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Test methods for evaluation of balloon expandable vascular stents – measurement of radial strength and stiffness

https://doi.org/10.1515/cdbme-2023-1104

Abstract: The radial strength of balloon expandable stents represents a key property for a successful recanalization of sclerotic blood vessels. This study focuses on the most commonly used method for investigation of radial strength and radial stiffness via segmented head test setup. A custom made user software was used for evaluation of the radial force curves considering requirements of international standards such as ASTM F3067. Contributing factors during measurement such as friction and test setup deformation as well as the single cycle and multi cycle approach were addressed and discussed.

Keywords: Vascular stents, radial strength, radial stiffness, ISO, FDA, ASTM.

1 Introduction

Stent implantation represents the gold standard for treatment of sclerotic blood vessels, especially when dealing with coronary artery disease [1]. Besides a general biocompatibility and structural integrity, the stent's radial strength is a key property for a successful recanalization of the vessel. Radial strength primary depends on the properties of the stents backbone material, but also on stent design. Since introduction of permanent metallic stents in the mid-1990s, engineers try to reduce strut thickness while maintaining radial strength by using materials with higher elastic modulus and higher tensile strength such as cobalt chromium (CoCr) or platinum chromium alloys (PtCr) [2]. However, when bioresorbable scaffolds were introduced to clinical practice, the decreasing radial strength over degradation time was often made responsible for vessel recoil and late lumen loss [3].

Physicians have to rely on the stent's radial strength, as they have no option to influence this crucial property during the implantation process. Measuring the radial strength is required for approval of balloon expandable stents (BES) to assess safety and efficacy [4, 5].

This study presents a method to determine the radial strength and radial stiffness of BES according to international standards and investigates the influence of test parameters and data analysis on the obtained test results.

2 Requirements of international standards

The FDA guidance document no. 1545 recommends determining radial strength as well as radial stiffness of BES for every labeled stent diameter and length, if a varying radial strength depending on stent length is expected. In this context radial stiffness is defined as diameter change depending on a uniformly applied external radial pressure [4]. No specific test method for investigation of the radial strength is proposed by the FDA.

ISO 25539-1 and ISO 25539-2 request the measurement of radial strength for endovascular or vascular BES, respectively, by determining the radial load at a pre-defined extent of plastic deformation [6, 7]. For the test methods the more specific standard ASTM F3067 is referenced [5].

ISO 5840-3 claims to determine the radial strength to confirm the ability of the stent structure of a transcatheter implantable heart valve to withstand a permanent radial deformation [8]. However, no specific test method is mentioned in this regard.

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ASTM F3067 represents a comprehensive standard about radial loading of BES and self-expanding stents, respectively. Radial strength is defined as a specific load on the radial loading curve that corresponds with a clinically or practically relevant amount of inward plastic deformation. The segmented head or sling methods are described [5]. This study focuses on the most commonly used segmented head test setup.

3 Materials and methods

Within this study, several contributing factors during radial force measurement and evaluation of radial strength as well as radial stiffness of BES are addressed.

For determination of radial strength, a segmented head test setup was used containing of a tensile testing machine equipped with a 100 lbf load cell (TTR2, Blockwise Engineering LLL, Tempe, USA) and a segmented head test station with a maximum diameter of 16 mm and a maximum length of 124 mm (J-Crimp, Blockwise Engineering LLL, Tempe, USA). The test principle is shown in Figure 1.

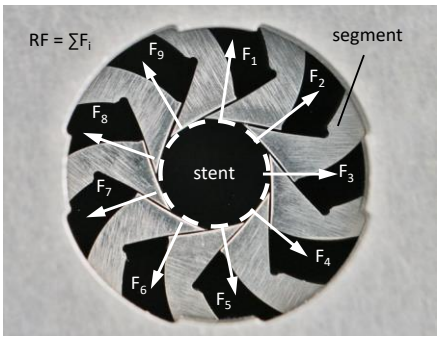

Figure 1: Test principle of radial force testing of a vascular stent via segmented head test mechanism, total radial force represents the sum of reaction forces at each segment

For all investigations, ten similar commercially available BES with a diameter of 4.5 mm and a length 30 mm were used.

Radial force measurements were started with an initial diameter of 5.0 mm (0.5 mm above the test sample diameter). Diameter was decreased to 3.0 mm (66.6 % of test sample diameter) and then increased again up to the initial diameter. The test speed was 0.05 mm/s for all measurements. Temperature within the segmented head test setup was 37 ± 2 °C for all measurements.

3.1 Compensation of friction and test setup deformation

In accordance to ASTM F3067, before each measurement series a baseline friction curve of the test setup without test stent was performed for the whole diameter range. Measurement of baseline friction has to be performed at the same test speed as the following stent measurements for the loading as well as the unloading direction [5]. The friction forces were subtracted from the radial force curves of the stents tested.

In addition, deformation of the test setup itself was measured during loading of a solid steel mandrel in order to compensate test setup deformation during stent measurements.

The influence of baseline friction compensation as well as test setup deformation compensation on the test results is shown exemplarily with one radial force measurement.

3.2 Determination of radial strength and radial stiffness

Figure 2 shows a representative radial force curve of a BES using the segmented head test setup.

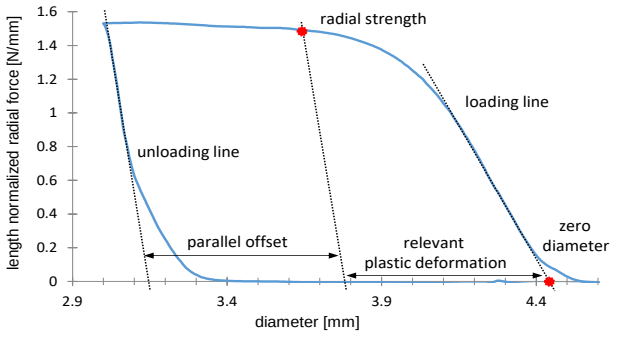

Figure 2: Representative radial force curve of a balloon expandable stent using a segmented head test setup

A custom made user software was used for investigation of the characteristic parameters of the radial curve (slope of the loading line, zero diameter, slope of the unloading line) and derived results for radial strength and radial stiffness.

According to ASTM F3067 the loading line was determined from the steepest slope of the initial linear part of the radial force curve. The intercept of the loading line with the x-axis represents the zero diameter. Alternatively, the determination of the zero diameter using a specified pre-load was used [5]. Based on the zero diameter relevant relative amounts of plastic deformation (10% and 15%) were defined. The steepest slope of the substantially linear part of the unloading curve was used to create the unloading line. The unloading line was then shifted parallel into the diameter value representing the relative amount of plastic deformation. Finally, the radial strength is the intercept of the shifted unloading line and the radial force curve. Radial stiffness was derived from the slope of the loading line in accordance with FDA guidance document no. 1545.

To investigate the influence of the zero diameter on the test results, radial strength was evaluated based on different methods to determine the zero diameter ($n = 5$): as intersect between the loading line and the x-axis as well as by defining two different pre-loads (2% and 5% of maximum force, respectively).

3.3 Single cycle and multi-cycle approach

The above described evaluation method for radial strength is based on the assumption that the unloading behavior of the stent does not depend on diameter, so that the slope of the unloading line would be identical for different compression rates. To prove this assumption, within ASTM F3067 an alternative approach to determine radial strength via stepped multi cycle test is suggested. In this case, the stent should be loaded stepwise by measuring several radial force curves by reducing and increasing diameter in smaller intervals from initial diameter to the maximum compressed state (e.g. 66.6%, Figure 3). The peak load of every cycle is paired with the subsequent plastic deformation generating a curve representing the peak load-plastic deformation-behavior [5]. Radial strength can then be derived via interpolation.

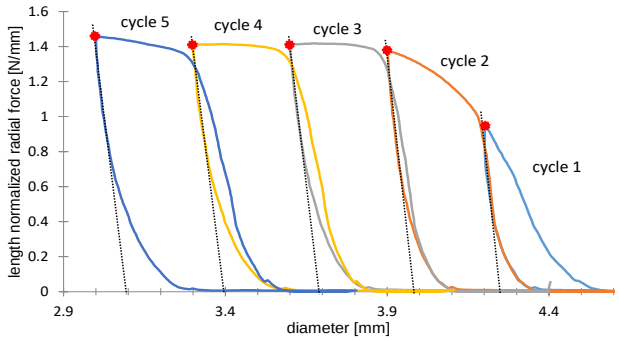

Figure 3: Representative radial force curves for a multi-cycle measurement with different slopes of the unloading lines (dotted lines) as well as peak forces (ret dots)

Single cycle measurements as well as multi cycle measurements were performed to evaluate differences between this two measurement approaches ($n = 5$ each).

4 Results

Figure 4 shows the radial force curves of the same measurement with and without friction as well as deformation compensation. Deformation compensation depends directly on the force measured. Therefore, high forces lead to higher deformations within the test setup. Maximum diameter deviation within the shown exemplary measurement was 0.08 mm. Friction compensation led to a slight reduction in radial force during compression (-0.025 N/mm) and a slight increase in radial force during expansion (+0.020 N/mm).

Table 1 shows the zero diameter and the radial strength at two different amounts of plastic deformation depending on the evaluation method of zero diameter. Zero diameter and radial strength at 10% plastic deformation vary between the three evaluation methods. However, radial strength at 15% plastic deformation was very similar for all evaluation methods.

Table 2 shows the zero diameter, radial strength as well as the radial stiffness as investigated with the single cycle method and the multi cycle method. The single cycle method revealed higher values compared to the multi cycle method. However, radial strength at 15% plastic deformation was not significantly different between the evaluation methods.

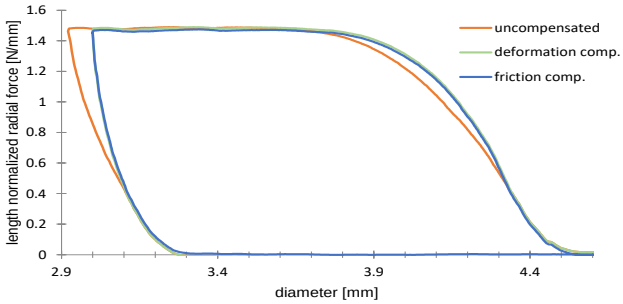

Figure 4: Comparative illustration of radial force curve progression of a balloon expandable stent with and without compensation of deformation as well as friction within the test segmented head test mechanism

Table 1: Radial strength depending on the amount of plastic deformation (p.d.) and the evaluation method of the zero diameter, $n = 5$

evaluation method	pre load [N]	zero diameter [mm]	radial strength 10% p.d. [N/mm]	radial strength 15% p.d. [N/mm]
loading line	n/a	4.48 ± 0.06	1.41 ± 0.02	1.46 ± 0.01
pre load 2% F_{max}	0.9	4.54 ± 0.05	1.37 ± 0.03	1.46 ± 0.01
pre load 5% F_{max}	2.25	4.50 ± 0.05	1.40 ± 0.02	1.46 ± 0.01

Table 2: Radial strength depending on the amount of plastic deformation (p.d.) and the measurement approach, each $n = 5$

evaluation method	zero diameter [mm]	radial stiffness [atm/mm]	radial strength 10% p.d. [N/mm]	radial strength 15% p.d. [N/mm]
single cycle	4.48 ± 0.06	3.18 ± 0.19	1.42 ± 0.01	1.46 ± 0.01
multi cycle	4.46 ± 0.02	3.05 ± 0.46	1.32 ± 0.03	1.44 ± 0.02

5 Conclusion

Within this study two measurement approaches for the investigation of the radial strength of BES were presented both based on the segmented head test method according to international standards. The influence of several contributing factors to the evaluation of radial strength was investigated.

According to ISO 25539-1, ISO 25539-2 and ASTM F3067 the segmented head test method represents one possibility for radial force testing of stents [5-7]. Advantageous is the ideal radial loading of the stent as well as the high precision in diameter and force measurement. Friction within the test setup as well as deformation of the test setup can be compensated with the help of reference measurements performed prior a measurement series. Disadvatageous is the complexity of the test mechanism. It is impractical to construct in the lab, but needs for a specialized manufacturer and therefore is expensive.

The alternative method for radial force testing, namely the sling method, is well described in the ASTM standard, but no data seem to be published. A third method, the v-block method, was described in an older version of the ISO 25539-2 [9]. It had the main disadvantage that the stents experience only insufficient radial deformation. On the other hand, the fixture are simple and only minor friction is expected. Thus, the method is suitable for mechanical characterization of stents with very low radial strength.

For the segmented head test, the investigations show that compensation measurements are important for correct radial force measurements. Deformation correction is necessary especially when measuring stiff stent structures, as test setup deformation increases with increasing load. Within our study, friction was very low compared to the radial forces measured and showed no big influence on the test results. However, friction compensation becomes more important when measuring more flexible stent structures with a critical low ratio of maximum radial force and friction.

The determination of the zero diameter is particularly important, as radial strength depends on the amount of plastic deformation defined related directly to the zero diameter. The ASTM F3067 allows different methods to determine the zero diameter [5]. However, for comparative purposes one method should be applied to all measurements.

Test results gained with the single and multi-cycle approach revealed similar test results concerning radial strength at the pre-defined plastic deformation of 15%. However, radial strength at 10% plastic deformation and radial stiffness was lower for the multi-cycle approach. One reason may be the slightly smaller zero diameter determined with the multi-cycle approach. A methodological cause cannot be excluded. According to ASTM F3067 the multi-cycle approach should be used when the unloading behavior of the tested stent is non-uniform for different compression diameters [5]. As a result, the multi-cycle approach should be preferred, especially if the radial force behavior of the stent to be tested is unclear.

The current study is limited to a small amount of measurements and to only one stent type tested. Therefore, further investigations should address a variety of different stent designs considering compensation of friction and deformation within the test setup as well as both the single cycle and multi-cycle measurement approach to gain reliable data to be used for benchmarking or approval, respectively.

Author Statement

Research funding: Financial support by the European Ministry of Education and Research (BMBF) within RESPONSE “Partnership for Innovation in Implant Technology” is gratefully acknowledged. Conflict of interest: Authors state no conflict of interest.

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