Maria Boeck*, F. Kamke, N. Grabow, and W. Schmidt

Investigation of the dynamic diameter deformation of vascular stents during fatigue testing with radial loading

Abstract: Endovascular stents are exposed to cyclic loads resulting from daily activity and pulsatile arterial blood pressure. DIN EN ISO 25539-2 and FDA guideline 1545 recommend durability testing, exposing stents to physiological cyclic loads for a 10 year equivalent. For accelerated testing, the simulated deformation has to be comparable to physiological in-vivo deformation. A new test setup is presented to determine diameter deformation of vascular stents during fatigue testing with radial loading.

Methods: The new setup allows the investigation of stents (n = 1–10) up to a length of 200 mm using a CCD line camera independent from special configurations. For demonstration, the radial deformation of two peripheral stents (stent 1: 8.0×40 mm, stent 2: 4.5×40 mm) and coronary stents (stent 3: 2.5×22 mm, stent 4: 4.0×40 mm) is determined as a function of the longitudinal measuring position. The stents are implanted in polyurethane tubes and exposed to physiologically relevant pressure at test frequencies ≤ 100 Hz.

Results: In addition to the verification of test frequencies for fatigue testing the setup can also be used for the investigation of radial deformation performance. The results show that radial deformation may vary along the stent length. Larger radial deformation was detected at the middle of the stent. For stent 1 a maximum deformation of 0.21 ± 0.07 mm (± 2.65 %) was measured at 50 ± 40 mmHg, 90 Hz. It was also measured that the radial deformation is dependent on stent design, geometric dimension and external loading.

Conclusion: The new setup allows for test frequency verification for accelerated fatigue testing with radial loading. It is also suitable for more detailed investigation of the radial deformation performance of stents along their longitudinal axis. This is necessary for a better understanding of potential mechanical failure especially in the case of long or overlapping stents.

Keywords: durability/ fatigue testing; vascular stents; radial deformation; pulsatile radial deformation

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1 Introduction

Nowadays, stent implantation has become the primary treatment of atherosclerosis in distinction from conventional balloon angioplasty and bypass surgery, where 30 – 40 % of the patients have developed restenosis within 6 months postoperatively [1, 2]. Stents are tubular structures that are implanted into narrowed or completely closed vessels with the goal to restore the blood flow, thus, the nutrient supply of the surrounding tissue [3]. The first coronary stent was implanted in 1986 by Sigwart and Puel. With the introduction of the bare metal stent and all the follow up innovations, it was possible to decrease the restenosis rate to 20 – 30 % [4, 5]. It is known that after implantation endovascular stents are exposed to substantial mechanical loads. Implanted stents have to withstand cyclic motions such as bending, torsion, tension and compression resulting from daily activity and pulsatile arterial blood pressure. Several studies have shown that over the time these loads can lead to mechanical failure, for instance strut fractures. Stent fractures cause endothelial injuries and perforations that lead to inflammatory reactions and endothelial hyperplasia finally leading to restenosis, bleedings and thrombosis. The studies confirm the importance of fatigue performance and design/material validation of endovascular stents [6, 7]. For the commercial approval, endovascular stents have to pass several tests to demonstrate functionality and efficacy of the geometric structure, biocompatibility and among these parameters fatigue strength. In DIN EN ISO 25539-2 and FDA guideline No 1545 it is recommended to perform durability testing where the stents are exposed to simulated physiological loads that are similar to in-vivo conditions for a cyclic equivalent of 10 years (380 million cycles) at physiological (1.2 Hz) or accelerated frequency. After durability testing, the test samples have to be examined for fractures [8, 9]. It is a basic requirement for accelerated durability testing to show that the deformations caused by the simulated loads are comparable with in-vivo occurring deformations [9]. In this paper a test setup is described to determine the diameter deformation during fatigue testing at an externally applied cyclic radial load. The testing device based on a CCD line camera measurement was developed and constructed at the Institute of Biomedical Engineering (IBMT) of Rostock University.

2 Methods

The new setup allows the investigation of stents (n = 1–10) with a diameter of 2–10 mm and up to a length of 200 mm using a CCD line camera. Therefore, the stents are expanded into mock vessels using polyurethane-tubes with known wall thickness and compliance. To expose the stents to an external dynamical pressure, the stented mock vessels are placed in the transparent pressure-proof testing chamber and surrounded by 37 ± 2°C deionized and degassed tempered water. Their inner lumen is filled with testing solution (PBS, deionized water). To allow the investigation of stents independently from its configuration two different sample holder systems were designed (Figure 1). The two systems enable the investigation of straight single or overlapping stents, as well as the investigation of bent stents with a radius of 15 mm which may be defined as a worst-case condition. The stents can be loaded with an external pressure up to 100 mmHg at test frequencies of 0-100 Hz. The external pressure load consists of dynamical and a static pressure component. The dynamic pressure component is generated by an electromechanical oscillator (S 52120, TIRA Schwingtechnik, Germany) plus amplifier. The static pressure is applied by a container at given height (hydrostatic pressure). The stent diameter is measured by optical means using a CCD line camera (LIXUS-I5000, OPTOLOGIC GmbH, Germany) with 5000 pixels of the size of 7 x 7 μm. In combination with a telecentric lens (S5LPJ9325, Sill Optics GmbH & Co. KG, Germany) an optical resolution of 1.8 µm is achieved. A dimmable LED light was installed in front of the CCD line camera but behind the test chamber for back light illumination. It is mechanically connected with the camera using a drive belt mechanism. Thus, the camera and the light source are movable but adjusted in vis-á-vis position. Camera images are taken at a rate of 1.2 kHz. Real time exposure and processing of the image row data, as well as the user interface for parameter adjustment are managed by the software LIXUS-I500 (developed by IBMT). The principle of the test setup is shown in Figure 2.

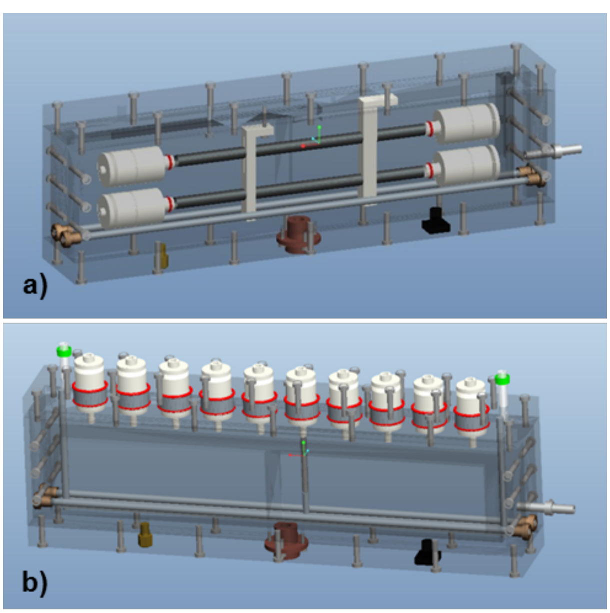

Figure 1: 3D-modell of the sample holder systems for the determination of the stent diameter. System 1 (a) is designated for long peripheral stents (n = 1–2) and system 2 (b) for short coronary or peripheral stents (n = 1–10).

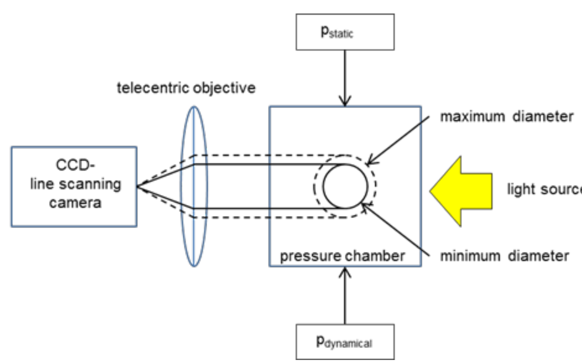

Figure 2: Schematic chart of the testing setup for the determination of the radial stent deformation.

For demonstration, the radial deformations of two peripheral (Stent 1: 8.0×40 mm, stent 2: 4.5×40 mm) and two coronary stents (Stent 3: 4.0×40 mm, stent 4: 2.5×22 mm,) are determined as a function of the measuring position along the stent axis. Three positions (proximal, middle, distal) were investigated at three pressure load modes (40 ± 30, 50 ± 30, 50 ± 40 mmHg) at test frequencies from 0 to 100 Hz. In all cases, the outer diameter of stent plus test tube was measured. To receive the actual stent diameter the tube wall thickness has to be subtracted from the measured diameter.

3 Results

DIN EN ISO 25539-2 advises the use of an optical measurement system for the diameter measurement of stents with an optical resolution of 1% of the smallest test object [9]. For the CCD camera setup a measurement uncertainty of u_{c95} = 6.4 µm was determined (95 % confidence level). This is better than the 1 % requirement limit (20 µm for a measuring range of 2-10 mm). Reproducible diameters were measured for all four stent types that coincide with the nominal expansion diameter of the stents under static circumstances (0 Hz). The results show that the measurement deviation increases for stents with smaller diameters, see Table 1.

The verification of test frequencies for accelerated durability testing of stents is demonstrated in Figure 3 which shows an exemplary measurement for Stent 3 at varying load frequencies (central position of the stent). Up to 40 Hz the diameter deformation is well within the 10% limit. At 50 and 60 Hz the deformations are even larger, but testing at 70-90 Hz would not meet the requirements. At these frequencies, the measured amplitudes are more than ±10 % smaller than at low frequency loading. In other words, the stent cannot complete its radial deformation and the applied stress would be not relevant. On the other hand, loading at 50, 60 and 100 Hz Stent 3 is expected to be overstressed. These observations were not confirmed for the distal and proximal end.

Similar observations were made for stent 1 and stent 4. No relevant test frequencies resulting in self-resonance of the stents were perceived.

The investigation also revealed that the radial deformation depends on the external load (radial deformation decreases when the external load is decreased). The radial deformation in the middle of the Stent 3 was measured with 8 ± 2 µm (± 0.20 %) at 40 ± 30 mmHg, 20 Hz, and 11 ± 3 µm (± 0.28 %) at 50 ± 40 mmHg, 20 Hz. Besides that the stents showed differing diameter changes along their axis. For example Stent 1 had a maximum deformation in the middle of the stent for all three pressure modes. For Stent 4 larger amplitudes were measured at the proximal and distal end for 50 ± 30 mmHg and 50 ± 40 mmHg while for 40 ± 30 mmHg larger diameter changes were measured in the central position, see Figure 4 and Table 2. Maximum deformation of Stent 3 was measured at 50 ± 40 mmHg, 20 Hz (11 ± 3 µm (± 0.28 %)). According to the detected deformation at the different pressure modes for test frequencies of 0-100 Hz there is no systematic correlation between the radial deformation and the test frequency. The measured low diameter changes are comparable to those Schmidt et al showed in their study [10]. It is an important result that the radial deformation is a function of the external load but diameter changes also depend on stent design, geometric dimension and external loading. The test setup enables diameter-frequency evaluation.

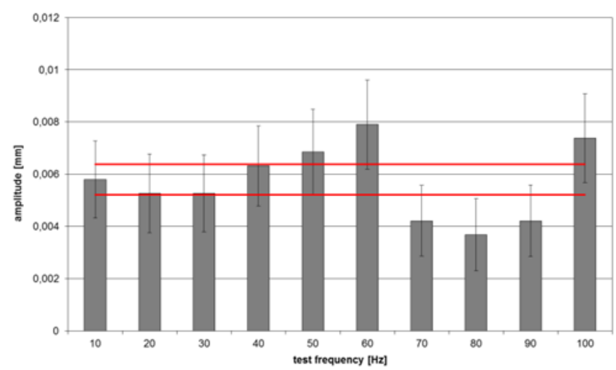

Figure 3: Stent 3 (4.0x40 mm) - radial deformation in the central position as function of test frequency for 50 ± 40 mmHg (exemplary). The red selected area is representing the tolerance range of radial deformation (± 10 % of amplitude at 10 Hz) at which it is reliable that the stent is performing its complete radial deformation.

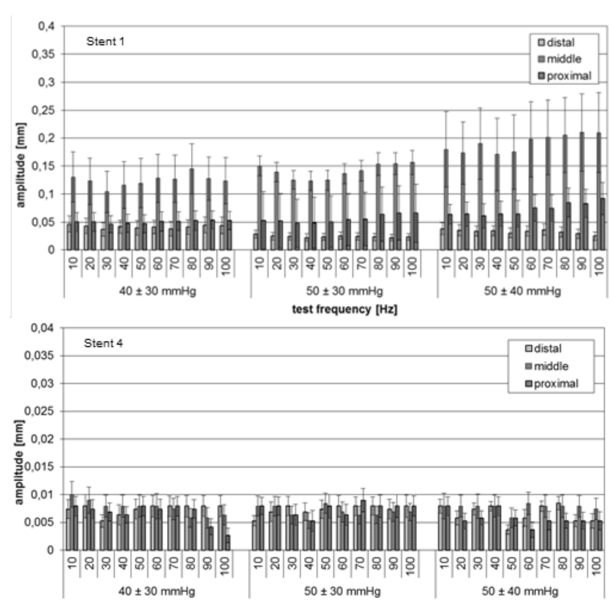

Figure 4: Radial deformation of stent 1 (8.0×40 mm) in comparison with stent 4 (2.5×22 mm).

Table 1: Detected diameter of test samples (50 ± 40 mmHg, 0 Hz) in comparison with test mandrels (diameter ± 0.001 mm) with diameters of 2.5 and 6.0 mm as reference (s: PUR-tube wall thickness).

	$d_{nominal\ [mm]}$	$d_{detected\ [mm]}$	$d_{detected - 2*s\ [mm]}$	Bb Δd bb $_{[mm]}$
Stent 1 (8.0×40 mm)	8.000	8.118	7.968	0.032
Stent 2 (4.5×40 mm)	4.500	4.702	4.462	0.038
Stent 3 (4.0×40 mm)	4.000	4.096	3.946	0.054
Stent 4 (2.5×22 mm)	2.500	2.513	2.363	0.137
Reference	2.500	2.458	–	0.042
	6.000	5.957	–	0.043

Table 2: Overview of the maximum dynamic stent-radial deformation as function of the longitudinal position (proximal, middle, distal) of the peripheral stents and coronary stents (p – proximal, m – middle, d – distal).

		maximum radial deformation [mm]					
		40 ± 30 mmHg		50 ± 30 mmHg		50 ± 40 mmHg	
Stent 1 (8.0×40 mm)	p	0.046 ± 0.014 (10 Hz)	± 0.58%	0.028 ± 0.006 (90 Hz)	± 0.36%	0.038 ± 0.009 (80 Hz)	± 0.48%
	m	0.145 ± 0.017 (10 Hz)	± 1.82%	0.156 ± 0.017 (90 Hz)	± 1.96%	0.210 ± 0.072 (90 Hz)	± 2.64%
	d	0.054 ± 0.045 (10 Hz)	± 0.67%	0.066 ± 0.021 (100 Hz)	± 0.83%	0.092 ± 0.025 (90 Hz)	± 1.15%
Stent 3 (4.0×40 mm)	p	0.007 ± 0.002 (60 Hz)	± 0.17%	0.008 ± 0.002 (60 Hz)	± 0.20%	0.011 ± 0.002 (20 Hz)	± 0.28%
	m	0.008 ± 0.002 (20 Hz)	± 0.20%	0.008 ± 0.001 (60 Hz)	± 0.20%	0.011 ± 0.003 (20 Hz)	± 0.28%
	d	0.006 ± 0.002 (60 Hz)	± 0.15%	0.008 ± 0.002 (80 Hz)	± 0.20%	0.008 ± 0.002 (40 Hz)	± 0.20%
Stent 4 (2.5×22 mm)	p	0.008 ± 0.002 (80 Hz)	± 0.33%	0.008 ± 0.001 (10 Hz)	± 0.33%	0.008 ± 0.001 (10 Hz)	± 0.33%
	m	0.010 ± 0.002 (70 Hz)	± 0.43%	0.008 ± 0.002 (50 Hz)	± 0.36%	0.009 ± 0.002 (70 Hz)	± 0.36%
	d	0.008 ± 0.002 (60 Hz)	± 0.33%	0.008 ± 0.002 (60 Hz)	± 0.33%	0.008 ± 0.002 (40 Hz)	± 0.33%

4 Conclusion

In this paper a new setup was demonstrated that allows the verification of test frequencies for fatigue testing of stents and an extended, detailed investigation of the radial stent deformation. The use of a high sample rate of the CCD line camera and the new provisions for stent placement under relevant loading conditions make the setup suitable to meet the requirements of DIN ISO EN 25539-2 and FDA guideline 1545 for fatigue testing of vascular stents.

The investigation showed that the setup allows diameter detection with a measurement inaccuracy of u_{c95} = 6.4 μm. The measured diameters coincide well with nominal expansion diameters of the test samples. The observation of previous studies was confirmed with respect to the radial deformation as a function of external load amplitude. Identification of test frequencies leading to effects of self-resonance of the stents or minimum/maximum radial deformation as function of longitudinal position will require further quantitative studies.

It was also found that the radial deformation depends on stent design, geometric dimension and external loading.

Conclusively, it was demonstrated that the testing set up is also suitable for more detailed investigation of the radial deformation performance of stents along their longitudinal axis. This is necessary for a better understanding of potential mechanical failure especially in the case of long or overlapping stents.

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Author's Statement

Conflict of interest: Authors state no conflict of interest. Material and Methods: Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use has been complied with all the relevant national regulations, institutional policies and in accordance the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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