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Original article

Impact of post-dilatation on longitudinal stent elongation: An in vitro study

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ABSTRACT

Objectives: To evaluate whether balloon inflation for post-dilatation causes longitudinal stent deformation (LSD).

Methods and results: Two stents, sized 2.5 mm × 28 mm and 3.5 mm × 28 mm (Nobori®, biodegradable polymer biolimus-eluting stent; Ultimaster®, biodegradable polymer sirolimus-eluting stent; Terumo Co., Tokyo, Japan), were deployed at nominal pressure in straight and tapered silicon vessel models. Then, post-dilatation was performed in two ways: dilatation from the distal (D-P group) or proximal (P-D group) side of the stent. Microscopic findings showed that the stents were elongated during every step of the procedure regardless of the post-dilatation method and type of vessel model. The D-P group showed linear elongation during each step of post-dilatation (straight model: 28.7 ± 0.3 mm vs. 29.9 ± 0.3 mm, $p = 0.002$; tapered model: 28.0 ± 0.1 mm vs. 29.9 ± 0.1 mm, $p < 0.001$). In contrast, in the P-D group, the most significant change was observed in the first step of post-dilatation and only slight changes were observed thereafter (straight model: 28.6 ± 0.1 mm vs. 29.5 ± 0.1 mm, $p < 0.001$; tapered model: 28.2 ± 0.1 mm vs. 29.5 ± 0.1 mm, $p < 0.001$). Optical frequency domain imaging analysis showed that the frequency of stent strut malapposition was positively correlated with the percentage change in stent length ($r = 0.74$, $p < 0.0001$).

Conclusion: LSD was observed during every step of post-dilatation in both the straight and tapered vessel models. However, some differences were observed between the D-P and P-D groups. Minimizing stent strut malapposition may reduce the risk of LSD.

Introduction

Recent bench tests and clinical observations have shown the occurrence of longitudinal stent deformation (LSD) with the use of the thin-strut stent platform [1–4]. Although LSD is an infrequent complication of percutaneous coronary intervention (PCI), small changes in stent length have been recognized as a common complication in routine clinical PCI [2]. Even small changes in stent length can cause severe problems, especially in stents used for the treatment of ostial or bifurcation lesions. New-generation coronary stents have been designed with improved flexibility, deliverability, and conformability to the vessel wall; however, these improvements come at the cost of longitudinal strength [3]. Therefore, the recent changes in stent design may have increased the incidence of LSD during PCI.

Direct force exerted by pushing and/or pulling of the stent struts together during the delivery of other devices, such as post-dilatation balloon, guide catheter extension system, distal embolic protection device, and intravascular ultrasound catheter, is considered an important cause of LSD [4]. However, under-expansion of the implanted stent is an important factor underlying target-lesion failure [5]. Therefore, post-dilatation of the implanted stent is often performed in clinical settings for optimized functioning [6], usually from the distal to the proximal side of the stent. The post-dilatation balloon is dilated in the radial axial direction and simultaneously elongated in the longitudinal

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axial direction. We hypothesized that implanted coronary stents may become elongated as the post-dilatation balloons expand in the longitudinal axis.

Thus far, few studies have attempted to evaluate the influence of post-dilatation of implanted stents and practical methods of post-dilatation on LSD. Thus, the aim of the present study was to examine the effects of post-dilatation on LSD and to determine how post-dilatation after stent implantation affects this complication.

Methods

Experimental models

In the present study, two types of silicon vessel models (Shonankasei Co., Kanagawa, Japan)—straight and tapered—were used (Fig. 1). The silicon model had a hardness of 5 points based on measurement with a type A durometer. Each silicon model had a stenosis lesion (lesion length, 20 mm), and both edges of the lesions were marked with red lines for confirmation. Biodegradable polymer biolimus-eluting stents (BP-BES) (Nobori®; Terumo Co., Tokyo, Japan) and biodegradable polymer sirolimus-eluting stents (BP-SES) (Ultimaster®; Terumo Co.) were used for the experiments. First, the stents were deployed to adjust the distal marker of the lesion and the distal edge of the stent. Each stent was deployed at a nominal pressure for 20 s. In this in vitro model, 2.5 mm × 28 mm sized stents were deployed in a straight fashion and 3.5 mm × 28 mm sized stents were deployed in a tapered fashion, depending on the vessel model size. Then, we performed post-dilatation by using two methods: dilatation from the distal (D-P group) or proximal (P-D group) site of the stent (Fig. 2A,B). We planned the method of post-dilatation to resemble the actual clinical procedure. As a result, the number of post-dilatations was different between the D-P and P-D groups.

(i) Distal–proximal group

In this group, post-dilatation was performed from the distal to proximal direction of the deployed stents. First, post-dilatation was performed at the proximal marker of the lesion immediately after stent deployment; second, post-dilatation was conducted at the proximal edge of the stent; then, the balloon size was increased, and a third post-dilatation was performed at the proximal edge of the stent.

(ii) Proximal–distal group

In this group, post-dilatation was performed from the proximal to distal direction. First, post-dilatation was performed at the proximal edge of the stent. Then, the balloon size was decreased, and a second post-dilatation was performed in the middle of the stent.

We used 2.5 mm × 15 mm and 2.75 mm × 12 mm post-dilatation balloons (Hiryu®; Terumo Co.) for the straight model. For the tapered model, we used 3.5 mm × 15 mm and 4.0 mm × 12 mm post-dilatation balloons (Hiryu®). Every step of post-dilatation was performed at 20 atm for 20 s. We performed the same experimental procedure three times for each stent.

Microscopy and optical frequency domain imaging

We used a microscope (SKM-S30B-PC; SaitohKougaku, Yokohama, Japan) to accurately calculate the stent length and check for stent deformation. Optical frequency domain imaging (OFDI) (Terumo Co.) was used to check for stent deformation and malapposition during each step of the procedure (pullback speed, 20 mm/s). Stent apposition was assessed at the cross-sectional level with an interval of 0.5 mm. We measured the distance between the stent surface reflection and the surface of the neighboring visible vessel model; if this distance exceeded the nominal stent strut thickness, the stent strut was considered malapposed (BP-BES: >130 μm; BP-SES: >80 μm) [7]. We calculated the percentages of malapposed stent struts within the site to be dilated in the next step of the procedure. Then, we examined the relationship between the percentage of malapposed struts and the percentage change in stent length during post-dilatation.

Statistical analysis

The distribution of continuous variables was examined using the Shapiro–Wilk test. Paired Student's *t*-test was used to compare the stent length before and after stent post-dilatation during each step of the procedure. Student's *t*-test was used to compare the differences in the percentage change of stent length during post-dilatation between the D-P and P-D groups. Linear regression and Pearson's correlation statistics were used to examine the correlation between the percentage change of stent length and the frequency of stent malapposition. All analyses were performed

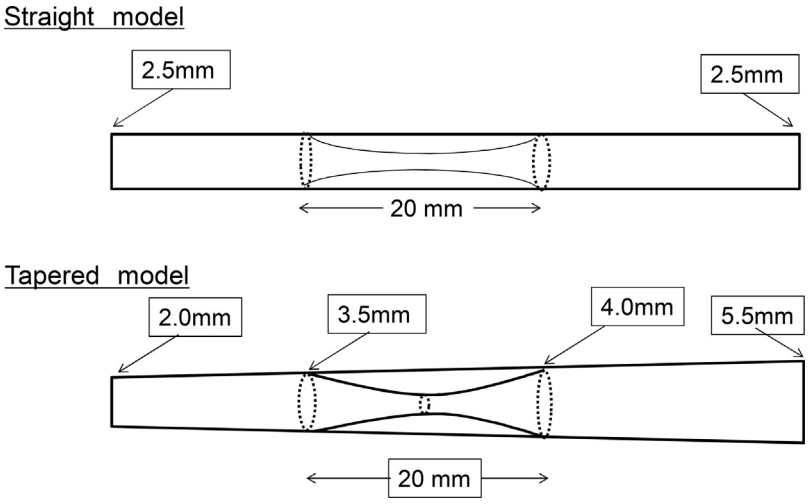

Fig. 1. Characteristics of the silicon vessel models used in this study. Straight (lumen diameter, 2.5 mm) and tapered (lumen diameter, 2.0–5.5 mm) vessel models were used. These models have a 20-mm stenosis lesion. The material of the silicon model reflects the actual vessel frictional resistance and hardness.

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