In-Vitro Examination of Clinically Relevant Stent Parameters

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Summary

For currently available coronary stents, important technical parameters were determined and compared in laboratory measurements. The resulting measured values for changes in length due to expansion, recoil, inner diameter after expansion, X-ray contrast, and the flexural and radial strength of the expanded stent are extremely important for handling the stent and for a treatment of stenosis that is aimed at permanent opening of the lumen. The results are discussed with a view toward clinical practice, the desired acute results, and possible long-term results.

Key Words

Coronary stent systems, technical parameters

Introduction

The examination of the structural mechanical characteristics of coronary stents forms the basis for evaluating the influence of individual technical parameters on the success of therapy in cases of coronary dilation with subsequent stent application [1,2]. In this article, the values with a fundamental influence on stent behavior are examined based on standardized measurements taken from nine different stent systems. These results are then compared. Fundamental measured values are recoil, the change in length occurring during stent implantation, the inner diameter, the flexural strength of the expanded stent, and the radial strength. X-ray density measurements are also performed on the expanded stent. In order to ensure that the results are comparable, the stents used in the study generally have the same dimensions (3.5 x 15 mm); the ACS RX Multilink Tristar and the Cordis BX Velocity only have dimensions of 3.5 x 13 mm available. The results serve primarily to characterize the implanted stent without the balloon catheter. Precisely these characteristics have a lasting effect on the success of therapy and the expected rate of restenosis. The likewise important issues of fatigue analysis [3], the surface area of the biomaterial and the influence on local hemodynamics due to the stent cannot be ascertained more closely, at least insofar as they are not determined by the inner diameter achieved and the elastic recoil. A separate study is conducted regarding the interaction between the stent and the PTCA catheter, which is extremely important for the application phase.

Materials and Methods

Two specimens of each of the industry-standard coronary stent systems documented in Figure 1 and listed below are studied.
All types were tested with 3.5 mm balloons so that the measurements would be comparable.
The tests were performed with reference to the following points:

- Stent expansion and determination of recoil.
- Measurement of the radial strength of the stent.
- Measurement of the flexural strength of the stent when expanded.
- Determination of the change in length after stent expansion and determination of the inner diameter of the stent.
- X-ray density measurement of expanded stent.

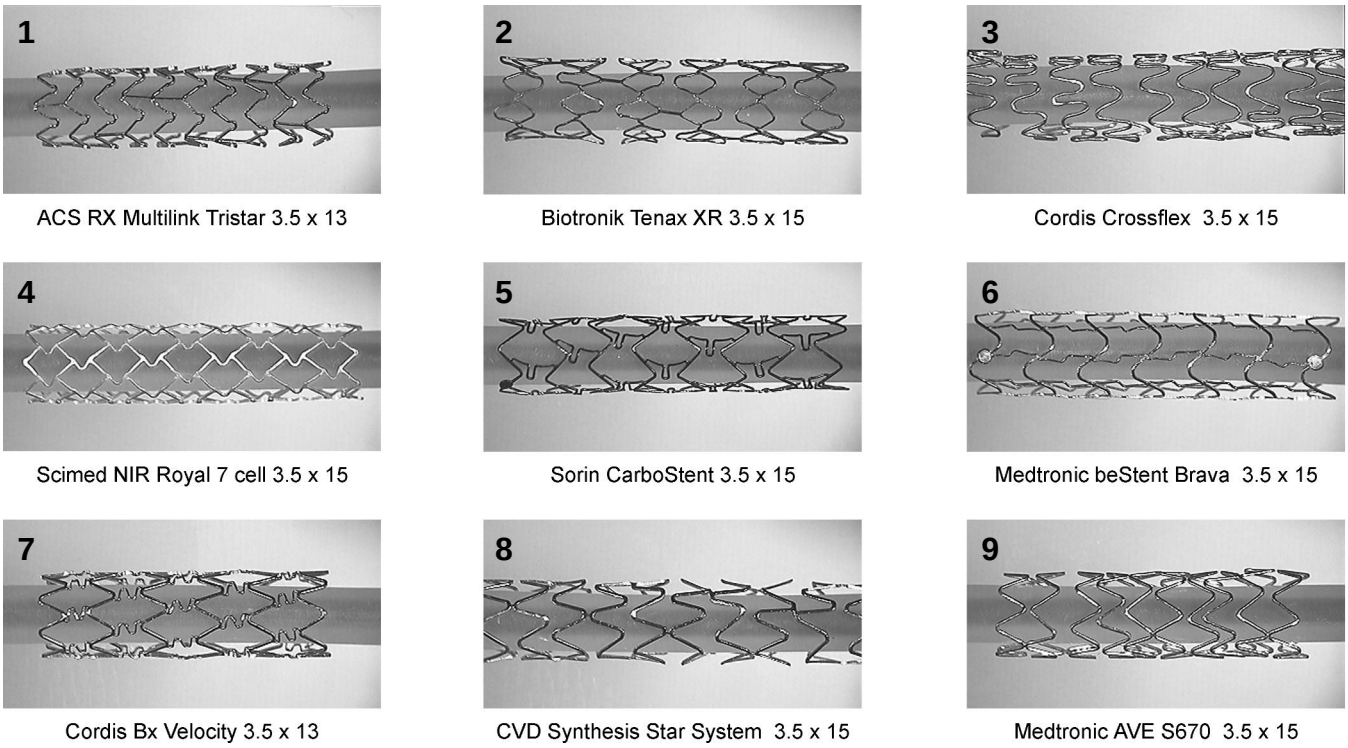

Figure 1. Identification and portrayal of test objects in expanded state.

Stent Expansion and Determination of Recoil

The measurements of stent expansion and recoil are conducted without touching the stent, using a laser measurement system specially designed for use in a water bath (Figure 2) [4].

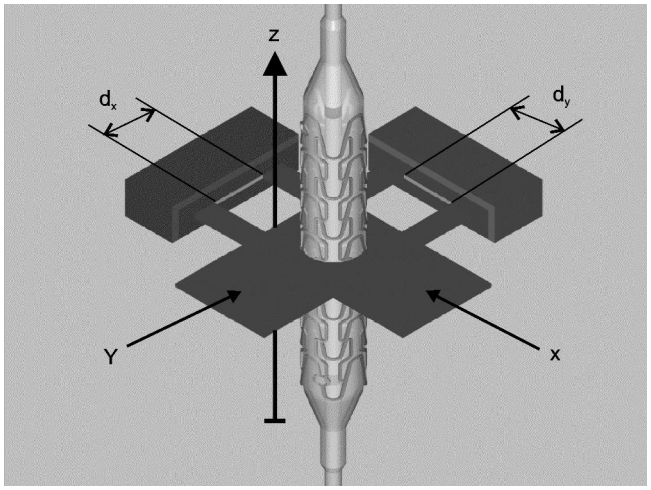

Figure 2. Measurement principle for determination of diameter via 2-axis laser scanner.

The expansion of the coronary stent was conducted with the balloon catheter.

The expansion of the stent was performed stepwise, in pressure steps from 1 bar up to the rated value of the stent system. By scanning the stent range in 0.5 mm steps at the given pressure steps, expansion profiles could be obtained that were able to supply information as to the current stent diameter, and thus served as a basis for calculation of the elastic recoil.

The average stent diameter during the individual pressure steps of expansion and after the subsequent release of pressure were calculated by taking the arithmetic average $\bar{d}$ of the diameters $d_{RMS}(z)$ resulting from the profile measurements. The following holds:

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

$$\bar{d} = \frac{1}{n} \sum_{z=z_a}^{z_e} d_{RMS}(z)$$

where d_x and d_y are the individual measured values for the *x*- and *y*-projections, z_a and z_e are the first and last

measured points on the stent, and n is the number of measured points at the stent.

Measurement of the Radial Strength of the Stent
To test the radial strength of the stent, the stent is used in the test arrangement described more extensively in [4]. The stent, implanted in a thin-walled tube (Pellethane, I.D. = 3.5 mm, wall thickness = 0.075 mm) is placed in a tempered test basin. The pressure in the test basin is increased to 1.5 bar in steps of 0.1 bar. This pressure creates a radial load on the tube around the stent. Environmental pressures above 1.5 bar are not deemed reasonable with reference to clinical practice.

Measurement of the Flexural Strength of the Expanded Stent
The measurement setup for determination of the flexural strength of the expanded stent is described extensively in [4] and is depicted schematically in Figure 3. The flexural strength *EI* of the stent is determined via reconstruction from the relationship between the bending deflection (*f*) and the point force (*F*), based on the general bending theory for a cantilever.
In order to consider the influence of stent geometry, the measurements of the flexural strength for all stents are performed at 5 measurement points, each shifted by 45° along the perimeter. Three measurements are performed at each measurement point in order to reduce random measurement error, and the results are determined. The resulting flexural strength that is determined for each stent is given with both reference to the measurement points and averaged over the entire range.

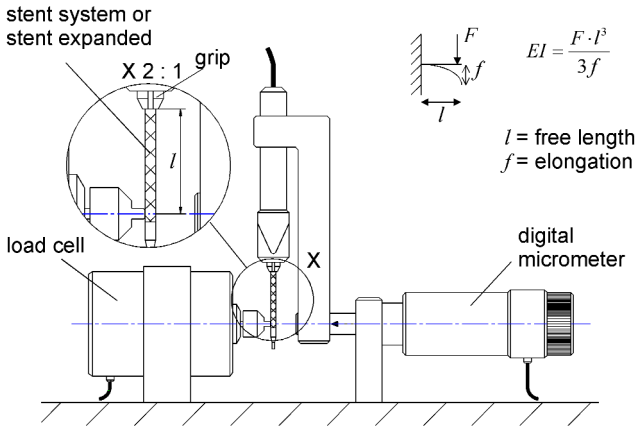

Figure 3. Test setup for measurement of flexural strength.

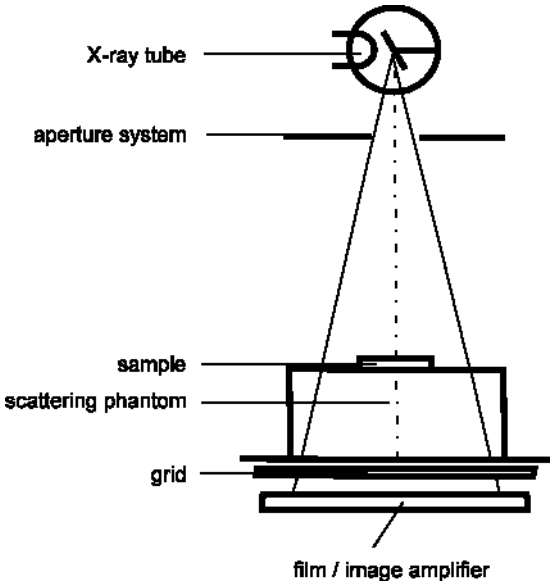

Figure 4. Measurement setup for determination of the attenuation of X-ray radiation as per DIN V 13273-7.

Determination of the Change in Length upon Stent Expansion and of the Inner Diameter of the Stent
The stent length before and after expansion is tested with a digital caliper gauge (Mitutoyo). The total length is measured with calipers under a microscope. The values are then rounded to the next 1 mm as per EN 12006 - 3. The change in length is the difference between the lengths before and after expansion.
The inner diameter of the stent after expansion is determined with test rods, which are available for the relevant diameter range in steps of 0.1 mm with a tolerance of ± 0.01 mm.

X-Ray Density Measurement of the Expanded Stent
The X-ray density of the expanded stent was determined with the analogous device (D800-1, TUR Dresden, with a 7:1 scatter-ray grid) at a high-voltage of 70 kV, with an energy dose of 2.5 µGy and a basic setup as per DIN V 13273-7:1996-12, Section 6 (Figure 4).
The distance between the radiation source and the film (Film focal distance) was 1150 mm. The distance between the focus and the test object depends on the device and the scattering body thickness of 150 mm. This came to 850 mm.
Film material with a sensitivity class of 200 was used, as per DIN 6867-1 (Kodak Lanex Medium).
The quantitative evaluation was performed through

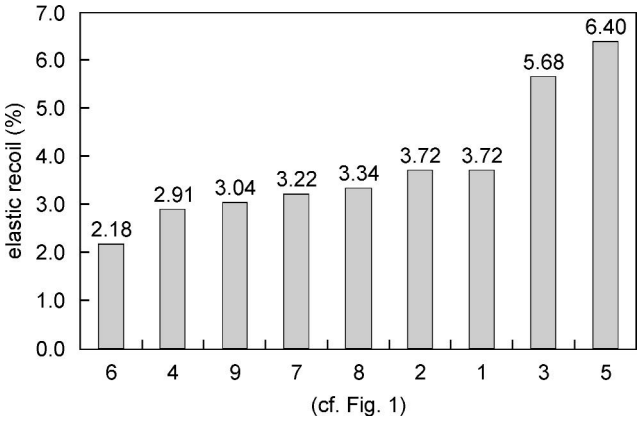

Figure 5. Recoil of stent systems studied after expansion at the nominal pressure.

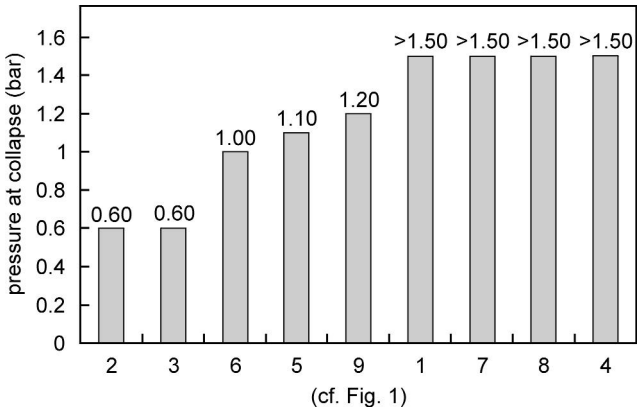

Figure 6. Pressure at collapse for the stent types studied.

scanning the film into a transmitted light scanner (HP ScanJet 6100) with fixed settings for brightness, contrast and resolution.

Then, the picture pixel values were determined as a measure for the gray tone of the picture and were averaged arithmetically. The researcher determined the tone and position of the evaluated surfaces where at least 5x5 pixels must be evaluated for the stent area. The gray tones were determined for the stent body (G_s), possible stent markers (G_{sm}), balloon markers (G_{bm}) and the immediately adjacent film area (G_f) without an object.

The characteristic values K

$$K_S = \frac{G_S}{G_f} - 1$$

$$K_{sm} = \frac{G_{sm}}{G_f} - 1$$

$$K_{bm} = \frac{G_{bm}}{G_f} - 1$$

are appropriate for comparison as a measure for the X-ray contrast.

Results

Stent Expansion and Determination of the Recoil

The elastic recoil after expansion is always an important characteristic value for balloon-expandable coronary stents. Types with small recoil values guarantee a large acute lumen with minimal strain on the vessel, and thus, reduce the risk of incisions or even ruptures of the vessel wall.

The measured recoil values were averaged for the two specimens of each individual stent type, and dis played in Figure 5. Seven types showed a recoil of < 4 %; only two were > 5 %. These good results and development that has been reached for modern stents.

Figure 6 shows a graphic display of the pressure at fail- p_{coll} one specimen of each.

Coil stents showed a special collapsing characteristic

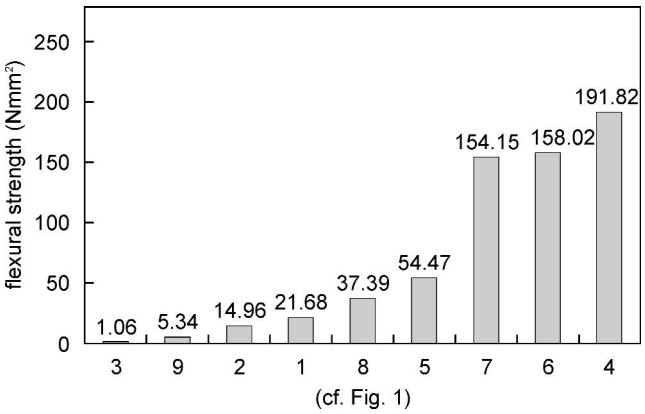

Figure 7. Average flexural strengths while expanded for the stents examined (averages over the perimeters of two specimens of each).

completely; instead, the external pressure causes the stent cross-section to collapse partially at individual stent segments. At the failure pressure portrayed in the figure, the stent function is no longer guaranteed, although the stent has not yet collapsed completely.

Flexural Strength of the Stent in Expanded Form

Figure 7 gives an overview of the average flexural strength for each stent type (averages around perimeter for the two specimens). A high flexibility is a condition of the construction of the coil stents, (Crossflex, S670), closely followed by Tenax XR, RX Tristar and Synthesis Star System, which, as slotted-tube types, are also very flexible. The BX Velocity, the beStent and the NIR Royal are noticeably stiff by contrast.

It is expected of flexible stents that they adjust optimally the vessel wall both at bends and during movement over the course of the heart cycle, and thus, cause less vessel irritation.

Change in Length upon Stent Expansion and Internal Diameter of the Stent

Figure 8 provides information as to the percent change in the stent length upon stent expansion when drawn as compared to the length of the stent type when contracted.

A low change in length due to expansion is desirable for sure positioning. This requirement is fulfilled for most types. Values > 5 % only occur for S670, NIR Royal and BX Velocity. Critical for the evaluation are especially the types with low longitudinal rigidity (e.g., S670), for which a change in length can additionally be influenced by external causes such as the vessel wall. Our expansions took place without a vessel simulation, since these conditions are easier to make objective.

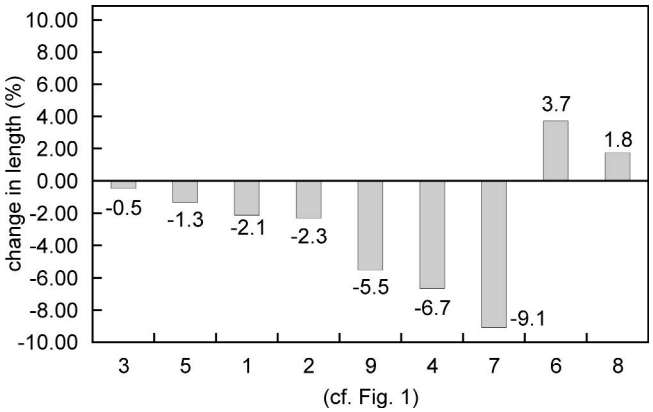

Figure 8. Percent change in length of stent systems studied after expansion to the nominal value (for each stent type).

Stent type	Inner diameter after expansion [mm]
Multilink Tristar	3.05
AVE S670	3.40
NIR Royal 7 cell	3.10
BX Velocity	3.35
Crossflex	3.30
BeStent Brava	3.40
CarboStent	3.00
Tenax XR	3.25
Synth.Star System	3.00

Table 1. Inner stent diameter measured after expansion (rounded as per EN 12006 - 3 and averaged over two specimens).

Table 1 shows the inner stent diameter measured after expansion. All stents were expanded to the nominal diameter of 3.5 mm. The measured inner diameters are partially a measure of the elastic recoil, which reduces the attainable inner lumen, but also for the partially uneven, not entirely circular cross-sectional geometry after pressure is released.

X-Ray Density Measurement of Expanded Stent

The X-ray pictures of the coronary stent systems studied are displayed in Figure 9. Figure 10 shows a comparison of the calculated contrast values *K*. A high value for *K* means good visibility; *K* = 0 means that the

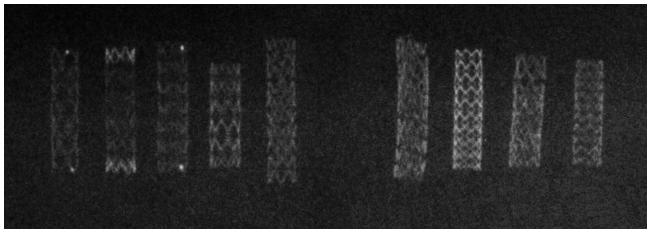

Figure 9. X-Ray picture of expanded coronary stents - From left to right: Sorin Carbostent; Biotronik Tenax XR; Medtronic beStent Brava; Cordis Bx Velocity; Cordis Crossflex; Scimed NIR Royal; Medtronic AVE S670; ACS RX Multilink Tristar.

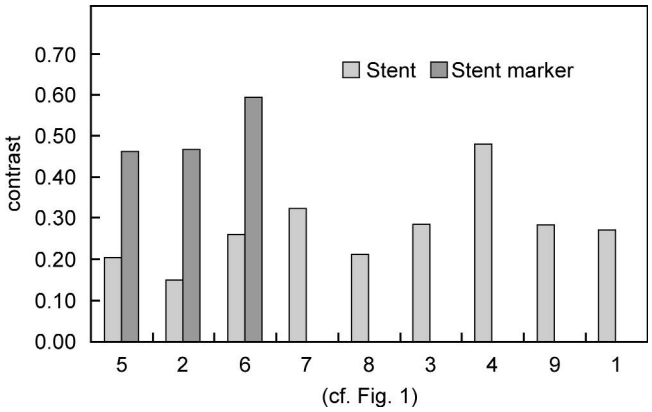

Figure 10. X-ray contrast of expanded stent.

lightness of the object and film are exactly the same, i.e., the object is not visible.

The X-ray visibility of the body of the expanded stent is low for Carbostent, Tenax XR and beStent along the entire stent; however, special markers at the stent ends more than make up for this disadvantage. The X-ray contrast of the stent markers is, at least for Tenax XR and beStent, even higher than that of the stents of types without special X-ray marking.

The visibility is not determined only through contrast, but also by the size of the visible surface [14]. Here, the types that are visible over the entire surface, as well as the extensively marked Tenax XR, are at an advantage.

Discussion

The elastic stent recoil should be small, since the hemodynamic lumen attained remains decisive for the success of therapy. High-grade recoil must otherwise be corrected during implantation by overstretching the balloon-stent system [5]. In the clinic, intravascular ultrasound (IVUS) diagnostics show evidence of recoil problems for some stents that are expanded incompletely. Certainly, stents that are not completely expanded, that have partially collapsed, or that show constrictions not due to focal calcifications or the vessel wall, are especially noticeable with IVUS. The measured recoil values are generally small. Due to the great importance of a hemodynamically effective vessel cross-section, even small increases in recoil above 4 or 5 % are definitely not to be neglected. There are ongoing discussions on this topic for coronary stents, but also with an eye toward peripheral stent implantation [7,9,10].

The percent change in length has a decisive influence on quality in stent expansion, and requires direct evaluation. Especially in central vessel sections with high-lumen side-branch apertures, disadvantageous placement can cause the additional problem of side-branch perfusion. However, the consistency, not necessarily the absolute value, of the change in length is decisive for a stent type, since reference relative to the stenosis or to the beginning and end of dissection must be possible during implantation.

Good X-ray visibility is necessary for safe placement of the stent and clear assignation to the vessel segment being [13]. Above all, exact marking of the ends is necessary in order to be able to judge whether the location of the implanted stent is appropriate to the vessel morphology. A high X-ray contrast over the entire range of the stent is thus not optimal, especially when overcontrast hinders or falsifies the evaluation of an in-stent restenosis with a contour procedure. With better imaging procedures such as digital coronary angiography (DCA) or IVUS, these problems can only be reduced, but not be remedied entirely [13,14].

A sufficient radial strength constitutes the main function of a vessel stent, although there is no foundational information as to minimum requirements. Clinical cases for the failure of support functions are extremely rare, and usually occur with relation to external influences such as resuscitation and heart massage, or with unclear anamnesis (complete dilatation?); for this reason, one cannot arrive at the general conclusion that requirements should be followed that exceed current practice.

Since a high radial strength often means an increased flexural strength [6,9,15], a compromise is necessary depending on the stent design.

The flexural strength of expanded stents is of particular clinical importance for very tortuous vessels, e.g., in connection with long-term hypertonia, accordingly mechanical loads are exerted so that there is clearly increased hyperproliferative inflammation at the stent ends. This means that stiff stents have a much higher restenosis rate, especially at the ends [11]. An injury to the endothelium then results, causing increased smooth muscle cell immigration.

In this context, the term "compliance mismatch" is coined in [8] for the situation arising between the generally stiff stent and the vessel wall that gives rise to hemodynamically unfavorable relationships. These effects are especially pronounced for length-to-diameter ratios of > 10 and in connection with the

overstretching of the vessel in the stent segment.
As a result, modern coronary stents must fulfill a number of requirements regarding their geometries and mechanical characteristics [12,15,16]. The results of this in-vitro study show how far the development and improvement of structural mechanical characteristics has already come. The results also show that the future in the field of coronary stents lies less in the founding of new principles than in the improvement of known characteristic values. In addition, further new parameters, including the relationship of the stent and delivery system as a unit, are being discussed. In the future, these new parameters would also require evaluation by means of objective measurement.
The influence of the stent material or stent coatings on improvements in hemocompatibility and on further reduction in the restenosis rate is also of extreme clinical importance. It is not, however, further examined in this study.

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