Development of Test Methods for Mechanical Property Evaluation of Balloon-Expandable CoCr Alloy Stent

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Abstract
The present study aims to establish comprehensive test methods to evaluate the mechanical properties of the intravascular coronary stent with a closed cell design. We focused on three important mechanical properties required to the stent, bending flexibility, radial strength, and longitudinal strength. Test apparatuses and testing procedures were then developed for precise evaluation of those properties. It was found that the developed test apparatuses and testing methods successfully evaluated the mechanical properties of the stent. The results revealed that the mechanical properties were strongly influenced by the structure of the stent, that is, combination of the cell strut and the link strut.

Key words
Balloon Expandable Stent, Mechanical Property, Testing Method, Bending Flexibility, Radial Strength, Longitudinal Strength

1. Introduction
Intravascular stent is a small medical device that is often used to treat a stenosed coronary artery to restore and keep blood flow, since 1990s. The design of stent continues to be developed to improve required functions, not only to hold the artery open but also to reach the stenosed area safely through blood vessels. In general, the stent consists of two components, as shown in Fig. 1. One is tubular-like ring called cell strut, the other is bridging member called link strut. The former mainly works to hold the blood vessel open, and the latter works to keep connection of the neighboring cell struts. Fig. 2 shows stenting procedure of the balloon-expandable stent with a closed cell design. The stent is mounted on the balloon catheter by crimping, and is delivered to the stenosis area through the artery and then is expanded to open the stenosed blood vessel.

Because the performance of stent is exerted by elastic and plastic deformations, the proper evaluation of its mechanical properties is essentially important. Many studies concerning mechanical properties of stent have been performed numerically by means of finite element analysis [1-3]. Regarding only the bending flexibility, three-point bending test method is standardized by American Society for Testing and Materials (ASTM) [4]. Mori [5] also reported the bending flexibility of stent by four-point bending test, in which bending moment became constant. Meanwhile, only a small number of studies have been reported on the radial and longitudinal strengths evaluation. Voûte et al. [6] suggested a special technique to use film loops along the stent body. Recently, Ormiston et al. [7] performed compression and elongation tests to evaluate the longitudinal strength of stent, by means of a commercial testing machine. However, standard methods have still not been established for the evaluation of radial and longitudinal strengths.

The final goal of the present study is to establish the universal test methods of mechanical properties of stents, for contribution to facilitate the improvement of the stent design. We focused on three important mechanical properties of the stent, bending flexibility, radial strength, and longitudinal strength. The bending flexibility is important to follow the curved blood vessel without excessive stressing, the radial strength works to support the stenosed blood vessel, and the longitudinal strength is necessary to prevent longitudinal deformation of the stent that may predispose to restenosis and stent thrombosis.
original test apparatuses were designed and fabricated for evaluations of those properties. The adaptability of the apparatuses to the precise evaluation of the mechanical properties of intravascular stent was then discussed.

2. Test Apparatuses and Experimental Methods

2.1 Specimen
The cobalt-chromium (CoCr) alloy balloon-expandable stent with a closed cell design manufactured by Japan Stent Technology Co., Ltd., was used as specimens throughout this study. Two conditions of stents shown in Fig. 3 were prepared, as manufactured one with smaller diameter \( D \approx 1.5 \) mm and expanded one with larger diameter \( D \approx 3.0 \) mm. The longitudinal nominal length of the stent was \( l \approx 17 \) mm, while the thickness of struts was \( t \approx 70 \) \( \mu \)m.

2.2 Three-point bending test for evaluation of bending flexibility
Three-point bending is a simple method to evaluate bending characteristics of the stent, as be defined in ASTM standards [4]. As far as authors know, testing system for three-point bending of stent is commercially available only by Instron Co. Ltd., as a combination of specially ordered attachments with a universal testing machine, which is still not easy to obtain. Fig. 4 shows the three-point bending apparatus designed and fabricated in the present study. The stent is set on two gently inclined brass plates to ensure the contact with two cylindrical supports. Those plates are fixed on a motorized \( x \)-axis stage (Chuo Precision Industrial, ALS-6012) having a precise feed resolution of 1 \( \mu \)m. In the opposite side, the indenter with the radius of curvature of 1.5 mm is directly attached to the loadcell. The loadcell with the rated capacity of 100 mN and the nonlinearity of within \( \pm 0.5 \) mN (Kyowa Electronic Instruments, LVS-10GA) is attached on a \( z \)-axis stage, which enable movement of the indenter to adjust various stent diameters. The three-point bending of the stent is then performed by feeding the stent together with cylindrical supports by using \( x \)-axis stage. One advantage of this apparatus is that it can be placed directly under a microscope that makes possible the in-situ observation of the stent deformation.

Since the load required to bend the stent is quite low, special attentions are paid to ensure accurate measurement of the bending load. The direct attachment of the indenter to the sensing part of the loadcell is effective to avoid the error caused by friction between components. In addition, the indenter should be light in weight enough to avoid damage to the loadcell, so that the indenter is made of aluminum alloy and designed to be small enough.

Besides, the slight displacement of the sensing part of the loadcell appears with loading. This displacement is principally necessary for the load sensing but it should be subtracted from the measured displacement for accurate evaluation of the load-displacement relation of the stent. The relation between the displacement of the sensing part and the load was then measured in advance, by using a rigid metal bar of known elastic modulus instead of the stent. All the tests were repeated three times under the same conditions to assess reliability of results.

In the three-point bending test, the bending moment \( M \) is given by

\[
M = \frac{PL}{4}
\]

where \( P \) is the applied load measured by the loadcell and \( L \) is the support span that is set to 10 mm. On the other hand, the index of curvature \( \rho \) is calculated by

\[
\frac{1}{\rho} = \frac{12\delta}{L^2}
\]

where \( \delta \) is the deflection of the center of stent. The bending flexibility of the stent \( F_b \) was then calculated by
2.3 Lateral local compression test for evaluation of radial strength

In order to evaluate the radial strength of the stent, the lateral local compression test was employed because the stenosis is generally not uniform. Another advantage of this test is that it can be performed by using the three-point bending apparatus with slight modifications and thus the precise load-displacement relation can be guaranteed. Fig. 5 shows set up for the lateral local compression test, mounted on the three-point bending test apparatus. The flat rigid die shown in Fig. 5(a) is set instead of two support cylinders. The stent is then fed toward the indenter that is directly attached on the loadcell, as shown in Fig. 5(b). The indentation load $P_i$ was measured by the loadcell with the rated capacity of 2 N (Kyowa Electronic Instruments, LVS-200GA). The normalized radial strength $F_{r_i}$ was then calculated by

$$F_{r_i} = \frac{P_i D}{\delta_i}$$

where $\delta_i$ is the indentation displacement after subtracting the displacement of the sensing part of the loadcell from the measured value.

2.4 Uniaxial tension test for evaluation of longitudinal strength

Until recently, it has been considered that the important mechanical properties of intravascular stent are the bending flexibility and the radial strength. However, the problem arose in terms of the longitudinal deformation of stent, which induced damage to the blood vessel after the stenting procedure [7]. Therefore, the longitudinal strength of the stent was also investigated in this study. Only the expanded stent was subjected to the tensile testing, because the longitudinal deformation of the stent often occurred after the stent was expanded in the stenosed area. The uniaxial tensile apparatus of the stent was designed as schematically shown in Fig. 6(a). Since the stent was not suitable for crimping, it was fixed at both ends to the rigid metal pipes by using stainless steel pins, as be shown in Fig. 6(b). The tensile displacement was given by a motorized stage (Chuo Precision Industrial, ALZ-4012) having a precise feed resolution of 1 μm. The loadcell with the rated capacity of 5 N (Kyowa Electronic Instruments, LTS-500GA), was directly attached to the z-axis stage. The displacement of the sensing part of the loadcell and the deflection of the pins at loading were subjected from the feed of the stage, in order to obtain the net tensile displacement of the stent.

3. Results and Discussions

3.1 Bending flexibility

Fig. 7(a) shows the load-deflection curves of the stents obtained by three-point bending tests. It was found that the load increment for the deflection of the expanded stent is larger than that of the as manufactured one, because of its larger diameter. From those load-deflection relations, the bending flexibility $F_b$ of the stents was calculated by Eq. (3). The variation of bending flexibility with the bending moment is depicted in Fig. 7(b). The bending flexibility of the expanded stent ($D \approx 3.0$ mm) was about three-times larger than that of the as manufactured one ($D \approx 1.5$ mm). Assuming pipes with wall thickness of 70 μm (same with the stent) instead of the stents, the ratio of the bending flexibility, namely flexural rigidity calculated by the product of Young’s modulus and the second moment of inertia, of the pipe with 3.0 mm diameter to that with 1.5 mm diameter becomes about 8.6. This fact indicates that the difference between the bending flexibilities of the stents of as manufactured and expanded conditions is not only by the
difference in diameter but also by the structural characteristics of the stent. It was also found that the bending flexibility of the stent slightly decreased with the progress of deformation. This property is supposed to be preferable to the application to prevent damage of blood vessel, even when the stenosed area is on the bustle blood vessel.

Fig. 7(c) shows the micrograph of the stent deformation in the vicinity of the contact area. Although the indenter contacts to cell struts of the stent, the collapse of the cell strut scarcely occurs and only the link struts deform. This characteristic is quite important to ensure the blood flow in the stenosed area, because the bending scarcely influences on the task of the cell struts that is keep the stenosed blood vessel open.

### 3.2 Radial strength

Indentation load-indentation displacement relations obtained by the lateral local compression test of the as manufactured and expanded stents are shown in Fig. 8(a). Although the indentation load increases with the indentation displacement, the load increment slightly decreases with the progress of indentation. The load increment of the as manufactured stent is larger than that of the expanded stent, due to its smaller diameter. However, when the indentation displacement is normalized by the initial diameter, expressed as the normalized radial strengths calculated by Eq. (4), the load increments of both stents coincide as seen in Fig. 8(b). This result implies the dependency of the radial strength on the stent diameter.

It was also found that the normalized radial strength slightly meandered with the progress of indentation. The in-situ observation of the stent deformation in the vicinity of the contact area (Fig. 8(c)) revealed that the meandering was related to the number of cell struts contacting with the indenter. The indenter first contacts to one cell strut. The indenter then starts to contact to the neighboring cell struts;
at that instant, the load increment tends to be large again. However, the cell strut contacting with the indenter gradually rotates along the curvature of the indenter and then the link struts start to deform instead. This fact is supposed as the reason of decreasing the normalized radial strength with the progress of the indentation.

3.3 Longitudinal strength
The tensile load-tensile elongation relation and the variation of load increment obtained by the uniaxial tension test were shown in Fig. 9(a). The variation of the tensile load can be divided into three stages. In stage I, the load rapidly increases mainly due to elastic deformation of the link struts. In stage II, the plastic deformation of the link struts becomes dominant. The S-shaped link strut gradually straightened, and that shape change induces gradual decrease of the load increment. At the beginning of stage III, the link struts are almost fully opened and then the longitudinal deformation of the cell strut begins, so the load increment turns to be large again. The deformed shape of the stent in Fig. 9(b) shows fully opened link struts and slight deformation of the cell struts. Those results imply that the longitudinal strength of the stent is governed in principle by the deformation ratio of the link and cell struts.

4. Conclusions
In the present study, the test methods for an intravascular stent to evaluate mechanical properties were investigated. The apparatuses for three-point bending test, lateral local compression test, and uniaxial tensile test were designed and fabricated to ensure precise evaluation of those properties, and thus the tests were performed on the balloon-expandable CoCr alloy stent with a closed cell design, manufactured by Japan Stent Technology Co., Ltd. The main results obtained were summarized as follows.

1. Three important mechanical properties, bending flexibility, radial strength, and longitudinal strength of the stent were successfully evaluated by means of the developed apparatuses, which were optimized for small load and small displacement.
2. The bending flexibility evaluated by the three-point bending test became larger with larger diameter of the stent, but it was found that the change of the bending flexibility was caused not only by the diameter but also by the structural characteristics of the stent.
3. The normalized radial strength evaluated by the lateral local compression test was meandered with the progress of the deformation, owing to the change in the number of cell struts contacting with the indenter. However, the radial strengths agreed well when they were normalized by the initial diameter of the stents.
4. The results of the uniaxial tensile test implied that the tensile deformation of the stent could be divided into three stages; rapid increase of the load due to elastic deformation of the link strut, the gradual decrease of the load caused by plastic deformation of the link strut, and the following load increase by the onset of deformation of the cell strut.

All the results obtained in this work clearly suggested that the mechanical properties of the stent were strongly influenced not only by the dimension but also by the structural characteristics as the combination of the cell strut and the link strut, namely stent design. The developed test methods as well as the obtained results are thus expected to contribute to the future optimization of the stent design.

Nomenclature
- \( D \): diameter of stent [mm]
- \( F_b \): bending flexibility of stent [mN-mm^2]
- \( F_r \): normalized radial strength of stent [mN]
- \( l \): length of stent [mm]
- \( L \): support span in three-point bending test [mm]
- \( M \): bending moment [mN-mm]
- \( P \): applied load [mN]
- \( t \): thickness of stent strut [mm]
- \( \delta \): deflection of the center of stent in three-point bending test [mm]
- \( \delta_i \): indentation displacement in local lateral compression test [mm]
- \( \delta_t \): tensile displacement of stent in uniaxial tension [mm]
- \( \rho \): radius of curvature of stent [mm]

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References


