

TRACKABILITY MEASUREMENT OF CORONARY STENT IN A CORONARY VESSEL MODELL

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Abstract: The EN 14299 standard describes in vitro tests of stent and stent system which are specified more precisely and cover a number of additional parameters. In this paper examination of bare metal coronary stents are shown, such as the trackability force measurement. The measurement of the system's trackability was performed using an in vitro coronary vessel model with the method worked out by us. The trackability is a very important property of the stent system.

Keywords: bare metal coronary stent, tracking force, trackability

1 INTRODUCTION

The illnesses of the cardiovascular system are among the most frequent diseases of the adult population in Hungary. The atherosclerosis and the kickback of the occlusions of the arteries are the main causes of death or stroke especially in the middle-age men population. In 1994 the Food and Drug Administration approved the balloon-expandable coronary stent for the prevention of restenosis.

A vascular stent is a surgically implanted endovascular prosthetic device which acts to scaffold a blood vessel permanently open and compress any lesions protruding into the vessel lumen. The operation of implantation of coronary stent is utilizing catheter balloon to place and deploy the stent where the plaque exists in the vascular lumen, which prevents recoil of the atherosclerotic vessel wall or protrusion of plaques or dissected intimal flaps into vascular lumen and thereby prevails as a new typical treatment method for the coronary heart disease. During the implantation, at first the balloon catheter and the stent are mounted onto is inserted to the place where the plaque of artery exists. Then, stent is expanded by the pressurized catheter balloon to a predetermined diameter. Finally, the balloon is deflated and taken out and stent is leaved there supporting the wall of the artery to alleviate the blockage of arteries due to plaque, so blood can flow properly.

The ideal stent possesses a low profile, good flexibility and good trackability to navigate tortuous vessels, adequate radiopacity, low recoil, sufficient radial strength, a low metal surface area, high scaffolding ability, etc [1].

According to the EN14299:2004 trackability in general means that to determine the ability of the delivery system to advance over a guidewire, following the guidewire tip, along the path of the vessel, including in narrow and tortuous vessels. The elements of the simulated anatomy that the delivery system had difficulty negotiating shall be evaluated. The trackability test of stents includes profile effect or flaring and dislodgement force too [2].

Several methods exist for the determination of stents trackability but no standard method exists [3]. To describe the process of tracking need the pushing force. This force

depends on the stent surface treatment, the friction between the stent and the vessel wall, the deviation of the stents rings, etc [4,5,6].

The majority of the trackability test methods are used an anatomic vessel model [1,4].

2 MATERIALS AND METHODS

The measurement of the system's trackability was performed using an in vitro coronary vessel model (Figure 1). The parameters of the model were $AB=20$ mm, $BC=25$ mm, $CD=20$ mm, $DE=65$ mm, $EF=35$ mm, $FG=40$ mm, $\alpha_{BD}=\pi/2$, $R_{BD}=30$ mm, $\alpha_{EG}=\pi$, $R_{EG}=15$ mm.

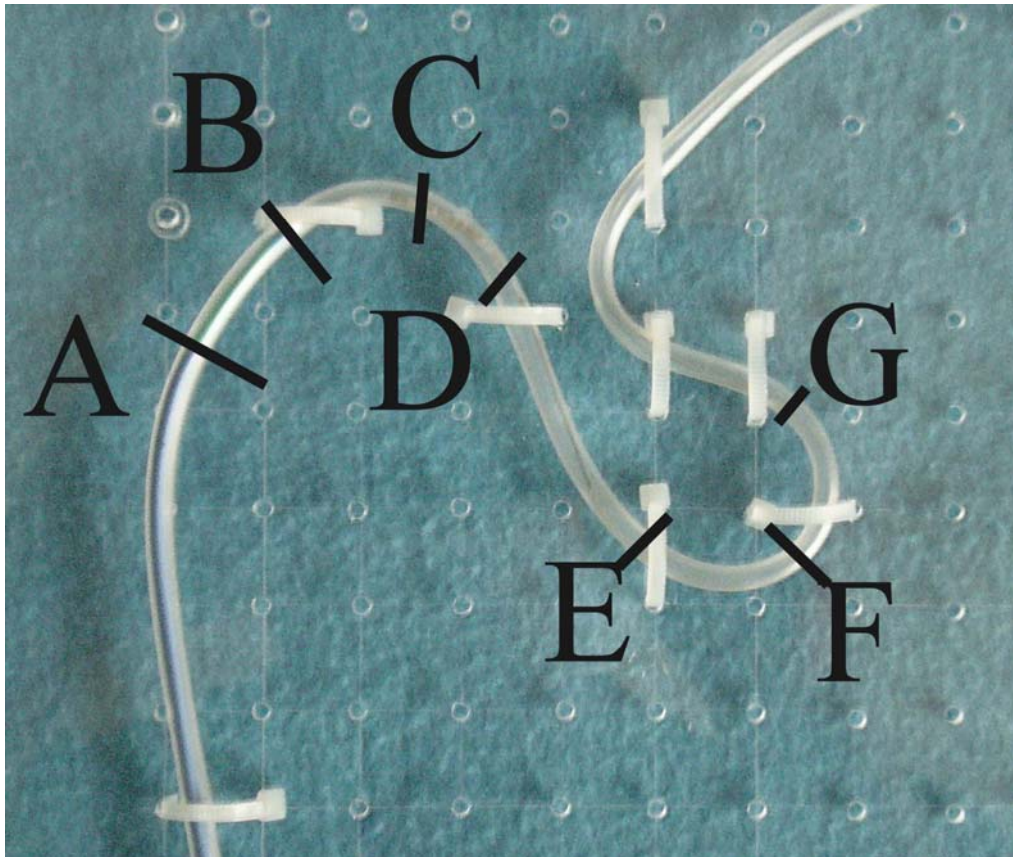


Fig. 1 Testing route for the measurement of trackability force

The model was prepared by using soft vinyl chloride tube 3.0 mm in diameter. A 6F (1.8 mm) guiding catheter (Launcher, Medtronic AVE) was connected to the vascular model. A 0.36 mm guidewire (Balance, Guidant) was inserted into the guiding catheter and the vascular model. A stent delivery system (Maverick 15/2.5) with a crimped stent (13 mm length Sanocor stent) was fixed to the ZWICK 005 equipment. 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. The maximum attainment distance was 220 mm. The stent delivery system was able to go over position G in Figure 1. At the start position the end of the guiding catheter was at the point A, the tip of the delivery system was at the point B.

The delivery system was tested in a linear tube also. Three different delivery systems were tested in the guiding catheter for comparison the force which needs to move forward.

The tested stents were examined with stereo microscopes and camera and photographs were taken to study the damage of them, the delivery system and stents avoided the damages.

3 RESULTS

The minimal tracking force is the force which needs to move forward the delivery system in the guiding catheter. Fig. 2 shows the force in function of the displacement. A constant force had to move forward a delivery system in the guiding catheter it was 0.4-0.8 N.

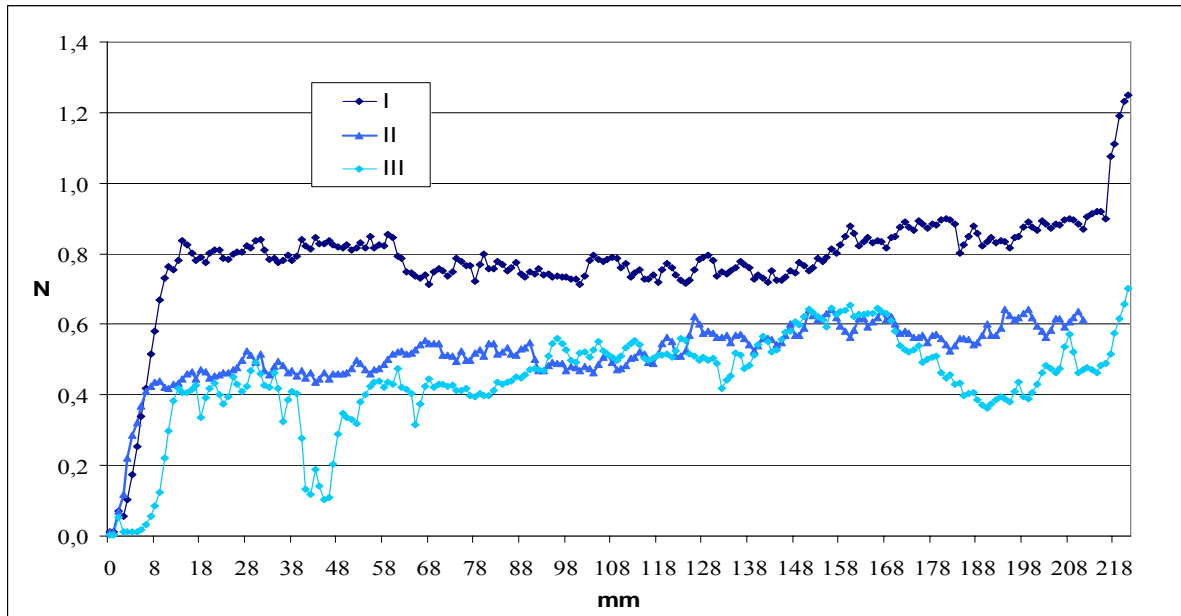


Fig. 2 Force–displacement curves of three different delivery system (I,II,III) in the guiding catheter

The trackability measurement of the examined stent system (Maverick 15/2.5) provided trackable force curves as shown in Figure 3, the distance in function with force.

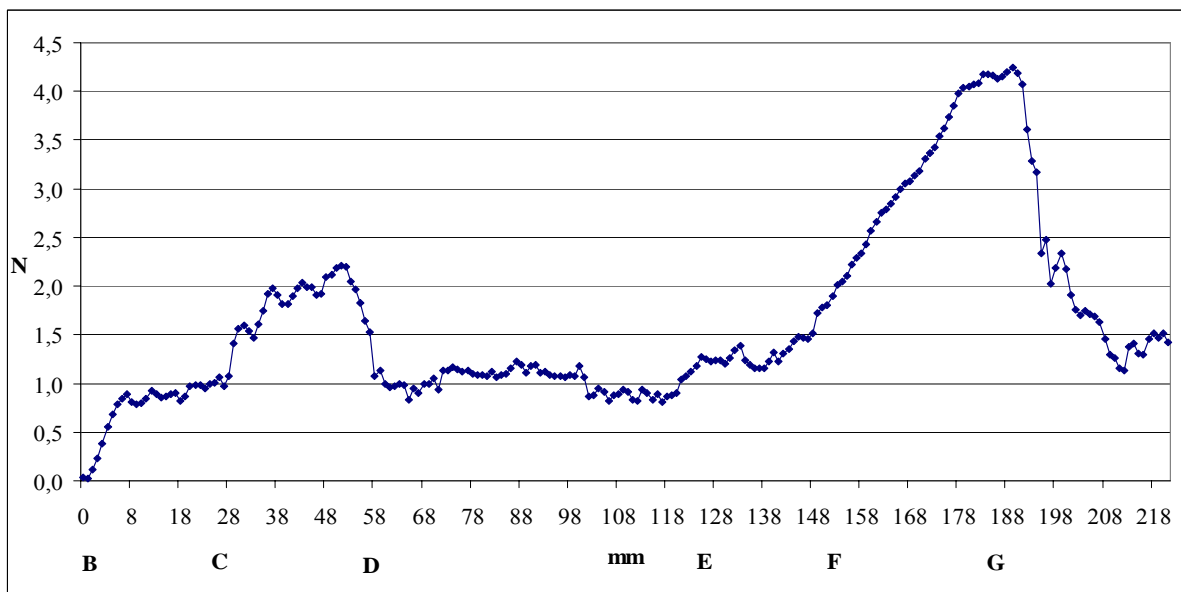


Fig. 3 Tracking force curve of the track test

The trackability measurement of Maverick delivery system and Sanocor stent provided tracking force curves in the guiding catheter the linear tube and the coronary vessel model as shown in Figure 4 the force in function of the displacement.

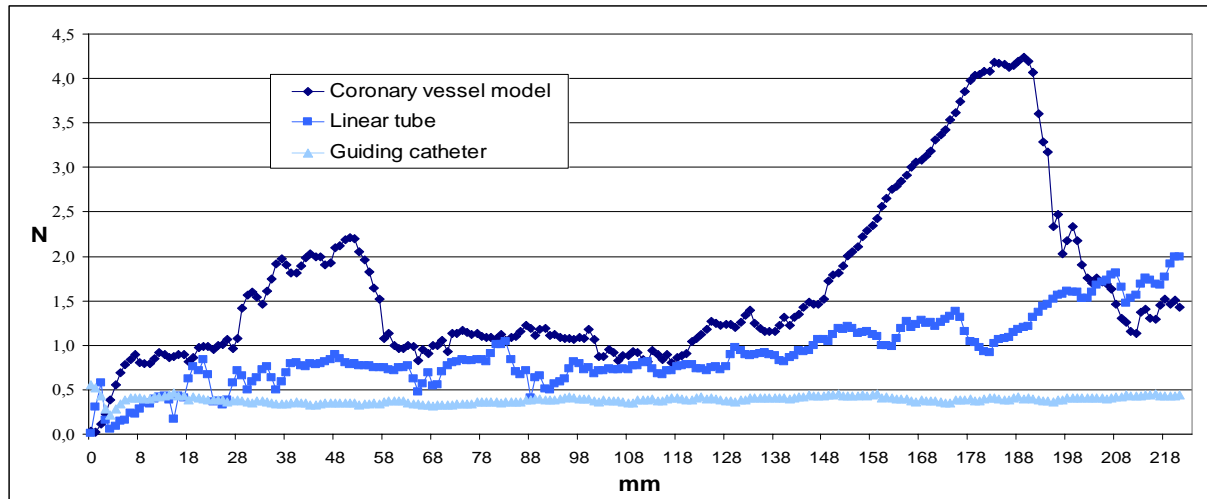


Fig. 4 Tracking force curves of the Maverick delivery system

4 CONCLUDING REMARKS

The aim of the present study was to measure the tracking forces in different condition and separate the guiding catheter and tube effect.

By the characteristic of tracking force curves was suggested that the friction in the system is permanent because to move forward the delivery system in the guiding had to be a constant force. In the linear tube was detected a smoothly growing force and it was suggested that the smoothly growing friction caused it.

In the vessel model was detected double peaks of tracking force curves and that corresponded of the curves of the model. The peaks of the curves suggested that in the curves was higher friction then the linear section. That means there was higher the compressive force.

The dissection of data could shown if the stent delivery system cause any injury during the tracking method or not.

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