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An Experimental Evaluation of Device/Arterial Wall Compliance Mismatch for Four Stent-Graft Devices and a Multi-layer Flow Modulator Device for the Treatment of Abdominal Aortic Aneurysms

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WHAT THIS PAPER ADDS

Loss of arterial compliance is an important cardiovascular risk factor. Compliance decreases with age, hypertension, and menopause, and its reduction is associated with endothelial dysfunction and adverse cardiovascular events. Pathological loss of compliance is, usually, an insidious process. However, endograft placement results in a more acute drop in compliance, which not only effects cardiovascular risk, but, also, through the fluid structure interactions may influence stent graft durability and the development of complications. The variation in compliance between commercially available stent grafts was investigated to examine which devices have the least adverse effect on aortic compliance.

Objective/background: To investigate experimentally the arterial wall/device compliance mismatch of four stent-graft devices and a multilayer flow modulator within the supra- and infrarenal locations for the treatment of abdominal aortic aneurysms (AAA).

Methods: Five devices (MFM, EndurantII, Excluder, Zenith, and Fortron) were tested under physiological flow conditions within a flow simulator system comprising of a patient-specific thin-walled flexible AAA perfusion model with replicated intraluminal thrombus, supported by the spinal column. Devices were submitted to circumferential force tests and implanted in the perfusion model for circumferential arterial pressure/diameter measurements. Parameters, including radial resistive force, supra-/infrarenal compliance, pulsatile arterial energy loss (PAEL), pulse wave velocity (PWV), and wave reflection coefficient (Γ), were computed to characterise the devices' performance.

Results: The Zenith and EndurantII devices had the highest radial resistive force (up to 3 N/cm), while the Fortron device had the lowest (0.11 N/cm). Supra- and infrarenal compliance varied between 6.9–5.1 $\times$ 10^{-4}/mmHg and 4.8–5.4 $\times$ 10^{-4}/mmHg, respectively. Two devices (EndurantII and Excluder) significantly decreased infrarenal compliance by 13–26% ($p < .001$). Four devices increased the PAEL by 13–44% ($p < .006$). The PWV ranged from 10.9 m/s (MFM; $p = .164$) to 15.1 m/s (EndurantII; $p < .001$). There was an increase of 8–238% ($p < .001$) in the reflection coefficient for all devices.

Conclusion: Commercially available endovascular devices lower the aortic wall compliance after implantation. The MFM was found to be the most compliant in the suprarenal region, while the Fortron device was the most compliant in the infrarenal region. Choosing the most compliant devices for treating AAAs produces positive gains in the aortic elastic recoil, thus minimising the device related complications.

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INTRODUCTION

Endovascular aneurysm repair (EVAR) is the contemporary first-line therapy for abdominal aortic aneurysms (AAA), with open repair reserved for those who are unfit for EVAR. EVAR offers clear benefits when compared with open repair,

in terms of less trauma, short hospital stay, reduced mortality, and lower morbidity. However, associated device fixation problems, such as endoleaks, migration, and proximal neck enlargement,[1,2] can affect the long-term success.[3] Radial arterial wall compliance (C) is a change in vessel diameter or cross-sectional area triggered by a change in blood pressure. C, relative pulsatility, and pulsatile diameter are dramatically changed following the arterial device implantation.[4,5] The changes in compliance at the interface stent/arterial wall, represent a result of the device-to-arterial wall mechanical coupling. To date, it is unclear how stents affect the compliance of an artery, as compliance varies from one type of stent to another. One stent type can cause the arterial wall to behave rigidly, while another type may have no effect.[6]

The reduction in C influences the haemodynamics in terms of blood flow patterns and von Mises stress in the wall,[7] as was shown by Ene et al.,[8] who computationally analysed six AAAs under different assumptions, such as static/transient pressures, steady/transient flows, and rigid/compliant walls. Vernhet et al. and Morris et al. showed a significant decrease in compliance when using small stents in small-calibre rabbit arteries and a stent-graft (SG) device within an AAA perfusion model, respectively,[2,7] while Pihkala et al. found that implanted stents in pig aortas did not affect C or alter the pulse wave velocity (PWV).[9] Also, *in vivo* monitoring by intravascular ultrasound within coronary lesions shows a decrease in compliance after the implantation of endovascular scaffolds.[10] Changes in C trigger arterial dysfunction and pathophysiology, which have a key role in vascular biomechanics and homeostasis.[11] Vlachopoulos et al. found that a 1 m/s increase in the PWV generates a 14% increased risk of cardiovascular events, cardiovascular mortality, and all-cause mortality.[12]

It was hypothesised, in this study, that SG devices play a major role in altering the local C after implantation. To test the hypothesis four SGs: EndurantII (Medtronic, Dublin Ireland), Fortron (Cordis, Sommerville, NJ, USA), Zenith (Cook Medical, Bloomington, IN, USA), Excluder (Gore Medical, Putzbrunn, Germany) and one Multilayer Flow Modulator (MFM) device (Cardiatis, Isnes, Belgium) were deployed in an AAA perfusion model.

METHODS

SG and MFM devices

Four bifurcated SG devices and the MFM device were dynamically tested within the AAA perfusion model (Fig. 1A).

All SGs have a thin-walled graft covering the aneurysmal sac region (Fig. 1A), while the MFM has no graft. The MFM device is also bifurcated by stapling at the bottom half by the manufacturer, thus creating two tubular channels in which two smaller MFM stents are fitted as device limbs. Table 1 summarises the devices sizes according to instructions for use (IFU). Based on the infrarenal internal/external neck sizes of the AAA, the clinicians sized the devices according to the manufacturers' IFU. The maximum proximal and distal diameters varied from 28—30 mm and 14—16 mm, respectively. The devices were deployed inside the perfusion model, as shown in Fig. 2(A, B), and outer neck diameters were measured at rest without any pressurisation, as shown in Table 2, in order to ensure that the experiment started at similar levels of neck dilatation.

Circumferential force test rig setup

The chronic outward force (COF) is a measure of the force the stent exerts on the artery as it tries to expand to its nominal diameter during vessel expansion. The radial resistive force (RRF) is a measure of the force the stent exerts, as it resists circumferential compression by constriction of the artery. Both parameters depend on the state of compression. The terms COF and RRF were coined by Duerig et al. to better describe the circumferential forces of self-expanding stents.[13]

COF and RRF were measured with the use of a high-strength, low-friction, 10-mm wide and 0.2-mm thick double-strip material (Tyvek paper with polyester/polyethylene laminated film; DuPont, Wilmington, DE, USA) that was looped around the proximal end of the devices, and threaded through a narrow gap between two rollers of the circumferential force test rig (Fig. 1B), similar to the tests conducted by Duda et al.[14] One end of the strip was attached to a fixed base, while the other end was attached to the clamp of a tensile tester machine (Instron 5544; Instron, High Wycombe, UK), equipped with ±10N static load cell.

The devices were mounted on a horizontal bar support, aligned with the material loop, in order to maintain their position during testing (Fig. 1C). There were 10 samples (cycles) per test, done for each SG, at an extension rate of 190 mm/min. The test was repeated 10 times for each device. All devices were compressed circumferentially, by a maximum of 20% reduction in the circumferential length. The reduction in diameter was given by the following formula:

$$\text{Diameter ratio} = 1 - \frac{Cd}{\pi D} \quad (1)$$

where

Cd is the circumferential displacement, D is the maximum proximal diameter of the device.

To ensure full stent expansion before testing devices were preheated in an oven at 45 °C for 10 min. The test started with the SGs expanded to the maximum proximal diameter state. All devices were crimped to 80% of the initial diameter and then unloaded to the nominal outer diameter, forming a cycle or a hysteresis describing the mechanical behaviour of the materials, as shown in Fig. 3.

Patient-specific AAA perfusion model fabrication

A patient-specific thin-walled flexible AAA perfusion model with intraluminal thrombus (ILT), and the inclusion of renal