In vitro measurement of quality parameters of stent-catheter systems

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Abstract

In addition to geometric measurements we evaluated the trackability, crossability of stents in an anatomic coronary model, as well as putatively correlating parameters like bending stiffness and withdrawal forces of the balloon catheter. Five different 3.0mm coronary stent systems (Medtronic AVE S7 15mm, Cordis Bx Sonic 13mm, Guidant Zeta 15mm, Boston Scientific Express 16mm, Biotronik Lekton Motion 15mm) were assessed by measurements of stent geometry and radiopacity estimation as well as by comparison of forces during simulated stenting in a coronary vessel model.
The stent diameter in the crimped state was 0.99 – 1.19 mm, and after expansion 3.15 – 3.32 mm. Elastic recoil was 2.6 – 3.3 %. The stents shortened during expansion by 0 – 7.8%. Radiopacity was 15 – 19% above the surrounding grey value. Mean track forces were measured to be 0.89 – 1.11 N while cross forces were 0.04 – 0.11 N. Mean force for pulling back of deflated balloon was 0.6 – 1.1 N. The bending stiffness of the crimped stents was 17.9 – 79.0 N/mm^2. In the result, geometrical data of the stents showed only a small variability. However, bending stiffness of stents and forces for tracking and crossing the model as well as pulling back the PTCA balloons were remarkable different between systems. Thus, the assessment in a coronary model allows further differentiation of mechanical properties between different stent systems.

1 Introduction

The impact of clinical conditions and patients' characteristics is well evaluated for the procedural success of coronary stenting. In contrast, comparison of the mechanical properties of coronary stent systems and stents is not easily available. In addition to geometric measurements we evaluated the trackability, crossability of stents in an anatomic coronary model, as well as putatively correlating parameters like bending stiffness and withdrawal forces of the balloon catheter.
The goal of this study was to assess parameters which may basically support the decision of physicians for the choice of stent systems for specific anatomical sites.

2 Material and methods

2.1 Material

Five different 3.0mm coronary stent systems (Medtronic AVE S7 15mm, Cordis Bx Sonic 13mm, Guidant Zeta 15mm, Boston Scientific Express 16mm, Biotronik Lekton Motion 15mm) were investigated. All these stent systems represent the current state of stent technology.

2.2 Methods

Generally, manufactures provide information about metric values of the stents like profile, recoil, percentage of shortening, and degree of radiopacity. These parameters were measured by specially adapted and standardized test methods [1].
Less established is a standardized measurement of the dynamic forces during the stenting process characterizing the trackability, crossability and pushability of the different stent systems. However, these values determine the handling properties and the deliverability of the stent systems.
The presented approach for the assessment of the trackability uses a specially developed anatomical vessel model simulating typical curvatures of the left coronary branches [2]. The proximal push force needed to pass the stent system through this model is measured and averaged as the track force parameter.

Crossability measurements were performed on a simulated stenosis model with an additionally attached load cell to measure the distal reaction force as the relevant parameter (**fig.1**).

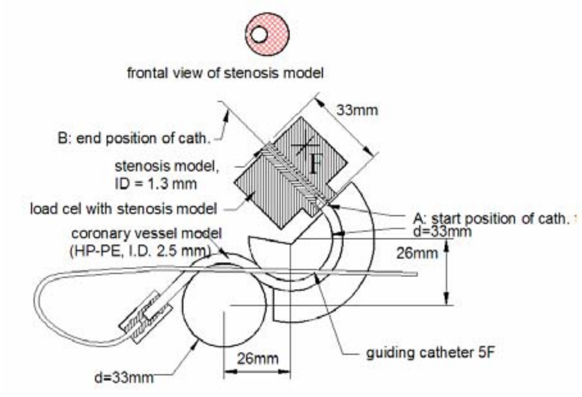

Figure 1: Test arrangement for crossability measurement with stenosis model and attached distal load cell

Pushability means the ratio of distal reaction force and proximal push force while pushing the catheter into a total occlusion model.

3 Results

The stent diameter in the crimped state was between 0.99 and 1.19 mm for all stents (**fig. 2**).

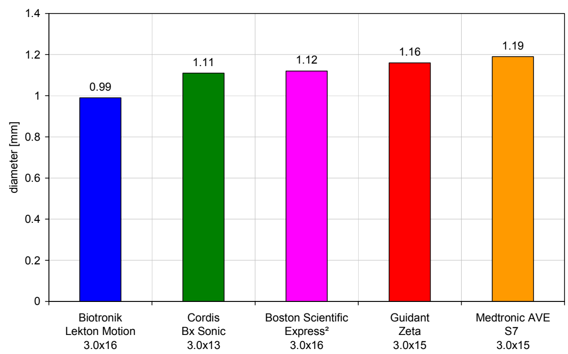

Figure 2: Crimped profile of stents

The bending stiffness of the crimped stents reached from 17.9 to 79.0 N/mm^2. The force for stent detachment while crimped on the delivery system was 1.6 to 4.9 N. After stent expansion a mean stent diameter of 3.15 to 3.32 mm was measured for the investigated stents. The elastic recoil was 2.6 – 3.3 %, and the stent length was reduced after expansion by 0 – 7.8% of the initial length. Radiopacity of the crimped stents was 15 – 19% above the surrounding grey value.
The mean track forces (**fig. 3**) measured during the passage of the model curvature were 0.89 to 1.11 N for all stent systems while the cross forces were 0.04 to 0.11 N (**fig. 4**). The mean force for pulling back of deflated balloon after stent placement was 0.6 to 1.1 N.

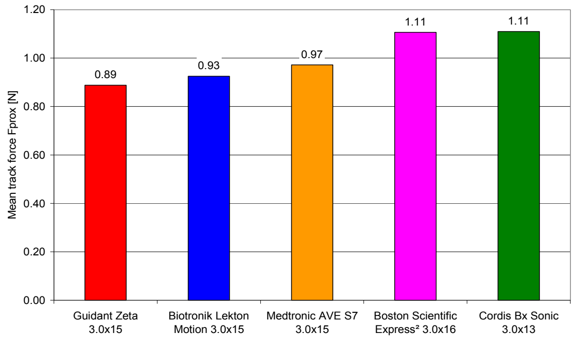

Figure 3: Mean track forces as measure of trackability of coronary stent systems

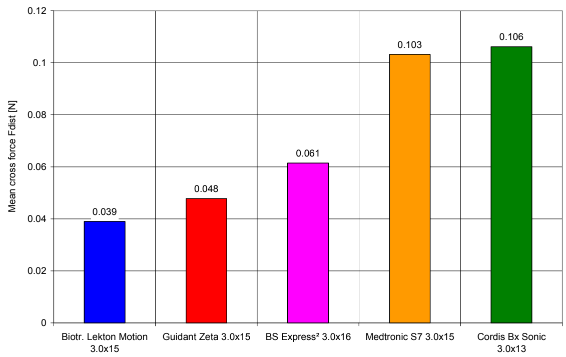

Figure 4: Mean distal reaction force as parameter of crossability

4 Discussion

Geometrical data of the stents showed a small variability. On the other hand, small variations may cause significantly differences between handling properties but data showed no clear correlation between single parameters.
The bending stiffness of stents and forces for tracking and crossing the model as well as pulling back the PTCA balloons were remarkable different between systems. Thus, the assessment in a coronary model allows further differentiation of mechanical properties between different stent systems.

5 Literature

[1] Schmidt W, Behrens P, Kaminsky J, Grabow N, Schmitz K-P: Methodenspektrum zur strukturmechanischen Charakterisierung von Kathetern und Stents für arterielle Blutgefäße, Biomedizinische Technik 48(2003) Erg., S. 394-395

[2] Schmidt W, Grabow N, Behrens P, Schmitz K-P: Trackability, Crossability, and Pushability of Coronary Stent Systems – An experimental approach, Biomed. Technik 47 (2002), Erg. 1, S. 124-126