Comparative Studies of Different Stent Designs

K.-P. SCHMITZ, D. BEHREND, P. BEHRENS, W. SCHMIDT
Institute for Biomedical Engineering, University of Rostock, Rostock, Germany

Summary

Before clinical studies on new stent designs can be started, it is important to use bench, in vitro, and animal tests to assess the likely performance of the stent in patients. Although each new stent is evaluated with numerous mechanical and dimensional measurements, experimental methods vary widely, which makes meaningful comparison between stents difficult. This investigation compared five commercially available coronary stents using consistent experimental techniques for each. The results were compared and an attempt was made to link each of the parameters measured to its clinical relevance.

Key Words

Stent, bench testing, clinical utility, elastic recoil

Introduction

The measurement of objective mechanical and dimensional parameters is of uncontested importance for reliable characterization of different stent designs that are currently on the market or still in development. While some of these parameters are mainly used to describe the design or for product placement and marketing, others are important for specifying the safety and performance of the implant. It is difficult to develop meaningful methods to evaluate the clinical characteristics of a stent through physical measurements expressed in terms of mechanical or dimensional parameters. Despite this limitation, comparative studies based on standardized measurements are useful to assess different designs and to attribute specific design features to measurable mechanical quantities. Collecting mechanical and dimensional data on different stent designs also makes it possible to link some physical characteristics of certain stents with in vivo performance once clinical experience with the stent has been acquired. This article summarizes the measurement of the most relevant mechanical and dimensional parameters for a given stent design. Based on the presented methods, the specific design parameters of five stent models available on the market are compared and discussed.

Investigated stent types

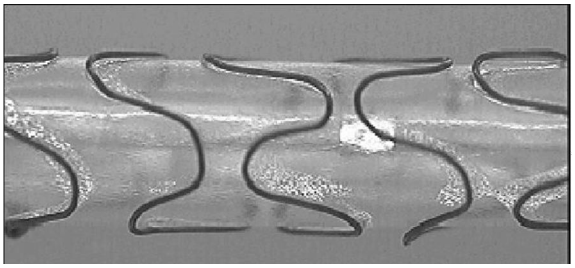
The following five commercially available coronary stents (Figure 1 a-e) have been investigated as examples to demonstrate the influence of the stent design on the measured specifications. The *Wiktor* and the *Freedom Force* stents consist of coiled wires. They do not have any struts in the longitudinal direction. The other stents (*Tenax Complete*, *RX Multilink*, *NIR Primo*) have circumferential ring groups which are connected by struts, a completely different geometrical structure. The experimental setups used in this investigation are presented together with the results.

Results

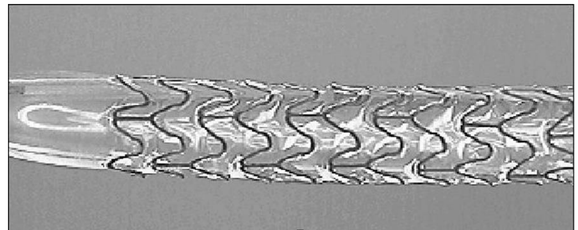
Longitudinal flexibility

The experimental setup for the measurement of the flexibility is shown in Figure 2. The specimen, which may be a stent crimped on a balloon, an expanded stent, or a balloon without stent, is fixed at one end in a grip (see upper part of the photograph). The free bending length (l) was fixed at 12 mm for all investigations.

The system was elongated at least 0.5 mm by the digital micrometer device and the resulting force was measured by a load cell (left part of the photograph) in

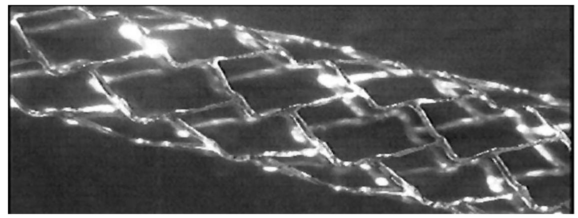


a

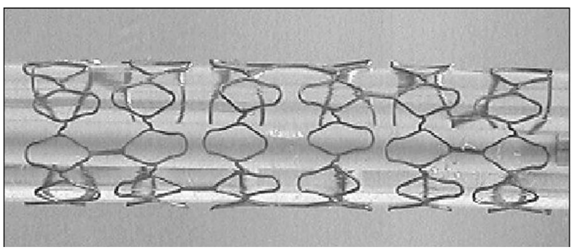


d

b



e



c

Figure 1. Commercially available coronary stents:
(a) Medtronic Wiktor, 3.5x15 mm (detail).
(b) Global Therapeutics Freedom Force 3.5 x 24 mm (detail without balloon catheter).
(c) Biotronik Tenax Complete, 3.5 x 15 mm.
(d) ACS RX Multilink, 3.5 x 15 mm.
(e) SciMed NIR Primo, 3.5 x 16 mm (detail without balloon catheter).

a range of ±50 mN with an accuracy of ±0.5% full scale. The force-distance relation obtained in this way de-scribes the spring modulus of the test object for bending.
The bending stiffness EI of the coronary stent, the balloon or the complete system can be calculated using the following relation comprising the elongation (f) and the single force (F), which is based on the bending theory:

$$EI = \frac{F \cdot l^3}{3f} \qquad (1)$$

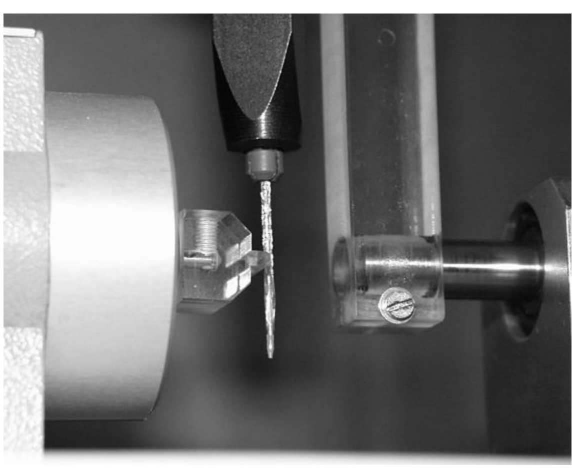


Figure 2. Setup for the measurement of the bending stiffness of a coronary stent system.

The measured values for the force (F) and the corresponding elongation (f) were transmitted to a computer via a serial interface to create a force-distance diagram as shown in Figure 3. As expected, the force-distance relation obtained this way exhibited a linear relationship. The values for the bending stiffness obtained for the five stent types under investigation are shown in Figure 4. In the case of the Biotronik *Tenax* stent it has to be mentioned that the bending stiffness was averaged over five individual measurements in different directions. This procedure was necessary because every segment was connected by one strut to the next, providing an asymmetrical structure.

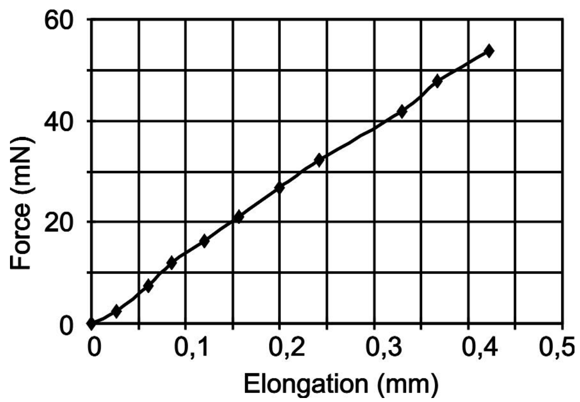


Figure 3. Force-distance curve of a bending stiffness measurement.

Radial stiffness

The determination of the radial stiffness was performed using the apparatus schematically shown in Figure 5. The stent was placed inside a polyurethane (PUR) tube with a wall thickness of 75 microns simulating the vessel and separating the stent from the surrounding water bath (37 °C). The pressure of the water on the PUR-tube and the stent inside was controlled by the BALTUS unit [2]. The stent-tube assembly was connected to atmospheric pressure by a tube that was sealed by a gland joint. During the measurement, the pressure in the test chamber was increased in steps of

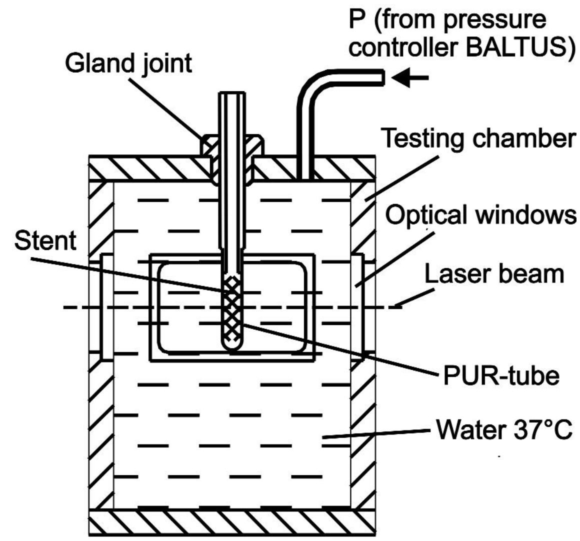


Figure 5. Test chamber for the measurement of the radial stiffness of coronary stents.

0.1 bar. In parallel, the deformation of the stent was measured via a 2-axis laser scanner at a central point of the stent until it collapsed.

The results of the measurements are given in Figure 6.

Foreshortening due to expansion

The measurement of the stent length before and after

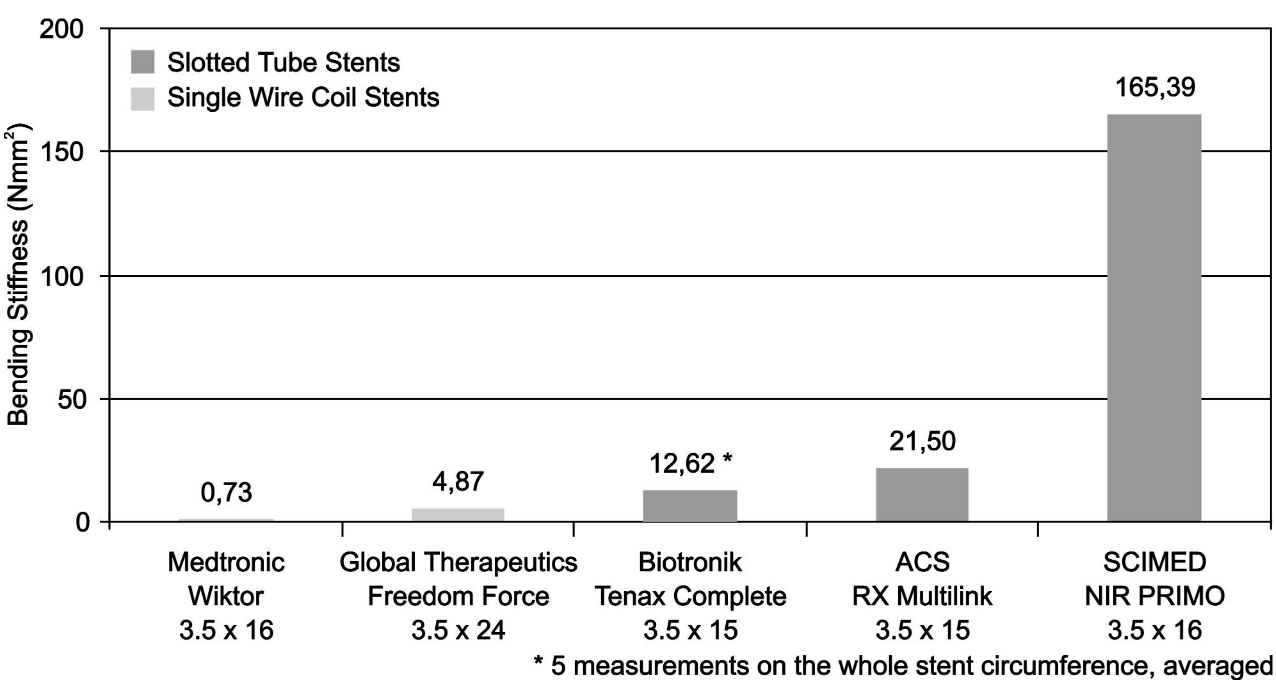


Figure 4. Bending stiffness values of the stents in the expanded state.

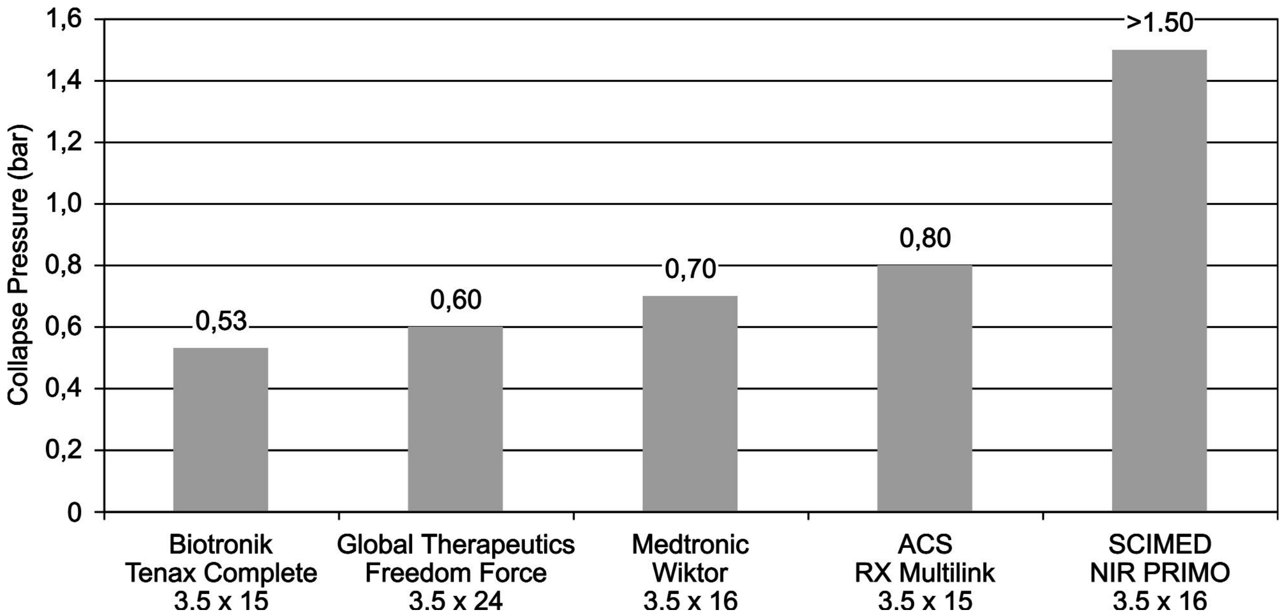


Figure 6. Collapse pressure values as parameters of the radial stiffness of the stents.

expansion was done manually with a digital caliper (Mitutoyo, resolution 0.01 mm). The instrument's error is much less than the subjective error lining up the caliper, which is approximately 0.1 mm. However, the EN12006-3 standard requires that the length be rounded up to full millimeters, which leads to relatively poor accuracy. Another test method using a calibrated microscope yielded equivalent results and is not reported separately.

We defined the length of the stent as the largest extension in axial direction, which is particularly important when the segments at the ends of the stent do not open

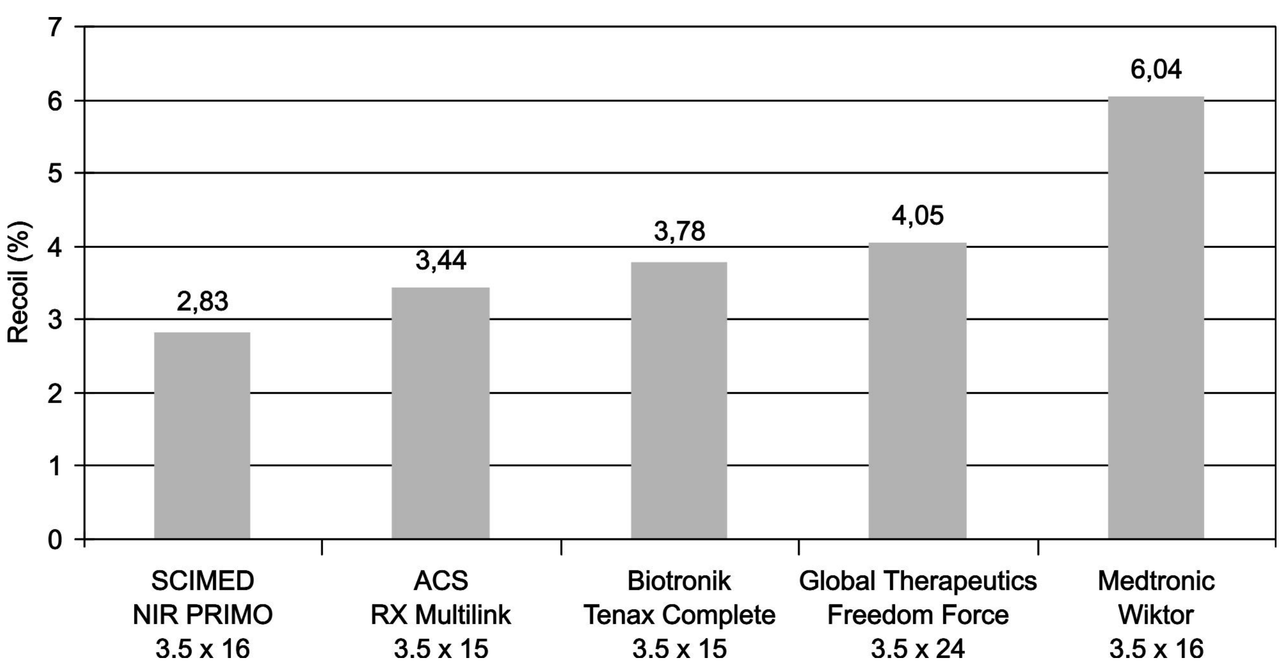


Figure 7. Elastic recoil values of the coronary stents.

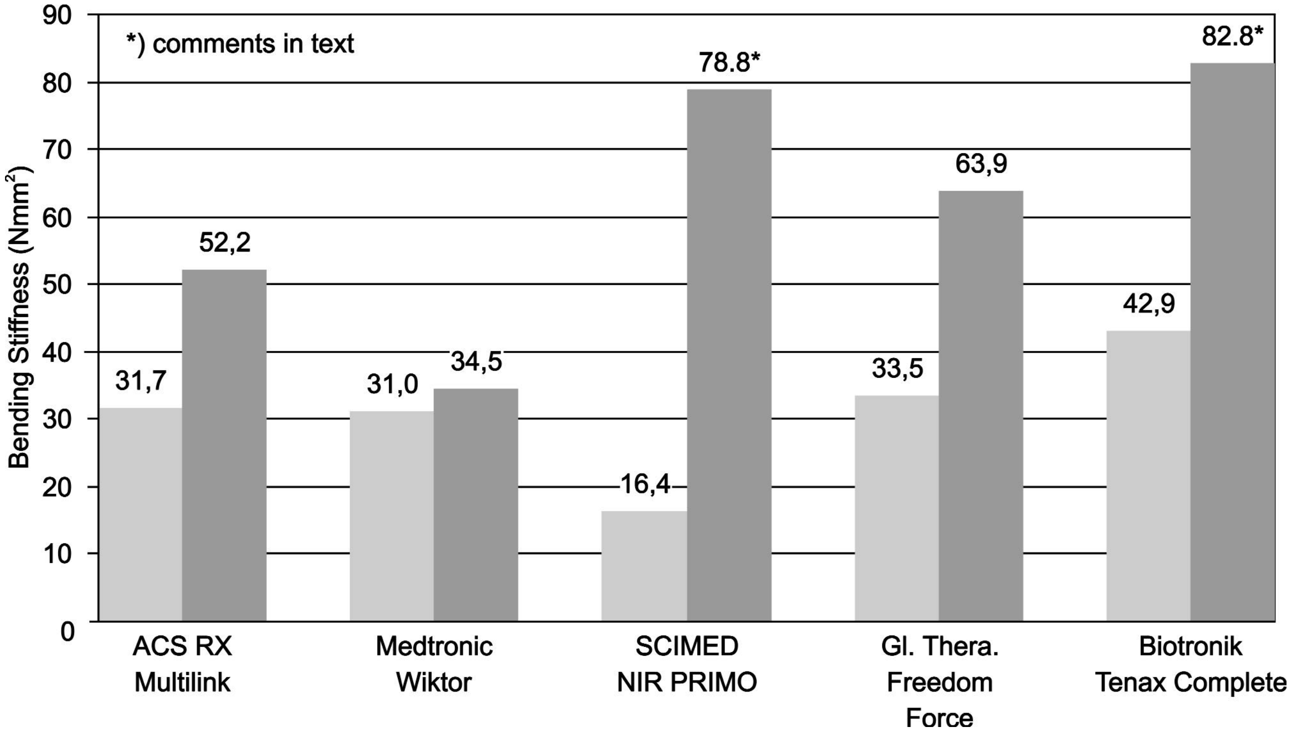


Figure 8. Bending stiffness of the stent systems (right bar) and the balloons without stents (left bar) of the investigated systems.

uniformly. The shortening of the *Wiktor* and *Freedom Force* stents after expansion strongly depends on the nominal diameter of the expanding balloon. This was caused by the absence of struts in longitudinal direction. The other stents showed a typical shortening of a few tenths of a millimeter.

Elastic recoil

The measurement setup used for this parameter allows the determination of the mean diameter of a stent on the expanding balloon without touching the system by using a laser scanner device [1,2][5]. The measurements were taken at different pressures of the delivery balloon, including the nominal pressure (p_{max}) and the subsequent deflation (p_0 = 0 bar). The outer diameter (d) at the pressure steps (p_{max} and p_0) were calculated as average values along the whole stent profile. The elastic recoil was calculated as follows:

$$recoil = \frac{d(p_{max}) - d(p_0)}{d(p_{max})} \cdot 100\% \qquad (2)$$

The results are illustrated in Figure 7. Obviously, all recoil values are quite small. Relative to the nominal outer diameter of 3.5 mm, 5% recoil represents an elastic decrease of 0.175 mm in diameter after expansion.

Flexibility of stent systems

Before the stent can be expanded inside the narrowed vessel, it has to be delivered there, crimped on a balloon delivery system. Pushability and trackability of the balloon catheter are significant criteria to describe the system's performance (see [4] for a detailed description). The stiffness of the complete system is an especially important parameter, because it may influence the passage of the stent delivery system through tortuous vessel segments. The bending stiffness of balloons alone and the complete stent delivery systems, were measured using the apparatus described above (Figure 2). The results are summarized in Figure 8.

Discussion

The comparative investigations described above were performed with stents of different design principles.

However, it is well known that even small differences in geometry, materials, or thickness of otherwise similar structures may influence the mechanical properties significantly. In the following, an attempt has been made to provide some insight into the relationship between the parameter values obtained (Figures 5-8) and the clinical performance of the different stent designs.

Radial stiffness and bending stiffness

Sufficient radial stiffness prevents the collapse of the stent immediately after implantation and assures long-term stability. On the other hand, extreme radial or axial stiffness may cause irritation of the vessel wall. While the radial stiffness is well established as an important functional parameter, the bending stiffness has been of less interest in the past. However, the longitudinal flexibility of a stent is an important variable, as it is a critical factor in determining the ability of the stent and the delivery system to pass through tortuous coronary anatomy.

Beginning with the hypothesis that a high radial stiffness can have negative effects on a stent's longitudinal flexibility, both parameters were measured for the stent systems examined in this study. However, this investigation showed no compelling relationship between the bending and the radial stiffness. Both parameters strongly depend on the stent design, but appear to be independent of each other.

The lowest values of bending stiffness were obtained for the two single wire coil stents (*Wiktor*, *Freedom Force*). This result is expected, due to the fact that these designs do not contain any struts in the longitudinal direction connecting radial segments. It should be noted that these results show that even very flexible stents may achieve a collapse pressure of $p_{coll} > 0.5$ bar.

Elastic recoil

The coil stents examined in this study showed the most elastic recoil. This finding may be understood by comparing the different design principles of single wire coil stents and stents with a system of interconnected radial groups. While the latter structural principle results in an inhomogeneous deformation in response to the mechanical stress during expansion, local irreversible plastic deformation is achieved throughout the stent. For coil stents without longitudinal connectors, deformation occurs more uniformly along the length of the wire, resulting in a higher degree of elastic deformation and, thus, elastic recoil. While elastic recoil may have clinical significance, it must be noted that the absolute values of this parameter for modern stents are too small to allow meaningful comparisons between stents.

Flexibility of stent systems

Coronary stents are usually expanded into place at the lesion site by a balloon catheter delivery system. The flexibility of the system is an evident parameter to specify its performance, as this parameter has been used to evaluate PTCA balloon catheters previously. Related comparative studies of PTCA balloon catheters were reported in detail in the past, as in [4].

As expected, the stiffness of all balloons is increased by the crimped stent (Figure 8). Furthermore, the stiffness of the system comprising a balloon and a stent is much higher than the stiffness in the expanded stage, except for the *NIR Primo*. This exception is to be understood by looking at the structure of the *NIR Primo*. While the radial ring segments of the *Tenax* and the *RX Multilink* are connected by only a few struts in longitudinal direction (*Tenax*: 2 struts; *RX Multilink*: 3 struts), the structure of the *NIR Primo* has several connecting struts between each of the ring segments. Upon expansion of the stent, these struts that were aligned longitudinally when the stent was crimped are aligned in an angle matching that of the radial groups, thus providing less resistance to longitudinal flexing.

It was found that the stent systems with the highest stiffness have the lowest profiles in the crimped stage (*NIR Primo*: d(0) = 1.14 mm and *Tenax Complete*: d(0) = 1.10 mm). This combination of low profile and high stiffness may be advantageous with regard to trackability into small lesions.

Conclusion

This study described methods and gave examples of objective measurements of mechanical and dimensional parameters with high relevance for evaluation of functionality and safety of stents [6][8,9]. To compare the results of measured parameters it is normally necessary to consider that many test methods are not standardized, which limits the utility of such comparisons. Thus, for a meaningful comparison of different stents, it is necessary to test each stent with identical methods. It is also important that the methods yield results which can easily be related to clinical performance. This can be achieved by using parameters which correspond to clinical criteria prioritized by published reports [7]. The measurements described in this paper provide objective comparison parameters for most stent types. Some of the methods described in this paper are currently not covered by national or international standards and may be quite useful for quality assessment of stents and stent delivery systems, as well as for setting design specifications for stent development.

References

[1] Schmidt W, Behrend D, Nawroth A, et al. Experimentelle Bestimmung der Qualitätsparameter von ballonexpandierbaren Koronarstents. Biomed Techn (Berl). 1995; 40: 363-364.

[2] Schmidt W, Behrend D, Behrens P, et al. Intravaskuläre Stents – Konstruktionsprinzipien und Aufweitverhalten. Biomed Techn (Berl). 1996; 41: 400-401.

[3] Behrend D, Schmitz KP, Martin H, et al. Absorbable stents: Material selection and deformation behavior. Proceedings from the 5th World Biomaterials Congress, Toronto May 29 - June 2, 1996. 585.

[4] Schmitz KP, Behrens P, Schmidt W, et al. Quality determining parameters of balloon angioplasty catheters. J Invasive Cardiol. 1996; 8(3): 144-152.

[5] Schmitz KP, Behrend D, Behrens P, et al. Experimentelle Überprüfung des Aufweitverhaltens von ballonexpandierbaren Koronarstents als Grundlage für in vitro Untersuchungen. Biomed Techn (Berl). 1997; 42: 203-204.

[6] Balcon R, Beyar R, Chierchia S, et al. Recommendations on stent manufacture, implantation and utilization. Eur Heart J. 1997; 18: 1536-1547.

[7] Serruys PW (ed). Handbook of coronary stents. London. Martin Dunitz Ltd. 1997.

[8] prEN 12006-3:1998 “Nichtaktive chirurgische Implantate – Besondere Anforderungen an Herz- und Gefäßimplantate – Teil 3: Endovaskuläre Implantate”. 1998.

[9] Committee draft ISO/CD ISO/DTR 15539 “Cardiovascular implants – Endovascular devices”. 1998.