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A Pilot Study for Evaluating the Longitudinal Strength and Flexibility of Coronary Stents : Results of a Bench Test

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ABSTRACT

Aim : Longitudinal stent deformation (LSD) in second-generation stent platforms has been recently reported. Because LSD is becoming a stent selection factor, we performed an in vitro bench test to understand the mechanism and relationship between LSD and stent flexibility.

Methods and Results : Two tests were conducted using three different second-generation drug-eluting stents (DESs) : PROMUS Element, Xience Prime and Resolute Integrity. Test 1 : Stents in a malapposed vessel model were compressed with 0.5 N and 1.0 N using a force machine, and the degree of stent deformation was evaluated. Test 2 : Stents were placed at 10 degrees in a U-tube vessel model, and the angle change before and after stent deployment was evaluated.

Only the PROMUS Element showed some degree of LSD with 0.5 N, and all three stents showed some degree of LSD with 1.0 N. The degree of LSD was smallest with the Resolute Integrity stent, and the degree of angle change was 30°, 46° and 56° for the PROMUS Element, Xience Prime and Resolute Integrity stents, respectively.

Conclusions : This pilot study showed a relationship between stent longitudinal strength and flexibility. It is necessary to understand the features of each stent platform and use them to select the appropriate stent depending on various lesion characteristics.

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Key words : Coronary stent, bench test, stent longitudinal strength, stent flexibility

INTRODUCTION

Second-generation DESs have enabled physicians to treat more challenging coronary lesions and vessel anatomies by improving deliverability and flexibility. However, the issue of longitudinal stent deformation has recently arisen[1-7]. Mamas analyzed the MAUDE database and reported that the incidence of stent deformation increased after 2010, when thinner second-generation stents were introduced in the market[8]. In particular, PROMUS Element stents have more incidence reports compared to the other stent type. Therefore, the stent platform may be a cause of stent deformation. In addition, we thought that there may be a relationship between the stent platform flexibility and stent deformation, because second-generation stents are much thinner and more flexible than first-generation stents. Therefore, we conducted longitudinal strength and flexibility tests in vitro using second-generation DESs to understand the mechanism and relationship between LSD and stent flexibility.

MATERIALS AND METHODS

To understand the relationship between stent flexibili-

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ty and stent deformation, three DES types were tested : 1) Pt-Cr EES : PROMUS Element ; Boston Scientific ; Natick, MA, USA ; 2) Co-Cr EES : Xience Prime ; Abbott Vascular, Santa Clara, CA, USA ; and 3) R-ZES ; Resolute Integrity ; Medtronic Santa Rosa, CA, USA. Two types of tests were conducted.

Test 1

Three DES type stents were placed in a taper vessel silicone model, with a proximal inner diameter of 5 mm and distal diameter of 3 mm, at a nominal pressure. Balloon inflation was repeated 3 times (Fig. 1-A). Stenosis was induced at the distal part of the vessel model, such that the

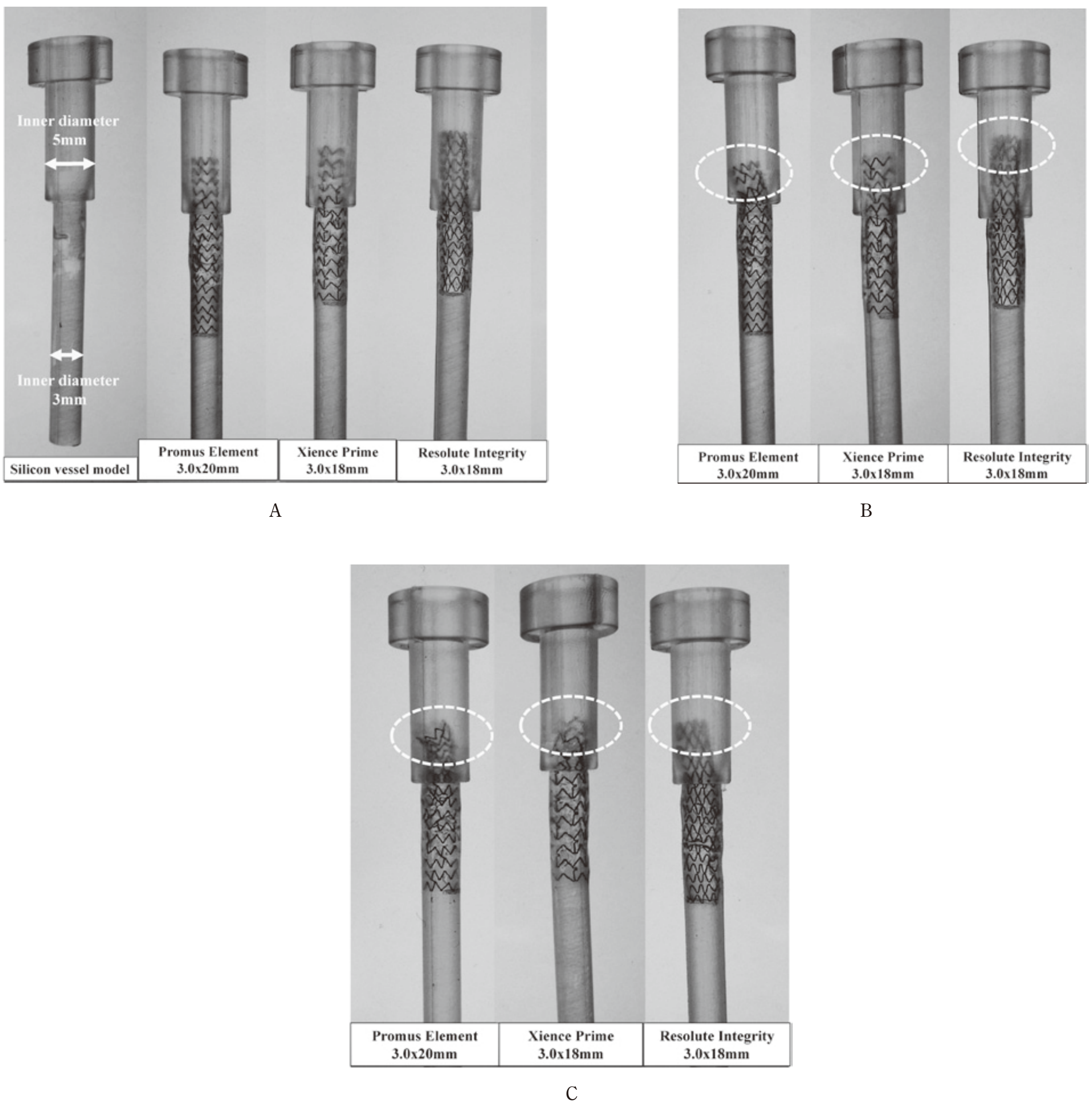

Fig. 1-A. Nominal pressure was applied three times to stents (3 mm in diameter) using balloon inflation in a taper vessel silicone model, with a proximal inner diameter of 5 mm and distal diameter of 3 mm. There was stenosis at the distal site to avoid slipping. A ; PROMUS element, B : Resolute Integrity, C : Xience prime

Fig. 1-B. Results of the compression test at 0.5 N. Only the PROMUS Element stent showed some degree of LSD.

Fig. 1-C. Results of the compression test at 1.0 N. All three stents showed LSD. The degree of LSD was smallest with the Resolute Integrity stent.

stent would not slip because the distal end of the model is unfixed. Six stents were compressed from above with a force of 0.5 N (three stents for 0.5 N) and 1.0 N (three stents for 1.0 N) (Finet showed that the force for ballooning is usually 0.1 to 1.0 N[1]) using a force machine (Chatillon LTCM-6), and the degree of stent deformation was evaluated.

Test 2

Three stents were placed at 10 degrees in a U-tube vessel silicone model at a nominal pressure, and the change in the angle before and after stent placement was evaluated.

The sample size of the present study was small, and thus our ability to perform a quantitative and statistical analysis was impeded. Because, this is a pilot study to evaluate stent longitudinal strength and flexibility.

Results

Test 1

Deformation was confirmed in the PROMUS Element stent after a 0.5 N force was applied (Fig. 1-B). All stents showed some degree of deformation after the 1.0 N force was applied. The extent of deformation was smallest with the Resolute Integrity stent (Fig. 1-C).

Test 2

The PROMUS Element stent showed the smallest change in the vessel angle. The angle of the PROMUS Element stent changed to 30 degrees, while that of the Xience Prime and Resolute Integrity stents changed to about 50 degrees (Fig. 2).

Discussion

DES placement dramatically reduces the incidence of early In Stent Restenosis (ISR) by potently inhibiting in-stent neointimal hyperplasia, which may occur after coronary stent implantation, and subsequently expanded the scope of DES indications[9-12]. On the other hand, the use of DES has generated new medical issues, such as the need for long-term dual antiplatelet therapy, incomplete stent apposition, stent edge restenosis, late ISR, stent fracture and endothelial dysfunction[13]. Recently, the following issues related to the stent platform have been found : incomplete stent apposition, LSD and stent fracture.

There have been several reported clinical observations of longitudinal stent deformation cases where second-generation stent platforms were used, and LSD is now becoming a stent selection factor. To understand the mechanism of the LSD phenomenon, we performed in vitro longitudinal strength and flexibility tests. According to our results, the

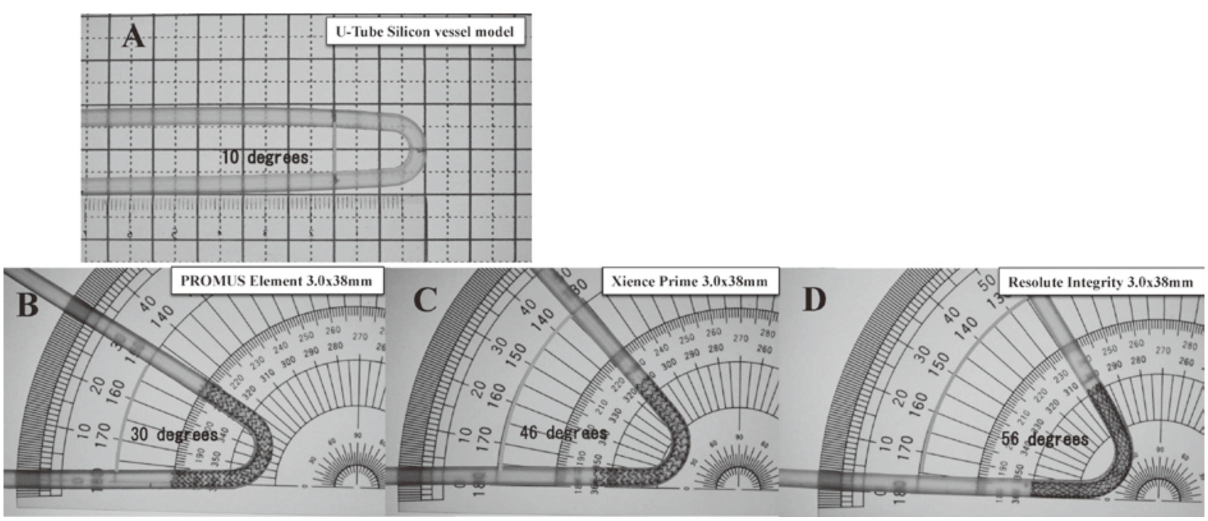

Fig. 2-A. Stents (3 mm in diameter) were placed at a 10-degree angle in a U-tube vessel model at nominal pressure, and balloon inflation was performed three times.
Fig. 2-B. Results for the PROMUS Element stent : the change in the angle was 30 degrees.
Fig. 2-C. Results for the Xience Prime stent : the change in the angle was 46 degrees.
Fig. 2-D. Results for the Resolute Integrity stent : the change in the angle was 56 degrees.

degree of stent deformation differs for each stent platform. Thus, it is important to know the differences among these stent platforms

The major components of stent platforms are generally recognized to be the stent material, strut thickness and stent design. Regarding the stent material, the PROMUS Element stent is made from platinum chromium, which has superior radiopacity ; however, the other characteristics are recognized to be equivalent to those of cobalt chromium, the material used in Xience Prime and Resolute Integrity stent[14]. The strut thickness is thinnest with the Element and Xience Prime stents (0.081 mm), although this is nearly equivalent to that of Resolute Integrity stent (0.091 mm). As a result, the main factor of the stent design that is thought to be different is the longitudinal strength.

These platforms have different stent designs for how the crown is connected. When the peak of each crown is facing the others, as in Resolute Integrity stents, the longitudinal force does not easily change the stent platform. However, when the peak to peak of the crown is offset, as in PROMUS Element stents, it is easier to apply the force to the stent. On the other hand, our tests also showed that PROMUS Element stents exhibit greater flexibility compared to the other stents. Briefly, these findings indicate a trade-off relationship between longitudinal strength and flexibility.

Stent fracture is also an important issue related to the stent platform, even in the current DES generation era. According to a recent report, the incidence of stent fracture is relatively low, but once this complication occurs, it becomes a strong predictor of major adverse cardiac events[15,16]. Ormiston et al. reported the results of a bench test on the degree of stent fracture resistance associated with current generation DESs and showed superior results for the PROMUS Element and Resolute Integrity stents compared to the Xience prime and Biomatrix stents[17]. This means that fracture resistance is strongly related to stent flexibility, and, for this reason, PROMUS Element stents are generally recommended for bending lesions. However, bending lesions are also recognized to be a predictor of stent deformation, because the guide wire is likely to touch the stent strut and as a result, secondary device delivery may deform the stent[8].

In a clinical setting, we refer to several factors regarding the stent platform, such as deliverability, flexibility, radial strength and ease of side branch access. Cardiologists should select the most appropriate stent for the patient after considering all of these factors, depending on the geometry and features of the lesions.

Study Limitations

This is a pilot study to evaluate stent longitudinal strength and flexibility. The sample size of the present study was small, and thus our ability to perform a quantitative and statistical analysis was impeded.

Conclusions

The results of the current two experiments showed that there is a relationship between stent longitudinal strength and flexibility. It is necessary to understand the features of each stent platform and use them to select the appropriate stent, depending on various lesion characteristics.

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