Wolfram Schmidt*, Klaus-Peter Schmitz, Peter Behrens, Niels Grabow, Hüseyin Ince and Alper Öner

Expansion characteristics of coronary stents in focal stenoses

Abstract: The presented experimental in vitro approach was designed to assess the expansion behavior of stent systems in a resistant focal stenosis model with respect to a potential dog-boning effect. Five different stent systems (nominal diameter 3.0 mm) were investigated. The focal stenosis was simulated by a stainless steel tube (ID ≤ 1.20 mm). Stent expansion was performed using a proprietary test device consisting of a test chamber with 37 °C water, 2-axis laser scanner and a pressure controller.

All stents could be properly expanded up to recommended maximum pressure (RBP). At nominal pressure (NP) maximum diameters ranged from 2.923 to 3.560 mm while at RBP the maximum diameters were 3.391 to 3.984 mm. Only minimal flaring of stent struts from the expanded balloon was observed. None of the stent systems failed under the extremely high stress at the edges of the focal stenosis.

Keywords: Cardiovascular Intervention, biomechanics, stent expansion, dog-boning

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1 Introduction

Direct stenting has become a common technique in coronary interventions which is no longer limited to bare metal stents (BMS) but also established for current generations of drug-eluting stents (DES) [1,2].

However, stenting of calcified concentric focal stenoses may require high balloon pressures for stent expansion and represents a challenge for balloon catheter and stent as well as the surrounding vessel. Before expansion of the lesion, the midsection of the stent remains compressed while the outer proximal and distal sections are extremely stressed. Increased diameters at the outer sections compared to nominal profiles (dog-boning) may bear the risk of vessel incisions adjacent to the stenosis.

The experimental in vitro approach was designed to assess the expansion behavior of stent systems in a resistant focal stenosis model.

2 Material and methods

2.1 Test samples

We investigated five commercially available stent systems with a nominal diameter of 3.0 mm (BIOTRONIK Synsiro, Medtronic Resolute Integrity, Boston Scientific Promus Element Plus, BIOSENSORS Biomatrix Neoflex, B.Braun Coroflex Isar).

All samples are drug-eluting stent systems representing current state of the art. Nominal pressure (NP) and rated burst pressure (RBP) are specified by the manufacturers **(Table 1)** [3-7].

Table 1: Investigated stent systems.

Stent system	Size [mm]	NP [atm]	RBP [atm]
BIOTRONIK Synsiro (Orsiro)	3.0/15	8	16
Medtronic Resolute Integrity	3.0/15	9	16
Boston Scientific Promus Element Plus	3.0/16	11	16
BIOSENSORS Biomatrix Neoflex	3.0/14	6	16
B.Braun Coroflex Isar	3.0/15	10	18

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2.2 Experimental setup

The focal stenosis was simulated by a stainless steel tube. For the Synsiro and Coroflex Isar the inner diameter of the tube was ID = 0.97 mm (OD = 1.40 mm) while the Resolute Integrity, Promus Element Plus and BiomatrixNeoflex were tested at ID = 1.20 mm (OD = 1.50 mm) due to their larger crimped profile. For testing the crimped stents were introduced in the focal stenosis model. Stenosis length was adapted individually leaving uncovered 3 mm of the distal and proximal stent section.

Stent expansion was performed using a proprietary test device consisting of a water filled test chamber, a 2-axis laser scanner, pressure controller and test software. The technical specifications are listed in **Table 2**.

Table 2: Technical specification of stent expansion and diameter measurement.

Device / Parameter	Specification
Laser Scanner	ODAC 64XY-RSN (ZUMBACH)
Measurement range	0.1 to 30 mm
Accuracy	± 0.01 mm
Resolution	0.001 mm
Pressure controller	neMESYS (cetoni)
Pressure range	0.5 to 40 atm
Accuracy	< 5 % of actual value
Environment	pure water
Temperature	37 ± 2 °C

2.3 Procedure and analysis

Stent expansion is conducted in two pressure steps: nominal pressure (NP) and rated burst pressure (RBP). The balloon pressure is hold at each pressure step for 5 s before measuring the outer diameter from the distal tip of the catheter to the proximal welding zone of the balloon at stepwise positions (Δz = 0.2 mm). Each value is summarized as the root mean square (RMS) of the perpendicular x and y projections.

The maximum outer diameter of balloon and stent outside the focal stenosis model was analysed. The entire process of stent expansion was recorded by a video camera. After profile measurement at RBP, the balloon pressure was hold at RBP and the stent systems were removed from the test chamber and photographs were taken for documentation.

The comparison of measured outer diameters with manufacturer information (diameter compliance) considers that according to [8] the inner diameter of the stents is provided. Therefore the compliance data were added by the 2-fold strut thickness of the stents to get the expected maximum outer diameter.

3 Results

All stents could be properly expanded up to maximum pressure (RBP). Only minimal flaring of stent struts from the expanded balloon was observed.

The following **Figure 1** shows the completely expanded stents at RBP.

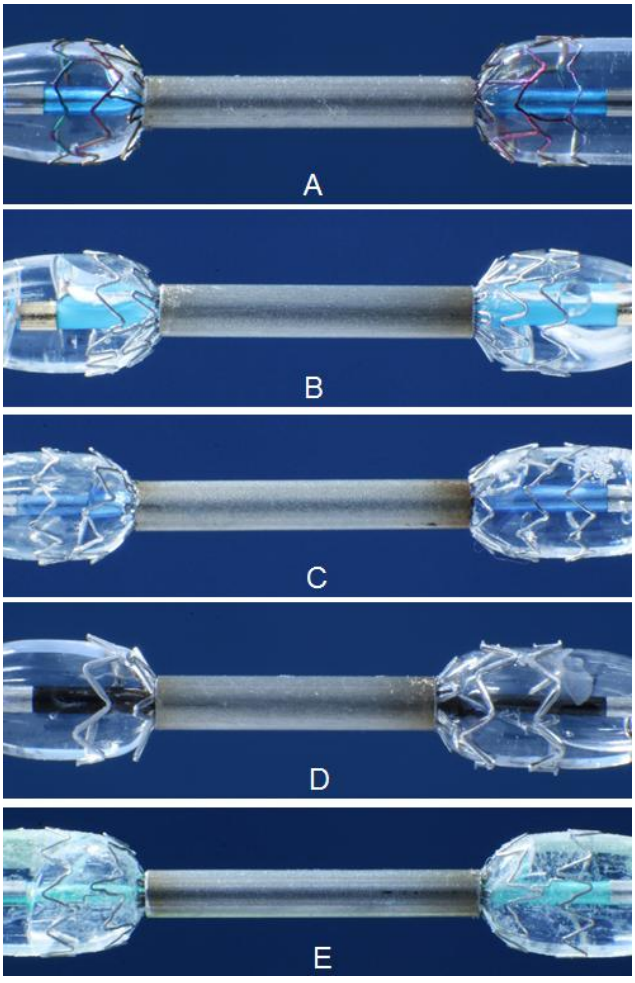

Figure 1: Expanded stents at RBP in the resistant focal stenosis model – A) Synsiro 3.0/15, B) Resolute Integrity 3.0/15, C) PROMUS Element Plus 3.0/16, D) BIOMATRIX Neoflex 3.0/14, E) Coroflex ISAR 3.0/16

A typical profile as measured by the laser scanner is demonstrated in figure 2 showing the profile of the distal and proximal balloon shoulders with expanded stent and the region of the stenosis model with the constant outer diameter of 1.5 mm.

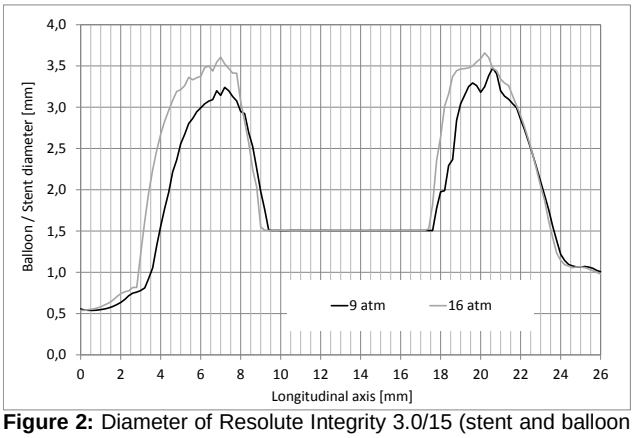

Figure 2: Diameter of Resolute Integrity 3.0/15 (stent and balloon catheter) at NP=9 atm and RBP=16 atm

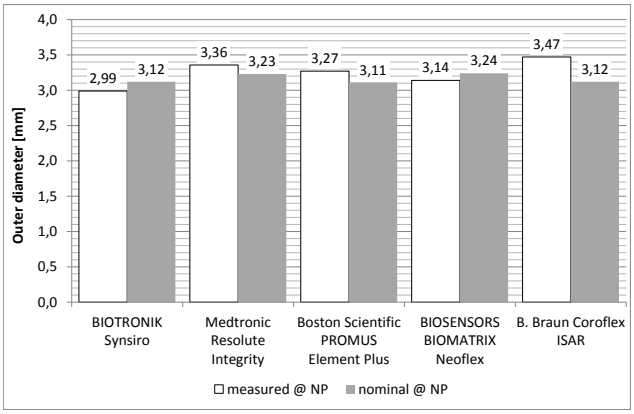

Figure 3: Measured maximum outer diameters compared to nominal outer diameters (corrected by stent wall thickness) at NP

At nominal pressure (NP) maximum diameters ranged from 2.923 to 3.560 mm while at RBP the maximum diameters were 3.391 to 3.984 mm (**Table 3**).

Table 3: Measured maximum outer diameters of expanded stents at NP and RBP.

		maximum outer diameter [mm] at balloon pressure			
		NP		RBP	
Stent system		**distal**	**prox.**	**distal**	**prox.**
BIOTRONIK Synsiro (Orsiro)	3.0/15	2.923	3.053	3.391	3.442
Medtronic Resolute Integrity	3.0/15	3.240	3.475	3.606	3.658
Boston Scientific Promus Element Plus	3.0/16	3.235	3.306	3.636	3.578
BIOSENSORS Biomatrix Neoflex	3.0/14	3.139	3.139	3.508	3.628
B.Braun Coroflex Isar	3.0/15	3.383	3.560	3.984	3.962

4 Discussion

None of the stent systems failed under the extremely high stress at the edges of the focal stenosis. The photographs demonstrate that no particular risk from flaring stent struts was detected even at RBP expansion.

Comparison with manufacturer data at NP (**Figure 3**) shows that two investigated stents had slightly lower profiles at the balloon shoulders outside the stenosis model than expected (Synsiro, Biomatrix Neoflex). This is also the case for the distal section of the Resolute Integrity but not at the proximal site. At the Promus Element Plus and in particular at the Coroflex ISAR larger diameters were measured compared to the individual compliance charts.

At RBP the maximum outer diameters outside the stenosis model are still smaller with the Synsiro and larger than expected from the compliance data with all other stent systems (**Figure 4**). The maximum difference of 0.3 mm was measured at the CoroFlex Isar.

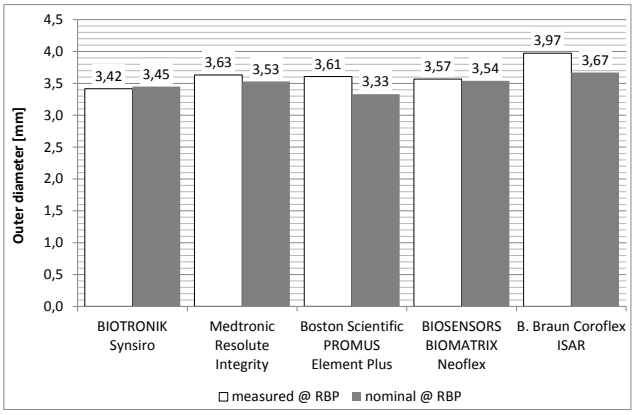

Figure 4: Measured maximum outer diameters compared to nominal outer diameters (corrected by stent wall thickness) at RBP

To achieve optimum vessel wall apposition and to avoid increased risk of vessel wall injury, the stent profile after expansion should be equal to the nominal values at NP and RBP, respectively. This should be true even in critical cases such as resistant focal lesions but also in less challenging situations. It was reported before that for coronary stents differences in the range of -0.097 to +0.294 mm can occur even after expansion without mechanical obstructions by a stenosis model [9]. This might be critical but let us conclude that the observed diameter differences did not result from the focal stenosis.

Summarizing the results it can be stated that a particular risk by flaring stent struts was not observed even in the case of stent expansion in a resistant focal stenosis. However, the data show a potential risk for vessel injury if the maximum

outer diameter at expansion is clearly above the expected diameter. Consequently, in particular at maximum balloon pressure care should be taken by the interventionists to achieve optimal stent sizing under such extreme conditions.

Limitations of the study may arise from measuring only one device per type. This way the obtained diameter values are not statistically proven but have to be interpreted as general observations. The use of two different stenosis models is not limiting because the diameter differences between maximum diameters outside the lesion and the inner diameter of the focal lesion are large in each case (> 2.5 : 1).

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Author's Statement

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