgery, graft surveillance indicates that 15-20% of grafts for peripheral vascular disease will fail within 5 years of implantation and that 60% of grafts fail due to in graft lesions.

In clinical practice, it is common to measure peak systolic velocity for the assessment of degree of stenosis. Non-invasive duplex ultrasonography allows graft surveillance using B-mode images and Doppler velocity measurements and further studying peak systolic and end diastolic velocities. High velocity criteria for peak systolic velocity and low velocity criteria are used to determine the failure or success of a bypass surgery. A significant stenosis is defined if peak systolic velocity appears to be greater than two times the normal inflow artery velocity. Fig. 2 presents characteristic ultrasound waveform and B-mode images of the proximal anastomosis, mid-graft and distal anastomosis of a successful bypass surgery (Kapadia et al., 2008).

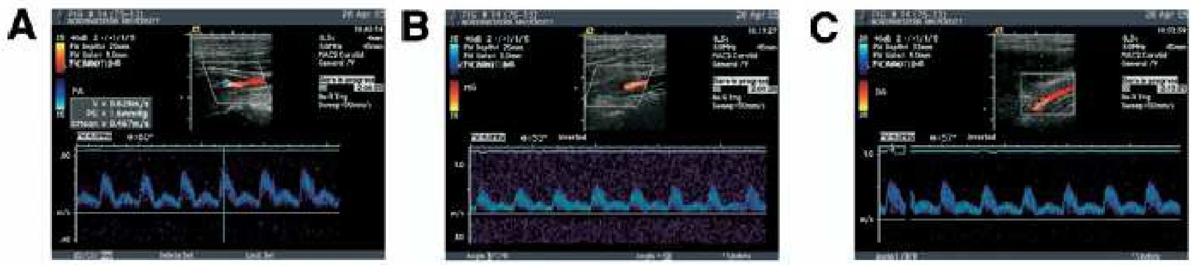

Fig. 2 Characteristic ultrasound waveform and B-mode images of the (A) proximal anastomosis, (B) mid-graft and (C) distal anastomosis (Kapadia, et al., 2008)

Traditional synthetic material technologies have not been able to fulfil the requirements of an ideal prosthetic conduit despite a larger volume of material research in this area. Polyurethanes have been investigated as alternative graft material because they are more compliant than Dacron and PTFE, and, thus, their mechanical and flow parameters are better matched to those of the native vasculature.

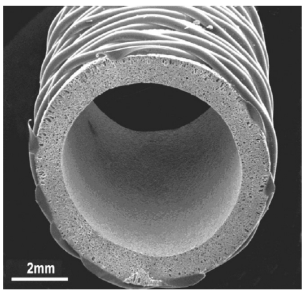

Fig. 3 Compliant polyurethane graft with external support; the sponge-like structure of the wall allows pulsatile elastic recoil (Desai et al., 2011)

The development of compliant, small-bore, vascular grafts one based on nanocomposite polymer (UCL-NanoTM consisting of polyhedral oligomeric silsesquioxane and poly (carbonate-urea) urethane) and another bio-resistant compliant polyurethane graft (MyoLink) (Fig. 3) appears to be resistant to biodegradation (Desai et al., 2011). There is insufficient follow-up to properly assess its performance in terms of patency rates, and the results of clinical studies are awaited.

RESULTS

In this work, idealized geometries are used to address wall stresses at the anastomosis and arterial wall modelled as anisotropic constitutive model for an accurate description of the mechanical behaviour of arterial tissue including the stiffening effect at higher internal pressure. Model calibration, in which model design values are modified for an optimal result, and quantitative comparisons are carried out on different sub-models by examining the effect of parameters on measurable properties. Finite element simulations (Castro et al., 2010; Sousa et al., 2011; Sousa et al., 2012) are performed considering a virtual bypass surgery on a fully occluded artery. For modelling purposes the simplified arterial graft prosthesis is a tubular vessel disposed around a longitudinal axis. Fig. 4 presents the model including both proximal and distal bypass junctions in order to analyse the flow development along the entire bypass.

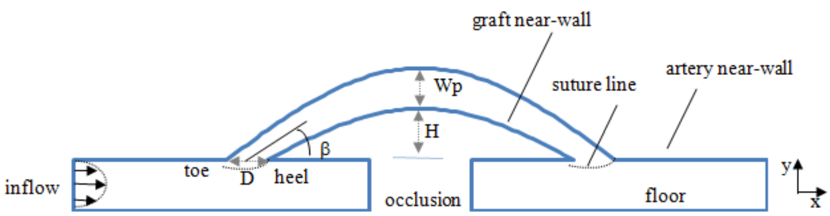

Fig. 4 Anastomotic configuration and nomenclature of the bypass graft

The developed finite element code simulates blood flow in artery and graft using 2261 nodes and 2024 four-node linear elements for a two-dimensional finite element approximation. Velocity simulations are carried out under physiological pulsatile conditions using a femoral inlet velocity waveform (Carneiro, 2009). Flow conditions at the inlet were considered as parabolic velocity profiles. Longitudinal velocity contours for a specific bypass on a 10mm artery at two different instants are displayed in Fig. 5.

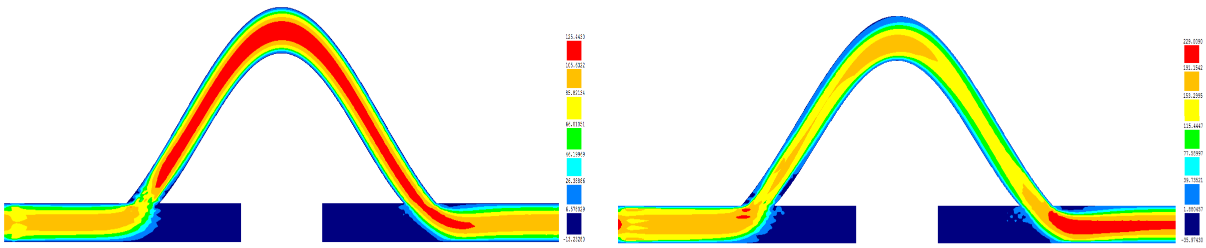

Fig. 5 Longitudinal velocity contours for the bypass graft at two different instants

Parametric geometry parameters are given as distance from the near wall of the graft to the near wall of the artery H= 38.47 mm, junction angle β= 0.736 rad, width of the prosthesis at its longitudinal symmetric line Wp= 11.86mm and suture line dimension D= 14.05mm. Analysing the velocity behaviour at different instants (Fig. 5) it can be noted that as blood flow progresses from the proximal junction of the bypass to the distal end, the axial velocity exhibits quite different behaviours. On the left plot the highest velocities are seen inside the graft and on the right end side instant of the plot maximum velocities are attained at the distal artery with a slight skewed parabolic profile at the outflow. To capture the flow features at peak systolic phase, computed velocity profiles at four cross sections of the distal artery domain are illustrated in Fig. 6. The velocity profile changes dramatically as blood flows downstream the distal junction. At sections x_1 and x_2 the computed axial velocity profiles along the vertical lines exhibit a skewing toward the top wall of the artery, which is due to the junction effects. As flow progresses downstream, the flow direction reverses. At section x_3 the computed axial velocity profile attains maximum values close to the artery floor. This is expected due to the impingement of blood on the floor of the artery. Then gradually the profile changes to a somewhat parabolic with increasing distance from the graft junction (section x_4). It can be noted that as the flow progresses further downstream in the artery, the effect of the distal anastomotic junction does not significantly affect the velocity profile.

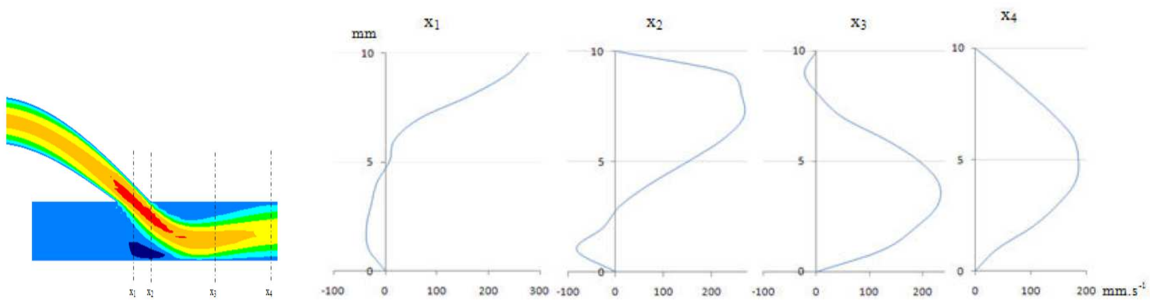

Fig. 6 Diagram depicting sections (left) and velocity distributions (right) throughout the distal junction at peak systolic phase

Despite the significance impact of the previous studies on the understanding of arterial bypass hemodynamics, models have only focused on only some aspects of the problem. For example, much of the modeling work in graft flow is limited to only a part of the total bypass conduit geometry, namely, the anastomosis site. A fully integrated model that accounts for all the relevant factors such as realistic geometry, inlet flow conditions, and anastomosis angle is yet to be discussed. The present analysis focused on the blood flow pattern because they are intimately related to the development of arterial diseases and hence the patency or failure of bypass graft. The results indicate that a properly contoured graft may contribute to improved patency.

CONCLUSIONS

There is widespread reporting that compliance mismatch, rather than geometric factors, is primarily responsible for IH and subsequent poor graft patency as a result of turbulent flow. Numerical simulations can provide such information using simplified arterial graft prosthesis. Information on the distribution of the stress in the arterial wall and the wall shear stress near an anastomosis may help to understand why distinct sites are prone to form intimal hyperplasia. The subject of model verification against experimental results remains an important issue for current computational approaches.

ACKNOWLEDGMENTS

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