New Aspects of in vitro Testing of Arterial Stents based on the new European Standard EN 14299

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Abstract

In the past, product approval of arterial stents required bench tests according to EN12006-3. Last year the level 3 standard EN 14299 was published. This standard describes in vitro tests of stents and stent system which are specified more precisely and cover a number of additional parameters. New test methods will be demonstrated to match these requirements. Special emphasis is put on tests providing quantitative results.
Most of the new aspects that arise from EN14299, are concerned with quantitative measurements of dimensions, visibility, pushability, trackability and profiles of stent catheters. The measurement of stent dimensions is performed using a laser scanning device combined with a specifically designed pressure controller. The distal, central and proximal diameters will be determined averaging the diameter values of the selected regions. Other tests include force-distance curves from track, push, and cross tests in a simulated environment as well as images of stent surface before and after stent expansion and bent stent systems to address a possible flex-kink problem. Results will be demonstrated from commercially available coronary stent systems.
The test methods presented have proven to match the requirements of the new standard EN 14299. Furthermore, due to the concept of this European standard the test methods can also be used to match a series of ISO and ASTM standards, which are also developed to ensure safety and efficacy of arterial stents.

1 Introduction

Recently, the established European standard EN12006-3 was completed by the new level 3 standard EN 14299 which was finally published in 2004. This standard is intended to describe the requirements on stents and stent systems for use in the human arterial system which are specified more precisely and cover a number of additional parameters. Known test methods had to be adapted and new test methods will be demonstrated to match these requirements.

2 Material and methods

The tests will be demonstrated by results from commercially available coronary stent systems, representing the current state of stent technology. Special emphasis was on the following test parameters:
Dimensions (length after expansion, outer diameter at each end and in the middle, mean diameter, for non-cylindrical implants: description of profile, minimum and maximum diameter for self-expandable stents)
For this test a setup is used which is based on a 2-axis laser scanner combined with a computer controlled pressure generator and a linear drive to scan the diameter of the stent or stent system over a length of maximal 45 mm (**fig. 1**).

The required diameter measures from both, the distal and proximal stent end and the middle of the stent are calculated from the relating region of the whole profile curve. Assessment of conical shape as well as minimum and maximum diameters can also be derived from these data.

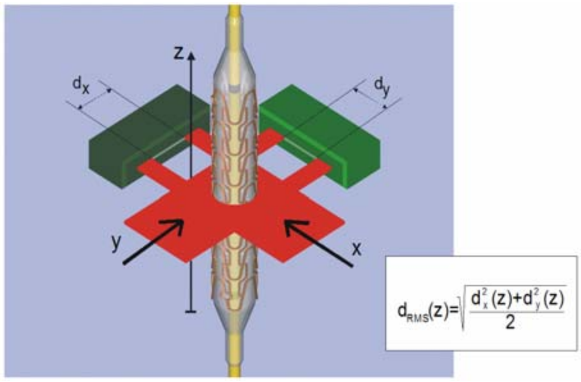

Figure 1: 2-axis laser scanner for profile measurement of stent systems and stents

Recoil for balloon expandable implants is calculated using the mean stent diameters at maximum (nominal) pressure and after balloon deflation. The data from the whole profile curves are used.
Crush resistance (diameter at increasing outer pressure loading, collapse pressure) is determined by introducing the stent into a thin-walled polyurethane

tube of the target diameter, and loading the assembly by an increasing outer hydraulic pressure.

Visibility (incl. under fluoroscopy) is measured using a test arrangement according to DIN 13273-7, and subsequent evaluation of image contrast a) on the basis of optical density measurement or b) compared to the related attenuation of an Al phantom (in mm Al).

Profile effects / flaring are investigated on a bended stent system measuring the distance between the outer contours of the stent and the balloon at both ends of the stent.

Dislodgement force (for balloon expandable implants) is determined by gripping the crimped stent by an adhesive tape and pulling the catheter with a universal tensile test machine.

Surface examination is performed by Scanning Electron Microscopy (SEM) in order to see also microcracks or fissures which may cause device failure in long-term application.

Pushability is to be determined as the ability of the delivery system to be pushed without bending or buckling. This qualitative assessment is usefully added by quantitative data, given by the ration of distal reactive force related to the proximal push force. Therefore a total occlusion model is used which is equipped by two separate load cells.

Trackability is generally defined as the ability of the delivery system to advance over a guidewire along the path of a vessel in a simulated anatomy. Quantitative assessment is not required by the standard, but can be provided by our test method. Details are given in [1].

3 Results

A typical profile curve at increased balloon pressure during stent deployment is given in fig. 2. New diameter data according to EN 14299 are provided from the distal, middle and proximal stent diameters.

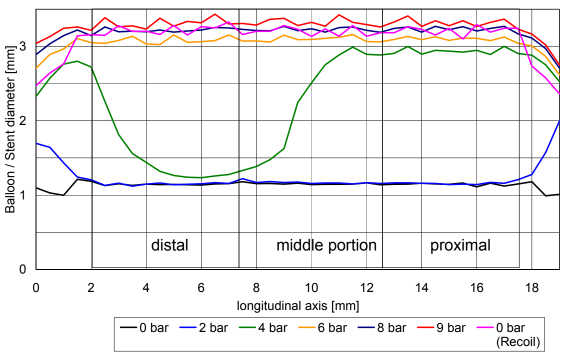

Figure 2: Stent profile at different balloon expansion pressures followed by balloon deflation (recoil), Boston Scientific Express² 3.0/16 mm

The profile of a bended stent can be seen in **fig. 3**. The quantitative assessment is based on a distance measurement using a calibrated microscope.

Figure 3: Proximal stent end while bended over a 7.5 mm radius; distance between outer contours d=120 µm, Medtronic AVE S7 3.0/15 mm

Force-distance curves of track tests in an anatomic model [1], path 5, allow evaluation of general trackability as well as qualitative assessment (**fig. 4**). Evaluation of peripheral stent systems requires adapted tortuous pathways for this test.

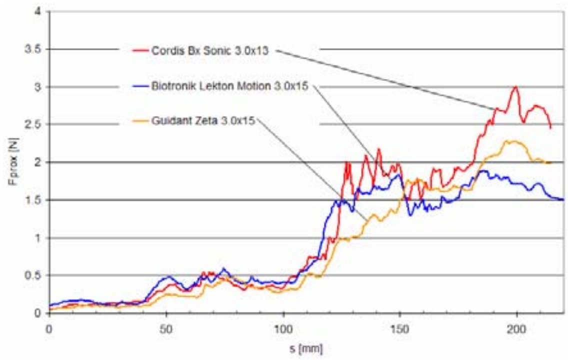

Figure 4: Trackability forces of 3 stent systems - Cordis BxSonic 3.0/13, Biotronik Lekton Motion 3.0/15, Guidant Zeta 3.0/15

4 Discussion

The test methods presented have proven to match the requirements of the new standard EN 14299. Furthermore, due to the concept of this European standard the test methods can also be used to match a series of ISO and ASTM standards, which are also developed to ensure safety and efficacy of arterial stents.

Beyond the scope of these standards, general progress in stent technology will require permanent development of new and specialized test methodologies, i.e. for biologically functionalized stents such as drug-eluting or biodegradable stents.

5 Literature

[1] Schmidt W, Grabow N, Behrens P, Schmitz K-P: Biomed. Technik 47 (2002), Erg. 1, S. 124-126

[2] EN 14299:2004