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Support function of self-expanding nitinol stents – Are radial resistive force and crush resistance comparable?

Abstract: The main task of any vascular stent is the mechanical support of the re-opened vessel. This support function may be quantified by the compressive properties of the stent in radial outer loading conditions. Different test methods are standardized and are accepted to provide relevant data. Six commercially available self-expanding stents were investigated with regard to their force-deformation behavior during radial as well as elliptical deformation. The measured radial resistive force and crush resistance were not qualitatively congruent for all stents. As a conclusion both test methods should be considered when describing the compressive properties of self-expanding stents.

Keywords: Radial resistive force, crush resistance, self-expanding stent

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1 Introduction

Lumen reduction of the femoropopliteal artery (FPA) due to arteriosclerosis is one cause for peripheral artery disease [1]. Besides surgical methods endovascular therapies, such as balloon angioplasty with or without stent implantation as well as drug coated balloon therapy are widely used for treatment of the affected patients [1, 2]. Due to severe mechanical deformations in the FPA during limb movement the implanted stents have to resist high mechanical loading caused by axial tension/compression, bending, torsion as well as radial compression [3]. In particular, the radial compression properties of the stent in combination with the chosen stent-to-vessel diameter ratio influence the interaction between stent and arterial wall, thus leading to a potential risk of arterial wall injury [2]. The impact of a high versus low radial force on neointimal hyperplasia in humans is not entirely clear, but is currently investigated within the BIOFLEX-COF trial [4].

Test methods to quantify the compressive properties of stents are standardized by international standards such as ISO 25539-2:2012 and ASTM F3067-14 [5, 6]. During stent design assessment the manufacturer has to evaluate the force that the stent can resist during deformation with parallel plates [5] as well as during radial deformation [5, 6].

The aim of this study was to evaluate two test methods for the investigation of the compressive properties of self-expanding stents.

2 Materials and methods

Six self-expanding nitinol stents for application at the FPA with a nominal diameter and length of 6.0 x 80 mm (Cordis S.M.A.R.T Control, GORE TIGRIS, Boston Scientific Innova, Abbott Absolute Pro, Medtronic Complete SE, BIO-TRONIK Astron Pulsar) were investigated concerning their compressive properties with two different test methods.

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The crush resistance (CR) was measured by means of parallel plates and a universal testing machine (ZwickRoell, Ulm, Germany) equipped with a 100 N load cell. The stents were compressed from the expanded state to a minimum distance of 3 mm between the parallel plates (50% diameter reduction, see **Figure 1a**).

Measurements of the radial resistive force (RRF) were conducted using a segmented head testing machine (Blockwise, Tempe, USA) from the expanded state to a minimum diameter of 3 mm (50% diameter reduction, see **Figure 1b**).

Figure 1: Schematic illustration of the compression mechanism during the testing of (a) crush resistance and (b) radial resistive force

Both measurements were conducted at 37 °C and a cross head speed of 5 mm/min. Testing was in accordance to ISO 25539-2:2012 and ASTM F3067-14, respectively [5, 6]. The compressive forces were determined at the minimum and maximum intended vessel diameter of 4 mm and 5 mm, respectively. All measured forces were normalized to the nominal stent length of 80 mm.

3 Results

The measured RRF are presented in **Figure 2**. The S.M.A.R.T. Control, Innova and Complete SE revealed a quite constant high RRF in the intended vessel diameter range between 4 and 5 mm, whereas the Absolute PRO and Astron Pulsar showed low RRF in the same diameter range. The Tigris showed a medium RRF at maximum intended vessel diameter and a high RRF at the minimum intended vessel diameter.

The measured CR is presented in **Figure 3**. All force-diameter curves show an almost linear progress within the complete diameter range and the intended vessel diameter range. The CR of the S.M.A.R.T. Control, the Tigris, Innova and Absolute PRO revealed comparable CR. The Complete SE showed a 27% higher CR and the Astron Pulsar a 63% lower CR.

The numeric results for CR and RRF at the minimum and maximum intended vessel diameter are listed in **Table 1**.

Figure 2: Radial resistive force as a function of stent diameter

Figure 3: Crush resistance as a function of stent diameter

Table 1: Numeric results for crush resistance (CR) and radial resistive force (RRF) at minimum ($d = 4 \text{ mm}$) and maximum diameter ($d = 5 \text{ mm}$)

	CR _{max} [N/mm]	CR _{min} [N/mm]	RRF _{max} [N/mm]	RRF _{min} [N/mm]
Medtronic Complete SE	0.050	0.078	0.868	0.938
Cordis SMART Control	0.041	0.061	0.773	0.885
Gore Tigris	0.038	0.064	0.610	0.915
Boston Scientific Innova	0.034	0.061	0.777	0.936
Abbott Absolute PRO	0.033	0.058	0.250	0.407
Biotronik Astron Pulsar	0.012	0.023	0.242	0.300

4 Discussion

The current study presented two standardized methods for measuring the compressive properties of commercially available self-expanding stents for the FPA.

Stents with a high crush resistance (Complete SE, TIGRIS, Innova and S.M.A.R.T. Control) showed also high radial resistive forces, and the stent with low crush resistance (Astron Pulsar) revealed a low radial resistive force at both intended vessel diameter. However, the Absolute Pro showed a comparable crush resistance to the TIGRIS, Innova and S.M.A.R.T. Control stents but revealed only about 44% and 33% of their radial resistive force at minimum and maximum intended vessel diameter, respectively (see **Figure 4**).

Figure 4: Crush resistance (CR) and radial resistive force (RRF) at minimum ($d = 4 \text{ mm}$) and maximum ($d = 5 \text{ mm}$) intended vessel diameter

The force-diameter behavior during CR measurements was almost linear for all investigated stent types, whereas the RRF-diameter behavior was very individual for the investigated stent types, not only according the absolute force level, but also the curve progression within the intended vessel diameter range.

Maleckis et al. determined the RRF by means of v-shaped clamps for the Complete SE, Tigris, Innova, Absolute PRO, S.M.A.R.T. Control and other devices [7]. The results are not directly comparable to the present study due to the different loading mechanisms of radial force testing. There is a qualitatively good agreement for the S.M.A.R.T. Control, Tigris and Absolute PRO Stents, but not for the Complete SE and the Innova Stent, that showed higher RRF determined by means of v-shaped clamps compared to RRF determined by the segmented head mechanism. A possible reason could be that v-shaped clamps do not guarantee a perfect circular deformation, but rather lead to a flattening of the stent within the clamps.

It is assumed that the RRF is representing the compression behavior of the stent in circular vessels and lesions. The CR

is relevant for non-radial loading which may occur in non-circular stenoses. A high RRF as well as high CR can be considered as a marker for radially stiff stents that resist high external loads, but most likely cause vascular overdilatation. On the other hand, it is assumed that stents with low RRF and low CR reduce vascular irritations.

5 Conclusion

The non-congruent results of the CR and RRF of the tested self-expanding stents are based on the different loading mechanisms of the test methods itself [2, 8]. The resistance against flattening or radial deformation depends on the individual stent design. Since both loads may apply in vasculature, both test methods should be considered to describe the compressive properties of self-expanding stents.

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