Stent Graft Biomechanics – Optimising Cover Design for Peripheral Applications

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Abstract
The biomechanical behavior of peripheral stent-grafts plays a key role in the success of endovascular surgery. In this study, a finite element model of stent-graft crimp and expansion was constructed to establish the potential of polytetrafluoroethylene as a covering material for a stent-graft system in peripheral applications. The biomechanical behavior of both covered and bare metal stents, as well as open- and closed-cell stent configurations was investigated. The results indicate that the addition of a polytetrafluoroethylene cover causes an increase in outward radial force. It was also shown that stent design has a significant effect on the level of plastic deformation in the cover.

1. Introduction
Endovascular aneurysm repair is a minimally invasive procedure where an endoprosthesis, in the form of a tubular stent-graft is delivered percutaneously to the site of the aneurysm to shield the weakened vessel from haemodynamic pressure, thus preventing rupture of the artery wall. Stent-grafts generally consist of a metallic stent frame that has been wrapped with a synthetic polymeric covering, usually made from Dacron or Polytetrafluoroethylene (PTFE).

A major challenge in developing stent-graft devices for peripheral applications is associated with delivery, where devices must be crimped to approximately 20% their original diameter during deployment. While Dacron and PTFE coverings have been widely used in large-diameter applications, their poor compliance and low flexibility may adversely affect device deliverability in small-diameter vessels and limit their potential in the peripheral vasculature applications [1].

To date, there has been considerable research on computational analysis of covered stents in a range of applications in the body [2-3], however the peripheral system has been somewhat neglected. The research presented in this study will evaluate two stent designs for use as a peripheral stent-graft, and provide an understanding of some of the effects of incorporating a cover.

2. Methods
Finite element models simulating radial crimp and expansion phases of bare and covered Nitinol stent segments were developed using Abaqus/Explicit (V6.14). Simulations were performed on two stent designs (closed- and open-cell), as shown in Figure 1. The stent geometries consist of a repeating unit structure with an outer diameter of 5.5mm and a thickness of 0.25mm. A 2D profile of the geometry was created, meshed and subsequently wrapped to 3D cylindrical system using a Python code. The stent designs consisted of approximately 10,000 eight-noded linear brick (C3D8R) elements with enhanced hourglass control. To select a suitable mesh for the stent, a mesh convergence study was performed. The PTFE cover was 30µm thick and modelled with 19,000 shell (S4R) elements. A tie constraint is implemented to represent bonding between the stent frame and the cover.

The stent was modelled with the Auricchio in-built nitinol constitutive model in Abaqus, which was calibrated with data from tensile testing conducted by Admedes Schuessler (Pforzheim, Germany) [4]. The PTFE cover was assumed to behave as an elastic-plastic material with a Young’s Modulus of 460MPa and a Poisson’s ratio of 0.46. It had a yield strength of 22.1MPa, after which it exhibits linear plastic hardening behaviour.

The stent is displaced radially through use of an equation constraint to crimp from a diameter of 5.5mm to a diameter of 1.5mm. In a second step, the radial displacement is reversed to simulate expansion. A general contact definition is used to define self-contact in the cover. The contact uses the penalty method, with coefficient of friction of 0.1 and hard normal contact. To ensure the simulation represented quasi-static conditions, the ratio of kinetic energy to internal energy was monitored throughout to ensure it remained below 5%.

2D Figure 1: (a) Closed- and (b) open-cell covered stent models.

3. Results
Figures 2 (a) and (b) show that the outward radial force required to crimp for both closed- and open-cell stent configurations is higher for the PTFE covered-stent, compared to the bare-metal stent (BMS). The radial force peaks at very small diameters as the cover begins to come in contact with itself.
Figure 2: Outward radial force for covered and bare metal stent systems, with (a) closed- and (b) open-cell stent configurations.

Figure 3 shows extensive plastic deformation in the cover, with permanent deformation evident when unloaded. The equivalent plastic strain is higher and more localised in the closed cell stent design as the cover is in tension between the closed geometry. These results indicate that equivalent plastic strain in the graft can be reduced by using an open cell stent configuration, instead of a closed cell stent.

Figure 3: Equivalent plastic strain in the PTFE graft at various stages of crimp and expansion with (a) closed cell configuration and (b) open cell configuration.

Figure 4 (a) shows that increasing the cover thickness on an open-cell stent results in an increase in radial reaction force, particularly at small diameters (<2mm). Excessively high radial reaction forces could induce high stresses on the aneurysm wall, leading to thromboembolism or rupture. The distinct stiffening response observed at final stages of the crimp phases, coincided with the cover folding and self-contact of the cover between stent struts. The parameter studies conducted show that plastic strain in the PTFE graft can be reduced by use of an open cell configuration and the radial force output can be reduced slightly by decreasing the cover thickness.

These studies demonstrate the need for a new graft material which does not cause elevated radial reaction forces when crimped to small diameters.

4. Discussion

The results presented have shown that the addition of a PTFE cover results in elevated radial reaction forces, particularly at small diameters (<2mm). Excessively high radial reaction forces could induce high stresses on the aneurysm wall, leading to thromboembolism or rupture. The distinct stiffening response observed at final stages of the crimp phases, coincided with the cover folding and self-contact of the cover between stent struts. The parameter studies conducted show that plastic strain in the PTFE graft can be reduced by use of an open cell configuration and the radial force output can be reduced slightly by decreasing the cover thickness.

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5. References


