Acta of Bioengineering and Biomechanics
Vol. 11, No. 3, 2009

Original Paper

Flexibility and trackability of laser cut coronary stent systems

PÉTER SZABADÍTS[1,*], ZSOLT PUSKÁS[2, 3], JÁNOS DOBRÁNSZKY[3]

[1] Budapest University of Technology and Economics, Department of Materials Science and Engineering, Budapest, Hungary.
[2] Minvasive Ltd., Budapest, Hungary.
[3] Research Group for Metals Technology of HAS, Budapest, Hungary.

Coronary stents are the most important supports in present day cardiology. Flexibility and trackability are two basic features of stents. In this paper, four different balloon-expandable coronary stent systems were investigated mechanically in order to compare their suitability. The coronary stent systems were assessed by measurements of stent flexibility as well as by comparison of forces during simulated stenting in a self-investigated coronary vessel model. The stents were cut by laser from a single tube of 316L stainless steel or L-605 (CoCr) cobalt chromium alloy. The one- and four-point bending tests were carried out to evaluate the stent flexibility $E \cdot I$ (Nmm^2), under displacement control in crimped and expanded configurations. The flexibility of stents would be rather dependent on the design than on raw material. In general a more flexible stent needs lower tracking force during the implantation. The L-605 raw material stents need lower track force to pass through in the vessel model than the 316L raw material stents. The sort and long stents passed through the curved vessel model in different ways. The long stents nestled to the vessel wall at the outer arc and bent, while the short stents did not bend in the curve, only the delivery systems bent.

Key words: *coronary stent, flexibility, trackability, bending force, bending moment*

1. Introduction

It was in 1994 that the U. S. Food and Drug Administration (FDA) approved the balloon-expandable coronary stent for the prevention of restenosis [1]. It brings about many changes as the development of the stents has paralleled the evolution of endovascular intervention as a new speciality [2]. New desirable features and abilities that the stents had to reach [3] appeared year by year. The first generations of stents were made of wire and the appearance was helical spiral or woven wire. The second generations of stents are produced by laser cutting from stainless steel tubes [4]. The vast majority of stents are laser cut from 316L stainless steel. Once the tube-like mesh stent is positioned correctly within the coronary artery, a balloon catheter is used to expand the stent, which subsequently maintains vessel patency via its ability to sustain stress in the radial direction. In addition to the obvious benefits of high radial stiffness for continued vessel patency, a high degree of longitudinal stent flexibility is also required for easy delivery of the stent through the vasculature to the stenotic lesion [5].

Diseases of the heart and circulatory system, often related to atherosclerosis, are the main cause of death and serious illness in the western world, accounting for 50 per cent of all deaths in Hungary [6].

The percentages of deadly heart attacks have become lower by using stents. The stents have the main advantages of preventing and decreasing the injury of heart attacks [7].

Thanks to this treatment the patients' quality and quantity of life have become better. The qualities of stents are determined by the clinical results [8].

The 2002 *Handbook of Coronary Stents* lists 43 coronary stents or stent families [9]. Over 100 different stent designs are currently being marketed or are

* Corresponding author: Péter Szabadíts, Department of Materials Science and Engineering, Budapest University of Technology and Economics, H-1111 Budapest, Goldmann tér 3., Hungary. Tel. +36 1 463 2175, e-mail: szabadits@freemail.hu
Received: March 18th, 2009
Accepted for publication: September 21st, 2009

in evaluation for vascular indications [10]. Stents have numerous abilities, some of them are listed in figure 1.

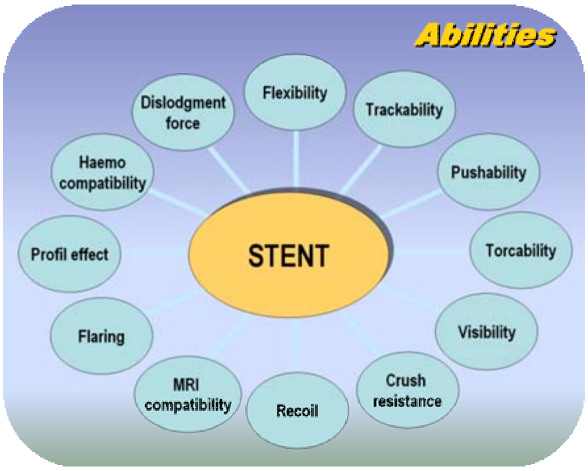

Fig. 1. Some important abilities of stents

The established European standard EN12006-3 was completed by the new level 3 standard EN 14299:2004 which was finally published in 2004 [2], [3]. The standard is intended to describe the requirements imposed on stents and stent systems for use in the human arterial system which specify more precisely and cover the number of additional parameters [11], [12].

Flexibility is generally defined as the ability of the stent and delivery systems to have sufficient flexibility to negotiate the vascular anatomy without compromising the function of the implant [13].

The flexibility of stents is determined by two other properties. The first one is that the balloon–stent system can get through the tortuous vessel (figure 2) and the second one is that the inflated stent can adapt to the vessel wall.

Several methods exist for the determination of stents flexibility but there is not any standard method [13], [14]. The methods can be enrolled in three groups. The first when a mechanical test is used to measure the bending stiffness of the test object [15]. In the case of the second group, the testing system simulates the anatomic vascular conditions [16], [17]. The third is the finite elements method (FEM) which has been widely used for the investigation of stents mechanics [18], [19].

Flexible stents are easily inflated and show great adaptability to vasculature compared with a rigid stent, but the flexible ones have smaller crush resistance. On the other hand, the flexibility is the one of the most important parameters allowing the restenosis to be prevented. The stent collapse incidence at the very flexible stents can achieve 5% of the implantation [5].

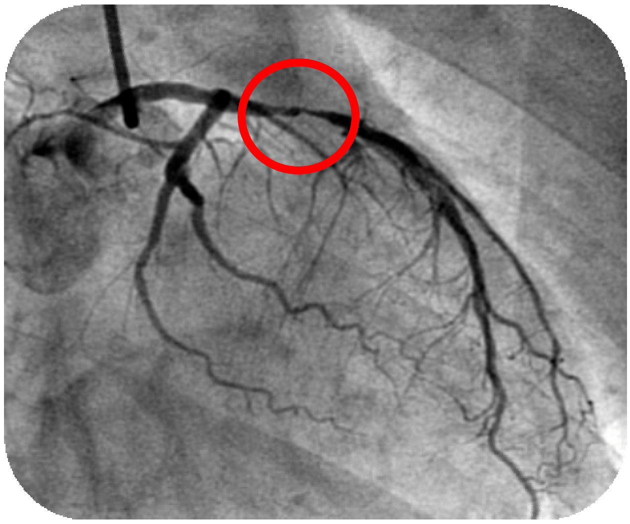

Fig. 2. Coronarogram with tortuous vessels

Trackability is generally defined as the ability of the stent and delivery system to advance over the guide-wire along the path of vessel in a simulated anatomy. Quantitative assessment is not required by the standard.

The profile effect and the dislodgment force are the parts of trackability [20], [21].

2. Experimental

2.1. Coronary stents

The stents tested were examined with stereomicroscopes. Photographs were taken to study their geometry and design (figures 3–8). Table 1 lists the main data of expanded stents, all the stents designed were opened cell for the comparability. Figures 3–5 show the stents in crimped state, and figures 6–8 in expanded state.

Table 1. Main parameters of the stents tested

Stent	Material	Length	Diameter
A_1	L-605	13 mm	2.75 mm
A_2	L-605	22 mm	2.84 mm
C	316L	23 mm	2.5 mm
D	316L	15 mm	2.78 mm

Fig. 3. A_2 Biotronik Pro-Kinetik stent

Fig. 4. C Guidant Multi-Link Pixel RX stent

Fig. 5. D Guidant Multi-Link Zeta stent

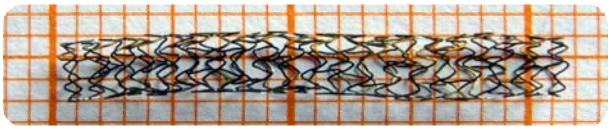

Fig. 6. A_2 Biotronik Pro-Kinetic stent

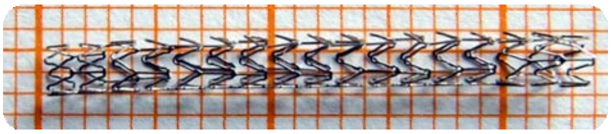

Fig. 7. C Guidant Multi-Link Pixel RX stent

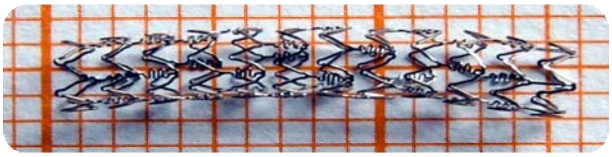

Fig. 8. D Guidant Multi-Link Zeta stent

2.2. Trackability

The testing of trackability according to EN 14299:2004 7.3.4.4 consist in the evolution of the properties of the system sliding over a guide-wire in a vessel. The measurement of the system's trackability was performed using an in vitro coronary vessel model (figure 12). The bench test was performed in an isotonic sol basin at 37±2 °C.

The model was prepared by using soft vinyl chloride tube of 3.0-mm inner diameter [16]. A 6F (1.8 mm) guiding catheter (Launcher, Medtronic AVE) was connected to the vascular model. A 0.36 mm guide-wire (Balance, Guidant) was inserted into the guiding catheter and the vascular model. A stent delivery system with a crimped stent was fixed to the ZWICK 005 equipment (figure 9). The delivery system was moved toward the vascular model at a rate of 10 mm/s. The position of the stent delivery system's tip and the force generated were recorded.

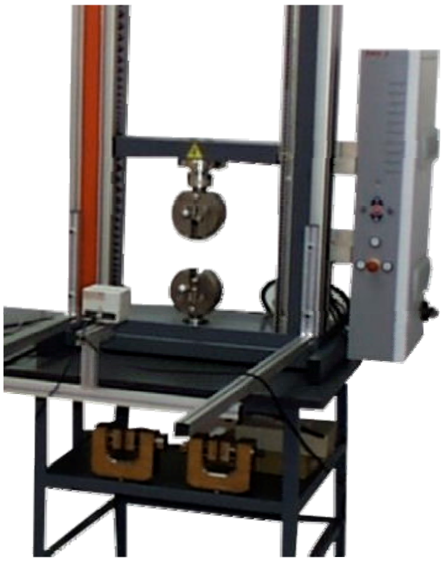

Fig. 9. ZWICK 005 testing machine

2.3. Flexibility

The measurement of flexibility was performed in the crimped state of the stents. To measure the flexibility of stents and their delivery systems, ZWICK 005 testing machine was used (figure 9). The load cell automatically detected the force F and the bending deflection f. One end of stent and delivery's system was gripped and the other end was pressed with a plate which moved at a constant speed of 10 mm/minute (figure 10). The f_{max} was 5 mm to avoid the stent damage. All stents were tested three times in three different positions. The three rotational positions were at 0°, 90° and 120° (figure 13).

The highest measured data was chosen to describe the flexibility.

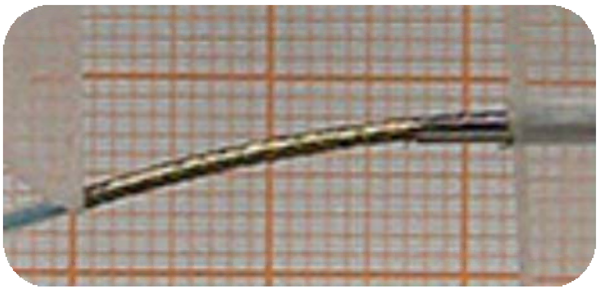

Fig. 10. Crimped stent during one-point bending test

It is very difficult to describe the stent geometry, therefore a flexible tube whose one end is gripped and the other free end is loaded with the point force simulates the stent [18], [19].

The flexibility $E{\cdot}I$ of the stent is determined by equation (1) which shows the relationship between the moment of inertia I, the Young modulus E, free bending length L, the bending deflection f and the point force F. It is based on the beam theory [3], [12].

$$E \cdot I = \frac{F \cdot L^3}{3 \cdot f} \quad (\text{Nmm}^2). \tag{1}$$

The flexibility of expanded stents was tested with two different methods. The first one was the one-point bending test described. The four-point bending test was applied in the second method [5].

Rods were attached to both ends of the stents prior to bending measurements (figure 11), thereby allowing the application of a constant moment to the specimen. The outer diameters of the rods were equal to the inner diameters of the stents. The rods were pushed into both stent ends and the stent was crimped and attached by a clip to the end of the rods. The attachment arrested the shift of the stent and rods Through contact with the punch on the rods, stent bending with constant moment and without radial deformation can be achieved. Bending stiffness of the rods is much higher than that of the stents, thus the deforming force only affects the stents.

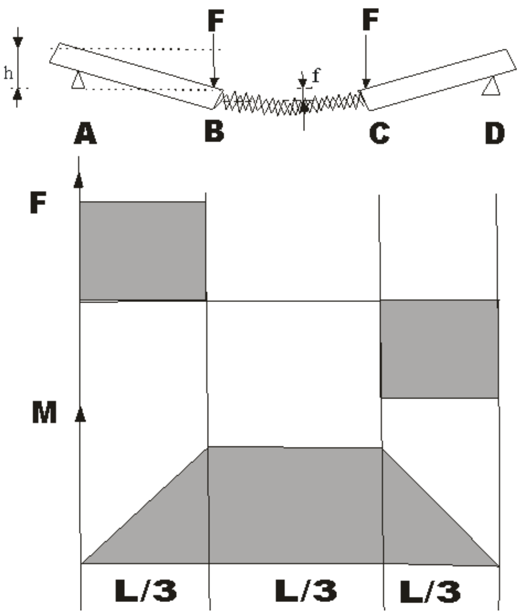

Fig. 11. Schematic of the bent specimen, force and moment distribution

The distance between the support points A and D is L where $L/3$ is the length of the stent tested. The displacements of the contact points of the punch B and C are defined as h, then the rods make an angle φ represented by the following equation:

$$\tan\varphi = \frac{h}{L/3}. \tag{2}$$

The constant moment $M_0 = F{\cdot}L/3$ is applied between the points B and C.

In this case, the deflection of the stent is equal to that of the supported beam, which makes an angle of φ at both ends of the beam under constant moment. Therefore the flexibility $E{\cdot}I$ is represented by:

$$E \cdot I = \frac{M_0 \cdot (L/3)^2}{8 \cdot f} \quad (\text{Nmm}^2). \tag{3}$$

It is difficult to measure the bending deflection f, therefore we apply equations (2) and (3) to arrive at the flexibility of the stent

$$E \cdot I = \frac{M_0 \cdot L/3}{2 \cdot \varphi} \quad (\text{Nmm}^2). \tag{4}$$

The value of h_{max} was 5 mm to avoid the stent damage [20].

2.4. Trackability

System's trackability tests were performed using an in vitro coronary vessel model (figure 12) with the following parameters:

AB = 20 mm, BC = 25 mm,
CD = 20 mm, DE = 55 mm,
EF = 35 mm, FG = 35 mm,
$\alpha_{BD} = \pi/2$, R_{BD} = 30 mm,
$\alpha_{EG} = \pi$ and R_{EG} = 15 mm.

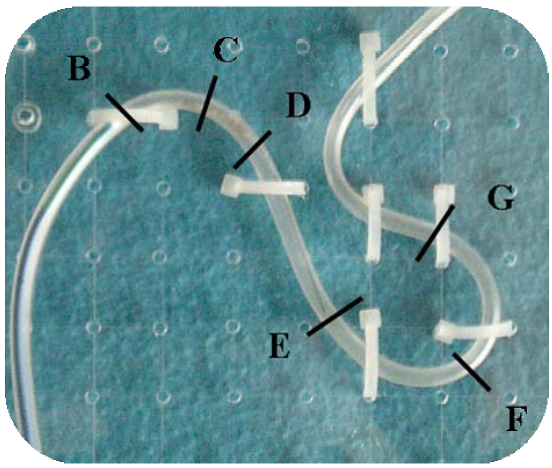

Fig. 12. Testing route for the measurement of trackability force

The maximum attainable distance BG covered 165 mm. The stent delivery systems were able to pass over the position *G*. At the start position the end of the guiding catheter and the tip of the delivery system were at the point *B*. Each stent and delivery systems were measured three times.

3. Results

3.1. Flexibility

Figure 13 shows the force measured versus deflection for three different rotational positions of gripped stent.

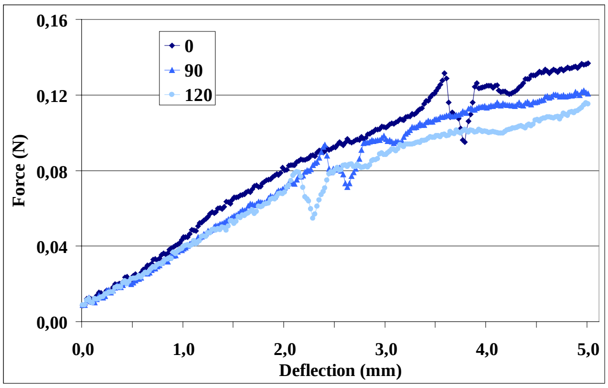

Fig. 13. The force versus deflection for three different rotational positions at 0°, 90° and 120°

According to the European standard EN14299:2004, the flexibility of crimped stents on the bending force of the delivery system was measured in a one-point delivery test presented graphically in figure 14. The length of stent and the deflection determined the angle α, and the force necessary to this deflection was detected.

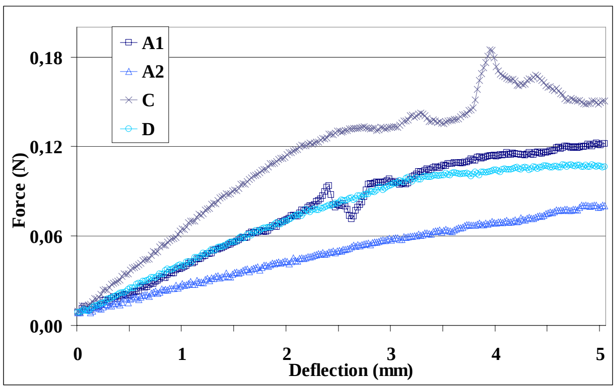

Fig. 14. Deflection–force curves in the determination of stent bending stiffness with one-point bending test

Figure 15 shows $E{\cdot}I$ calculated using equation (1) versus displacement in one-point bending test. The curves focus a discrete value, i.e. the flexibility of stent and delivery systems.

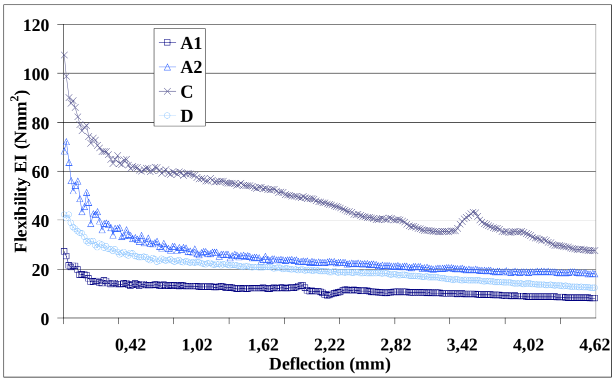

Fig. 15. The calculated $E{\cdot}I$ versus displacement in one-point bending test on crimped stents

The one-point bending test examines a measurable flexibility at the expanded stents as well. The bending force curves represent the deflection versus force in one-point bending test (figure 16).

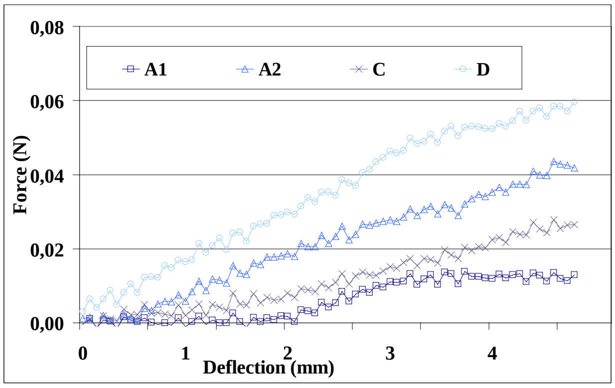

Fig. 16. Deflection–force curves in the determination of stent bending stiffness with one-point bending test

Figure 17 shows $E{\cdot}I$ calculated using equation (1) versus displacement in one-point bending test.

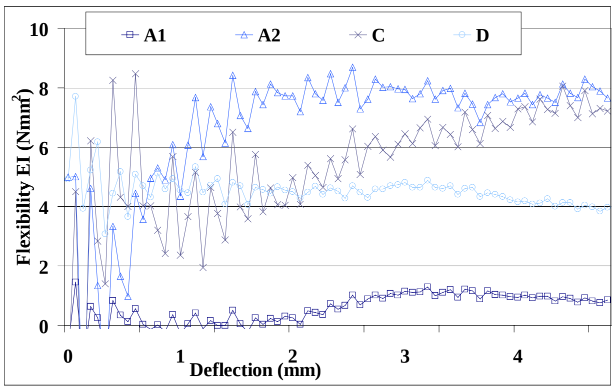

Fig. 17. $E{\cdot}I$ versus displacement in one-point bending test

In the case of bending moment, the curves representing the deflection versus force are shown in figure 18. The rises of curves are different in one- and four-point bending tests.

The curves focus a discrete value, i.e. the flexibility of stent.

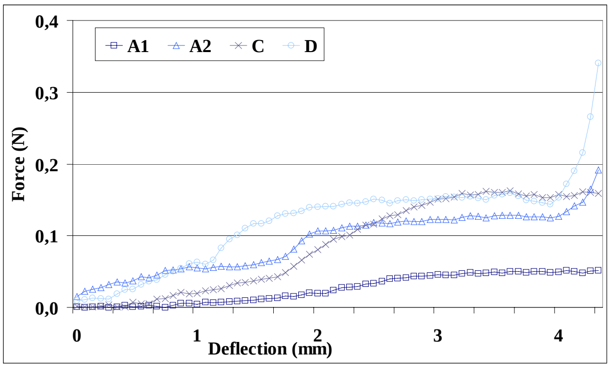

Fig. 18. Deflection–force curves in the determination of stent bending stiffness with four-point bending test

Figure 19 shows *E·I* calculated using equation (4) versus displacement in four-point bending test. The curves focus a discrete value, i.e. the flexibility of stent.

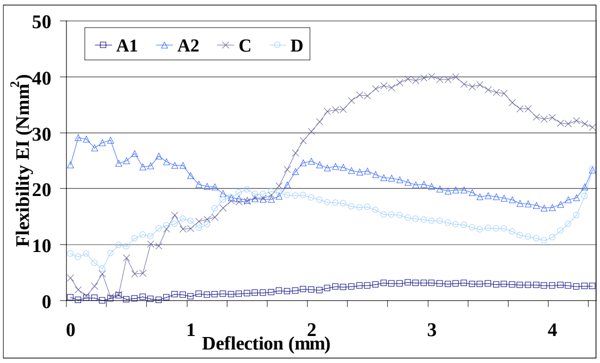

Fig. 19. *E·I* versus displacement in four-point bending test

The results of the two tests do not have the same numerical value, but the methods applied are effective for comparative examination of stents.

Table 2. Calculated *E·I* of the stents examined

Stent	Flexibility *E·I* (N·mm^2)		
	Crimped	One-point	Four-point
A_1	8.12	0.96	2.66
A_2	17.95	7.51	17.09
C	27.57	7.14	31.69
D	12.26	4.18	11.51

After the flexibility tests all stents were examined with stereomicroscopes and camera. In case of injuries or damage, the photographs are also taken, but in our examinations they did not occur.

Table 2 lists the calculated *E·I* of the stents in figures 15, 17, 19.

3.2. Trackability

All the stent and delivery systems examined passed the vessel model without damage and reproducible results in the force measurements were achieved. The force–distance curves based on the trackability tests are shown in figures 20 and 21.

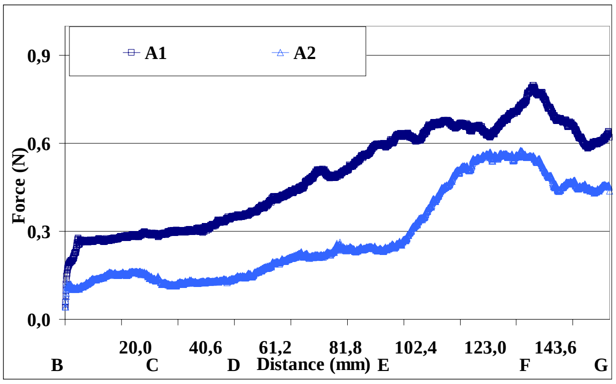

Fig. 20. The trackability forces of A_1 and A_2 stent systems in the vessel model

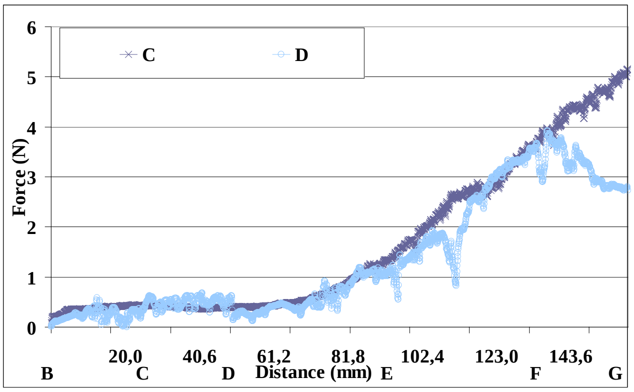

Fig. 21. The trackability forces of C and D stent systems in the vessel model

The short and long stents passed through the curved vessel model in different ways. The long stents nestled to the vessel wall at the outer arc and bent, while the short stents did not bend in the curve, only the delivery system bent.

After the trackability tests all stents were examined with stereomicroscopes and camera. Photographs were taken also if there were injuries or damage but there were not any.

4. Discussion

One of the most important features of stents is their flexibility. According to the European standard EN14299:2004, the flexibility has to be measured in crimped stent.

The rotational direction theoretically influences the measured bending stiffness of the stent [23], no effect of the rotational direction has been found when using the one-point bending test (figure 13). The stents used in the present study have different links in the circumferential direction, which may make the inhomogeneity of mechanical properties in the circumferential direction negligible, subsequently preventing the effect of the rotational direction on the measured bending stiffness.

The present study used one and four-point bending tests to investigate the stent flexibility. The four-point test apparatus produced uniform moment without radial deformation. The use of a stent in the treatment of vascular occlusion requires that the stent possesses specific mechanical properties.

The flexibility depends on numerous features, e.g. the type of raw material or the size of the stent. The main effect of the stent design is to drive a stent flexible or rigid. Figures 17 and 19 show that the stents made of two different raw materials have the same flexibility and some stents made of the same raw material have different flexibility [21].

The length of the stent influences its flexibility. Figure 14 shows the bending stiffness in the case of A_1 and A_2 stents. The conclusion is that the flexibility of a longer one is not sufficient [24].

In the present study, two different measurements were used to define numerically the stent flexibility. The flexibility could be described by $E{\cdot}I$ according to equations (1) and (3). The calculated $E{\cdot}I$ in the function of the displacement is charted in figures 15, 17, 19 and the data focus on the a value which describes the flexibility. These values are suitable for the comparison of the stent flexibility. The lower numerical result means higher flexibility. The one-point and the four-point bending tests did not give the same numerical values. The difference arises from the two methods applied. The four-point bending test allowed an uniform bending moment to the specimen while in the one-point bending test, the maximum moment acts on the fixed end, and the apparent bending stiffness is higher when the rigid cell region is placed at the fixed end.

All the stents and delivery systems under examination passed the vessel model without any damage and reproducible results in the force measurements were achieved. The short and long stents passed through the curved vessel model in different ways. The long stents nestled to the vessel wall at the outer arc and bent, while the short stents did not bend in the curve, only the delivery system bent. In this case, it was not the flexibility of short stents and delivery systems, but the rigidity of a short stent and the flexibility of its delivery system because only the delivery system was bent. The stents made of L-605 raw material need a lower tracking force to pass through the vessel model (figure 20) compared to those made of the 316L raw material (figure 21). Gathering the trackability parameters it can be stated that low tracking forces are necessary to reach the lesion to be treated. Some stents need on average 6 N force to be pushed through the EG curve. It is important for two reasons. The first one is that this force is close to an average dislodgement force [25] and other feature of stents. The second one is that a high force could cause mechanical injuries to the vessel wall and thromoembolism.

Acknowledgement

The authors wish to thank BUTE Department of Polymer Engineering. This work was supported by the Hungarian Research Fund, NKTH-OTKA K69122, OMFB-01321/2007, INNO-4-2008-0005.

References

[1] JULIO L., PALMAZ C., *Intravascular stents in the last and the next 10 years*, Journal of Endovascular Therapy, 2004, 11(2), 200–206.

[2] SCHMIDT W., BEHRENS P., SCHMITZ K.-P., *New aspects of in vitro testing of arterial stents based on the new European standard EN 14299*, http://www.iib-ev.de/pl/pdf/EN14299.pdf

[3] SCHMIDT W., GRABOW N., BEHRENS P., SCHMITZ K.P., *Measurements of mechanical properties of coronary stents according to the Eurpean standard prEN 12006-3*, Progress in Biomedical Research, 1999, 4(1), 47–53.

[4] PETRINI P., MIGLIAVACC F., AURICCHIO F., DUBINI G., *Numerical investigation of the intravascular coronary stent flexibility*, Journal of Biomechanics, 2004, 37, 495–501.

[5] MORI K., SAITO T., *Effects of stent structure on stent flexibility measurements*, Annals of Biomedical Engineering, 2005, 33, 733–742.

[6] *Yearbook of Health Statistics 2005*, KSH, Budapest, 2005.

[7] ALMAGOR Y., FELD S., KIEMENEIJ F., SERRUYS P.W., MORICE M.C., COLOMBO A., MACAYA C., GUMERMONPREZ J.L., MARCO J., ERBEL R., PENN I.M., BONAN R., LEON M.B., *First international new intravascular rigid-flex endovascular stent study (FINESS): clinical and angiographic result after elective and urgent stent implantation*, Interventional Cardiology, 1997, 30, 847–54.

[8] WHOLEY M.H., FINOL E.A., *Designing the ideal stent*, Endovascular today, 2007, 3, 25–34.
[9] *Handbook of Coronary Stents*, Martin Dunitz, London, 2002.
[10] STOECKEL D., BONSIGNORE C., DUDA S., *A survey of stent designs*, Minimal Invasive Therapy and Allied Technologies, 2002, 11(4), 137–147.
[11] RING Gy., BOGNÁR E., MAJOR L., MESZLÉNYI Gy., *Testing methods of coronary stents*, Gépészet, 2006, 57(11), 3–7.
[12] SCHMIDT W., BEHRENS P., WERNER D., GRAF B., *In vitro measurement of quality parameters of stent–catheter systems*, Biomedical Technik, 2005, 50, 1505–1506.
[13] http://www.certiga.com/en/flexibility.en.htm
[14] BALCON R., BEYAR R., CHIERCHIA S., De SCHEERDER I., HUGENHOLTZ P.G., KIEMENEIJ F., MEIER B., MEYER J., MONASSIER J.P., WIJNS W., *Recommendations on stent manufacture, implantation and utilization*, European Heart Journal, 1997, 18, 1536–1547.
[15] TANA L.B.,, WEBBB D.C., KORMIB K., AL-HASSANIC S.T.S., *A method for investigating the mechanical properties of intracoronary stents using finite element numerical simulation*, International Journal of Cardiology, 2001, 78, 51–67.
[16] OHYAMA T., NISHIDE T., IWATA H., TAKI W., *Development of gold stents for the treatment of intracranial aneurysms: an experimental study in a canine model*, American Journal of Neuroradiology, 2004, 25, 53–59.
[17] ARSLAN E., IGDIL M.C., YAZICI H., TAMERLER C., BERMEK H., TRABZON L., *Mechanical properties and biocompatibility of plasma nitrided laser-cut 316L cardiovascular stents*, Journal of Material Science: Materials in Medicine, 2008, 19, 2079–2086.
[18] WU W., YANG D.-Z., QI M., WANG W.-Q., *An FEA method to study flexibility of expanded coronary stents*, Journal of Materials Processing Technology, 2007, 184, 447–450.
[19] PETRINI L., MIGLIAVACC F., AURICCHIO F., DUBINI G., *Numerical investigation of the intravascular coronary stent flexibility*, Journal of Biomechanics, 2004, 37, 495–501.
[20] BÁLINT-PATAKI Zs., BOGNÁR E., RING Gy., SZABÓ B., GINSZTLER J., *Koszorúérsztentek vizsgálata*, Gép, 2006, 57 (11), 3–7.
[21] RING Gy., BOGNÁR E., DOBRÁNSZKY J., GINSZTLER J., MAJOR L., *Mechanical behaviors of coronary stents*, Advanced Search Technology, 2006, 49, 85–90.
[22] De BEULE M., MORTIER P., BELIS J., Van IMPE R., VERHEGGHE B., VERDONCK P., *Plasticity as a lifesaver in the design of cardiovascular stents*, Key Engineering Materials, 2007, 340–341, 841–846.
[23] SCHMIDT W., BEHRENS P., BEHREND D., SCHMITZ K.P., *Experimental study of peripheral, balloon–expandable stent systems*, Progress in Biomedical Research, 2001, 5, 246–255.
[24] DYET J.F., WATTS W.G., ETTLES D.F., NICHOLSON A.A., *Mechanical properties of metallic stents: how do these properties influence the choice of stent for specific lesions*? Cardiovascular Interventional Radiology, 2000, 23, 47–54.
[25] BOGNAR E., RING Gy., BALÁZS T., DOBRÁNSZKY J., *Investigation of drug eluting stent*, Material Science Forum, 2008, 589, 361–366.