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

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ABSTRACT

Purpose:

To experimentally investigate the arterial wall/device compliance mismatch of four stent-graft devices and a multi-layer flow modulator within the supra- and infra-renal locations for the treatment of Abdominal Aortic Aneurysms (AAA).

Methods:

Five devices (MFM™, Endurant II™, Excluder™, Zenith™ and Fortron™) were tested under physiologically flow conditions within a flow simulator system comprising of a patient-specific thin-walled flexible AAA perfusion model with replicated intraluminal thrombus (ILT), 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 waves reflection coefficient (Γ), were computed to characterise the device performance.

Results:

The Zenith™ and Endurant II™ devices had the highest radial resistive force (up to 3 N/cm), while the Fortron™ device had the lowest (0.11 N/cm). The compliance varied between 6.9 to 5.1×10^{-4}/mmHg (suprarenal), and between 4.8 to 5.4×10^{-4}/mmHg (infrarenal). Two devices (Endurant II™ and Excluder™) significantly decreased the infrarenal compliance by 13 – 26% ($p<0.001$). Four devices increased the PAEL by 13 – 44% ($p<0.006$). The PWV ranged from 10.9 m/s (MFM™, $p=0.164$) to 15.1m/s (Endurant II™, $p<0.001$). There was an increase of 8 – 238% ($p<0.001$) in the reflection coefficient for all devices.

Conclusions:

Commercially available endovascular devices lower the aortic wall compliance after implatation. The MFM™ was found to be the most compliant in the surprarenal region, while the Fortron™ device was the most compliant in the infrarenal region.

INTRODUCTION

The endovascular treatment (EVAR) of abdominal aortic aneurysms (AAAs) is the contemporary first line therapy, with open repair reserved for those who are unfit for EVAR. EVAR offers clear benefits when compared to open repair, in terms of less trauma, short hospital stay, reduced mortality and lower morbidity. However, associated stent-graft (SG) fixation problems, such as endoleaks, migration and proximal neck enlargement [1,2] can affect the long-term success of the EVAR.[3] The changes in compliance after stenting, at the interface between the stent and the arterial wall, represent a compliance mismatch. Compliance mismatch between these devices and the arterial wall may contribute to these reported issues. Arterial compliance is a change in vessel diameter or cross-sectional area triggered by a change in blood pressure. The arterial compliance, relative pulsatility, and pulsatile diameter are dramatically changed following the introduction of an implant SG in an artery, as found by Humphery[4] and Tortoriello[5]. Therefore a device/arterial wall compliance mismatch can be attributed to the change in arterial compliance in the vicinity of the implanted stent. 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 compliance mismatch alters the haemodynamics due to the reduced compliance within the vicinity of the SG/arterial wall interface[3,7] which may lead to increased pressure due to pulse wave reflections[2]. The reduction in arterial wall compliance influences the haemodynamics in terms of blood flow patterns and von Mises stress in the wall, as was

shown by Ene et al.[8], who computationally analysed the haemodynamics in six abdominal aortic aneurysms under different assumptions, such as static/transient pressures, steady/transient flows and rigid/compliant walls. Vernhet et al.[7] and Morris et al.[2] showed a significant decrease in compliance when using small stents in small-calibre rabbit arteries and a SG device within an AAA perfusion model respectively, while Pihkala et al.[9] found that implanted stents in pig's aortas didn't affect aortic compliance or alter the pulse wave velocity (PWV). Also, *in-vivo* monitoring by intravascular ultrasound within coronary lesions shows a decrease in compliance post implantation of endovascular scaffolds.[10] Changes in arterial compliance triggers arterial dysfunction and pathophysiology, which have a key role in vascular biomechanics and homeostasis.[11] Vlachopoulos et al.[12] found that a 1 m/s increase in the PWV generates a 14% increased risk of cardiovascular events, cardiovascular mortality and all-cause mortality. Also, an increase of 1 SD in PWV is associated with a further increased risk of over 40%.

To date, little is known on the influence that commercially available devices have on the SG/arterial wall compliance for the treatment of AAAs. The hypothesis of this study is that SGs play a major role in altering the local arterial compliance after implantation. In this study we are investigating the mechanical behaviour of five commercially available endovascular devices: four SGs (Endurant II™, Fortron™, Zenith™, Excluder™) and one multilayer flow modulator (MFM™) device, in order to discover if and how, the arterial compliance, is affected after implantation, by using an AAA perfusion model that, accurately, replicates the mechanical behaviour of the human aorta artery. The device/arterial wall compliance mismatch may be accounted for SG fixation problems such as Type I endoleaks and migration.

METHODS

Stent-Graft and MFM Devices

Four bifurcated SG devices and a Multilayer Flow Modulator™ (MFM™) device (Figure 1B) for the treatment of AAAs were dynamically tested within the AAA perfusion model. The five tested devices were as follows:

- MFM™ (Cardiatis, Belgium),
- Endurant II™ SG (Medtronic, USA),
- EXCLUDER™ (Gore Medical, USA),
- Zenith™ (Cook Medical, USA),
- Fortron™ (Cordis, Sommerville, NJ).

All SG devices (Figure 1B) have a thin walled graft covering the aneurysmal sac region, while the MFM™ has no graft covering along the stent structure. The MFM™ device is, also, bifurcated by having the lower tube half, stapled along the middle by the manufacturer, thus creating a bifurcation configuration with 2 tubular channels, in which two smaller MFM™ stents were deployed during implantation in the perfusion model as device limbs. Table 1 summarises the devices sizes according to IFU documentation. Based on the infrarenal internal/external neck sizes of the AAA, the clinicians sized the devices according to the manufacturer's indication for use (IFU) and not the maximum proximal diameter. The maximum proximal and distal diameters varied from (28 - 30mm) and (14 - 16mm), respectively. The AAA had an infrarenal neck angle of 57°, which falls within the IFU recommendations for four devices, but the MFM™. The Zenith™, Excluder™ and Fortron™ devices can be used if the minimum neck length is 15mm and the infrarenal neck angle is <60°, while Endurant II™ can be used if the infrarenal neck angle is <75°, for the same minimum neck length of 15mm. The IFU of the MFM™ does not specify a threshold for the

infrarenal neck angulation. The MFM™ is the last device to collapse in a neck angulation situation greater than 60°, judging by its observed bending behaviour, due to its stent design.

The different lengths resulted when selecting the devices used from the ones that we had access to. The devices were deployed inside the AAA perfusion model, as shown in Figure 2 (A & B), and neck outer diameters were measured at rest without any pressurization, as shown in Table 2, in order to ensure that the experiment started at similar levels of neck dilatation. The measurements were focused on the proximal neck of the aneurysm without being influenced by the length of each device.

Circumferential force test rig setup

The chronic outward force 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 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 chronic outward force and radial resistive force were coined by Duerig et al.[13] to better describe the circumferential forces of self-expanding stents.

Chronic outward and radial resistive circumferential forces were measured with the use of a high strength, low friction, 10mm wide and 0.2mm thickness, double strip material (DuPont™ Tyvek® paper with polyester / polyethylene laminated film), that was looped around the proximal end of the SG devices, and threaded through a narrow gap between two rollers, of the circumferential force test rig (Figure 1A), 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, UK), equipped with 10N static load cell.

The SGs were mounted on a horizontal bar support, aligned with the material loop, in order to maintain their position during testing (Figures 1B). The SGs were tested for 10 cycles at an extension rate of 190 mm/min. All six SG 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.

Devices were preheated in an oven at 45°C for 10 min, to ensure full stent expansion before testing. The test started with the stent-grafts 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 as shown in Figure 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 and common iliac arteries was fabricated from translucent silicone elastomers (Figures 2 A&B) by injection moulding technique as previously described for idealised cases.[15,16] This AAA perfusion model was based on a 72-year old patient, with the 3-dimensional geometry segmented within the commercially available image reconstruction software package Mimics® 16.0 (Materialise, Belgium). The AAA had a conical shaped proximal neck with constant internal diameters cranial of 23mm and caudal of 27mm on overall circumferences, neck length of 48mm and infrarenal neck angulation of 57º.

The maximum aneurysm outer diameter was 65mm, iliac bifurcation inner diameter was 33mm and the left/right common iliac inner diameters were 13mm. The arterial wall was replicated by Elastosil 4641 silicone (Wacker Chemie AG, Germany) with 5% silicone fluid (Dow Corning, UK) by weight and the ILT was replicated by Elastosil 4600 (Wacker Chemie AG, Germany) silicone with 25% silicone fluid (Dow Corning, UK) by weight. Due to poor resolution of the CT images the aortic wall thickness couldn't be measured and reconstructed. Therefore, we assumed aortic wall thickness to be constant with the value of 2mm. The Young's Modulus for the silicone wall and ILT was 1.2 and 0.2MPa, respectively, as tested on a uniaxial tensile testing machine (Instron 5544, UK). These elastic properties were within previous reported tensile testing values for the abdominal aortic wall (1 to 6MPa)[17] and ILT (0.05 to 0.27MPa)[18] tissues. The spinal column model (Figures 2 A&B) was rapid prototyped by a 3D printer (Stratasys Prodigy Plus, Stratasys, U.S.A) and supported the AAA model.

Flow simulator system

Blood was replicated with 56% deionised water and 44% glycerine (Univar Ltd., West Yorkshire, UK) that had a dynamic viscosity of 0.0035 Pa·s at 37°C as found from a digital cone and plate viscometer (DV-II +PRO, Brookfield, USA) and a density of 1055kg/m^3 found by a 50ml burette and weighing scales. The required temperature of 37°C was controlled by a heating unit (Julabo Ltd., UK), with constant fluid stirring.

A custom-built flow simulator (Figure 2C) replicated the aortic flowrate and pressure waveforms (Figure 2 D & E)[19] by a programmable linear actuator (Aerotech, UK). An ultrasonic flow meter (TS410 plug-in module, Transonic, US) and flowsensor (25PXN Inline flow sensor, Transonic, US) recorded the flowrates. 22 and 28% of the inlet flowrate travelled through each renal and common iliac arteries respectively.[19] A distal compliance

chamber and outlet valves controlled the pressure within physiological limits (Figure 2C). The pressure waveform was recorded using a 3F pressure catheter (Scisense Inc., Canada), positioned at the current site of measurement, along the imaginary centreline of each device, according to the measurement specified locations: infrarenal/suprarenal. The average difference between the supraceliac input (230ml/s) and measured (220.8ml/s) peak flowrate and pressure (input = 119mmHg and output = 114mmHg) were less than 5%, as shown in Figures 2 D&E.

The change in diameter (ΔD) was measured by a 4 Mega Pixel CCD camera (Dalsa 4M30, Dalsa Corporation) with attached Schneider Enlarger lens (aperture F 2.8) and a frame rate of 30 frames per second. An automatic edge detection tool (IMAQ software, National Instruments, UK) identified the outer edges of the perfusion model. The ΔP-ΔD curve found by Sonesson et al.[20] (Figure 2F) describing the infrarenal stiffness behaviour of the arterial wall, for a 69-year old age group, was used to validate the reproducibility of the human aortic wall behaviour within the AAA perfusion model. Pressure and change in diameter (ΔP - ΔD) measurements were taken at the suprarenal and infrarenal locations, 30mm above and below the renal arteries, prior to stenting (Figures 2 G&H). The ΔP-ΔD supra- and infrarenal curves for the AAA perfusion model are shown in Figures 2 I&J. There was very good agreement between the replicated perfusion model's behaviour with the *in-vivo* AAAs.

The compliance (C)[21] of the non-stented and stented AAA perfusion models were calculated by the following formula.

$$C = \frac{1}{A_{sys}} \cdot \frac{(A_{sys} - A_{dias})}{(P_{sys} - P_{dias})} \qquad (2)$$

Where, the pressure (*P*) and area (*A*) were based on the systole and diastole values of the cardiac cycle. The AAA perfusion model had a median compliance variation of 5.4 – 7.1x10^{-}

^{4}/mmHg. These results agreed with the non-invasive ultrasonic arterial compliance measurements for the native aorta found by Vorp et al.[21] (5.1 – 19.0x10^{-4}/mmHg),

All statistical comparisons were generated within the Minitab® 16.2.0 statistical software (State college, PA, USA) by employing the Mann-Whitney non-parametric confidence interval (CI) testing method. All comparisons were conducted for 20 pulse cycles at the 95% CI.

In order to compare and validate the results with other studies from the literature, the following derived parameters were calculated: pulsatile arterial energy loss (PAEL), pulse wave velocity (PWV) and wave reflection coefficient (Γ).

Pulsatile Arterial Energy Loss (PAEL)

The ΔP-ΔD curve of the AAA perfusion model exhibits a hysteresis effect similar to the *in-vivo* measurements of Sonesson et al.[20] and Stefanadis et al.[22] This area within the aortic loop represents the pulsatile arterial energy loss[22] (PAEL). The calculated energy loss for the unstented AAA perfusion model, at the suprarenal location, was 3.5mm·mmHg. This was within the descending aortic range of 3.16 to 14.10mm·mmHg.[22]

Pulse wave velocity (PWV)

The PWV was measured by monitoring the pressures and diameters at the systolic and diastolic phases. This data was used to estimate the local PWV by applying Equation (3)[23], as shown in Table 2 at the infrarenal location.

$$PWV = \sqrt{\frac{A}{\rho}\frac{\Delta P}{\Delta A}} \tag{3}$$

Where,

A is the diastolic cross-sectional area,

ΔA is the difference between systolic and diastolic areas,

ΔP is the difference between systolic and diastolic pressures,

ρ is the density of the fluid.

Wave reflections

The wave reflections generated within the infrarenal aortic artery, before and after stenting, were computed by Equation 4[19] (Table 2). This equation calculates the proportion of the pressure waveform being reflected, and is given by the reflection coefficient (Γ),

$$\Gamma = \frac{\frac{A_U}{c_U} - \frac{A_S}{c_S}}{\frac{A_U}{c_U} + \frac{A_S}{c_S}} \quad (4)$$

Where

A_U - cross-sectional area upstream from the proximal side,

A_S - cross-sectional area at the location of the proximal side,

c_U - PVW upstream from the proximal side,

c_S - PVW at the location of the proximal side.

RESULTS

Device deformation characteristics

The curves describing circumferential loading cycles and device deformation behaviour are shown in Figure 3. The circumferential load was divided by the length of the stent in contact with the strip, and this is shown in Table 2, which presents the magnitudes of the radial resistive and chronic outward forces expressed in N/cm, for all five SG devices at the

diastolic diameter of the aorta perfusion model. The Zenith™ and Endurant II™ devices had the highest radial resistive force (up to 3 N/cm), while the Fortron™ device had the lowest magnitude of 0.11 N/cm. In the second half of the cycle, the Zenith™ devices had the highest chronic outward force of up to 0.68 N/cm, while the Fortron™ and MFM™ had the lowest magnitude of 0.03 N/cm and 0.06 N/cm, respectively.

Arterial wall/device interface compliance

Figures 4 & 5 show the change in pressure (ΔP) and change in diameter (ΔD) curves for the stented AAA perfusion model at the supra and infra renal locations, respectively. Equation 2 was applied to find the compliance values based on these ΔP – ΔD curves, as shown in Figures 4 & 5. Table 2 shows the median and interquartile range (IQR) and the % median value compliance variations, when compared with the unstented aortic values based on the 95% Mann-Whitney CI test. At the suprarenal region, all devices, except the Excluder™, significantly decreased the compliance by 10 – 21% ($p<0.002$). At the infrarenal region, two devices (Endurant II™ & Excluder™) significantly decreased the compliance by 9 – 11% ($p<0.001$), while the MFM™, Zenith™ and Fortron™ didn't significantly ($p<0.057$) influence the aortic compliance. Table 3 shows the infra to suprarenal device compliance index, which is the ratio of the mean infrarenal compliance divided by the mean suprarenal compliance. This compliance index for the unstented aorta was 0.75, which may represent a reference for device performance characterisation. The compliance indexes for all devices ranged from 0.71 (Excluder™) to 0.88 (Endurant II™). The MFM™ compliance index (0.76) was very close to the aortic compliance index.

At the infrarenal region, the MFM™ did not significantly alter the unstented perfusion model PAEL median value of 2.3 mm·mmHg ($p=0.903$), while the other four devices increased the PAEL by 13 – 44% ($p<0.006$), as shown in Table 2.

Stented perfusion model pulse wave analysis

The PWV of the unstented infrarenal section had a median value of 10.6m/s, which was in agreement with the postoperative findings of Paraskevas et al.[24], who clinically measured the mean aortic PWVs of 7.84 ± 1.85m/s (preoperatively) and 10.08 ± 1.57m/s (postoperatively) within AAA cases. The PWV ranged from 10.9 m/s (MFM™, p=0.164) to 15.1m/s (Endurant II™, p<0.001) (see Table 2) for all devices tested. High PWVs were recorded for the Endurant II™ (15.1m/s, p<0.001) and Excluder™ (14.9m/s, p<0.001) devices. The Zenith™, Fortron™ and MFM™ devices recorded the lowest PWV measurements, with values of 11.1 (p<0.001), 10.8 (p=0.036) and 10.9m/s (p=0.164), respectively.

For the unstented infrarenal perfusion model, Γ had a median value of 7.6%, due to the tapering vessel and decreased compliance across the suprarenal and infrarenal regions. The Γ was increased by 205 - 212% (p<0.001) for the Endurant II™ and Excluder™ devices and by 8 - 17% (p<0.001) for the MFM™, Fortron™ and Zenith™ devices.

DISCUSSION

As far as the authors are aware, this is the first in-vitro study, which assessed the haemodynamic effects of a number of devices for the treatment of AAAs, within a patient-specific AAA perfusion model with the inclusion of ILT and correlated these effects with applied device fixation forces. Previous *in-vivo* studies have focused on the compliance mismatch of stents in small calibre arteries with one stent type stiffening the arterial wall while another has no effect.[7,9]

The arterial wall is physiologically responsive to flow disturbances and material mismatch. The compliance, relative pulsatility and pulsatile diameter are dramatically changed for implanted stents.[4,10] 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[7], while another type may have no effect[10]. The compliance mismatch at the arterial/stent interface increases impedance to blood flow. This may result in decreased distal perfusion, increased pressure wave reflections and increased pulsatile mechanical stress at the interface between noncompliant stented vessels and native artery.[5,25] For a complete study on compliance mismatch six SG types were tested. The radial force characterisation of SG devices within the proximal region is required to determine the fixation force that would be acting against the arterial wall. A low radial force can result in reduced stent fixation and eventual migration[26], while a high radial force can lead to continued dilation leading to migration, Type I.[27] Previous studies applied point loads on stents to assess the radial force.[28] The problem with this method is that stents do not experience point loads *in vivo*. Another approach has externally compressed[29] stent/SG devices and this study found the stents/SGs to deform asymmetrically with hysteresis during the loading and unloading cycles. Johnston et al.[29] concluded that no usable relationship between pressure and area reduction could be determined due to this asymmetrical deformation. To apply axisymmetrical loading a strip can be wrapped around the proximal stent and pulled via a tensile testing machine deforming the stent circumferentially.[14] The advantage of this approach is the realistic response of the stent which provides quantifiable results.[29] The radial resistive force is a measure of the force the stent exerts, as it resists circumferential compression by constriction of the artery.[13] There was a significant amount of hysteresis associated with these circumferential loading and unloading curves, with the radial resistive force, considerably, larger than the chronic outward force. Similar findings were observed by Duda et al.[14], who obtained the radial resistive and chronic outward circumferential forces, for four 8mm diameter uncovered self-expanding stents. The Zenith™ and Endurant II™ devices had the highest radial resistive force (up to 3 N), while the Fortron™ device had the lowest magnitude of 0.11 N. In the second half of the cycle, the Zenith™ device had the highest chronic outward force of up to

0.68 N, while the Fortron™ and MFM™ had the lowest magnitude of 0.03 N and 0.06 N, respectively. The MFM™ had the greatest discrepancy of 14 fold between the chronic outward force and radial resistive force, even though these circumferential forces were one of the lowest recorded. The radial resistive force was greater by 3.7 to 5.3 fold, when compared with the chronic outward force for the other five devices.

The patient-specific perfusion model was chosen to recreate, as close as possible, an example of real life geometrical constraints, in which the devices have to perform. The intraluminal thrombus did not affect the compliance measurements, but it was replicated as part of a complex AAA perfusion model. Part of the aim of this study is to predict how these devices may behave in real patients. Further studies may be carried out regarding the influence of anatomy over the device performance, where straight cylindrical models can be used for performance comparison.

There was a considerable reduction in the dynamic response in the region of the proximal side for the Excluder™ and Endurant II™ devices, when compared to the unstented AAA perfusion model, as it can be seen from Figures 5 and Table 2. This resulted in a decreased compliance of 18 - 23 % and 14 - 25% for the suprarenal and infrarenal regions, respectively. The other three devices (MFM™, Zenith™ and Fortron™) had a reduced compliance of 11 - 14 % and 1 - 7 % for the suprarenal and infrarenal regions, respectively. These differences in compliance between devices may be explained by the different elastic properties of the fabrics: woven polyester for Endurant II™ and ePTFE for Excluder™. Tai et al.[30], measured the compliance of Dacron (woven polyester) and ePTFE grafts, used for vascular reconstruction, and found that the Dacron has a higher compliance value (1.8 ± 1.2 per cent per mmHg$\times 10^{-2}$), compared to ePTFE (1.2 ± 0.3 per cent per mmHg$\times 10^{-2}$).

Referring to Table 3, the vertical label (device names in bold) is read against the horizontal label (device names in italics). If the percentage difference values are both positive, it shows

that the first data set (vertical label) was significantly greater than the second (horizontal label), and conversely two negative values indicate that the first data set was significantly lower than the second. For example, in the suprarenal region the vertical label (Endurant II™) was compared to the horizontal label (MFM™). This comparison showed a negative % difference (-22.8, -3.9; p=0.008), which means that MFM™ is more compliant than Endurant II™ at the suprarenal region. The three devices with suprarenal fixation (MFM™, Zenith™ and Fortron™) had no significant difference in compliance at the suprarenal ($p>0.508$) and infrarenal ($p>0.172$) regions. At the infrarenal region, the Excluder™ device, without proximal stent fixation, was less compliant than MFM™ (p=0.0013) and Fortron™ ($p<0.001$) devices.

The hysteresis effect or the pulsatile energy losses within the infrarenal region was increased by the presence of the SG devices (Table 2 and Figure 5). The stiffest SG devices (Excluder^{TM} and Endurant II^{TM}) within the infrarenal region increased the pulsatile energy losses. The MFM^{TM} device generated only a 0.4% increase in the infrarenal aortic energy loss, while having the highest pulsatile energy loss within the suprarenal region (16%) due to the much higher metallic content within the suprarenal region. There were two highly nonlinear regions occurring for a normalised cumulative P - ΔD, values of 0 - 0.2 and 0.85 - 1, for the normalised cumulative chronic outward and normalised cumulative radial resistive force, respectively. These two regions occurred during maximum compression of the proximal stents, during the loading and unloading cycles. For the rest of the pulse cycle, 0.2 - 1 (chronic outward force) and 0 - 0.85 (radial resistive force) a more linear relationship existed between the normalised cumulative force values and the normalised cumulative P - ΔD values. These nonlinear regions may be attributed to stent and graft interactions and the bending of the stent material at the hinges.

Compliance mismatch increases impendence to blood flow by increasing the PAEL within the arterial wall.[6] This increase in PAEL may result in decreased distal perfusion, increased pressure wave reflections and increased pulsatile mechanical stress at the interface between the noncompliant stented vessels and the native artery.[5,6] The elasticity of the arterial wall is responsible for the existence of wave reflections. The propagating pressure or flow waveforms will be reflected, if the wave encounters any change in calibre along the arterial wall, such as, a variation in cross-sectional area or material properties as given by Equation 4.[19] This variation in arterial calibre occurred after the insertion for all five devices with varying degrees of severity. Wave reflections lead to the early arrival of the pressure and flow waveforms reflected by the prosthetic junction. The early arrival of a reflected wave increases left ventricular load which affects both ventricular emptying and driving pressure for coronary perfusion[19,31], which eventually leads to low cardiac output, impaired coronary perfusion, heart failure, hypertension and shock.[19,32]There was a maximum of 7% variation in the maximum proximal diameter between the five devices tested (Table 1). Unfortunately, this variation was unavoidable since the preferred intended for use aortic diameters as documented by the manufacturers were within the aorta's infrarenal diameter range. This variation in maximum proximal diameter would further contribute to the differences in compliance found for all devices. Lower percentage radial pulsations would reduce the relative movement between the aortic wall and stent struts and may induce endothelialisation.

This study found differences between the devices performance in terms of the main parameters analysed, such as the compliance and radial forces. These differences arise mainly from the unique combination of material properties for the fabric and stent in each device (briefly described in Table 1), and partly from the stent struts configurations. Three devices have a Z stent design (Endurant II^{TM}, Zenith^{TM} and Excluder^{TM}), one device has a proximal diamond stent design (Fortron^{TM}) and one device has a braided mesh design (MFM^{TM}). The

stent design of last two devices produced the smallest radial forces among all tested devices as showed in Table 2. This fact may suggest that similar stent designs may be suitable towards achieving the right balance for future devices, between compliant device behaviour and fixation radial force, which would prevent proximal migration without stiffening the arterial wall.

The reflection coefficient measurements that offer superiority to one device over another, may characterise the situations of highly angulated AAA necks, as it is the case in this study, which hasn't been reported yet. Therefore caution should be taken when interpreting these results.

Limitation

Two limitations to the circumferential loading test approach are the unknown: the friction effects and the local impingement of the stent against the roller and base. With our circumferential loaded test, the local impingement effects were eliminated by employing a combination of two rollers. The film used, DuPont™ Tyvek®, has a low coefficient of friction. The chronic outward force is a measure of the force the stent exerts on the artery, as it tries to expand to its nominal diameter during vessel expansion.

In this study we have assessed a homogenous and isotropic silicone wall, which is in contact with the device wall, thus creating a composite material. We assumed material homogeneity and isotropy, to allow the use of Equation (2) for calculating wall compliance because the fabric of the SGs was not stretched after deployment, and the devices struts strain within the ΔP was low. The relative movement between the stent struts and the aortic wall was not monitored. The PAEL parameter was assessed, only at the infrarenal neck, and not at the devices limbs, therefore it may not provide a strong relation with a potential cardiac risk.

Conclusion

The commercially available bifurcated aortic SG devices lower the arterial wall compliance at the stent/arterial wall interface after implantation. The Excluder™ device was found to be the most compliant in the surprarenal region, as this was the only tested device with no suprarenal fixation stent, while the MFM™ device performed better within the infrarenal region. From a clinical perspective, it is desired to select devices for treating AAAs, which produce the minimum arterial wall stiffening, in order to prevent long-term device related complications. Future studies should analyse, in a similar manner, a wider range of commercially available SG devices to identify those that would pertain for low or zero complications rate.

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Table 1: Characteristics of the five endovascular AAA devices

Device features	**MFM ™**	**Endurant II ™**	**Excluder ™**	**Zenith ™**	**Fortron ™**
Intended for use aortic vessel diameter [mm]	24-28	23-25	24-26	23-24	23-27
Maximum proximal diameter [mm]	30	28	28.5	28	30
Maximum distal diameter [mm]	16.0	16.0	14.5	14.0	16.0
Device length [mm]	150	170	160	184	200
% Degree of oversizing (IFU)	25	17	18.8	17	25
Uncovered fixation length [mm]	-	15	0	30	30
Fixation type	Radial force	Radial force, Barbs	Radial force, Barbs	Radial force, Barbs	Radial force, Barbs
Proximal fixation location	Suprarenal	Renal	Infrarenal	Suprarenal	Suprarenal
Stent material	Cobalt alloy	Nitinol	Nitinol	Stainless steel	Nitinol
Fabric material	-	Woven Polyester	ePTFE	Woven Polyester	Woven Polyester
Measured wall thickness [mm]	0.7	0.5	0.4	0.4	0.5
Activation type	Self - expanding	Self - expanding	Self- expanding	Self -expanding	Self-expanding
Activation temperature [°C]	-	>30°C	>30°C	-	>30°C

Table 2. Outer diameter of the perfusion model infrarenal neck after device implantation at rest, without pressurization, Chronic outward and Radial resistive force measurements at the infrarenal region, Perfusion model AAA Compliance, Pulse wave velocity (PWV), Reflection coefficient (Γ) and Pulsatile Arterial Energy Loss (PAEL) parameter comparisons for unstented/stented sections within the supra/infrarenal perfusion model's regions, at the 95% Mann-Whitney confidence interval.

Device	Neck outer diameter after device implantation [mm]	Chronic outward force [N/cm]	Radial resistive force [N/cm]	Energy loss (hysteresis) [mm·mmHg]	Pulsatile energy loss (PAEL)		
					Median (IQR) [mm mmHg]	CI [% variation]	p-value
Unstented	28.00	N/A	N/A	N/A	2.3 (2.1, 2.5)	N/A	N/A
MFM ™	28.14	0.06	0.84	0.03	3.3 (3.0, 3.4)	(+48.5, +33.3)	<0.001
Endurant II ™	28.63	0.54	2.85	0.15	2.3 (2.0, 2.5)	(-9.4, +7.6)	0.903
Excluder ™	28.49	0.34	1.70	0.05	2.3 (2.0, 2.4)	(+54.7, +40.5)	<0.001
Zenith ™	28.31	0.67	2.88	0.14	2.7 (2.6, 2.9)	(+27.1, +10.2)	<0.001
Fortron ™	28.24	0.03	0.11	0.01	2.6 (2.3, 2.9)	(+23.1, +3.6)	0.006

	Perfusion AAA model wall compliance						Pulse wave velocity (PWV)			Reflection coefficient (Γ)		
	Suprarenal			Infrarenal								
	Median (IQR) [10^{-4}/mmHg]	CI [% variation]	p-value	Median (IQR) [10^{-4}/mmHg]	CI [% variation]	p-value	Median (IQR) [m/s]	CI [% variation]	p-value	Median (IQR) [%]	CI [% variation]	p-value
Unstented	7.1 (6.9, 7.6)	N/A	N/A	5.4 (5.2, 5.7)	N/A	N/A	10.6 (10.4, 11.0)	N/A	N/A	7.6 (7.4, 7.8)	N/A	N/A
Endurant II™	5.1 (5.0, 6.1)	(-16.4, -27.9)	<0.001	4.8 (4.2, 5.0)	(-12.4, -22.4)	<0.001	15.1 (14.2, 15.2)	(+43.5, +39.5)	<0.001	23.7 (23.4, 24.0)	(+212.6, +207.8)	<0.001
MFM™	6.4 (5.8, 7.3)	(-5.0, -17.8)	0.002	5.4 (4.8, 6.2)	(-7.4, +8.8)	0.925	10.9 (10.5, 11.0)	(-3.4, +0.4)	0.164	8.2 (8.0, 8.4)	(+11.0, +5.7)	<0.001
Excluder™	6.9 (6.2, 7.7)	(-8.8, +3.8)	0.675	4.9 (4.4, 4.9)	(-9.7, -17.5)	<0.001	14.9 (14.6, 15.0)	(+41.4, +37.4)	<0.001	23.2 (22.9, 23.5)	(+206.4, +201.2)	<0.001
Zenith™	6.0 (5.7, 6.7)	(-10.0, -19.2)	<0.001	5.3 (4.4, 5.8)	(-2.6, +14.0)	0.262	11.1 (10.9, 11.4)	(+6.5, +2.7)	<0.001	8.9 (8.8, 9.3)	(+20.9, +15.8)	<0.001
Fortron™	6.1 (5.7, 6.8)	(-8.4, -18.5)	<0.001	5.2 (5.0, 5.6)	(-0.15, +8.3)	0.057	10.8 (10.6, 11.1)	(+3.8, +0.3)	0.036	8.6 (8.3, 8.8)	(+15.5, +11.0)	<0.001

IQR = interquartile range, CI = Confidence interval (95%), a positive sign refers to a percentage increase, while a negative sign refers to a percentage decrease, N/A means not applicable.

Table 3. Statistical comparisons for suprarenal and infrarenal AAA perfusion model wall compliance using the Mann-Whitney confidence interval (C.I.) method at the 95% confidence interval for all five device configurations. The values in the round brackets refer to the % difference between the vertical and horizontal labels, and device Compliance index based on the ratio of the mean infrarenal compliance to the mean suparenal compliance. The mean compliance values are given in [10^{-4}/mmHg].

	Suprarenal				
	Endurant II™	*MFM™*	*Excluder™*	*Zenith™*	*Fortron™*
Endurant II™	X	X	X	X	X
MFM™	(-22.8, -3.9) p = 0.008	X	X	X	X
Excluder™	(-45.5, -23.9) p = 0.0005	(-24.5,-6.7) p = 0.002	X	X	X
Zenith™	(-17.4, -0.16) p = 0.044	(-4.5, +11.9) p = 0.508	(+3.3, +17.2) p = 0.004	X	X
Fortron™	(-19.1, -2.1) p = 0.017	(-6.1, +10.3) p = 0.655	(+1.48, +15.9) p = 0.021	(-6.7, +4.6) p = 0.617	X
	Infrarenal				
	Endurant II™	*MFM™*	*Excluder™*	*Zenith™*	*Fortron™*
Endurant II™	X	X	X	X	X
MFM™	(-28.3, -10.0) p =0.0003	X	X	X	X
Excluder™	(-10.0, +3.3) p =0.218	(+4.8, +20.7) p =0.0013	X	X	X
Zenith™	(-22.9, -4.0) p =0.005	(-4.0, +13.2) p = 0.172	(-19.2, +0.4) p = 0.060	X	X
Fortron™	(-22.7, -9.1) p =0.0001	(-4.6, +11.3) p=0.525	(-16.2, -6.1) p = 0.0003	(-10.1, +7.0) p = 0.903	X

	Device Compliance Index					
Parameter	***AAA perfusion model***	**MFM ™**	**Endurant II ™**	**Excluder ™**	**Zenith ™**	**Fortron ™**
Suprarenal Compliance	7.43	6.89	5.37	6.93	6.04	6.19
Infrarenal Compliance	5.55	5.21	4.72	4.92	5.25	5.22
Index	0.75	0.76	0.88	0.71	0.87	0.84