Measurement of Mechanical Properties of Coronary Stents according to the European Standard prEN 12006-3

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Summary

This investigation examined the mechanical and geometric parameters of stents. All measurements were performed according to the requirements of prEN 12006-3:1998. The test protocol examined the following characteristics in 9 samples: inner and outer diameter, length after expansion (as well as a visual inspection), elastic recoil, radial stiffness, fatigue, and an additional property, which surpasses the standard requirements, stent adherence and crimp firmness. It can be concluded that in comparing commercial products it is necessary to consider more than one property, as has been done with elastic recoil in the past. The mechanical interactions and requirements on a coronary stent and its delivery system are complex and require complex treatment and evaluation.

Key Words

Stent testing, prEN 12006-3, coronary stents, mechanical properties

Introduction

In clinical use for over twelve years, coronary stents assist in keeping coronary arteries open after expansion with a balloon catheter — a procedure known as percutaneous transluminal coronary angioplasty (PTCA) — and prevent the expanded artery from collapsing.

A number of specific parameters to be determined for implants are specified in the draft of the standard prEN 12006-3: 1998 "Non-active surgical implants - Special requirements for heart and vascular implants - Part 3: Endovascular implants" [1]. This draft specification is nearing final approval and is currently used as the guideline for testing. A specification especially for stents is in preparation, but information on the content of this specification is currently not available.

In our test laboratories various measurements were carried out according to the requirements of prEN 12006-3 for determining the mechanical and geometric parameters of stents [2-6]. Some measurements that lay beyond the scope of the above specification have proven to be especially useful for determining handling and functioning characteristics as well.

Materials and Methods

Our standard test protocol contains the following:

1. Measurement of the outer diameter after expansion
2. Measurement of the inner diameter after expansion
3. Measurement of the length of the stent after expansion
4. Measurement of the elastic recoil
5. Determination of radial stiffness
6. Visual surface examination after expansion
7. Measurement of fatigue

An additional test in our testing protocol is the measurement of stent adherence and crimp firmness (which is not covered by any international standard for coronary stents). This parameter provided a significant characteristic for safety during implantation.

To obtain statistically relevant results, the investigation of a sufficient number of test specimen has to be performed. However, testing a very large number of test specimens is rather cost-intensive. With the use of nine samples of the same type and same size for both the expansion and radial stiffness measurements, an acceptable compromise is reached. Fatigue analysis is
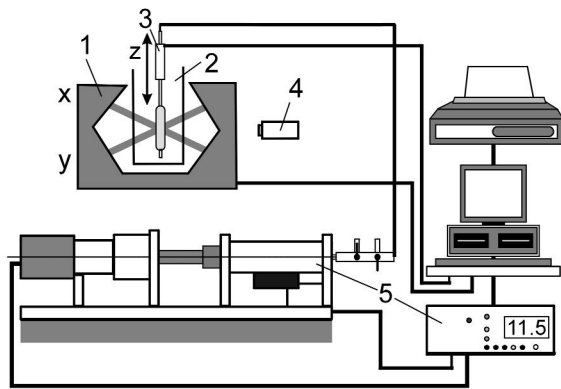
Figure 1. Components of the measurement system.

Laser:	2-axis laser scanner ODAC 32 XY (Zumbach)
Range:	0.1...30 mm
Total error:	± 0.01 mm
Resolution:	± 0.001 mm
Dataacquisiton:	average of 10 measurements, acceptance if variance < 0.1
Temperature:	37 ± 1°C

Table 1. Technical specifications of the laser measurement system.

done in parallel with nine additional specimens.

All measurements were carried out with specially designed test equipment according to international standards. This testing technology and its application are described in detail in the following sections.

Outside diameter and elastic recoil after expansion

Outside diameter and elastic recoil after expansion are determined without touching the specimen by a special laser measuring head ODAC 32XY (Zumbach Electronic GmbH) designed to make measurements in a water bath. The components of the measurement system are shown in Figure 1. A temperature-controlled, water-filled test chamber (2) is situated in the center of the two-axis laser measurement head (1). The linear drive motion section (3) consists of a DC motor with encoder and gears, as well as fixtures for clamping the catheter. A CCD-camera (4) with a video recorder documents the course of the measurement. Stent expansion is computer-controlled by a pressure controller (BALTUS, Institute for Biomedical Engineering, Rostock) (5). The most relevant technical data of the laser measurement system are summarized in Table 1.

The coronary stents are expanded with a balloon dilation catheter, which conforms to ISO/DIS 10555-4 and whose geometry is appropriate for the testing in question. Coronary stents of a single design can be expanded to a range of diameters. Since the mechanical properties, in general, depend on the final diameter and the balloon expansion behavior, selection of the balloon catheter is critical. For measurement, the balloon catheter with a crimped-on stent is slipped over a guide wire. The guide wire directs the motion within the measurement chamber, so the balloon catheter is positioned such that the laser beam strikes the distal end of the balloon. The catheter is connected to the BALTUS pressure controller.

The measurement parameters are specified in the software (LASERSTENT, Institute for Biomedical Engineering, Rostock). The most important parameters for the linear motion of the stent in the measurement apparatus are the distance traveled and the step size, which governs the distance between the profile measurement points. For the BALTUS pressure controller, the starting pressure (generally 0 bar), the pressure increment and the final pressure, which is the nominal pressure or the maximum allowable pressure (rated burst pressure), have to be specified. A dwell time ensures equilibrium prior to initiating measurement at each pressure increment.

All diameter values stored in a data table are mean values calculated over the effective stent length. The complete stent profile is obtained at each pressure step from the individual measurements performed at the orthogonal x- and y-axes. This is accomplished by generating the root mean square value (RMS) of $d_x(z)$ and $d_y(z)$:

$$d_{RMS}(z) = \sqrt{\frac{d_x^2(z) + d_y^2(z)}{2}} \quad (1)$$

Here z denotes the measurement position at the length axis. All these values $d_{RMS}(z)$ of the scan along the z-axis are recorded as the stent profile during expansion (Figure 2).
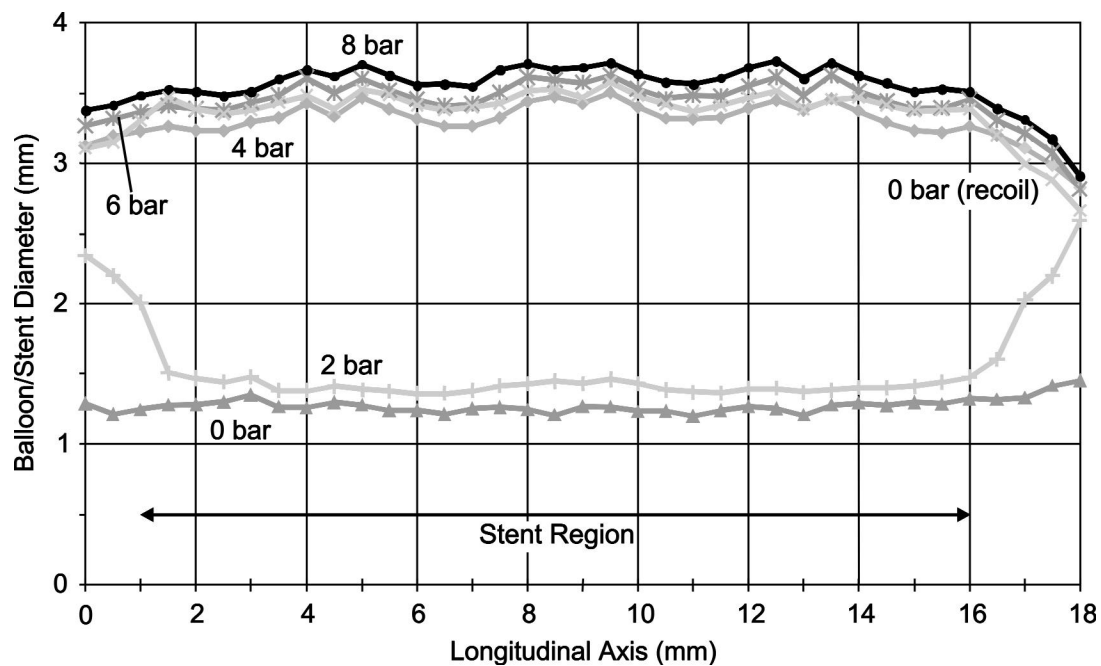
The stent diameter along the entire stent length is

Figure 2. Stent profile during expansion of a 3.5 mm balloon catheter and subsequent deflation.

measured at each pressure increment. The mean outer diameter at final pressure $d(p_{max})$ is used as the reference diameter for the determination of elastic recoil. After reaching the final pressure (total stent expan-

sion), the balloon is deflated (0 bar). After deflation the stent profile is again measured. This outer diameter is called $d(p_0)$ (outer diameter after expansion). The calculation of elastic recoil is as follows:
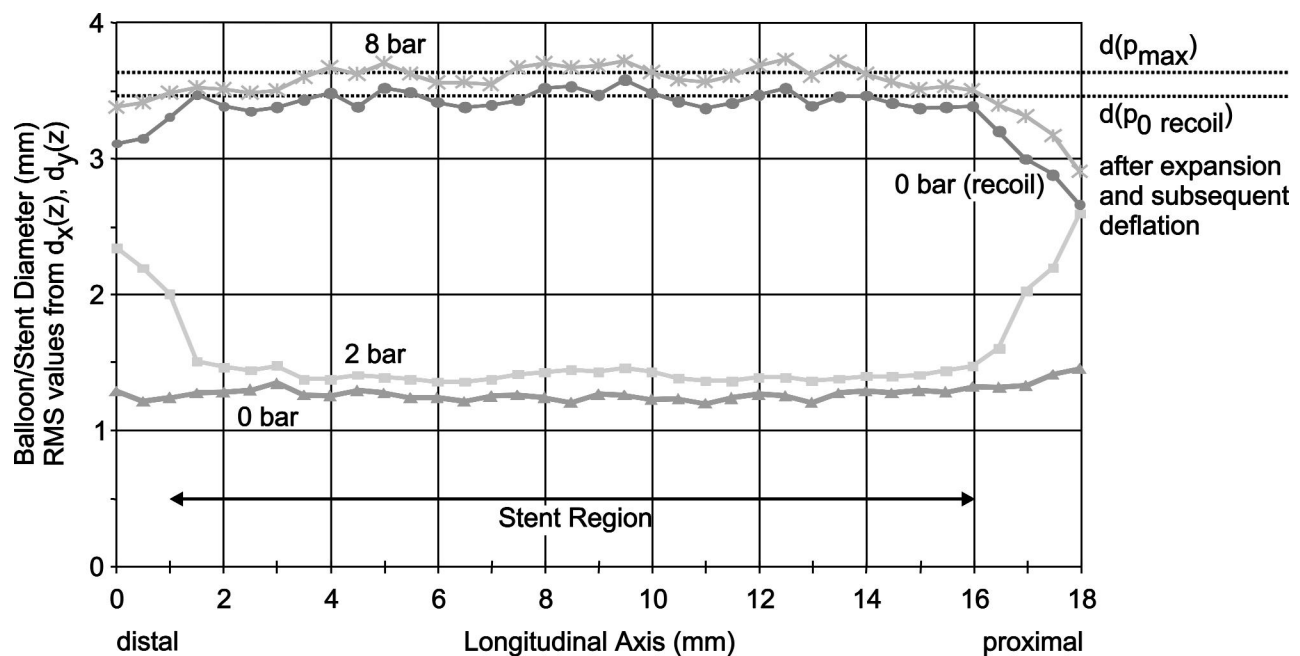

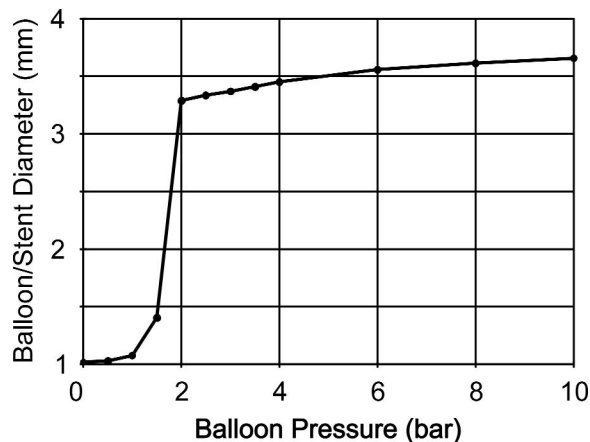*Figure 3. Principle for obtaining the mean value of the stent diameter at different increments of pressure.*

Figure 4. Pressure-diameter curve for stent expansion on a 3.5 mm diameter balloon catheter.

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

For each tested stent a recoil value is obtained, which is calculated according to equation (2) using the mean diameters at p_{max} and p_0 (after deflation), as demonstrated in Figure 3.

Although it is not required by the draft standard, the pressure-diameter curves for the PTCA balloon catheter and coronary stent system are inherent in the profile curves. To obtain the pressure-diameter curves, the mean diameter at the indicated pressure is used (Figure 4). This curve shows that expansion of the stent occurs essentially at a pressure above 2 bar. The type of balloon used primarily determines the subsequent progression of the pressure-diameter curve.

Measurement of the inner diameter after expansion

Measurement of the inner diameter after expansion provides information on the inner lumen within the blood vessel. This parameter is related to the elastic recoil, but it is also influenced by unevenly expanded sections. Thus, the measured value of the inner diameter is often considerably smaller than would be indicated by the difference between the outer diameter and twice the wall thickness of the stent.

It is not possible to measure the inner diameter after expansion with a laser scanner or a similar test method. Consequently, a plug gauge is used, which has a tolerance of ± 0.01 mm in the relevant diametrical range with steps of 0.1 mm (Figure 5).
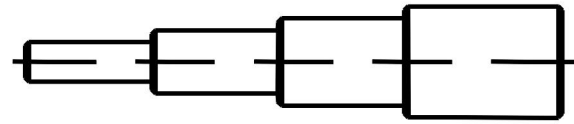

Figure 5. Plug gauge with diametrical steps of 0.1 mm.

For measurement, the expanded stent is removed from the balloon and pushed as far as possible onto the plug gauge. The diameter of the last step onto which the balloon fits is then determined the "inner diameter after expansion."

Measurement of stent length after expansion

Stent length before and after expansion is an important parameter with regard to the placement of the stent in the blood vessel. Generally, depending on the specific design commercially available stents shrink as a result of diameter expansion. This shortening should be as small as possible and at least be known (defined).

The length of the stent after expansion is measured with a digital vernier micrometer. The resolution of the measurement is 0.01 mm. To minimize subjective errors, these measurements are made under a reflected light microscope.

Measurement of radial stiffness

The measurement of radial stiffness is also performed with the laser test apparatus described earlier. For this measurement the test chamber (Figure 6) is sealed with a pressure-tight cover and is connected with a tubing system to the BALTUS pressure controller (1). The stent to be tested is enclosed in a tube that simulates a blood vessel and separates the stent from the temperature-controlled, water-filled test chamber. The tube simulating the blood vessel is made of polyurethane (PUR) and is produced by a dip process specifically for the stent diameter to be measured. The stent is open to atmospheric pressure by means of a tube that passes through a gland nut in the cover of the test chamber.

The most important result of the radial stiffness measurement is the determination of the pressure at which the stent can no longer resist the pressure the vessel exerts upon it. The collapse pressure according to this definition can be determined uniquely, whereas other definitions based on diameter reduction with
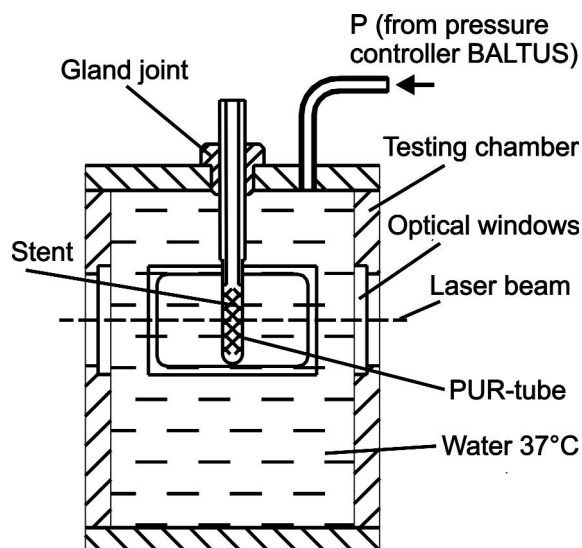
Figure 6. Test chamber used in the measurement of radial stiffness.

Figure 7. Detail of an expanded coronary stent.

increasing applied pressure are merely in reference to the diameter under normal loads. Measurements performed on various commercial coronary stent types showed values for the collapse pressure in the range of 0.5 bar to more than 1.5 bar.

In the case of extreme radial stiffness it is especially important to determine how much the especially stiff design affects the longitudinal flexibility of the stent — a property necessary for proper stent placement and minimized mechanical irritation of the vessel wall.

Visual surface examination after expansion

The stent surfaces are examined after expansion with a reflected light microscope. The stent surfaces are examined for damage and, in particular, for filament tearing as a result of expansion.

The general condition of the stent is visually inspected with a microscope at 20 to 70 times magnification. Special attention is given to critical areas such as the junction of the filaments, deformation zones and the inner surface of the filaments (Figure 7). For the newly developed stents with a surface coating, the adhesion and the state of the coating are of special interest. The images are documented.

Often it is not possible at 20 to 70 times magnification to provide a detailed explanation for the type and course of defects or to address questions of the adhesion strength of possible coatings. For these tasks,
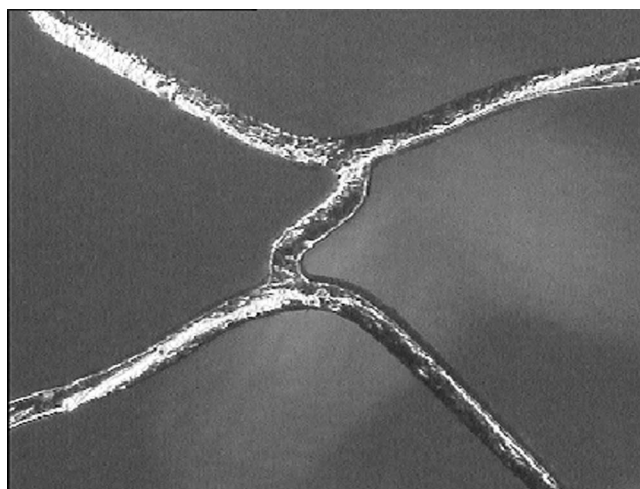
scanning electron microscopy (SEM) examination is generally required. This method was not a part of this standard program.

Measurement of fatigue (fatigue analysis)

In the draft of the standard prEN 12006-3 [1] the following test criterion is required: "The in vitro testing simulates ten years life." This means 420 million cycles in the shortest possible time period. At an accelerated testing frequency of, for example, 50 Hz, the time required is 98 days.

Loading the stents for physiological conditions is not well defined and has not been quantified. In the fatigue test (carried out in a physiological saline solution at a regulated temperature of 37 °C), a symmetrical load is applied: a static preload p_{stat} and a superimposed cyclic load p_{dyn} with an amplitude of 100 mmHg (Figure 8).

These values were empirically obtained from the radial stiffness measurements. In commercially available stents, collapse was not observed with a static loading of this magnitude. After the test was concluded, the condition of the stents was determined with reflected light microscopy and scanning electron microscopy in selected cases.

Additionally, the diameters at the applied pressure levels $p = 0$, $p = p_{stat} - p_{dyn}$, $p = p_{stat}$ and $p = p_{stat} + p_{dyn}$ are obtained before and after cyclic testing using the laser scanner device.

Outer diameter
at

cyclic load
$p_{stat} + p_{dyn}$

cyclic load
$p_{stat} - p_{dyn}$

static preload
p_{stat}

p = 0
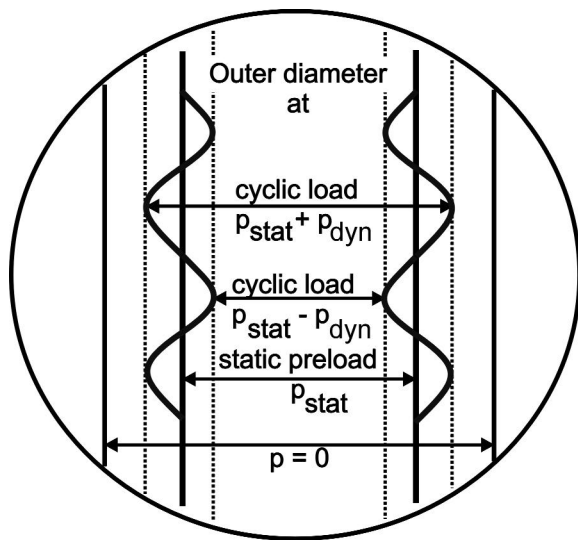
All diameters are outer diameters of the test-sample added by the simulated vessel wall (tube)

Figure 8. Schematic of dynamic loading in fatigue testing.

Laser beam

Figure 9. Coronary stent subjected to dynamic loading in the accelerated test chamber.

Measurement of stent adherence and firmness of crimp

Stent adherence is defined as the force required to remove the crimped stent from the non-inflated balloon. To measure this force, the shaft of the balloon catheter is gripped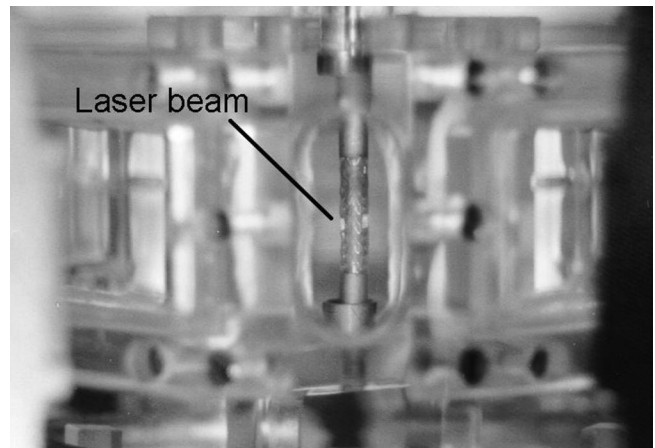 at one end of a tensile testing fix-ture. The stent is attached with adhesive tape to the other grip (Figure 10). The force required to pull the grips apart is measured as a function of the grip separation distance. The force at which the stent first moves relative to the balloon is called stent adherence.

The force-distance curve in Figure 11 first shows an elastic deformation of the catheter, illustrated as an almost linear rise in the measured force. At the maximum force value the adhesive friction changes to a lower glide friction value. The first maximum peak
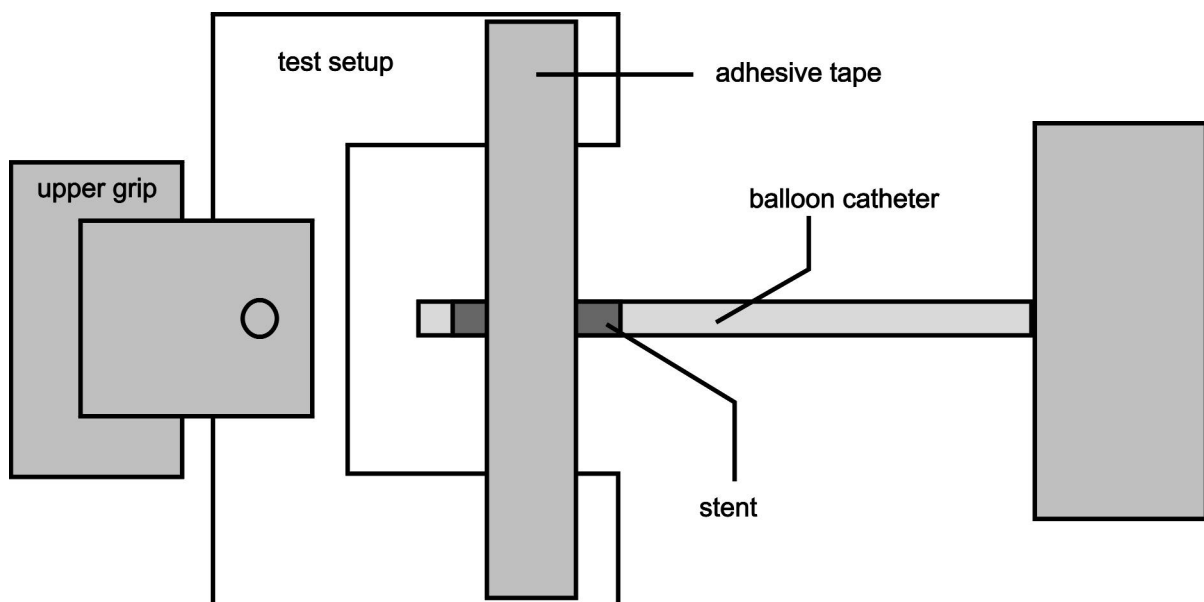

test setup

adhesive tape

upper grip

balloon catheter

stent

Figure 10. Experimental setup for the measurement of the stent adherence to the balloon catheter intended for stent delivery.
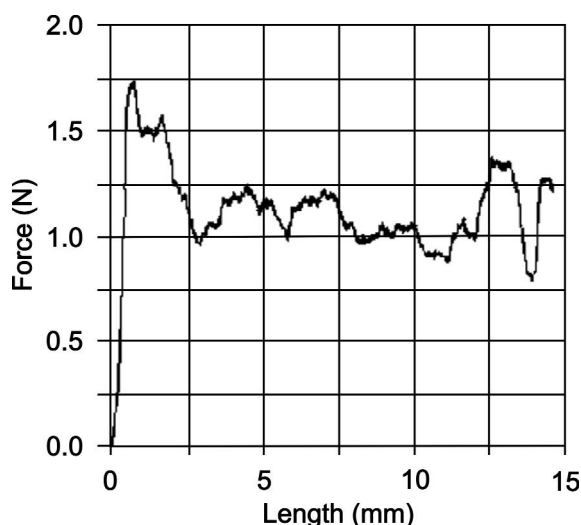
Figure 11. Force-distance diagram of a typical measurement of the stent adherence parameter.

value of the force is taken for the parameter of stent adherence to the balloon. High values of stent adherence are required to avoid the danger of loosing the stent before it is placed within the lesion to be treated.

Discussion

The test equipment and techniques described above have been in use for several years and are continuously developed into new experimental methodologies. Even though the requirements of the standard prEN 12006-3 are met, additional characterizations are necessary. In this regard the above-mentioned measurements, firmness of crimp or the determination of bending stiffness can be mentioned. Significant for comparing commercial products is the bending stiffness, which is measurable for balloon catheters, of coronary stents in their original or crimped and even in

their expanded state. It makes sense to expand the testing procedure of coronary stents to include testing of PTCA balloon catheters according to ISO/DIS 10555-4 within the complete stent testing protocol, because these catheters are used as delivery systems for the safe placement and deployment of balloon expandable stents.

The clinical relevance of the measurement parameters is the subject of discussion by the end users. However, it is clear that objective measurement data are necessary for product comparisons. In general, it is not sufficient to characterize a coronary stent by only one parameter, as was often done with elastic recoil in the past. The mechanical interactions and requirements on a coronary stent and its delivery system are complex and require complex treatment and evaluation.

References

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