Comparing the mechanical properties of a self-expandable metallic stent for colorectal obstruction: Proposed measurement method of axial force using a new measurement machine

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Objectives: Colorectal stenting is widely performed using self-expandable metallic stents (SEMSs), but the mechanical properties have not been evaluated. Therefore, we conducted an in vitro study to evaluate the mechanical properties of colorectal SEMSs.

Methods: Eighteen individual types and sizes of uncovered SEMSs were evaluated for their mechanical properties. Radial force was measured using a measurement machine. Axial force (AF) was measured by two methods: a conventional manual method and a new method using a measurement machine. The correlation of these two methods was evaluated. We also proposed an “AF zero border” that was defined as the angle at which the torque force disappeared.

Results: Radial force versus diameter curves and AF versus angle curves were influenced by the structure and the size of each stent. There was excellent correlation of AFs measured by the new and conventional manual method (y = 21.434x, R = 0.881, P < 0.0001). Colorectal SEMSs could be categorized into five subgroups according to the mechanical properties. Most hook-wired SEMSs had the AF of zero border.

Conclusions: This is the first report to evaluate the mechanical properties of colorectal SEMSs, and these data may provide useful information for the clinical use and development of colorectal SEMS. Furthermore, the new measurement machine might standardize the measuring method of AF.

Key words: axial force, colorectal obstruction, mechanical property, radial force, self-expandable metallic stent

INTRODUCTION

Colorectal stenting with a self-expandable metallic stent (SEMS) is now widely accepted as a less-invasive alternative treatment compared to surgery or ileus tube insertion for decompressing the large intestine due to colorectal obstruction. Demand for colorectal stenting has been increasing due to the high incidence of cancers worldwide. It is often performed for malignant colorectal obstructions (MCROs) caused by colorectal cancer (CRC) and extracolonic malignancies, and there are also two indications: bridge-to-surgery and palliation.

Many types of colorectal SEMSs have been used in clinical practice. It is important to know its characteristics and to use it according to the clinical situation. To evaluate the mechanical properties of SEMSs, radial force (RF) and axial force (AF) are considered to be important. RF is subdivided into radial expansion force and radial resistance force. Radial expansion force is the force generated when the stent is expanded from the collapsed state. Radial resistance force is the force to keep the shape from the external force. AF is defined as the force to keep the SEMS straight after it has bent. The characteristics of a SEMS represented by the pattern of RF and AF are used in...
classifying biliary\textsuperscript{13} and esophageal\textsuperscript{14} SEMSs. However, there is currently no report evaluating these characteristics for colorectal SEMSs.

In evaluating the mechanical properties of SEMSs, it is important to standardize the measurement method. RF is usually measured using a measurement machine, but there is no standard method particularly for AF. AF is conventionally measured manually with a force gauge.\textsuperscript{13} Therefore, a new and improved measurement method is required. In this \textit{in vitro} study, we evaluated the mechanical properties of several colorectal SEMSs and also evaluated the correlation between a new method using a measurement machine and a conventional manual method for AF.

\textbf{METHODS}

\textbf{Types of colorectal self-expandable metallic stent}

Nine types of colorectal SEMSs were tested for mechanical properties (Table 1, Fig. 1). Because two sizes of stent diameter were brought in each stent type, 18 individual types and sizes of colorectal SEMSs were evaluated. Every three new stents in each stent type and size were used for the measurement. Therefore, a total of 54 colorectal SEMSs were measured by five doctors (T.S., R.I., S.Y., T.F., and H.I.). Two engineers (H.S. and C.G.) instructed these doctors on how to measure RF and AF and observe actual measurements.

All the stents evaluated in this study were uncovered SEMSs. The stent length used in this study was 12 cm. The ZEOSTENT COLON was a laser-cut type of SEMS. The WallFlex Colonic Stent was woven only by a cross wire, and the Niti-S Enteral Colonic Uncovered Stent was woven by only a hook wire at its body. For the other SEMSs, the structures of the hook and cross were interwoven. Only the WallFlex Colonic Stent had a flare at the proximal end. All the SEMSs were made of nickel-titanium alloys.

\textbf{Measurement of radial force}

An RF measurement machine (MODEL TTR2; Blockwise ENGINEERING LLC, Tempe, AZ, USA) was used to measure RF (Fig. 2). The measured value of hoop force (HF) is given in the previous paper,\textsuperscript{13} and RF measured by MODEL TTR2 in this study is converted by RF = HF \times \pi. RF versus diameter curves were created by taking the average value of every three stents. Radial expansion forces of the several stents were compared at the point of 10 mm. We set the typical value of radial expansion force at 10 mm for the following reasons: we usually evaluate the severity of colorectal stenosis by passing with the colonoscope in clinical practice. Half the diameter of colorectal SEMS is approximately 10 mm, which is almost the size of a general colonoscope. Additionally, it is considered important to evaluate the synchronous colorectal cancer by colonoscopy after SEMS insertion. Furthermore, feces could pass the SEMS if the SEMS could expand more than 10 mm.

\textbf{Measurement of axial force}

Axial force was measured by two methods (Fig. 3). The first is the conventional manual method\textsuperscript{13} and the second is the new method using a measurement machine. The force gauge (DPX-0.5; Imada, Tokyo, Japan) was used to measure the AF by the conventional manual method, and the average of three data points was extracted as the AF. A new machine for measuring AF is introduced as a new method in this study (Video S1). This machine is a custom-made product (i-course

\begin{table}[h]
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\begin{tabular}{|l|l|l|l|}
\hline
Self-expandable metallic stent & Manufacturer & Structure & Diameter (mm) & Material \\
\hline
WallFlex Colonic Stent & Boston Scientific Corporation, Marlborough, MA, USA & Cross & 22, 25 & Nickel-titanium alloys \\
\hline
HANAROSTENT Naturfit Colon & M.I. TECH., Seoul, Korea & Hook & Cross & 18, 22 & Nickel-titanium alloys \\
\hline
JENTLLY Colonic Stent & Japan Lifeline Co., Ltd., Tokyo, Japan & Hook & Cross & 18, 22 & Nickel-titanium alloys \\
\hline
NEXENT Colon Stent & NEXTBIOMEDICAL Co., Ltd., Incheon, Korea & Hook & Cross & 18, 22 & Nickel-titanium alloys \\
\hline
Niti-S Enteral Colonic Uncovered Stent & Taewoong Medical Co., Ltd., Gimpo, Korea & Hook & 18, 22 & Nickel-titanium alloys \\
\hline
EGIS Colorectal Stent Single bare & S & G Biotech Inc., Yogin, Korea & Hook & Cross & 18, 22 & Nickel-titanium alloys \\
\hline
EGIS Colorectal Stent Double bare & S & G Biotech Inc. & Hook & Cross & 18, 22 & Nickel-titanium alloys \\
\hline
ZEOSTENT COLON & Zeon Medical Inc., Tokyo, Japan & Laser cut & 18, 22 & Nickel-titanium alloys \\
\hline
HILZO Stent & BCM Co., Ltd., Goyang, Korea & Hook & Cross & 22, 24 & Nickel-titanium alloys \\
\hline
\end{tabular}
\caption{Types of self-expandable metallic stents for colon}
\end{table}
AF versus angle curves were created by taking the average value of every three stents. AFs of the several stents in the stretching phase were compared at the point of 60 degrees. We set the typical value of AF at 60 degrees because MCRO often occurs at the bending site. Moreover, we also evaluated the correlation between the conventional manual method and this new method using a measurement machine. The value of 60 degrees in the stretching phase of the new method was compared with the value of the conventional manual method.

As another indicator, the “AF zero border” was set in this study. The AF zero border was defined as the angle at which the torque force became <0.05 mNm in the stretching phase. This angle indicates an angle at which the force applied to the intestinal wall almost disappears.

**Statistical analysis**

To evaluate the relationship between the new and conventional methods of AF, linear regression analysis of the data was
performed by the least squares method using JMP Pro software (version 14.2.0; SAS, Chicago, IL, USA). A P value of <0.05 was considered statistically significant. The correlation strengths of the correlation coefficient were categorized as excellent (>0.7), excellent-good (0.61–0.7), good (0.4–0.6), and poor (<0.4).

RESULTS

Measurement of radial force

RADIAL FORCE VERSUS diameter curves for each stent type and size are shown in Figure 4. The same type of SEMS with different diameters indicated similar shaped curves. The radial expansion force of all the SEMSs other than the ZEOSTENT COLON showed a rapid drop at the beginning of the expansion phase. The radial expansion force of the WallFlex Colonic Stent and the JENTLLY Colonic Stent dropped linearly at the end of the expansion phase. In all stents, the resistance force was stronger than the expansion force. RF at a diameter of 10 mm in the expansion phase is shown in Table S1. The radial expansion forces of the same type of SEMSs with different diameters were almost the same strength.

Measurement of axial force and comparison of two measurement methods

The data of AF in the stretching phase at 60 degrees and conventional AF for each SEMS are shown in Table S2. There was excellent correlation of AFs measured between these two methods (y = 21.434x, R = 0.881, P < 0.0001; Fig. 5).

Axial force versus angle curves for each stent type and size are shown in Figure 6. The curves of the WallFlex Colonic Stent, JENTLLY Colonic Stent, NEXENT Colon Stent, and EGIS Colorectal Stent Double bare were slightly different between each stent size. AF versus angle curves of the other SEMSs were neatly overlapped. The curves in the bending phase and stretching phase were similar in the WallFlex Colonic Stent and the ZEOSTENT COLON. In other SEMSs, AF in the stretching phase was weaker than that of the bending phase at the same degree. AF versus angle curves of the ZEOSTENT COLON were slightly distorted.

The AF zero border of the SEMSs are shown in Figure 6 and Table S3. Most SEMSs had an AF zero border, and the AF zero border of the HANAROSTENT Naturfit Colon, Niti-S Enteral Colonic Uncovered Stent and HILZO Stent were more than 45 degrees.

Scatter plots of radial force and axial force

Scatter plots of radial expansion force at 10 mm and AF stretching phase at 60 degrees measured by a new measurement machine are shown in Figure 7. AF was subdivided into three groups: low group (<2 mNm), moderate group (2–6 mNm), and high group (more than 6 mNm). The radial expansion force was subdivided into

Figure 3 (A) Conventional manual measurement method of axial force. A plastic rod was placed inside the self-expandable metallic stent (SEMS), the lower portion was fixed in a vise, and the upper portion was left flexible. The force required to maintain an angle of 60 degrees was measured by pushing the SEMS vertically at the point that the center of the observation device is 3 cm from the stent tip. The temperature inside the box was controlled at 37°C. (B) New measurement method of axial force. A stent fixing arm, a torque measuring arm, a torque meter, and a shaft rod were arranged in a box of the measuring apparatus. The shaft rod and the torque measuring arm were connected to each other and arranged in a straight line with the stent fixing arm in the neutral position. By rotating the shaft rod, the resistance to the torque measuring arm was measured with a torque meter. A fixing jig was attached to the stent fixing arm, and a measuring jig was attached to the torque measuring arm. The shaft rod attached to the torque meter was positioned at the center of both jigs. The fixing jig was designed in a cylindrical shape so that the stent can be fixed all around. The measuring jig was designed in a half-moon shape to contact the half surface of the stent. Both jigs had a length of 3 cm. The box temperature was set to 37°C. The stent was set on the jig at the neutral position, and the shaft rod was rotated to a 90 degree position at a rotation speed of 10 degrees/second (bending phase). After stopping for 2 s, the shaft rod was returned to the neutral position at the same speed (stretching phase). The torque value was measured continuously with a torque meter (UTM II-0.5Nm; UNIPULSE CORPORATION, Tokyo, Japan).
three groups: a low group (<10 N), moderate group (10–30 N), and high group (more than 30 N). Therefore, we categorized each SEMS into five subgroups: (i) Group 1, high AF with moderate RF; (ii) Group 2, low AF with low RF; (iii) Group 3, low AF with moderate RF; (iv) Group 4, low AF with high RF; and (v) Group 5, moderate AF with high RF. The SEMSs of Group 1 were woven only by a cross wire, while Group 5 contained laser-cut type SEMSs. Groups 2–4 were the SEMSs whose hook and cross structures were interwoven or with only a hook wire structure, and the subgroups were defined by RF.

**DISCUSSION**

This is the first *in vitro* study to evaluate the mechanical properties of colorectal SEMS. Many types and sizes of SEMSs were measured in the same measurement system. To eliminate product-specific differences, three new SEMSs were measured for each stent type and size, and the average value was adopted for the data of mechanical properties. In addition, it is significant that a new measurement system of AF using a measurement machine was introduced, and the correlation of this new method and the conventional manual method was excellent. Moreover, we also propose the “AF zero border”, which might be clinically important to determine the sustained pressure load on the intestinal wall.

Self-expandable metallic stents are now widely used in various fields in clinical practice. Until now, mechanical properties have been evaluated for biliary and esophageal SEMSs. Biliary trees are sometimes intricately bent and accompanied by a slightly hard stenosis. The mechanical

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**Figure 5** Correlation diagram of axial force comparing new and conventional measurement methods.

**Figure 6** Axial force versus angle curve in each self-expandable metallic stent.
properties of biliary SEMSs are extremely important and greatly affect the clinical outcomes.\textsuperscript{15-18} For the esophageal SEMS, the upper part of the esophagus is usually straight, but the lower part is bent. The stenosis of the esophagus is usually tighter than that of the biliary tract. Therefore, higher RF SEMSs are often required.\textsuperscript{19} The colorectal SEMS is used in various situations, therefore, its mechanical properties are considered to be more important than those of the biliary and esophageal SEMSs.

To date, there is no standard method for measuring the mechanical properties of SEMSs. The most representative method is that RF was measured by a measurement machine, whereas AF was measured manually.\textsuperscript{13} Therefore, it is necessary to develop a new method for performing more precise and reproducible AF measurements using a measurement machine. The major difference between this new method and the conventional method is that the conventional method measures a static force, whereas the new method measures a dynamic force. Dynamic force was measured as a torque force, and it is more likely to reflect a clinical phenomenon. Many parts of the large intestine are not fixed in the abdominal cavity, and regardless of our will, bowel movement is caused by diet or body position. Considering such environment that is consistently affected by the force of gravity or peristalsis, dynamic force is more optimal than static force for colorectal stenting. Overall, a high correlation was confirmed between these two methods. Therefore, it is considered that this new method could be standardized for the measurement of AF.

Various RF versus diameter curves and AF versus angle curves were drawn by continuous measurement using measurement machines. The difference in these curves seems to be affected by the difference in the structure of the SEMS. For RF, the forces of all the SEMSs other than the laser-cut stent showed rapid drops at the beginning of the expansion phase. The SEMSs with hooks and cross wires have more friction between the wires when the SEMS opens due to the crossover structure, while there is less friction at the beginning of SEMS opening for the laser-cut type SEMS. This phenomenon might affect the resistance at the beginning of stent deployment. The RFs of the WallFlex Colonic Stent and the JENTLLY Colonic Stent drop linearly at the end of the expansion phase, which might be caused by the structure of the cross wire. Unlike RF, there is a difference in the AF curves between the WallFlex Colonic Stent and JENTLLY Colonic Stent, which seems to be influenced by the hook element in the JENTLLY Colonic Stent. The laser-cut type SEMS (ZEOSTENT COLON) has less interference for each wire, so it exhibits curves similar to that of the cross wire SEMS (WallFlex Colonic Stent). However, it is a slightly distorted curve due to the friction with the measurement device.

The AF zero border is a new parameter that we propose in this study. This parameter could be measured precisely due to the continuous measurement of AF using this machine. This angle indicates an angle at which the force applied to the intestinal wall almost disappears. For a SEMS without an AF of zero border, the pressure load on the intestinal wall is sustained. This might result in perforation due to the injury of the intestinal wall. Therefore, we believe that the AF zero border is an important parameter of mechanical properties for SEMSs.

According to the scatter plots of RF and AF, we categorized the SEMSs into five subgroups. Because a colorectal SEMS is deployed in various situations, these mechanical properties are useful for selecting the best SEMS for each situation. For example, stenosis caused by CRC is

\begin{figure}[h]
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\includegraphics[width=\textwidth]{scatter_plots.png}
\caption{Scatter plots of radial force and axial force for all evaluated self-expandable metallic stents.}
\end{figure}
not usually tight; therefore, low to moderate RF is enough. Because the stenosis caused by extracolonic cancer, such as peritoneal dissemination, is quite tight, a high RF SEMS is required. When the SEMS is deployed at the bending site, low AF SEMS is preferred. Furthermore, the SEMS with AF zero border might be better when the SEMS is deployed for palliation. However, whether these recommendations actually affect clinical outcomes is still unclear. Therefore, we need to clarify the relationship between in vitro data and the clinical data.5,20,21

There are several limitations in this study. First, this was an in vitro study, and clinical evaluation was not performed. The second limitation is that all the colorectal SEMSs available in the clinical setting worldwide could not be evaluated in this study. The third limitation is that it is still difficult to discuss the relationship between the mechanical properties and the structure of the SEMS precisely because the detailed structure was not always disclosed. The fourth limitation is that it might be difficult to measure a covered SEMS or a SEMS with bilateral flares, which can be a subject for further study. The last limitation is that this new AF measurement machine was a custom-made product, therefore, AF measurement cannot be performed elsewhere using this machine at present.

In conclusion, we examined the mechanical properties of several colorectal SEMSs. We also introduced a new measurement machine for AF and proposed the new indicator of the “AF zero border”. These evaluations may be helpful for the clinical use and development of colorectal SEMS in the near future.

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CONFLICT OF INTERESTS

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REFERENCES


**SUPPORTING INFORMATION**

ADDITIONAL SUPPORTING INFORMATION may be found in the online version of this article at the publisher’s web site.

Table S1 Comparison of radial force at 10 mm in expansion phase.

Table S2 Comparison of conventional and new measurement methods of axial force.

Table S3 Comparison of axial force and axial force zero border.

Video S1 New axial force measurement machine.