COMPARISON THE FLEXIBILITY OF BALLOON-EXPANDABLE CORONARY STENTS

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ABSTRACT

Five balloon–expandable coronary stents were investigated and compared. We measured the flexural stiffness of stents.
The bending stiffness of a stent can be used as a proxy for stent flexibility. The comparison of the selected stents showed typical differences between the bending force at the same deflection. This means the stent geometry is the one important feature which determine the stent flexibility. The bending stiffness of open-cell stent was lower as compared to the closed-cell stent. That means they are more flexible which may be an advantage for application in tortuous vessel and vessel which could be loaded with bending moments.

KEYWORDS

coronary stent, flexibility, bending stiffness

1. Introduction

Balloon-expandable coronary artery stents were introduced for treatment in 1994. It has been increasingly used over the past several decades for non-invasive treatment of coronary artery stenosis.
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 [1].
According to the European standard EN14299, the flexibility means that the implant has sufficient flexibility to negotiate the vascular anatomy for which it is intended without compromising

the function of the implant or causing it to kink. Also determine the minimum radius of curvature that the implant can accommodate without kniking [2].

Balloon-expandable stents are dilated by 0.8-1 MPa pressure for the final form and pressed into the internal tissue of arteries. Some rigid stents need higher pressure it is means 1.8 MPa to achieve the final form but those stents proof against the elastic recoil of vasculature. To inflate the flexible stens are easily and they have great adaptability force to vasculature then a rigid stent but the flexible stens have smaller resistance against the pressure. In the other hand the flexibility is the one of the most important subjects to preventing the restenosis. The stent collapse incidence at the very flexible stents can achieve 5% of the implantation [3]. The flexibility of stents means two things. The first the balloon-stent system can get trough the tortuous vessel and the second the inflated stent how can adapted to the vessel wall. Several methods are exist for the determination of stents flexibility but not exist a standard method. 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. In case of the second group the testing system simulates the anatomic vascular conditions [4]. The third the finite elements method (FEM) has been widely used for the investigation of stents mechanics [5,6,7,8].

The first generations of stents were made of wire and those look was helical spiral or woven wire. The second generations of stent are produced by laser cutting from stainless steel tubes [9]. The majority of the stent geometries can be described by the structural elements as struts and connecting elements as bridges. The laser cutting stents have two categories. The open and the closed-cell form stents. The open cell category describes construction wherein some internal inflection points of the structural members are not connected by bridging elements [10].

2. Materials and Methods

In this study the flexibility of five different balloonexpandable coronary stents are investigated and compared.

Figure 1 shows the main properties of the examined stents.

The tested stents were examined with stereo microscopes and camera and photographs were taken to study the geometry and design of them (Figure 2-6).

Name	Material	Length [mm]	Diameter [mm]	Type of cells	Type of bridges
Express	316L laser cutting	18	2.5	Open	Straight peak-valley connection
Orbus R	316L laser cutting	15	3.0	Open	Straight peak-peak connection
Tecnic Carbostent	316L laser cutting	20	3.5	Closed	Curved midstrut-midstrut connection
Tentaur	316L Wire welded	20	4.5	Closed	Do not contain
Zeta	316L laser cutting	23	3.0	Open	Curved peak-valley connection

Figure 1 Important parameters of the examined stents

Figure 2 Express stent (18×2.5 mm)

Figure 3 Orbus R stent (15×3.0 mm)

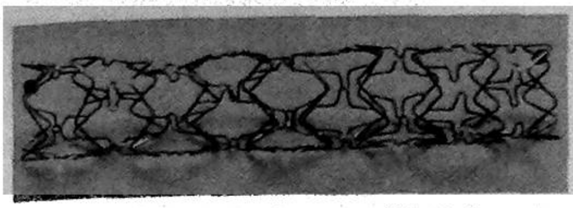

Figure 4 Tecnic Carbostent (20×3.5 mm)

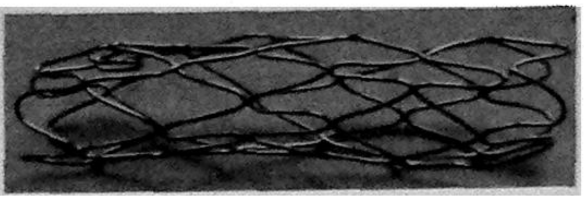

Figure 5 Tentaur TCS-20 stent (20×4.5 mm)

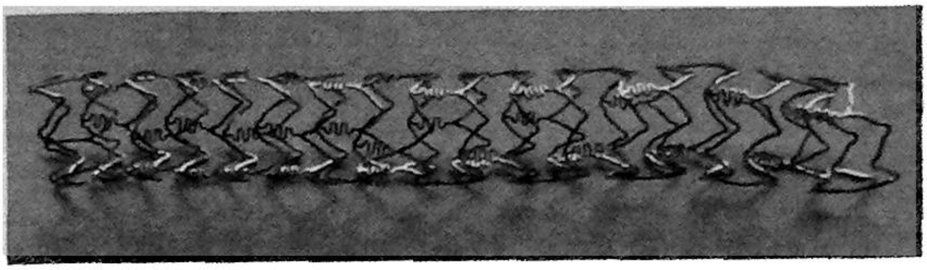

Figure 6 Zeta stent (23×3,0 mm)

To measure the flexibility of stents ZWICK 005 bending machine was used. The load cell is automatically detected the force [F] and the bending deflection [f]. One end of stent was griped and the other end was pressed by a plate which moved 10mm/minute (Figure 7). The fMax was 5 mm to avoid the stent damage. All stents were tested three times.

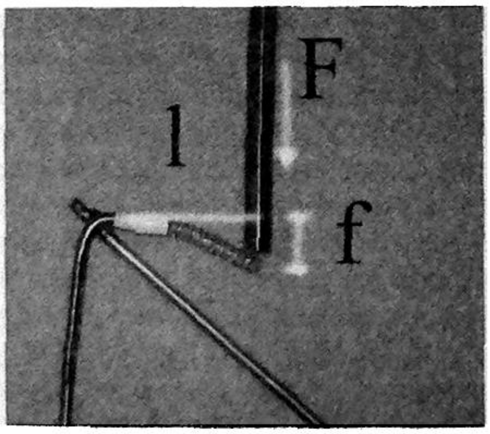

Figure 7 Tensile equipment griped stent

To describe the stent geometry is very difficult therefore the stent is simulated as a flexural tube which one end is griped and the other free end is loaded by the point force.

The flexural strength EI of the stent is determineted by Equal (1) which describes 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].

$$EI = \frac{Fl^3}{3f} \qquad [\mathrm{Nmm}^2] \ (1)$$

3. Results

The flexibility measurements of the five examined stents provided bending force curves presented graphically in Figure 8, the distance in function with force.

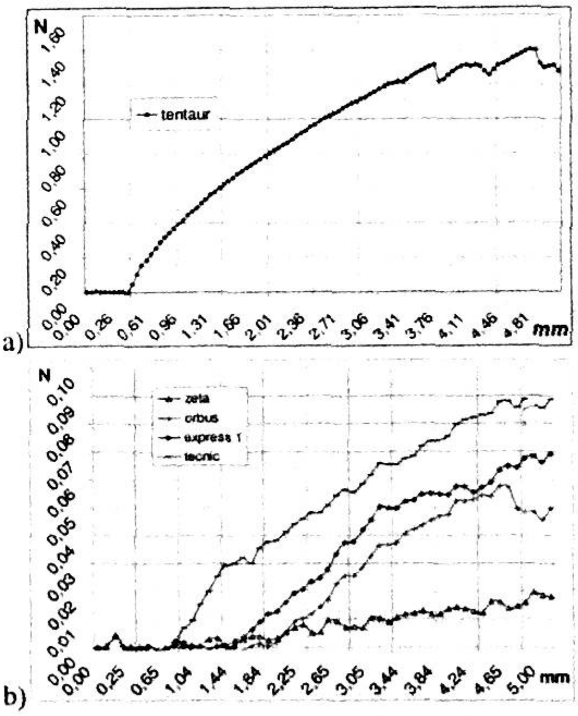

Figure 8 Bending force curves of the flexibility test for all stents a) Tentaur stent, b) Zeta, Orbus R, Express and Tecnis Carbostent

Tentaur stent was damaged during the experiment. As the detected forces show, the Tentaur stent is more rigid than the others. For the bending test, 20 times higher force needed in case of Tentaur stent.

Figure 9 shows the calculated EI by Eq. (1) and this value the flexibility of stents. The results of the total calculating are presented graphically in Figure 10. The material of stents are 316L stainless steel it is mean [E] the Young modulus is the same constant.

Name	F_1 [N]	F_2 [N]	F_3 [N]	f [mm]	I [mm	EI [Nmm^2]
Express	0.069	0.07	0.067	5	12.66	9.29
Orbus R	0.059	0.05	0.05	5	11.85	5.88
Tecnic carbostent	0.089	0.081	0.079	5	13.81	14.57
Tentaur	1.278	1.377	0.87 (3.7mm)	5	14.45	352.02
Zeta	0.02	0.026	0.019	5	18.23	8.75

Figure 9 The bending force and the calculated EI at 5mm deflection

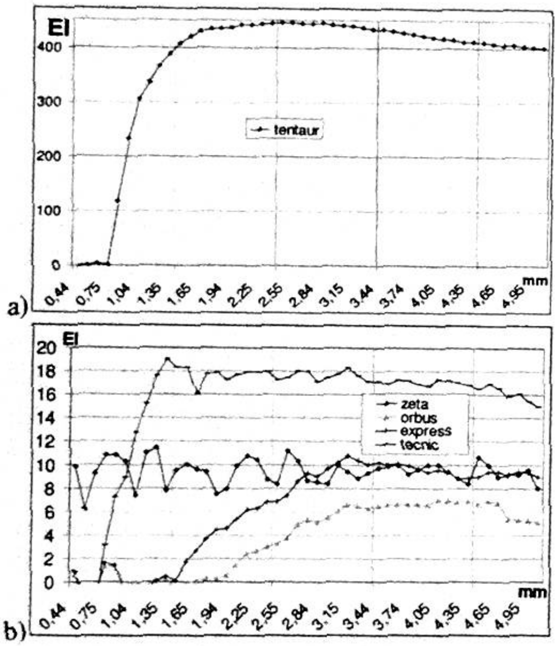

Figure 10 shows the EI value of different stents which can describe the flexibility of stents. The Orbus R stent was the most flexible stent. The flexibility of Express and Zeta stents can mark the same value.

4. Conclusions

The comparison of the selected stents showed typical differences between the bending force at the same deflection.

This means the stent geometry is the one important feature which determines the stent flexibility. The bending stiffness of open-cell stent was lower as compared to the closed-cell stent. That means they are more flexible which may be an advantage for application in tortuous vessel and vessel which could be loaded with bending moments. The Orbus R stenthas the fewest bridges between the tested open-cell stents and it was the most flexible stent. The higher cells and the less bridges allows higher flexibility for the stent but it allows too to kink easiest and it could leads to the higher incidence of in stent occlusion. Early clinical experience with the helically designed stents has also demonstrated excellent flexibility and kink resistance. The helical design allows uniform cell size at flexion points without scaling [10].

The desired features of coronary stents would include scaffolding that is adequate enough to control plaque prolapse but has acceptable levels of flexibility conformability and control recoil.

The type of lesions are different there are ulcerated calcareous and soft fatty. The different types of lesions need different types of stents. This is why need the rigid and the flexible stent. The operator has a big responsibility to choose the correct stent which is respond to the lesion.

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