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Mechanical analysis of braided dissection stents – Influence of stent foreshortening on radial force behaviour

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Abstract: Acute type A aortic dissection (ATAAD) remains a life-threatening condition with high morbidity and mortality rates despite advancements in surgical and perioperative management. The Ascyrus Medical Dissection Stent (AMDS) has been introduced as an adjunct to the hemiarch procedure to reduce complications such as true lumen collapse and false lumen patency. Knowledge of radial force behaviour, is essential when selecting endovascular stents, as it ensures vessel support and maintains true lumen patency. This study compares the mechanical behavior of the AMDS to conventional aortic stent grafts, focusing on differences in radial force characteristics. Using the Jotec E®-VITA Thoracic 3G stent graft as a reference, radial force measurements were taken using a segmented head testing machine, and axial elongation was measured at corresponding diameters. While the absolute chronic outward force (COF) increases similarly for all devices during compression, the AMDS 55-40 exhibits the highest COF, followed by the Jotec device and the AMDS 40. When normalizing force to device surface area (COF/A), the Jotec device shows a steeper increase, indicating that its impact on the vessel wall is more dependent on vessel diameter. In contrast, the AMDS devices maintain a more consistent COF across different diameters, suggesting a broader application range in terms of aortic diameters.

Keywords: aortic dissection, radial force, AMDS, braided stent, nitinol wire

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1 Introduction

Acute type A aortic dissection (ATAAD) remains a life-threatening condition with high morbidity and mortality rates despite advancements in surgical and perioperative management. Open surgery remains the standard of care, involving resection of the primary entry tear and distal anastomosis under cerebral protection to prevent rupture and restore true lumen perfusion. Current guidelines recommend at least a hemiarch replacement; however, this approach leaves the aortic arch and descending aorta untreated in DeBakey type I dissections. In cases involving supra-aortic vessel compromise or malperfusion, a more extensive repair may be beneficial. The Ascyrus Medical Dissection Stent (AMDS) has been introduced as an adjunct to the hemiarch procedure, aiming to reduce complications associated with true lumen collapse and false lumen patency [1-3].

Radial force behaviour is a key property in the selection of endovascular stents, as it ensures adequate vessel support, maintains true lumen patency, and provides secure arterial fixation. Since radial force varies depending on stent design, deployment location, and structural composition, understanding these factors is essential for optimal device selection [4]. In the treatment of aortic dissections, lower radial force is generally preferred compared to aneurysm repair, as excessive radial force at the distal ends may contribute to stent graft-induced new entry (SINE) tears [2].

Given that radial force plays a critical role in the mechanical performance of dissection stents, direct comparisons between different devices can be challenging due to variations in design and manufacturing processes. In particular, the Artivion AMDS features a wire-braided structure with a high elongation capacity, distinguishing it from traditional stent grafts composed of independent strut rows.

The aim of this study was to analyse and compare the biomechanical behaviour of the braided AMDS stent with that of conventional aortic stent grafts, focusing on differences in radial force characteristics.

2 Materials and methods

2.1 Device description

The Artivion® AMDS (CryoLife, Kennesaw, USA) is a hybrid device designed to complement surgical aortic dissection repair by addressing both short-term malperfusion syndrome and long-term aneurysmal progression. It consists of a proximal PTFE-felt graft and a distal uncovered Nitinol wire-braided stent. Implanted in an antegrade manner during hypothermic circulatory arrest, it extends into the aortic arch and descending thoracic aorta. The stent is available in four sizes to accommodate the aortic diameters range. In this study, the 55-40 mm (tapered design) and 40 mm variants were used (Figure 1). Due to the wire-braided design, the AMDS shows a large foreshortening depending on stent diameter.

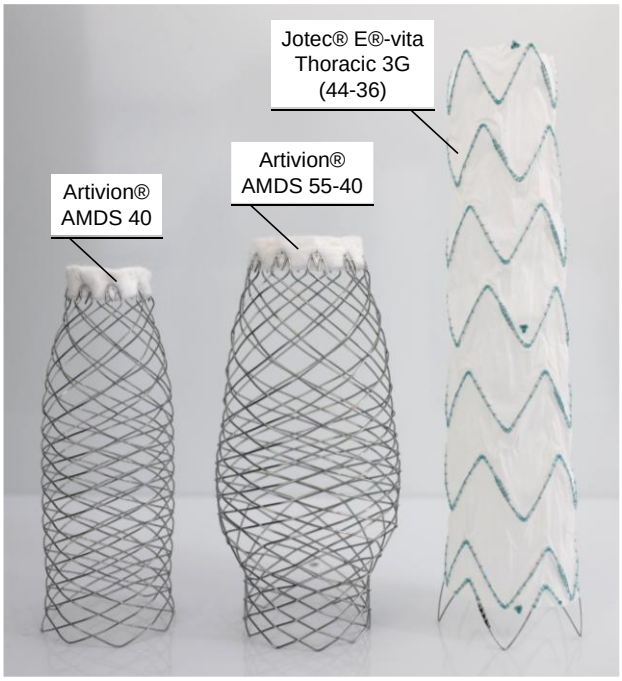

Figure 1: Investigated devices: Artivion® AMDS 40, Artivion® AMDS 55-40 and Jotec® E®-vita Thoracic 3G (size 44-36)

In contrast to the AMDS, the Jotec® E®-VITA Thoracic 3G device maintains a constant length during diameter change due to its peak-valley wire stent design and inelastic cover material. The Jotec thoracic stent graft system is approved for the endovascular treatment of aneurysms, dissections, penetrating aortic ulcers, and intramural hematomas of the thoracic aorta. The stent graft consists of eight individual meandered Nitinol wires connected to a PET cover. For this study, the 36-44 mm (tapered design) variant was used (Figure 1). Even though the application of both devices is not fully identical [5], in the scope of the mechanical investigation these devices were chosen due to the comparable sizes (diameter and length) when deployed in a vessel and the contrasting elongation capacity, see Figure 2.

Figure 2: Size comparison of Artivion® AMDS 40 deployed in acrylic tube (D = 30 mm), Artivion® AMDS 55-40 deployed in acrylic tube (D = 40 mm) and Jotec® E®-vita Thoracic 3G (free standing)

2.2 Foreshortening of the AMDS

To determine the axial foreshortening / elongation of the AMDS, as illustrated in Figure 2, the device length was measured stepwise at corresponding diameters ranging from 20 mm to 40 mm in 2 mm increments. The measurements were conducted manually inside the iris diaphragm of the radial force tester using a steel scale. These measurements were performed subsequently after radial force measurement.

2.3 Radial force measurements

Measurements of the radial force (RF) were conducted in accordance with ISO 25539-1:2017, FDA Guidance 1545 as well as ASTM F3067-14(2021) [6-8] using a segmented head testing machine (TTR2 with Large Twin-Cam head, Blockwise, Tempe, USA). The AMDS stent was deployed into the segmented head (20 mm diameter) according to the instruction for use. RF behaviour was measured three times during expansion to 40 mm followed by subsequent compression to 20 mm. Testing was performed at 37 ± 2°C

and a velocity of 0.1 mm/s. The test parameters are summarized in Table 1. To consider the influence of axial elongation of the AMDS during diameter reduction radial force was referred to the surface area of the stent A_{stent} as well as the stent length L_{stent}. Both metrics can be found in literature. For calculation of the stent surface area a cylindrical shape ($A_{stent} = D_{stent} * \pi * L_{stent}$) is assumed.

Table 1: Test parameters of radial force measurement using segmented head testing machine

Parameter	Parameter value
Initial diameter	40 mm
Final diameter	20 mm
Open / closing speed	0.1 mm/s
Holding time	0 s
Temperature	37 °C
No. cycles	3

3 Results

3.1 Foreshortening of the AMDS

The results of the elongation measurement of both AMDS devices are depicted in Figure 3.

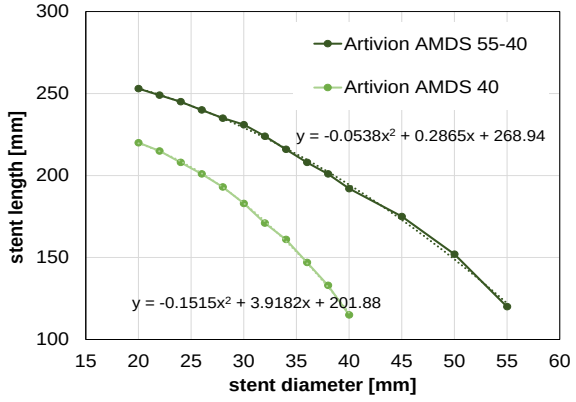

Figure 3: Results of the elongation measurement depicted as stent length as function of outer stent diameter of the Artivion AMDS 55-44 and AMDS 40

Stent length decreased with increasing diameter (20 to 40 mm) for the AMDS 55-40 from 253 mm to 122 mm and for the AMDS 40 from 220 mm to 115 mm. In contrast, the length of the Jotec device remains constant (L = 184 mm) regardless of the device diameter. The resulting surface area (A_{stent}) of the AMDS 40 and the Jotec device is presented in Figure 4. Please note that the surface area of the AMDS 55-40 is omitted for clarity, as the data are comparable to those of the AMDS 40. Due to its constant stent length, the Jotec stent graft exhibits a linear decrease in surface area during radial compression. In contrast, the surface area of the AMDS 40 follows a parabolic trend, reaching a maximum at D = 31 mm.

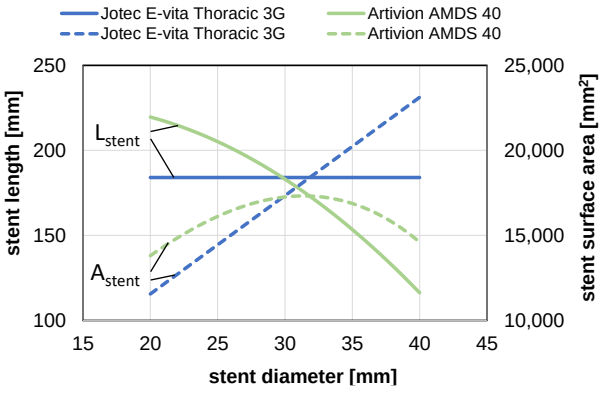

Figure 4: Stent length and stent surface area of AMDS 40 and Jotec® E-vita® Thoracic 3G as a function of stent diameter

The substantial increase in stent length during compression compensates for the decreasing stent diameter when calculating the total device surface area.

3.2 Radial force measurements

Figure 5 presents the results of the radial force measurements. During compression, the radial force, referred to as radial resistance force (RRF), increases, whereas, during decompresssion, the radial force, described as chronic outward force (COF), decreases. The measurement curves show a typical hysteresis indicating energy dissipation, for example due to material deformation, alteration of metallic phase of Nitinol and external friction.

It is evident that the hysteresis is more pronounced in the AMDS devices, suggesting increased friction between the braided Nitinol wires and additional interaction between the segmented head of the radial force tester and the device itself, likely due to elongation during compression. In contrast, the Jotec device exhibits a much narrower hysteresis loop, as it does not elongate and lacks friction between stent struts. COF quantifies the interaction between the device and the vessel wall during deployment and is therefore a crucial parameter for the treatment of aortic dissections. When considering absolute force values, the COF of all three devices increases similarly during expansion.

However, the AMDS 55-40 exhibits the highest COF, followed by the Jotec device and the AMDS 40. When normalizing the measured force to the actual device surface area (COF/A), the Jotec device shows the steepest increase during expansion. This suggests that its local impact on the vessel wall is highly dependent on the vessel diameter. In contrast, the normalized COF values (COF/A) of both AMDS

devices remain more consistent across different vessel diameters, indicating a more uniform distribution of RF.

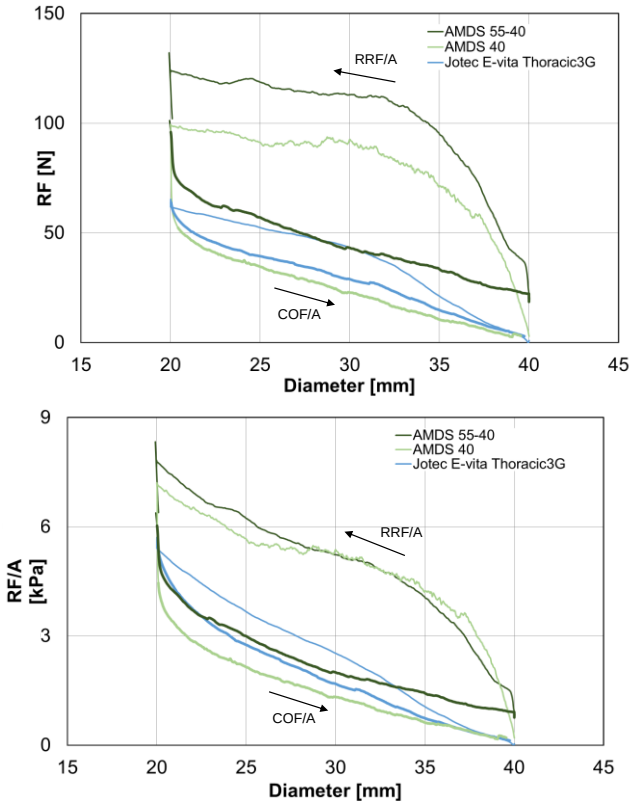

Figure 5: Results of the radial force measurement: radial force RF as a function of the segmented head diameter (top); radial force referred to the actual device surface area (RF/A) as a function of the segmented head diameter (bottom)

4 Discussion and conclusion

This study highlights the distinct biomechanical behaviour of the wire-braided AMDS in comparison to the Jotec E®-VITA Thoracic 3G stent graft, with a particular focus on axial elongation, radial force characteristics, and their implications for aortic dissection treatment. Clinical studies have emphasized the importance of maintaining a low radial force when treating dissected vessels just high enough to press the intima against the media and adventitia but not too high in order to minimize the risk of intimal damage [3]. The current results demonstrate that the AMDS exhibits significant axial elongation during radial compression, whereas the Jotec device maintains a constant length due to its rigid cover material. The COF, which plays a crucial role in vessel wall interaction during deployment, shows a similar absolute increase across all tested devices. However, when normalized to stent surface area (COF/A), the Jotec device demonstrates a steeper increase during expansion. In contrast, the AMDS devices maintain a more consistent force distribution and the COF is therefore more independent from the vessel diameter. In general, high foreshortening / elongation rates and therefore the alteration of the contact area between device and vessel wall during compression or expansion increases the plateau of the COF. But foreshortening or elongation of the device could lead to relative movement between the stent struts and the vessel wall.

Please note that RF measurements were conducted in a cylindrical segmented head and due to the tapered designs of both devices the local differences (distal vs. proximal end) in RF could not captured.

Overall, these findings emphasize the differences in mechanical behaviour between wire-braided and conventional covered stent grafts. But further RF analysis such as measurements of local RF distribution should be conducted.

Author Statement

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