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Biomechanics and clinical experience of a 3D biomimicking vascular stent

Abstract: The presented investigation was designed to assess the biomechanical behavior of a 3D biomimicking self-expanding stent with respect to general technical parameters added by first clinical tests.

The test sample was a Veryan Medical Biomimics 3D with 6.0 mm expanded diameter and 80 mm length. The profile of the delivery catheter with mounted stent, the strut thickness, the bending stiffness, the axial stiffness for tension and compression and the length change during expansion were measured.

The bending stiffness was 2.73 Nmm², axial stiffness at tension 7.77 N/mm and at compression 97.61 N/mm. The stent shortened during expansion by 11.54 %. Radial force at 5 mm diameter was 2.54 N. Clinical experience provided no stent fractures after 24 months. Duplexsonography showed stent patency without any binary restenosis or intimal hyperplasia.

Keywords: helical stent design, vascular intervention, biomechanics, clinical experience

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1 Introduction

Stenting has become a widely established option to treat vascular diseases. In most cases excellent procedural results can be achieved. However, treatment of upper extremities, such as the superficial femoral artery (SFA), remains challenging because of the critical biomechanical loading conditions [1].

Several approaches have been developed in the past to design implants for ‘adapted stenting’. Known principles were

- stents with low radial force
- low strut thickness
- matched flexibility by changing cell design (closed, open, corrugated rings …)

Mechanical parameters of such specific stent designs were previously measured and discussed [2].

Several observations have shown that arterial geometry is commonly helical leading to a swirling blood flow, which is known to elevate wall shear stress. Stenosis and intimal hyperplasia mostly occur where the wall shear stress is low [3-5]. Recently, a new approach was introduced to improve adaptation of the stent to the treated vessel, the Biomimics 3D (Veryan Medical). It is an attempt to improve biomechanical compatibility and to reduce the risk of stent fracture [6].

The aim of this study was to explore dimensions and general mechanical behavior of the Biomimics 3D to assess whether the specified claims can be hold compared to first clinical experiences.

2 Material and Methods

2.1 Test sample

We investigated two Biomimics 3D (Veryan Medical, Horsham, UK) which are self-expanding vascular stents indicated for use in the SFA. The catheter is designed to place and deploy the stent over a 0.035” guide wire.

The device is a slotted tube stent made from Nitinol. The shape memory effect of Nitinol was used to achieve the typical non-cylindrical outer contour which is meant to improve adaptation to the curved vasculature (**Figure 1**).

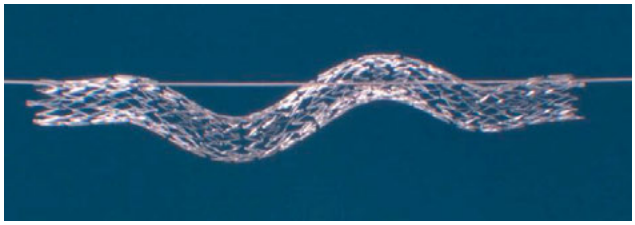

Figure 1: Biomimics 3D, Veryan Medical, in unrestricted state

2.2 Experimental setup

As parameters, the profile of the delivery catheter with mounted stent, the strut thickness, the bending stiffness, the axial stiffness for tension and compression and the length change during expansion were measured.

The profile of the delivery catheter was measured using a proprietary test device consisting of a water filled test chamber, a 2-axis laser scanner and test software. The technical specifications are listed in **Table 1**.

Table 1: Technical specification of diameter measurements

Device / Parameter	Specification
Laser Scanner	ODAC 64XY-RSN (ZUMBACH)
Measurement range	0.1 to 30 mm
Accuracy	± 0.01 mm
Resolution	0.001 mm
Environment	pure water
Temperature	37 ± 2 °C

The strut thickness was obtained from calibrated Scanning Electron Microscopy images (QUANTA FEG 250, Thermo Fischer Scientific, Hillsboro, OR, USA).

The bending stiffness was measured by fixing the stent in a grip and perpendicular deflecting it by f = 0.5 mm maximum (free length l = 12 mm). The required force F for deflection was measured. The bending stiffness EI was calculated according to equation (1).

$$EI = \frac{Fl^3}{3f} \quad (1)$$

Axial stiffness was determined by fixing one end of the stent at the lower grip of a universal testing machine (BT1-FR2.5TN.D14, Zwick, Ulm, Germany) equipped with a 10 N load cell. The axial force was measured during elongation by 3 mm and length compression by 6 mm. The obtained force per mm length change is taken as the measure for axial stiffness in mN/mm.

The length of the stent was measured both while mounted at the delivery catheter and after stent release into a vessel model with the inner diameter of 5 mm.

For comparison of radial force with previously published data the stents were expanded within prismatic fixtures with increasing distance (V block method).

The surface coverage, also known as the metal-to-artery ratio was calculated indirectly from the measured mass of the stent, the wall thickness and the theoretical mass of a cylinder which would represent 100 % coverage. The material density ρ of the stent material was estimated (Nitinol: $\rho = 6450\ kg/m^3$ [7]).

2.3 Clinical procedure

The complete implantation procedure is shown in **Figure 2**. After completing an angiography using standard technique and 5,000 IU heparin (UFH) were administered, the nominal vessel diameter was estimated in the target lesion and a suitable stent size was selected. A 6-F sheath was used. Then a 0.035" hydrophilic coated guide wire was passed through the lesion under the guidance of a roadmap display. After insertion of the stent, the device was slowly deployed to prevent deployment inaccuracy. It is recommended to watch on fluoroscopy as the device opens to ensure safe and accurate deployment.

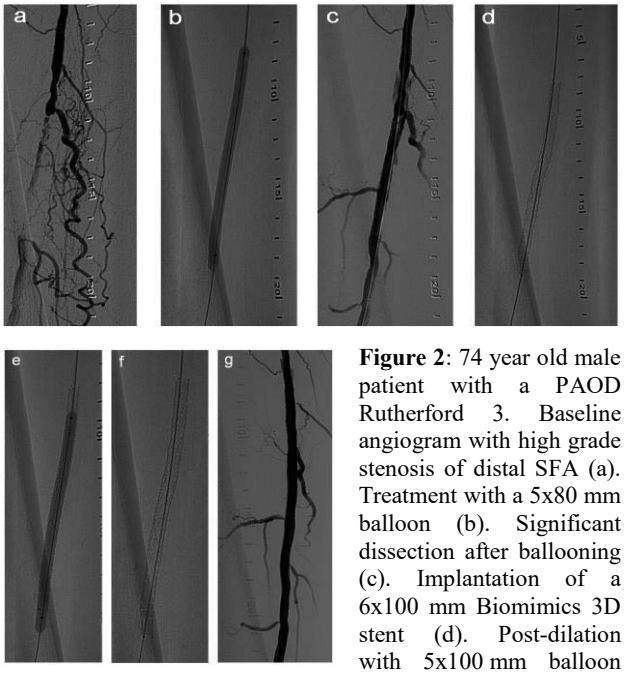

Figure 2: 74 year old male patient with a PAOD Rutherford 3. Baseline angiogram with high grade stenosis of distal SFA (a). Treatment with a 5x80 mm balloon (b). Significant dissection after ballooning (c). Implantation of a 6x100 mm Biomimics 3D stent (d). Post-dilation with 5x100 mm balloon (e). Final result (f+g).

After implantation, the catheter was withdrawn and a control angiography was conducted. Post-dilation was performed by pressure only balloon angioplasty with a balloon size depending on the diameter of the implanted stent. Hemostasis was achieved using a closure device (StarClose SE, Abbott Vascular, Santa Clara, USA) and an additional compression bandage.

3 Results

The profile as measured by the laser scanner is demonstrated in **Figure 3** showing the profile of distal section of the delivery system with mounted stent.

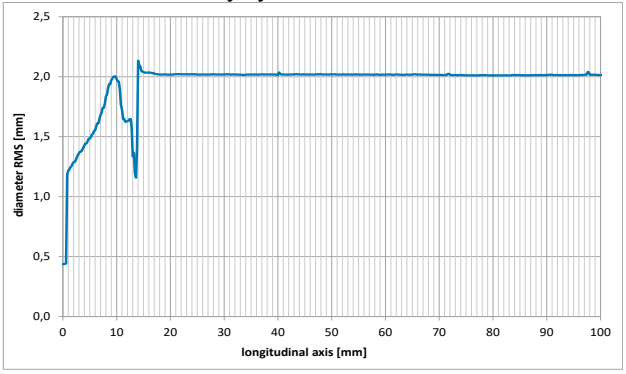

Figure 3: Biomimics 3D – diameter of the distal section (first 100 mm) of the stent delivery system with mounted stent, catheter tip starts left

The micrographs in **Figure 4** demonstrate the design principle, corrugated rings connected by longitudinal struts, thus forming large and open cells. The mean wall thickness was measured with 231 µm over the two samples.

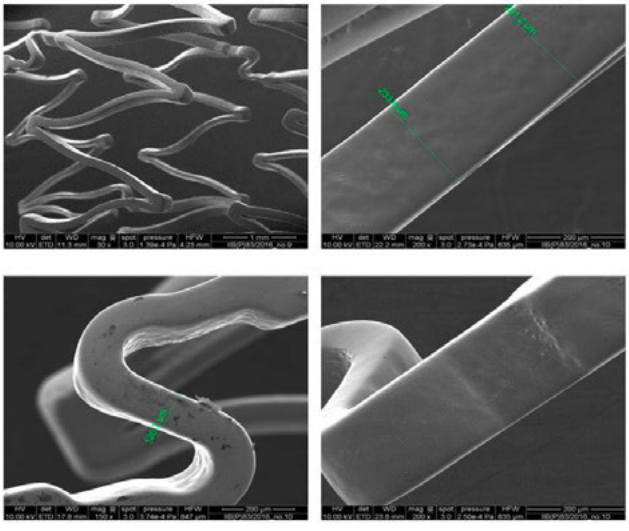

Figure 4: Biomimics 3D – calibrated SEM images of stent structure

The measurement of radial force provided the force – diameter curve as shown in **Figure 5** (averaged over the two samples in test). A low but measurable radial force was exerted to the clamps even when their distance was larger than 6 mm because of the stents curved outer shape. The radial force at the diameter of 5.0 mm was 2.64 N.

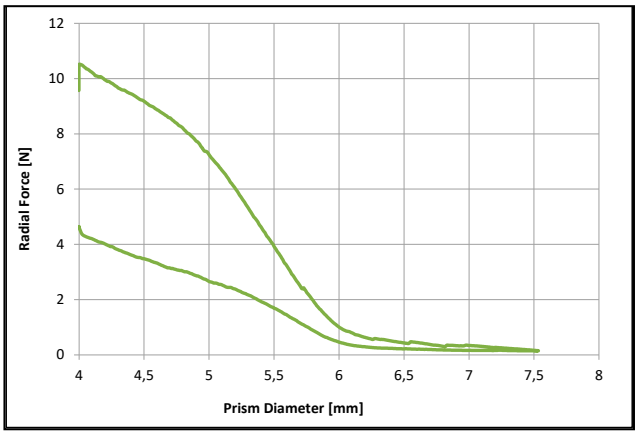

Figure 5: Force-diameter curve of radial force measurements (V-block method)

All numerical results of in vitro measured parameters are summarized in **Table 2**.

Table 2: Summary of numerical test results

Parameter	Result
Surface coverage	18,54 %
Bending stiffness, small deflection	2,73 Nmm²
Axial stiffness (tension, @ 3 mm)	7,77 mN/mm
Axial stiffness (compression, @ 6 mm)	97,61 mN/mm
Length change	-11,54 %
Strut thickness	231,52 µm
Radial force (expansion, @ 5 mm)	2,64 N

In the clinical test the stent was easy and save to deploy. Accurate placement was achieved by slow deployment. There were no problems or technical failure observed. The delivering catheter could easily be withdrawn after implantation of the stent. The implantation was technical and clinical successful.

After 24 months a conventional xray observed no stent fracturs or structural problems of the helical stent. (**Figure 6**). An additional duplex sonography (DUS) showed that the stent is patent without any binary restenosis or intimal hyperplasia (**Figure 7**).

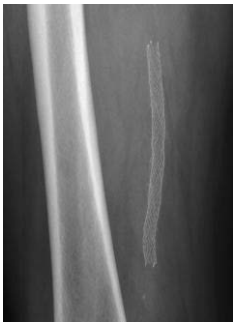

Figure 6: X-ray image of the right leg 24 months after implantation of Biomimics 3D stent without visible stent fracture.

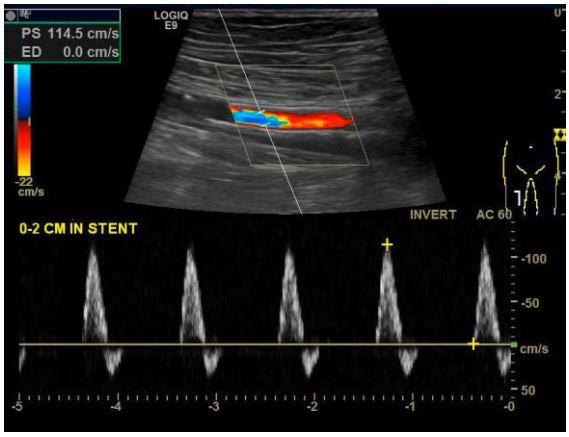

Figure 7: Duplex sonography observed a normal triphasic pulsatile blood flow without restenosis or intimal hyperplasia in the stent.

4 Discussion

Mechanical parameters were measured to be comparable to established SFA stents [2]. The stent is highly flexible at bending and exerts a low radial force to the vasculature. The length shortening during expansion demands cautious deployment for accurate placement. The strut thickness of about 230 µm is relatively high even for SFA stents. The axial stiffness for tension and compression is low which is assumed to adequately match to the vasculature. The helical structure is unique.

The first randomized trial using the Biomimics 3D stent in one group and the Life-Stent (Bard) for comparison in the control group met the primary safety endpoint for the helical stent. In addition a primary patency of the Biomimics 3D at 12 and 24 months of 80 % and 72 %, respectively compared to the control group of 71 % and 55 % was observed [8]. The freedom from clinically driven target lesion revascularization for the helical stent compared to the conventional straight stent was 91 % versus 92 % at 12 months and 91 % versus 76 % after 24 months. It appears that the helical stent structure has an improved long-term patency [8].

The positive effect of the helical stent had already been demonstrated in animal models with inducing of a swirling flow and reducing intimal hyperplasia in comparison to straight nitinol stents [9,10].

The presented clinical case in our study can serve as an example for technical and clinical successful implantation with respect to stent integrity and patency after 24 months.

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Author's Statement

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