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A Pilot Study for a Bench Test of the Mechanical Properties of the Platforms for Second-generation Drug-eluting Stents

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ABSTRACT

Little information is available regarding the mechanical properties of platforms for second-generation drug-eluting stents (DESs). These mechanical properties must be considered when selecting a coronary stent for treating a target lesion. Four DES platforms, i.e., the Driver™ stent, the Liberte™ stent, the Multilink Vision™ stent, and the S-Stent™, were used to assess deformability (radial strength) in the air compression test, conformability (radius of curvature) in the radius of curvature measurement, and flexibility (load induced deflection) in the 3-point bending test. Radial strength was measured in the pressure range of 0 to 1 kg/cm^2, where the Liberte™ and the Multilink Vision™ stents constantly showed slight decreases. In contrast, the Driver™ stent exhibited little, moderate, and marked decreases in radial strength as pressure increased in 3 stages. However, the S-Stent™ exhibited marked decreases in radial strength at all pressures. Furthermore, reductions in the radius of curvature and deflection were least with the Driver™ stent and were followed, in order of greater reduction, by those of the Liberte™stent, the Multilink Vision™ stent, and the S-Stent™. This preliminary bench test was challenging to perform but has provided basic information on the physical properties of 4 coronary stents and basic mechanical information for selecting the optimal stent for each patient. Further mechanical bench tests using new measurement instruments are required to examine how the information of each stent properties are reflected in clinical outcomes. (Jikeikai Med J 2014 ; 61 : 29-34)

Key words : coronary stent, bench test, mechanical property, deformability, conformability, flexibility

INTRODUCTION

First-generation bare-metal stents (BMSs), which were developed in the early 1990s, were expected to reduce the incidence of early in-stent restenosis (ISR) after percutaneous transluminal coronary intervention (PCI) by inhibiting vessel recoil to a greater extent than could balloon catheters. Although BMSs of various designs were developed, the rate of early ISR remained as high as 20% to 40% in patients who were at high risk for ischemic heart disease[1]. Therefore, first-generation BMSs could not overcome the problem of early ISR.

Drug-eluting stents (DESs), which are the current mainstream devices for PCI, have reduced the rate of early ISR by inhibiting neointimal hyperplasia associated with vascular healing after PCI through the continuing local release of an antiproliferative drug from the DES platform. As a result, DESs have expanded indications for PCI, and DESs and have been used to treat complex lesions, such as bifurcation, small vessels, bend lesions, and calcified le-

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sions. Accordingly, DESs have replaced BMSs for PCI in 70% to 80% of patients[2]. This tendency has accelerated after the introduction of second-generation DESs.

Previous randomized controlled trials have indicated that second-generation DESs have significantly better safety and efficacy profiles than first-generation DESs[3,4]. However, for interventional cardiologists who perform PCI, little information is available on 3 essential mechanical properties of coronary stents : deformability, conformability, and flexibility as assessed by radial strength, radius of curvature, and deflection, respectively.

Unfortunately, no instruments to measure these mechanical properties are widely used. New methods of assessment should be developed. Therefore, the present study was a pilot study for developing new methods of assessing the mechanical properties of deformability, conformability and flexibility of DES platforms.

MATERIALS AND METHODS

The following BMSs were used as DES platforms : a cobalt-alloy, 0.091-mm-thick strut stent of open-cell design and modular type (open-modular type) (Driver™ : platform of Endeavor™ stents ; Cardiac and Vascular Group, Medtronic, Inc., Santa Rosa, CA, USA) ; a L-605 cobalt-chromium alloy, 0.081-mm-thick strut stent of open-cell design and tube type (open-tube type) (Multilink Vision™ : platform of Xience™ V stents ; Abbott Vascular, Santa Clara, CA, USA) ; a 316L stainless steel, 0.097-mm-thick strut stent of closed-cell design and tube type (closed-tube type) (Liberte : platform of Taxus Liberte™ stents ; Boston Scientific, Natick, MA, USA) ; and a 316L stainless steel, 0.12-mm-thick strut stent of open-cell design and tube type (open-tube type) (S-Stent™ : platform of Nobori™ stents ; Terumo, Tokyo, Japan). The dimensions of the BMSs used were a diameter of 3.5 mm and a length of 14 to 16 mm (Table 1).

Bench test

The bench test of each stent was performed once to examine the 3 mechanical properties of deformability, conformability, and flexibility.

Deformability (radial strength) in the air compression test

A silicon tube (inside diameter, 2.0 mm ; thickness, 0.2 mm ; and length, 20 mm) was set in a metal hermetic chamber where the tube was in direct contact with open air, and the stent delivery system was inserted into the midpoint of the stent where the nominal pressure specific to the stent was applied for 30 seconds to dilate the stent. The interior of the chamber was pressurized for 30 seconds from 0.1 to 1.0 kg/cm^2 atm, and a laser device was used to measure the outer diameter of the tube. A schematic diagram of the chamber is shown in Figure 1-A.

Conformability (radius of curvature)

The stent delivery system was inserted into the midpoint of a soft tube containing the test stent that was curved with a radius of 12.5 mm, and the stent was then dilated at its nominal pressure for 30 seconds. Subsequently, the delivery system was slowly removed to measure the radius of the stent curvature with an image processor (Digital Microscope VH-200 ; Keyence, Osaka, Japan) in Figure 1-B.

Flexibility (load-induced deflection) in the 3-point bending test

The stent delivery system was inserted into the interior of a soft tube with a distance between supporting points

Table 1. Characteristics of the 4 drug-eluting stent platforms : the Driver™, the Liberte™, Multilink Vision™, and S-Stent™ stents

DES platform	Length (mm)	Diameter (mm)	Strut thickness (mm)	Material	Cell design	Stent Type
Driver™ (n=1)	15	3.5	0.091	Cobalt alloy	Open cell	Modular
Liberte™ (n=1)	16	3.5	0.097	316L stainless steel	Closed cell	Tube
Multilink Vision™ (n=1)	15	3.5	0.081	Cobalt alloy	Open cell	Tube
S-Stent™ (n=1)	14	3.5	0.12	316L stainless steel	Open cell	Tube

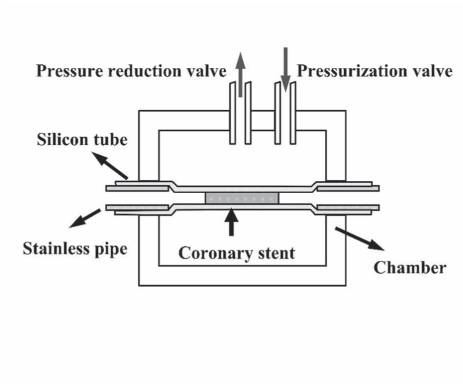

Fig. 1-A

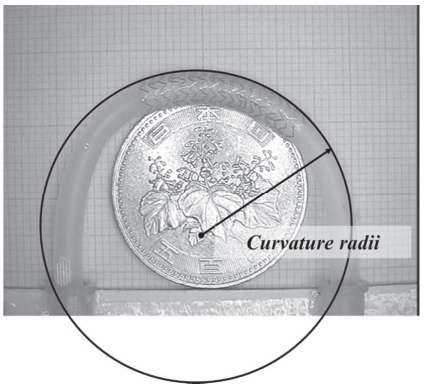

Fig. 1-B

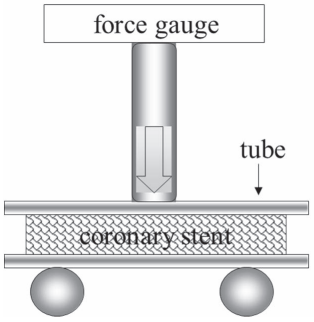

Fig. 1-C

Fig. 1-A. Schematic diagram of the hermetic chamber used in the air compression test
Fig. 1-B. Curvature radii of the stents inflated in curved tubes were measured along with the curve of a Japanese 500-yen coin.
Fig. 1-C. Force readings were measured with the 3-point bend method.

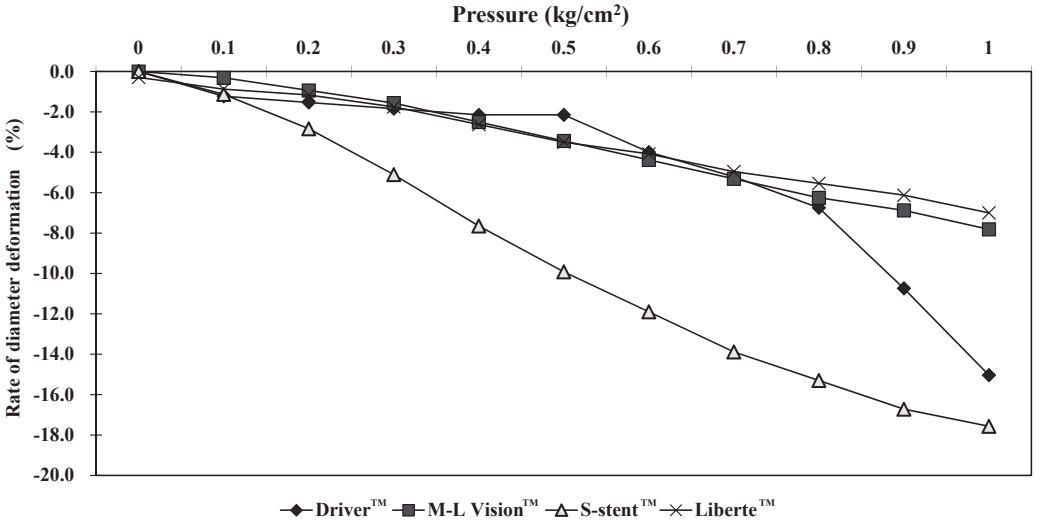

Fig. 2. The deformability profile as determined by radial strength of the Drive™, Liberte™, Multilink (M-L) Vision™, and S-Stent™ stents in the air compression test.

of 25 mm, and a strength gauge (Force Analyzer EXPLORE 2 ; Aiko Engineering, Osaka, Japan) was used to measure the value that was obtained when the tip of the pressure bar of the strength gauge was depressed by 2 mm. The schematic diagram of the 3-point bending test is shown in Figure 1-C.

Results

Deformability (radial strength)

The Driver™ stent showed little decrease in radial strength up to a pressure of 0.5 kg/cm^2 but showed moderate and marked decreases at pressures of 0.5 to 0.8 kg/cm^2 and 0.9 to 1 kg/cm^2, respectively. In contrast, the Multilink Vision™ and Liberte™ stents showed constant moderate decreases in radial strength at pressures of 0.1 to 1 kg/cm^2 (Fig. 2). The S-Stent™ stent showed consistent and marked decreases in radial strength at pressures of 0.1 to 1 kg/cm^2. Therefore, only the Driver™ stent showed an obvious inflection point at 0.8 kg/cm^2. Only the S-Stent™ stent showed large deformations from the early stage of incremental pressurization but, in contrast, did not show further deformation at pressures greater than 0.8 kg/cm^2.

Conformability (radius of curvature) and flexibility (load-induced deflection)

The Driver™ stent (open-modular type) showed greater conformability than did the 3 tube-type stents (Fig. 3). Furthermore, the Liberte™ stent (closed-tube type) showed slightly greater conformability than did the Multilink Vision™ stent (open-tube type) or the S-Stent™ stent (open-tube type). On the other hand, with regard to flexibility, comparable results were observed among stents (Fig. 4).

DISCUSSION

The use of DESs has markedly reduced the incidence of early ISR by potently inhibiting in-stent neointimal hyperplasia and has expanded the indications for DESs[5-8]. On the other hand, DESs have led to new concerns, such as the need for long-term dual antiplatelet therapy, incomplete stent apposition, stent-edge restenosis, late ISR, stent fracture, and endothelial dysfunction[9]. Specifically, one of these would be issue related to the stent platforms : incomplete stent apposition and stent fracture. The characteristics of each DES can be obtained from its package insert. In general, better deformability is obtained with the

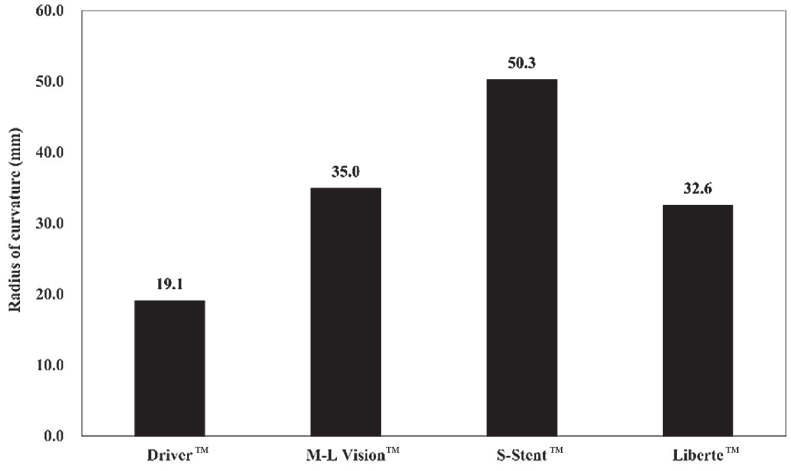

Fig. 3. The conformability profile as determined by the curvature of radius of the Driver™, Liberte™, Multilink (M-L) Vision™, and the S-Stent™ stents in the curvature of radius measurement.

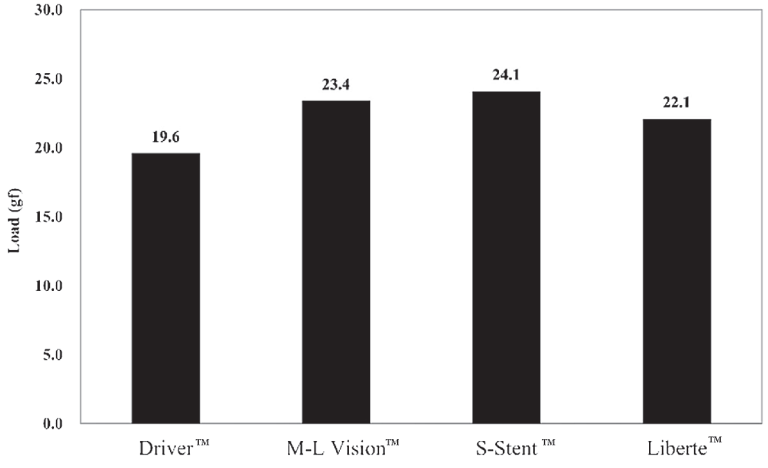

Fig. 4. The flexibility profile as determined by the load to the Driver™, Liberte™, Multilink (M-L) Vision™, and S-Stent™ stents in the 3-point bending test.

coronary stent of closed-cell design and tube type than with those of open-cell design and modular type. However, because no previous study has, to our knowledge, examined and compared 3 mechanical properties of several stents in clinical use, we were motivated to perform the present study.

In the present study, the Liberte™ stent (closed-tube type), showed less reduction in radial strength than did the both stents of Driver™ and S-Stent stent™, regardless of stent strut thickness. However, the Multilink Vision™ stent (open-tube type) showed similar deformability. In contrast, the S-Stent stent™ (open-tube type) showed large deformation from the early stage of incremental pressurization. These results suggest that factors other than stent design, such as stent material, number of links, and strut thickness, are responsible for differences in share stress[10].

Generally, better conformability and flexibility are obtained from open-cell stents than from closed-cell stents. In the present study, the Driver™ stent (open-modular type) showed greater conformability than the 3 tube-type stents. Furthermore, the Liberte™ stent (closed-tube type) showed slightly greater conformability than did the Multilink Vision™ stent (open-tube type) or the S-Stent™ stent (open-tube type). We believe these results can be attributed to the Multilink Vision™ stent (open-tube type) and the S-Stent™ stent (open-tube type) sharing comparable strut configurations, such as the "slotting" manufacturing process, which produces equivalent numbers and areas of structural links. Although strut thickness, stent material, and stent design had some effect on the conformability of the stents tested, these results suggest that a stent's "type" (modular or tube) has a greater effect on conformability than does its "design" (open or closed cell). On the other hand, we found no significant difference in flexibility among the stents tested. Our findings suggest that conformability does not necessarily correlate with flexibility.

Several studies have examined the relationship between the mechanical properties of the stent platform and clinical outcome. Whereas Kastrati et al have reported that thin-strut stents are associated with a significant reduction in coronary artery restenosis[11], Gyongyosi et al. have reported that the longitudinal straightening effect of coronary artery stents contributes significantly to the occurrence of major adverse cardiac events[12]. Additionally, Kuramitsu et al. have reported that the fracture of everolimus-eluting stents and biolimus-eluting stents appears to be associated with the need for target lesion revascularization due to symptom recurrence[13,14]. These findings suggest that to achieve better outcomes, a better understanding of the mechanical properties of second-generation DES platforms is necessary. Nonetheless, recent randomized controlled trials have found no significant difference in long-term outcomes among second-generation DESs.

Our study indicates the importance of selecting a coronary stent with a better-balanced mechanical profile to allow for successful implantation in the target lesion.

Study Limitations

The sample size of the present study was small and prevented us from performing any statistical analysis. The study was not repeated, longitudinal deformation of the struts was not examined, and longitudinal data on the 3 mechanical properties of the test stents were not obtained.

Conclusions

The present study was a challenging but preliminary bench test that has provided basic information on 3 physical properties (deformability, conformability, and flexibility) of 4 coronary stents and has provided basic mechanical information for the selection of an optimal stent for each patient. We hope that this study has emphasized the necessity of developing new instruments for evaluating the physical properties of stents.

Authors have no conflict of interest.

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