

In vitro evaluation of the radial and axial force of self-expanding esophageal stents

Authors

Meike M. C. Hirdes¹, Frank P. Vleggaar¹, Matthieu de Beule^{2,3}, Peter D. Siersema¹

Institutions

¹ Department of Gastroenterology and Hepatology, University Medical Center Utrecht, Utrecht, The Netherlands

² FEops bvba, Ghent, Belgium

³ IBiTech-bioMMeda, Faculty of Engineering and Architecture, Ghent University, Ghent, Belgium

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Corresponding author

Meike M. C. Hirdes, MD
 Department of
 Gastroenterology and
 Hepatology
 University Medical Center
 Utrecht
 Heidelberglaan 100
 Utrecht 3584CX
 The Netherlands
 Fax: +31-88-7555533
 m.m.c.hirdes@umcutrecht.nl

Background and study aims: Technological innovation in esophageal stent design has progressed over the past decades, but the association between the mechanical properties of stent design and clinical outcome is still poorly understood. In this study the radial force and axial force of currently available stent designs were evaluated using an in vitro testing model.

Methods: A total of 10 partially and fully covered self-expanding metal stents (SEMSs), a self-expanding plastic stent (SEPS), and an uncovered biodegradable stent were evaluated. Radial force and axial force were measured using a radial force measurement machine (RX500) and a force gauge in an oven at 37°C.

Results: A wide range of radial force measurements were observed between the different stent designs, ranging from 4 to 83 N at 15 mm expansion. All braided nitinol stents displayed comparable mechanical characteristics with a relatively

low radial force (<150 N) that gradually decreased to 0 N during expansion, whereas plastic and metal stents that were constructed in a nonbraided manner displayed an initially high radial force (>300 N) followed by a steep decline to 0 N during expansion. Conversely, peak axial force was relatively high for braided nitinol SEMSs (>1.5 N), whereas nonbraided SEMSs showed a much lower peak axial force (<1.5 N). Based on radial and axial force data, five groups of stents with comparable mechanical properties could be distinguished.

Conclusions: All currently available stents have a characteristic radial and axial force pattern, which may aid in the understanding of the occurrence of specific symptoms and complications after stent placement. Nonetheless, the overall clinical behavior of a stent is probably more complex and cannot be explained by these factors alone.

Introduction

Endoscopic placement of a self-expanding stent is an established treatment for both malignant and benign esophageal strictures [1]. Over the past decades, various new stent designs with innovative features to reduce migration rates, ensure stent patency, and to improve removability and flexibility have been developed [2, 3]. Despite the large number of innovations in this field, level A evidence to prove superiority of one stent design over another is limited to a few randomized controlled trials (RCTs) in patients with malignant esophageal strictures [4, 5]. In patients with benign esophageal strictures, no RCTs have yet been performed. Safety and efficacy of most new stent designs have been evaluated in prospective, single-arm studies, precluding a fair comparison with other stent designs in the same patient population [6–11]. In particular, when high complication rates are reported in a series, it is difficult

to determine whether stent-related factors (e.g. design, radial force, and flexibility) are indeed partially responsible for stent dysfunction [6, 9, 11].

The association between the mechanical properties of esophageal stents and clinical outcome is poorly understood. In 1999, Chan et al. were the first to evaluate the mechanical properties of different commercially available stent designs using a load cell, a stationary bracket, and a movable bracket into which the devices were placed [12]. A wide variability in radial force between different stent designs was found, with the Ultraflex (Boston Scientific, Natick, Massachusetts, USA) having the lowest radial force. In 2001, the radial force of Ultraflex stents and other stent designs was measured using a comparable testing method [13]. With the exception of the Ultraflex, none of the stents tested in these studies is still available [12, 13].

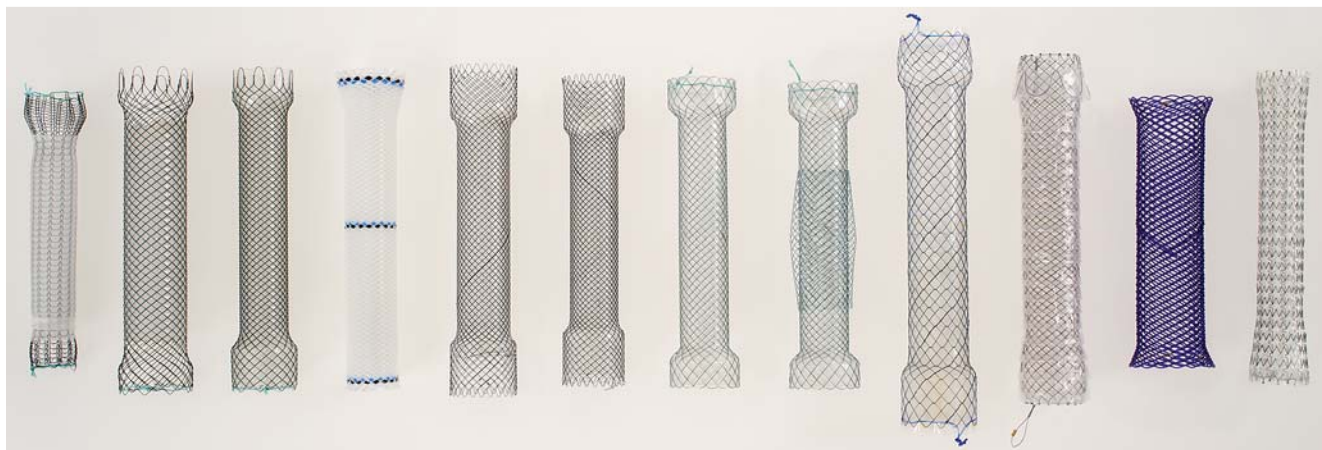


Fig. 1 An overview of all self-expanding stents. From left to right: the specially knitted Ultraflex stent; the small- and large-diameter partially covered Wallflex stent; the polyester Polyflex stent; the small- and large-diameter braided, partially covered Evolution stent; the single- and double-layered Niti-5 stent; the Hanaro stent; the braided Ella-HV stent; and the laser-cut Alimaxx stent.

Over the past decade, the range of commercially available stents has expanded from laser-cut and braided nitinol stents to stents made from polyester, including a novel stent design that is made of degradable polyester material (polydioxanone).

As well as the radial force, flexibility is probably another important stent characteristic [14]. However, instead of measuring the force to bend the stent (flexibility) it would be better to assess the force required for a stent to straighten after bending. This so-called axial force is the force exerted to the luminal wall when the stent is positioned in a curved position, for example through an exophytic stricture or across the gastroesophageal junction. If the axial force is too high, a stent will exert strong forces to straighten its shape, which may cause damage to the esophageal wall. Recently, Isayama et al. tested mechanical properties of biliary self-expandable stents using a more advanced testing method that continuously records forces during contraction and expansion [15]. The authors concluded that as well as the radial force, axial force can also be considered as one of the main mechanical properties affecting clinical outcome [15]. So far, an assessment of both the axial force and the radial force has not been performed in currently used esophageal stents.

The aim of this study, therefore, was to evaluate the radial and axial force of the currently most frequently used commercially available esophageal stents.

Material and methods

A total of 12 more recently manufactured stent designs (i.e. 10 nitinol stents, 1 polyester stent, and 1 polydioxanone stent) were provided by the respective manufacturers. These different stent designs tested are shown in **Fig. 1** and stent features are listed in **Table 1**. Most stents are braided from nitinol wires (nickel and titanium alloy), whereas the Alimaxx-ES (Merit Medical, South Jordan, Utah, USA) is a laser-cut nitinol stent, and the Ultraflex stent is made from specially knitted nitinol. All selected designs were approximately 10 cm long (range 9–11) and both small- and wide-diameter versions were measured. Biodegradable Ella-BD stents (ELLA-CS, Hradec, Czech Republic) were placed in a solution of 0.9% saline in an oven at 37°C for 2, 4, and 8 weeks. Force measurements of the different biodegradable stent samples were performed at these time points.

Radial force measurement

Radial force can be divided into radial resistance force and the chronic outward force (measured in Newton). Radial resistance force is the force that stents exert as they resist compression by the pressure of the esophageal wall. Chronic outward force is the force that stents exert on the lumen as they expand to their original nominal diameter.

Both forces were measured using a radial force measurement machine (RX500; Machine Solutions, Flagstaff, Arizona, USA) comparable to the one used in the study by Isayama et al. [15]. Each stent sample was placed in the measuring cylinder of the machine, which was placed in an oven at 37°C. A force gauge inside the cylinder continuously recorded the forces required to contract and expand the stent. The sample was evenly contracted to measure resistance force until a diameter of 9 mm, thereafter the cylinder was reversed by the expansion force of the stent until it was fully expanded (**Fig. 2**).

The radial force of the various stent designs was compared at 15 mm expansion in the measuring head, as it was assumed that a regular esophageal stenosis (mimicked by the measuring head) after stent placement generally has a diameter of approximately 15 mm. In addition, during uniform radial compression, the relative degree of elongation of each stent was categorized into four groups: none (0%), mild (5%–10%), moderate (10%–30%), and high (>30%).

Axial force measurement

Axial force is considered to be the force that a stent exerts when it bends along the longitudinal axes. The larger the axial force, the more pronounced the tendency to be straightened. An axial force close to zero indicates that the stent lacks the ability to restore its straightened shape. For axial force measurements, the samples were fixed in a set-up comparable to the previous report by Isayama et al. [15]. The sample was placed over a rod and inserted into a 5-cm tube matched to the size of the rod to tightly fix the sample in the plastic tube (**Fig. 3**). The fixed part of the set-up aimed to simulate the situation of a stent fixed in the esophagus, whereas the other part of the sample was left flexible, mimicking the distal part of the stent that usually moves freely in the stomach, at least when the stent is placed across the gastroesophageal junction. For axial force measurements, the flexible part of the sample was pushed perpendicularly by a force gauge until an

Table 1 Overview of stent characteristics of all evaluated self-expanding esophageal stents.

Type	Manufacturer	Maximum body/ flare diameter, mm	Structure	Stent mesh	Stent cover
Ultraflex	Boston Scientific	18/23 23/28	Knitted	Nitinol	Partially covered, polyurethane
Wallflex Part. Cov	Boston Scientific	23/18/23 28/23/28	Braided	Nitinol	Partially covered, permalume silicone
Wallflex Fully cov	Boston Scientific	28/23/28 23/18/23	Braided	Nitinol	Fully covered, permalume silicone
Polyflex	Boston Scientific	16/20 21/25	Braided	Polyester	Fully covered, silicone
Evolution Part. Cov	Cook Medical	25/20/25	Braided	Nitinol	Partially covered, silicone
Evolution Fully cov	Cook Medical	23/18/23 25/20/25	Braided	Nitinol	Fully covered, silicone
Niti-s single layer	Taewoong Medical	24/16/24 28/20/28	Braided	Nitinol	Fully covered, polyurethane
Niti-S double layered	Taewoong Medical	24/16/24 28/20/28	Braided	Nitinol	Partially covered, polyurethane (inner layer)
Hanaro	M.I. Tech	26/20/26 28/22/28	Non-diagonal braided	Nitinol	Fully covered, silicone
Ella-HV	Ella-CS	20/25	Braided	Nitinol	Fully covered, silicone
Ella-BD	Ella-CS	25/20/25 31/25/31	Braided	Poly-dioxanone (braided)	None
Alimaxx-ES	Merit Medical Endotek	18 22	Laser-cut	Nitinol	Fully covered, polyurethane (silicone inside)

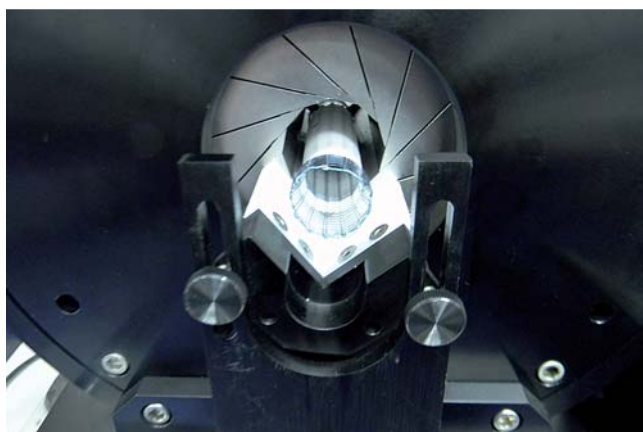


Fig. 2 A stent sample placed in the measuring cylinder of the radial force machine (RX500; Machine Solutions, Flagstaff, Arizona, USA) was evenly contracted to measure resistance force. The expansion force was measured by the cylinder until the stent was fully expanded.

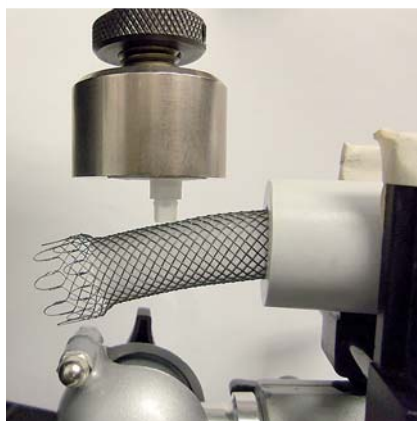


Fig. 3 Axial force measurement set-up. A force was applied to part of the free end of the stent until it bent at a 20° angle; the force to keep it there was recorded. The distance from the bending point to the point that the force was applied was 20 mm.

angle of 20° was reached, which aimed to mimic the angle of the stent alongside the lesser curvature of the stomach. The force gauge recorded the force required to keep the sample at the same angle at 20 mm from the bending point, as it was previously demonstrated that this distance from the bending point results in the highest differences in axial force between various stent designs [15]. All measurements were performed in an oven at 37°C.

Results



Radial force

Fig. 4a–I show the graphs of the chronic outward force and the radial resistance force of each stent design. This study focused mainly on the chronic outward force (lower line of each curve), which is considered to mimic the mechanical process of stent expansion in the esophagus.

When contracted to 9 mm, the radial force of different designs varied widely from less than 50 N to over 400 N. At 15 mm expansion, the differences between radial force curves gradually became smaller, ranging from 4 N to 83 N. When looking at the shape of the expansion curves, two types of curves could be detected. One curve type showed a relatively low expansive radial force (< 150 N) at the start of expansion, with a somewhat linear decrease to 0 N when fully expanded. This feature can be detected in all braided nitinol stents, such as Niti-S (Taewoong Medical, Seoul, Korea), Evolution (Cook Medical, Bloomington, Indiana, USA), and Wallflex (Boston Scientific) stents. The braided poly-dioxanone Ella-BD also showed a low radial force, which gradually decreased to 0 N. The other characteristic curve showed a high initial expansive radial force (between 300 N and 400 N), followed by a sharp drop in radial force until the stent reached 15 mm expansion. This more exponential curve could be detected in specially braided (Ultraflex, Hanaro [M.I. Tech, Gyeonggi-do, Korea]) and laser-cut (Alimaxx-ES) nitinol stents, and in polyester (Poly-

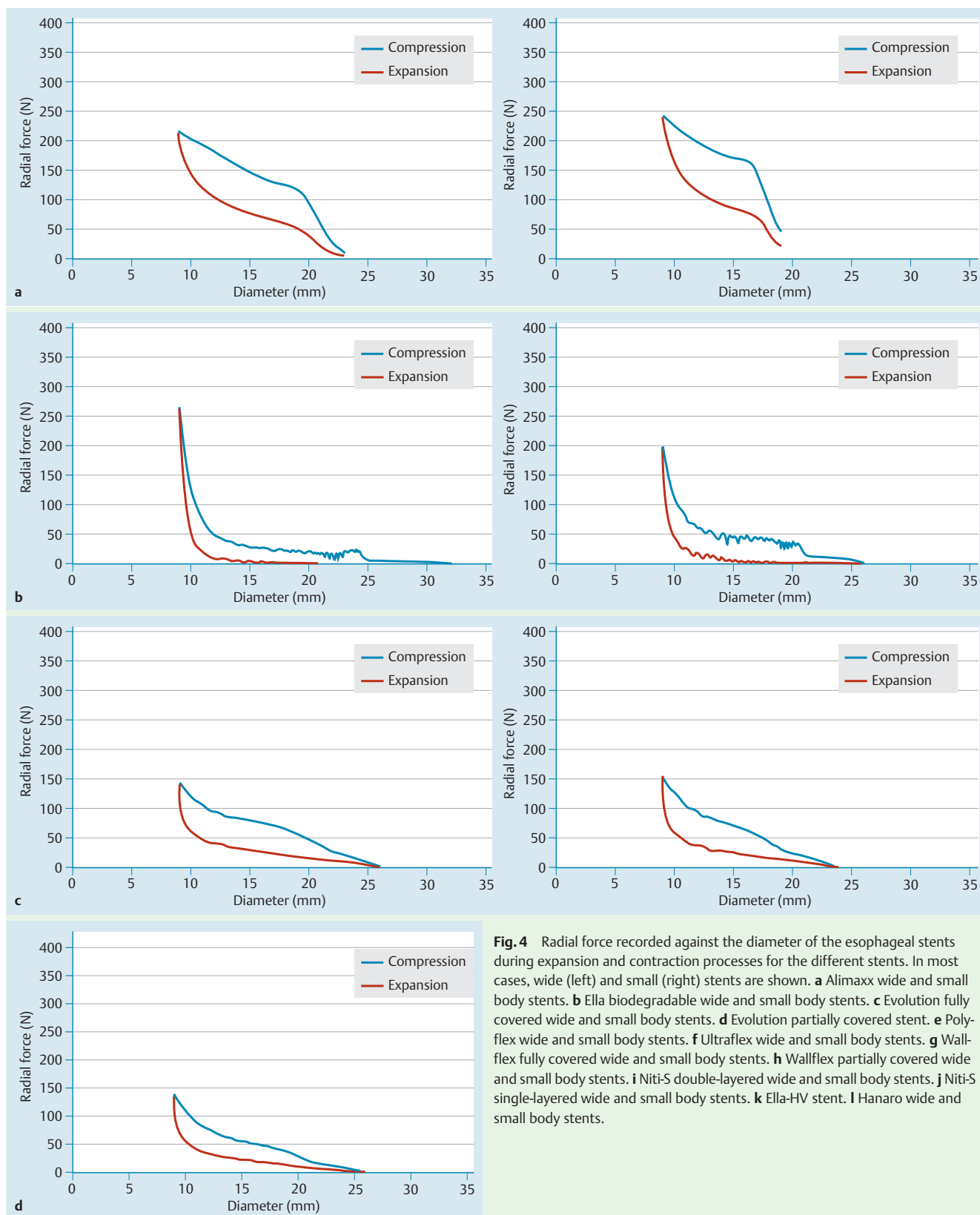
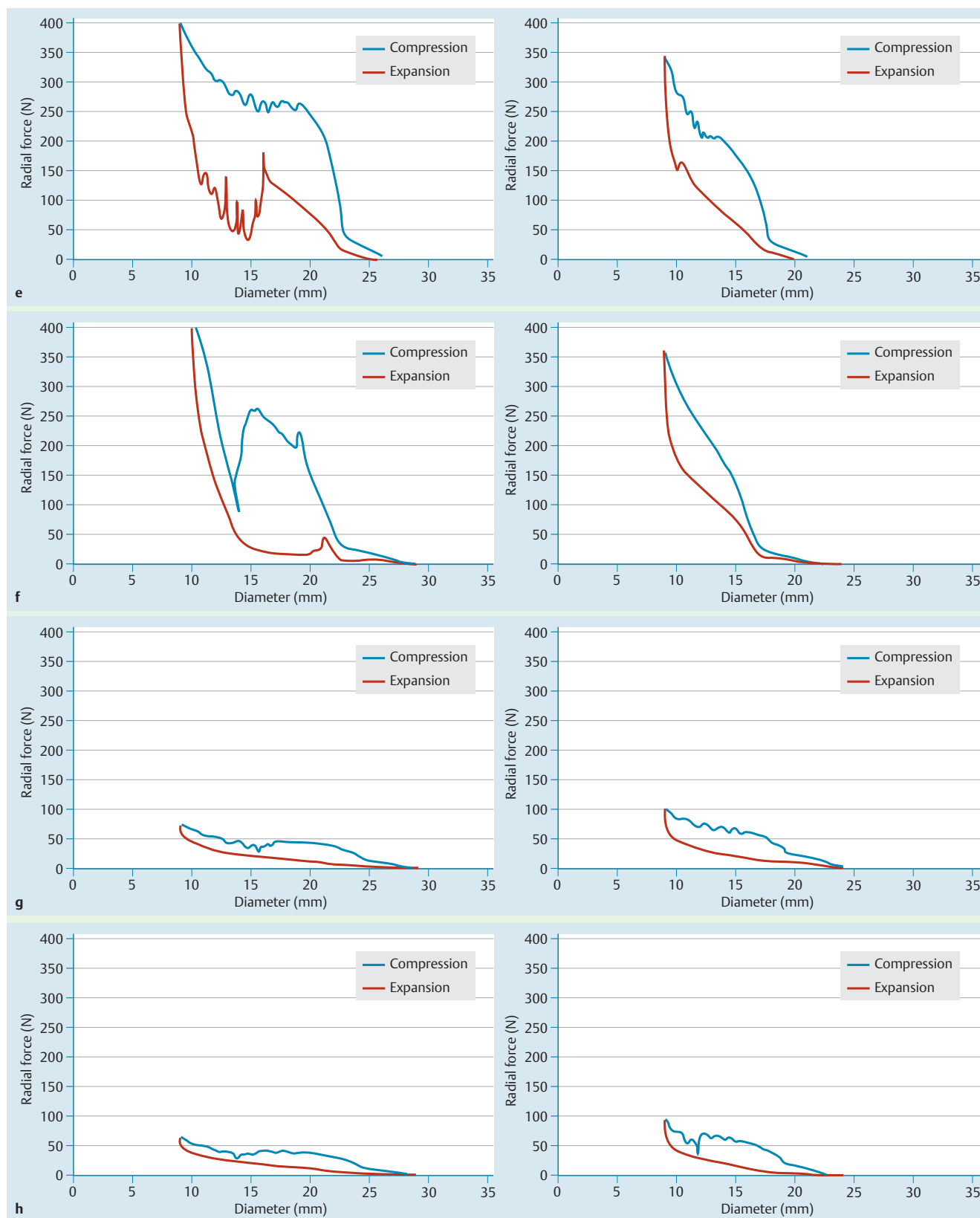
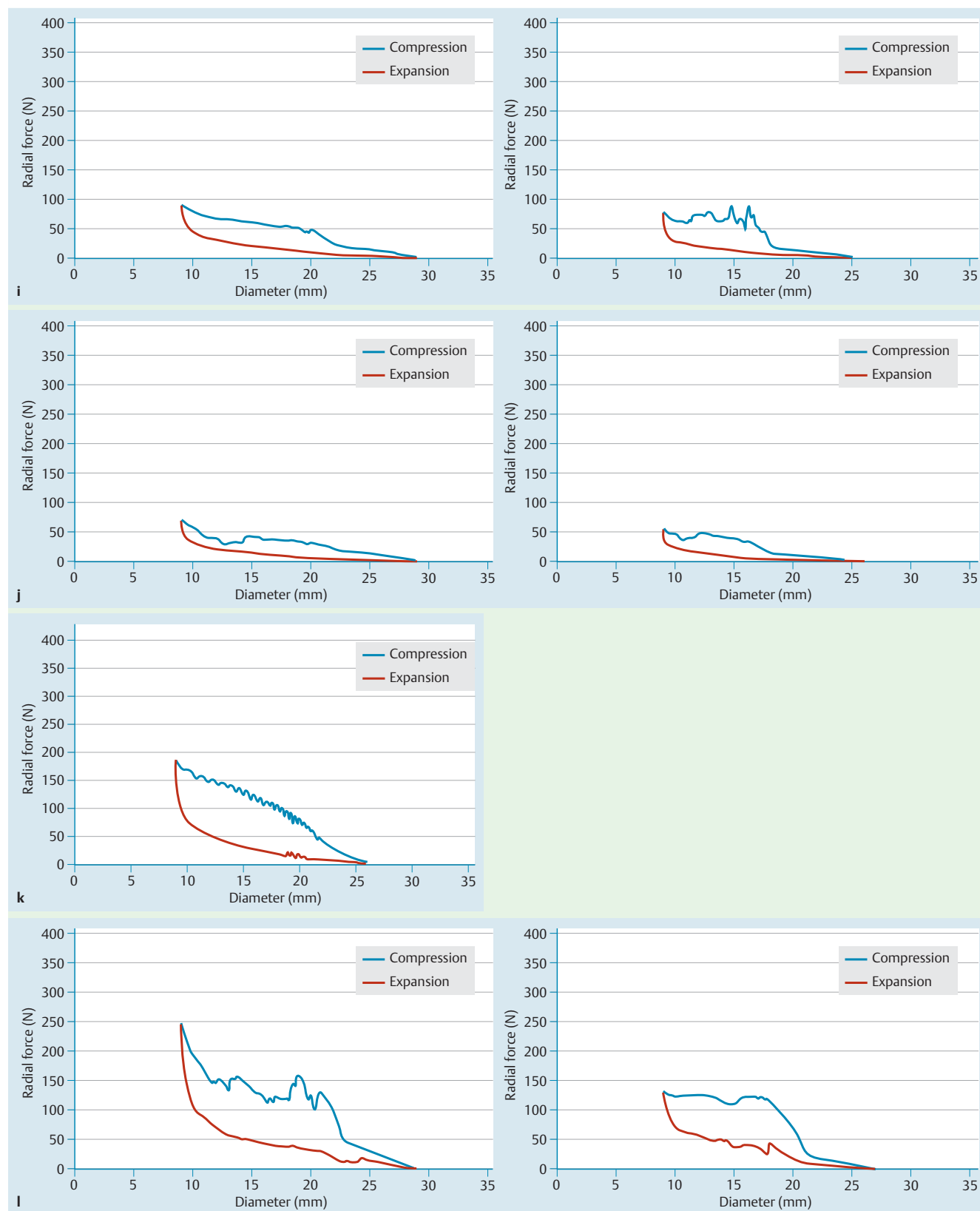


Fig. 4 Radial force recorded against the diameter of the esophageal stents during expansion and contraction processes for the different stents. In most cases, wide (left) and small (right) stents are shown. **a** Alimaxx wide and small body stents. **b** Ella biodegradable wide and small body stents. **c** Evolution fully covered wide and small body stents. **d** Evolution partially covered stent. **e** Polyflex wide and small body stents. **f** Ultraflex wide and small body stents. **g** Wallflex fully covered wide and small body stents. **h** Wallflex partially covered wide and small body stents. **i** Niti-S double-layered wide and small body stents. **j** Niti-S single-layered wide and small body stents. **k** Ella-HV stent. **l** Hanaro wide and small body stents.





Stent type	Radial force (Newton at 15 mm expansion)	Degree of elongation	Peak axial force (Newton at 20° bending)
Small body Ultraflex	79	None	0.44
Wide body Ultraflex	37	None	0.55
Wide body Alimaxx	76	None	1.01
Small body Alimaxx	83	None	1.07
Wide body Hanaro	47	None/Low	1.30
Small body Hanaro	38	None/Low	1.32
Small body Niti-S single layer	8	Medium/High	1.14
Wide body Niti-S single layer	17	Medium/High	1.16
Small body Wallflex partially covered	16	High	1.41
Small body Niti-S double layer	12	Medium	1.45
Wide body Niti-S double layer	17	Medium	1.57
Evolution partially covered	25	Medium	1.66
Evolution fully covered wide body	22	Medium	1.8
Evolution fully covered small body	29	Medium	1.8
Ella-HV	32	Medium	2.1
Small body Ella-BD	4	High	1.8
Wide body Ella-BD	5	High	1.9
Niti-S double layered	20	High	2.01
Wide body Wallflex fully covered	21	High	2.4
Wide body Wallflex partially covered	19	High	2.4
Small body Wallflex fully covered	21	High	2.6
Polyflex wide body	62	Low/med	2.3
Polyflex small body	53	Low/med	2.7

Table 2 Radial and axial force measurements of evaluated self-expanding esophageal stents.

flex; Boston Scientific) stents. There was no consistent difference in radial force between smaller- and larger-diameter stents for each stent design. The radial force of biodegradable stents was below 10 N at all time points measured; there was no change in the radial force between baseline measurements and after 2, 4, and 8 weeks in a saline solution. Fracturing of the stent mesh of biodegradable stents was noticed when samples were contracted after being soaked in saline for 8 weeks. • **Table 2** shows the radial force for each stent as well as the degree of stent elongation during compression.

Axial force

Peak axial force of each stent is also shown in • **Table 2** and varied between 0.44 and 2.70 N. Axial force was lowest in the specially knitted Ultraflex stent and the lasercut Alimaxx stent. The specially braided Hanaro stent also had a relatively low axial force. Axial force was highest in braided nitinol stents, particularly the partially and fully covered Wallflex, Niti-S, and partially and fully covered Evolution stents. Stents that were constructed from polyester (i.e. the Polyflex stent and the Ella-BD stent) were also found to have a relatively high axial force. For biodegradable stents, there was a slight increase in axial force from 1.6 N at baseline to 1.9 after 4 weeks, whereas at 8 weeks, axial force had decreased somewhat to 1.7 N.

Axial force vs. radial force

In • **Fig. 5**, radial force and axial force data are plotted against each other in a graph that shows five different stent categories. Group 1 has a high radial force and a low axial force (Ultraflex and Alimaxx-ES); Group 2 has a moderate axial and radial force (Hanaro); Group 3 has a low radial force and a moderate axial force (Evolution, Niti-S single, and Niti-S double layered, Ella HV); Group 4 has a low radial force and a high axial force (Wallflex fully covered, Wallflex partially covered, and BD Ella); and Group 5 has both a high radial and axial force (Polyflex).

Discussion

▼ This study is the first to evaluate radial and axial force of currently commercially available esophageal stents. There was a wide variation in the radial force between stent designs. It was possible to distinguish two groups with distinctly different radial force curves. In the group of braided, nitinol self-expanding stents such as Wallflex, Evolution, and Niti-S stents, the radial force was initially relatively low and gradually decreased to 0 N at full expansion. The braided biodegradable Ella stent, although not made of nitinol, showed a comparable curve, with an initially low radial force that gradually decreased to 0 N. It was noticed that during contraction these stent types were able to elongate, which may be the characteristic that actually keeps the radial force of these stents relatively low. The ability to elongate can probably be explained by the braided structure of the stents, with wires crossing diagonally over and under each other. When contracted, the angle of the crossover wires diminishes, which allows the stent to easily elongate, resulting in a lower radial force. Although biodegradable stents are not constructed of nitinol, the braiding pattern of the stent mesh is comparable to the nitinol braiding pattern.

The second group of radial force curves demonstrated a high radial force when contracted followed by a steep drop in radial force during expansion, which was seen with Ultraflex, Alimaxx, Hanaro, and Polyflex stents. The high radial force may be attributed to the fact that these stent designs allow hardly any elongation during contraction, all for different reasons. The Ultraflex stent is made from knitted nitinol rather than braided nitinol with diagonal crossover wires. Although the Ultraflex feels soft and pliable, during uniform circumferential contraction of the measurement head, the knitted wires cannot fold like the braided crossover wires of most other nitinol stents. This prevents the Ultraflex from stent elongation, which probably explains the high radial force. The Alimaxx stent is lasercut from one piece of nitinol, which prevents this stent from increasing in length even during

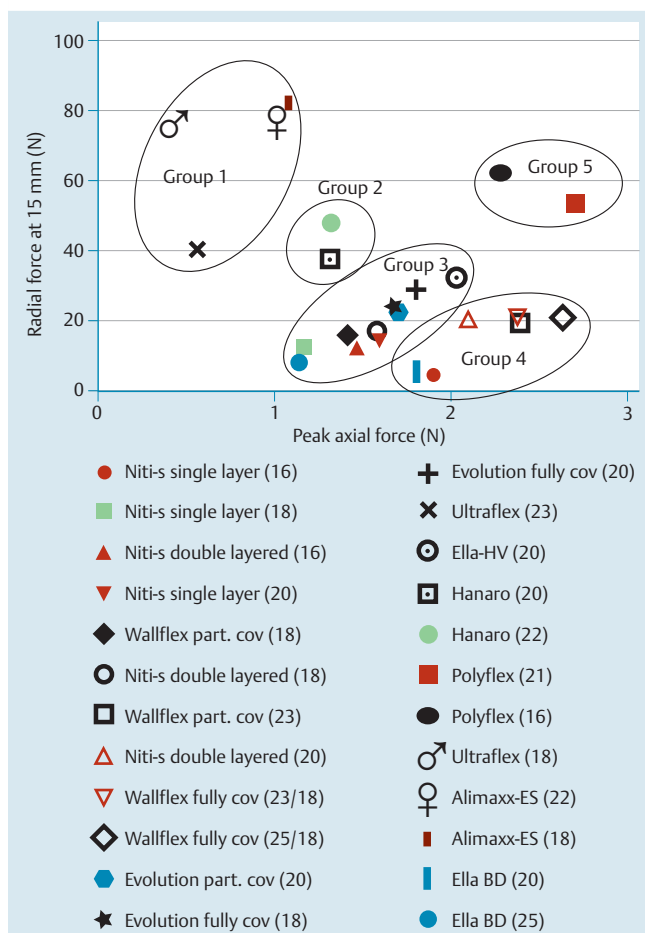


Fig. 5 A plot of radial force against axial force for all of the esophageal stents tested. Group 1 shows a moderate to high radial force and a low axial force. Group 2 shows a moderate radial force and axial force. Group 3 shows a low radial force and a moderate axial force. Group 4 shows a low radial force and a high axial force. Group 5 shows a high radial force and axial force.

circumferential compression. The inability to elongate probably results in a high radial force.

In addition to stent mesh structure (braided, knitted or laser-cut), other factors also contribute to a higher radial force, such as stiffer stent material, thicker wire diameter, and a fully covered design. This can be seen in the Polyflex stent, which seems to have a crossover braiding similar to most braided nitinol stents, but was still found to be associated with a high radial force. This can probably be explained by the fact that the crossover wires in the Polyflex are more tightly connected to the polyester cover, which precludes changes in braiding angle and easy elongation. Secondly, the polyester struts are thicker and the cell size between the wires of the Polyflex stent is smaller than, for instance, in the Wallflex stent, resulting in higher resistance during compression due to the amount of material that needs to be relocated.

Results on axial force were found to be more or less opposite to those of the radial force tests, with stent designs showing a high radial force mostly having a lower axial force and vice versa. The Polyflex stent was the only stent design that had both a high axial and a high radial force. Again, the degree of axial force mostly depends on the structure of the stent mesh. The knitted Ultraflex and laser-cut Alimaxx stents were found to have the lowest axial force, whereas the braided nitinol stents such as the Wallflex and Evolution stents had the highest axial force. When bent, the knitted

structure of the Ultraflex allows the struts to easily fold together without the need to exert substantial force, which probably makes the stent flexible to peristaltic movements. The Alimaxx stent cannot be folded but still has a low axial force. This may be explained by the fact that the density of the nitinol struts is relatively low, meaning that the distance between struts is large. Parts of the polyurethane cover without nitinol wires may bend more easily. Finally, the Wallflex, Polyflex, Ella-BD, and Evolution stents have a high axial force, which can at least partially be explained by the crossover type of braiding, which does not allow "local" bending, as the bending force is distributed evenly over the entire stent. In addition, the density of the struts in the Polyflex stent is relatively high, making bending more difficult. It is also important to note that the struts of the Wallflex stent are also relatively thick compared with other nitinol stents (clinical observation).

How do these mechanical findings relate to clinical outcome after stent placement? We hypothesize that the ideal stent should have a relatively high radial force in order to maintain sufficient luminal patency in an esophageal stricture and to ensure proper fixation of the stent to the esophageal wall, preventing stent migration [15]. With regard to the axial force, we suppose that a lower axial force will result in a stent design that causes less trauma and is more pliable to the esophageal wall. Stents with higher axial force do not adapt well to the contour of the esophageal lumen, which consequently may make them more prone to cause damage to the esophageal wall [15]. Additionally, stents that do not adapt well to the local esophageal anatomy may subsequently have problems in maintaining an adequate position in the esophagus and are more likely to migrate. Previous studies on coronary artery stenting have also reported that a higher stent straightening force, or, in other words, recovery force to keep the stent straight after bending (i.e. the axial force), was the main predictor of serious adverse events, mostly re-stenosis leading to death or revascularization [16]. **Table 2** shows the peak axial force and radial force at 15 mm expansion for all stents. If our assumptions on optimal mechanical properties of a stent are correct, the Ultraflex and Alimaxx-ES stents (with high radial and low axial force) would be the most optimal stents to use in a clinical setting.

There is little evidence from RCTs that can be used to test these assumptions. In one RCT, which compared Ultraflex (low axial, high radial force) and Polyflex (high axial, high radial force) stents in patients with malignant strictures [5], the authors found higher complication and stent migration rates after Polyflex placement. In another RCT, however, this difference was not statistically significant, with major complications in 21% of cases after Ultraflex and in 20% after Polyflex placement [4]. We recently evaluated partially and fully covered Wallflex stents (with low radial force and high axial force) in nonrandomized prospective studies [6, 9] and found that the fully covered Wallflex and, to a lesser degree, the partially covered Wallflex stents were used in a subgroup of patients who experienced major complications, such as a relatively high rate of retrosternal pain and pressure ulcers [6, 9]. It can be imagined that the high axial force of this stent design in combination with the ability to elongate has a negative effect on clinical outcome. A stiff stent that does not adapt well to the esophageal wall, and also elongates and foreshortens during esophageal peristalsis may easily rub into the esophageal wall causing friction and pressure ulceration.

As several other variables probably also play a role in the behavior of a stent in the esophagus, it is difficult to completely predict

the clinical performance based on axial and radial force data alone. In addition to the radial and axial force, the material used to construct the cover and wires, and the diameter of the wires may also contribute to clinical outcome, as well as the size of each cell and the angle of the crossover wires. Furthermore, the degree of resistance produced by the outside of the stent (flares, uncovered outer layers, anti-migration collars, struts) and the number of crowns at the flares of a stent used to evenly distribute the pressure over the flares, may also affect stent behavior and symptoms after stent placement. Nonetheless, we think that the in vitro radial and axial force data presented in this study help, at least partially, to explain results of stent patency and the occurrence of adverse events.

In conclusion, to our knowledge this study is the first to evaluate both radial and axial force of the majority of currently available esophageal stents. The results demonstrated an association between the radial and axial force and specific stent characteristics and as a result it was possible to classify all evaluated stent designs into five separate groups. In addition, this was the first attempt to improve our understanding of the specific stent characteristics that may be clinically important in the maintenance of stent patency and the occurrence of adverse event rates. It is important for clinicians to be aware of these forces in order to select the most suitable stent for each patient. However, the lack of high-quality clinical data from RCTs and the fact that more factors are probably involved in clinical stent behavior make it difficult to completely relate these in vitro results to clinical outcome. For a better understanding of the relationship between stent design on the one hand and specific symptoms and complications following stent placement on the other, more studies are needed. In vitro model testing, or, as in experimental cardiology, image-guided or virtual simulation modeling can be used for this. It is also important to include esophageal peristalsis as a factor in these measurements [17–19]. A closer collaboration between parties involved (i.e. stent manufacturers, technical engineers, and endoscopists) may prove to be helpful in increasing technological developments with the ultimate goal of designing stents that fulfill the characteristics that are required for specific patient groups.

Competing interests: None

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