

Understanding mechanical properties of biliary metal stents for wise stent selection

Seok Jeong

Department of Internal Medicine, Inha University College of Medicine, Incheon, Korea

See “Evaluation of the mechanical properties of current biliary self-expandable metallic stents: axial and radial force, and axial force zero border” by Wataru Yamagata, Toshio Fujisawa, Takashi Sasaki, et al., Clin Endosc 2023;56:633–649.

Biliary self-expandable metal stents (SEMSs) have been used clinically for biliary decompression and internal biliary drainage as primary palliative treatment and as a bridge therapy for surgery in patients with malignant biliary obstruction. Over the past few decades, SEMSs with various designs and characteristics have been developed and are used clinically worldwide. Endoscopists need to understand the mechanical properties (MPs) and structure of SEMSs to make informed choices regarding safety and performance when selecting biliary SEMSs.¹

Commercially available biliary SEMSs possess unique MPs with various characteristics and advantages through various manufacturing methods, such as braiding or laser cutting. MPs, according to the material and design of these biliary SEMSs, have been defined and evaluated,²⁻⁶ and studies have examined how these characteristics affect the clinical outcomes when SEMSs are applied in patients.⁷⁻¹¹

Isayama et al.⁵ has dedicated the past 10 years to establishing a stent research laboratory to ascertain the MPs of metal stents

along with basic research on the structure, design, and constituent materials of commercially available biliary SEMSs, and to develop devices and measurement methods capable of objectively assessing these values. In addition, stents were classified based on the unique MP values of these biliary SEMSs.⁵ Several of their and other clinical data on the effect of these MPs on complications have been reported.⁷⁻¹¹ Through them, it informs endoscopists about the specific MPs, strengths, and weaknesses of biliary SEMSs with various structures, designs, and functions worldwide, helping guide appropriate metal stent selection based on clinical situations.

The important MPs of SEMS suggested by the investigators were axial force (AF) and radial force (RF), and it was proved that these two values can affect the occurrence of various complications that can occur when SEMS is applied to malignant biliary obstruction.⁹⁻¹¹ A high AF value (>0.4 N) can lead to poor conformability of the SEMS placed in the bile duct, and both sides of the inserted SEMS compress the bile duct wall, cystic duct orifice, and pancreatic orifice resulting in complications such as bile duct kinking, acute cholecystitis, and pancreatitis.^{9,11} On the other hand, a low RF value (4.0 N) causes insufficient stent expansion, which may cause cholangitis and early stent migration.¹⁰

Two years ago, investigators conducted an *in vitro* study to evaluate and compare the MPs of SEMS to be applied to colonic obstruction and proposed an AF measurement method using a newly developed measuring machine.¹² Moreover, they

Received: August 25, 2023 **Revised:** September 4, 2023

Accepted: September 5, 2023

Correspondence: Seok Jeong

Department of Internal Medicine, Inha University Hospital, Inha University College of Medicine, 27 Inhang-ro, Jung-gu, Incheon 22332, Korea

E-mail: inos@inha.ac.kr

© This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/4.0/>) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

proposed the AF zero border (AFZB) as a significant new parameter in their study, made possible by the precise continuous measurement of AF using this new machine. This new SEMS parameter refers to the angle relative to the central axis at which the AF becomes zero, leading to a near disappearance of the pressure load on the gastrointestinal tract wall. In other words, the higher the AFZB, the lower the persistent pressure or mechanical stress on the bile duct wall.

In the current issue of *Clinical Endoscopy*, Yamagata et al.¹³ evaluated and compared MPs, including a newly developed parameter, AFZB, in 29 types of 10 mm SEMS commercially available around the world for biliary endoscopists to select a more appropriate SEMS in terms of efficacy and safety of biliary metal stenting for the management of malignant biliary obstruction. By utilizing combined AF and RF data, which are representative MPs of SEMSs, they were able to classify SEMSs into three groups according to the stent structure as follows in the current study: braided-hook-and-cross-type (both low AF and RF), braided-cross-type (high AF and low RF), and laser-cut-type (intermediate AF and high RF). Based on the *in vitro* data of this study, hook-and-cross-type SEMSs were suggested to be suitable in terms of safety, as they have low AF and high AFZB and exert minimal mechanical stress and pressure on the wall of the bile duct compared to the other two stent groups. However, stents with this structure inevitably increase the RF value because of the nature of the wire-knitting structure. Therefore, validation of the safety and efficacy is required through a prospective comparative clinical study involving these three groups.

This study is part of a decade-long series of basic SEMS studies conducted by the investigators. The results of the study provided endoscopists with a meaningful message that helped them select an appropriate stent according to the case by increasing their understanding of the basic knowledge of SEMS used clinically. In addition, they have become important basic data for the development of new and improved SEMS designs.

Conflicts of Interest

The author has no potential conflicts of interest.

Funding

None.

ORCID

Seok Jeong

<https://orcid.org/0000-0001-6178-8338>

REFERENCES

1. Jeong S. Basic knowledge about metal stent development. *Clin Endosc* 2016;49:108–112.
2. Dyet JF, Watts WG, Ettles DF, Nicholson AA. Mechanical properties of metallic stents: how do these properties influence the choice of stent for specific lesions? *Cardiovasc Intervent Radiol* 2000;23:47–54.
3. Nuutinen JP, Clerc C, Törmälä P. Theoretical and experimental evaluation of the radial force of self-expanding braided bioabsorbable stents. *J Biomater Sci Polym Ed* 2003;14:677–687.
4. Stoeckel D, Pelton A, Duerig T. Self-expanding nitinol stents: material and design considerations. *Eur Radiol* 2004;14:292–301.
5. Isayama H, Nakai Y, Toyokawa Y, et al. Measurement of radial and axial forces of biliary self-expandable metallic stents. *Gastrointest Endosc* 2009;70:37–44.
6. Minaga K, Kitano M, Imai H, et al. Evaluation of anti-migration properties of biliary covered self-expandable metal stents. *World J Gastroenterol* 2016;22:6917–6924.
7. Suk KT, Kim HS, Kim JW, et al. Risk factors for cholecystitis after metal stent placement in malignant biliary obstruction. *Gastrointest Endosc* 2006;64:522–529.
8. Sakai A, Masuda A, Eguchi T, et al. A novel fully covered metal stent for unresectable malignant distal biliary obstruction: results of a multicenter prospective study. *Clin Endosc* [Epub ahead of print].
9. Nakai Y, Isayama H, Kawakubo K, et al. Metallic stent with high axial force as a risk factor for cholecystitis in distal malignant biliary obstruction. *J Gastroenterol Hepatol* 2014;29:1557–1562.
10. Nakai Y, Isayama H, Kogure H, et al. Risk factors for covered metallic stent migration in patients with distal malignant biliary obstruction due to pancreatic cancer. *J Gastroenterol Hepatol* 2014;29:1744–1749.
11. Kawakubo K, Isayama H, Nakai Y, et al. Risk factors for pancreatitis following transpapillary self-expandable metal stent placement. *Surg Endosc* 2012;26:771–776.
12. Sasaki T, Ishibashi R, Yoshida S, et al. Comparing the mechanical properties of a self-expandable metallic stent for colorectal obstruction: proposed measurement method of axial force using a new measurement machine. *Dig Endosc* 2021;33:170–178.
13. Yamagata W, Fujisawa T, Sasaki T, et al. Evaluation of the mechanical properties of current biliary self-expandable metallic stents: axial and radial force, and axial force zero border. *Clin Endosc* 2023;56:633–649.