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Original Article

'Radial force' of colonic stents: A parameter without consistency, definition or standard

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ABSTRACT

Background: To investigate the expansion force of current colonic stents and to match these to industry standards.

Methods: Samples of all colonic stents were requested from manufactures world-wide. Expansion forces were tested with an RX650 compression tool (MSI, Flagstaff, AZ, USA). Measurements were averaged over three cycles of compression and expansion, independently performed at 37°C by specialist engineers of MSI. In parallel, a survey was undertaken on standards, and tests used by manufacturers in their production process. As a lab-based study, Institutional Review Board approval was not required.

Results: A literature search did not identify any industry standards for testing expansion force or a suggested range for this primary stent function. Median expansion force of all stents was 24.4 N, (35.1 N for braided, 20.7 N for knitted stents) with a vast range from 5.6–130.8 N. Covering braided stents in liquid silicone increased their median force 5.5-fold, separate membranes attached to knitted stents only had a minor effect on expansion force. Five of eight manufacturers replied, describing three different test methods with three different units for expansion force.

Conclusion: There are no standards on assessing expansion force, or what the ideal range should be. Consequently, the variation is remarkable, but values are not published, and even if they were, they could not be compared. Consequently, interventionists are unable to discriminate between different stents and to select the most suitable device for their patients, and no recommendation can be made on the 'best stent'. The industry needs an agreed test standard and an acceptable range of stent forces.

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Keywords: Colonic neoplasms; Medical device legislation; Reference standards; Stents

Introduction

Self-expanding metal stents have been used for decades to treat malignant obstruction of the gastrointestinal (GI) tract. Their sole purpose is to mechanically expand the luminal obstruction caused by tumor growth, or—less frequently—by external compression. The primary parameter for selecting a stent, therefore, should be the outward expansion force, usually quoted as 'radial force'. This must be large enough to re-establish the lumen of the respective hollow organ as quickly as possible. At the same time, the pressure exerted on the wall of the viscus should not be so high as to cause ischemia or pressure necrosis, and the resultant risk of permanent pain and perforation. Factors requiring an increased expansion force are a large tumor bulk, additional fibrosis from previous radiotherapy or other inflammatory processes in-

cluding infection and mechanical restriction by a surgical suture line.

Expansion force is intrinsically linked to the type of stent construction, notably to the wire gauge used. Depending on the way the stent skeleton is woven from the wire filament further force is provided by the way the interstices support the stent structure.¹ This also affects the stents longitudinal (axial) rigidity.

Stents constructed in a traditional 'braided' fashion, also termed 'crossing wires' or 'S-stent' tend to have a higher intrinsic elasticity and outward force. Intuitively, this is appealing, but they also retain higher axial straightening forces. In tortuous segments of the bowel, this can lead to embedding of the stent ends in the wall of the organ and functional obstruction.

Stents of a 'knitted' construction also termed 'hooked wires' or 'D-stents' have much reduced, or absent straightening forces and

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can readily conform to a flexure, but subjectively they tend to have lower expansion forces.

High, as well as low expansion forces are marketed as an advantage by different stent manufacturers; the former for re-establishing the bowel lumen, the latter for reduced complication rates. This makes it even harder to choose the correct device.

It needs to be borne in mind that nitinol develops its full shape memory at body temperature, and subjective assessment of demo models is very inaccurate.

Stent properties may be altered further by applying a stent covering. Braided stents are most commonly covered by liquid silicone, which 'glues' the wires of the stent skeleton together, resulting in an even more rigid construction. Knitted stents are commonly covered with a separate expanded Poly-Tetra-Fluoro-Ethylene (ePTFE) or silicone membrane, which does not restrict the movement of the interstices or the axial rigidity.

As a consequence, the characteristics of metal stents vary widely.

The purpose of this study was to establish whether there are any standards that guide the industry in their construction of self-expanding stents of the GI tract, to establish how manufactures test the expansion force of their stents and to document the range of forces across commercially available devices. In the context of a national study comparing outcomes after covered and uncovered colonic stents, this study focuses on stents available for insertion into the large bowel.

Methods

Many different ways of assessing stent forces have been described, relating to vascular devices^{2–5} or biliary stents.^{6,7} A search for standardized testing for GI stents was performed on the websites of the two main standardization bodies globally (International Organization for Standardization, ISO) and in the USA (American Society for Testing and Materials, ASTM).

Stent manufacturers worldwide were asked to confidentially provide information on their method of testing expansion force. In addition, demonstration samples of all their commercially available colonic stents were requested. The companies were asked to provide stents of at least 24 mm diameter as recommended by

the international consensus guidelines⁸ and approximately 10 cm in length.

The stents were taken to Machine Solutions Inc. (MSI, Flagstaff, AZ, USA), a specialist manufacture of test equipment for medical devices. Stent testing was performed by independent MSI engineers on an RX650 compression tool designed for assessing the expansion force of medical stents, which has been applied to the assessment of esophageal stents.⁹ The test system consists of a 22 cm long tunnel with 1 cm iris-shaped concentric compression segments (Fig. 1). The system itself is encased in a transparent plastic housing, which allows control of the ambient temperature, which for these tests was set to 37°C (body temperature).

Twenty-five different devices from 8 manufactures were included in the tests, summarized in Table 1.

The stents were introduced into the compression tunnel in their relaxed state and compressed to a minimum diameter of 5 mm, equating to 15 Fr. Following this, compression was released and the stents allowed to expand to their original size. This cycle was repeated three times and the expansion force averaged over these. For comparison, two fully covered esophageal stents were included, a fully covered braided Ella-HV+ stent (Ella-CS, Hradec Králové, Czech Republic) and a membrane covered knitted Egis stent (S&G Biotech, Yongin, Korea).

The tests were performed by MSI personnel independent of the study investigators.

Due to this being a laboratory-based study, not involving patients, Institutional Review Board approval was not required.

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MSI waived all test fees to enable this academic study to take place.

Results

Standards

The manufactures indicated that they were not aware of any industry standard for testing radial force. The search performed on ISO and ASTM standards revealed three ISO standards relating to testing cardiovascular stents and grafts.^{10–12} One hundred and six ASTM standards related to the key word 'stent' were found, of which the majority represented guidance on materials, stress responses and corrosion resistance. Six standards vaguely related to mechanical testing of vascular endoprostheses,^{13–18} none identified a range of recommended expansion forces and no standards exist in relation to mechanical characteristics of GI stents.

Manufacturers in-house testing

Five out of eight manufactures supplied information on their expansion force testing. A range of tests for expansion forces was described, including concentric compression by iris segments as applied in this current study, compression between two parallel plates and point compression by a pointed gauge. Units given for the test results included newton, pounds per square inch, and gram force.

Assessment of commercial stents

Twenty-five different stents from 8 manufactures were tested in total, all were stents constructed from nitinol monofilament,

Fig. 1. RX650 compression tool with an uncompressed stent at the beginning of the test.

Table 1 Stents Tested and Expansion Force Averaged over Three Compression Cycles

Test-No.	Make	Model	Weave	Cover	Cover type	Diameter (mm)	Length (mm)	Force (N)
6	Boston	Wallstent	Braided	Bare	-	22	90	5.6
5	Boston	Wallflex	Braided	Bare	-	25	60	5.8
9	Cook	Evolution	Braided	Bare	-	25	100	7.9
14	MI Tech	CNZ	Knitted	Bare	-	24	60	8.7
23	Ella	Enterella	Braided	Bare	-	25	112	13.8
12	MI Tech	TLC	Double knitted	Part	Membrane	24	80	14.9
13	MI Tech	NCS	Knitted	Bare	-	24	80	15.4
17	BCM	Hilzo bone	Knitted	Part	Membrane	20	120	16.9
19	Micro-Tech	Colon	Braided	Bare	-	30	80	17.2
8	S&G Biotech	Egis covered	Double knitted	Part	Membrane	24	110	17.5
7	S&G Biotech	Egis bare	Double knitted	Bare	-	24	110	20.5
16	BCM	Hilzo straight	Double knitted	Bare	-	24	120	20.9
18	BCM	Hilzo bone	Knitted	Fully	Membrane	20	120	24.4
21	Micro-Tech	Rectum	Braided	Bare	-	30	80	31.8
15	MI Tech	HRC (flare)	Knitted	Part	Dipped	20	100	32.9
4	TaeWoong	ComVi Flare	Double knitted	Part	Membrane	26	95	33.3
2	TaeWoong	D-stent	Knitted	Bare	-	28	90	33.4
11	MI Tech	CCBA	Braided	Fully	Dipped	20	100	35.1
3	TaeWoong	ComVi	Double knitted	Part	Membrane	26	100	45.9
25	Ella	BD	Braided	Bare	-	26	60	53.3
10	MI Tech	CCI	Braided*	Fully	Dipped	24	100	61.7
24	Ella	Enterella	Braided	Fully	Dipped	30	135	84.4
1	TaeWoong	S-stent	Braided	Bare	-	28	80	85.1
22	Micro-Tech	Rectum	Braided	Part	Dipped	30	80	104.9
20	Micro-Tech	Colon	Braided	Fully	Dipped	30	80	130.8
Reference esophageal stents								
290	S&G Biotech	Egis	Knitted	Fully	Membrane	20	110	39.3
280	Ella	HV+	Braided	Fully	Dipped	18	110	133.8

Numbering is in order of test performed, stents are listed in ascending order of radial force.

*CCI stent classified as 'braided' due to mechanical behavior as a consequence of the silicone covering, despite a knitted underlying wire construction.

Fig. 2. Different stent constructions. (A) Classic bare braided stent. (B) Silicone dipped stent: the wires are stuck together by the silicone covering. (C) Knitted stent, note the lack of straightening forces. (D) Stent covered by an expanded Poly-Tetra-Fluoro-Ethylene membrane, not fixing the wires against each other.

Fig. 3. Close-up of covered, double knitted stents. The membrane is sandwiched between an inner (black arrow) and an outer layer (white arrow) of nitinol mesh. Note the 'hooked wire' or 'D-weave' construction, which allows flexion of the stent without straightening forces.

except for two:

- The original Wallstent (Boston Scientific, Marlborough, MA, USA), which is made from Elgiloy, a highly corrosion resistant Cobalt-Chromium-Nickel-Molybdenum super-alloy.
- The SX Ella-BD stent (Ella-CS, Hradec Králové, Czech Republic), the only biodegradable GI stent, which is manufactured from polydioxanone. Although officially only licensed for use in the esophagus, it has been used successfully for benign, anastomotic colorectal strictures.

Thirteen stents were of a braided construction (8 bare, 5 covered by spraying or dipping in liquid silicone), and 12 were knitted metal stents (5 bare, 7 covered by a separate membrane) (Fig. 2, 3). The distribution of stent configurations is seen in Table 2.

Although of a mostly knitted skeleton, the CCI stent (MI Tech, Pyeongtaek, Korea) was classified as “braided covered”. The covering by immersion in liquid silicone determines its characteristics, very similar to a conventional braided stent.

The majority of stents showed a characteristic force loop on compression and release:

On compression of the stent from the fully expanded state, the force rose initially until a plateau occurred and the stents compressed steadily. The force measured on this part of the curve reflects the ‘radial force’, the resistance to compression.

Approaching complete compression, a further steep increase was observed, as increasing friction in the stent skeleton restricted further reduction in size. On release the curve was reversed, with the plateau reflecting the ‘expansion force’ of the stents.

The median expansion force averaged across all stents was 24.4 N. Braided stents had a median expansion force of 35.1 N

(bare: 15.5 N; silicone covered: 84.4 N), knitted stents had a median force of 20.7 N (bare: 20.5 N; membrane covered: 24.4 N).

In comparison, the forces for the two esophageal stents were measured as 133.8 N for the braided Ella-HV+ stent covered by liquid silicone and 39.3 N for the membrane-covered knitted Egis stent.

The expansion force of braided stents was significantly increased by covering in liquid silicone (median increase, 545%; mean increase, 302%) (Table 3). The expansion force of knitted stents was only marginally increased by a cover (median increase, 20%; mean increase, 34%).

The extremes of the distribution of forces were dominated by braided stents. Four of the five weakest stents were bare braided stents, whereas the six strongest stents were also braided, 4 of which were covered (Fig. 4).

The two strongest of the covered braided stents exceeded the load of the test system and full compression could not be ob-

Table 3 Average Stent Forces by Construction

	Braided stent			Knitted stent			All Stents (n = 25)
	Bare (n = 8)	Covered (n = 5)	All (n = 13)	Bare (n = 5)	Covered (n = 7)	All (n = 12)	
Median (N)	15.5	84.4	35.1	20.5	24.4	20.7	24.4
Mean (N)	27.6	83.4	49.0	19.8	26.6	23.7	36.9
Minimum (N)	5.6	35.1	5.6	8.7	14.9	8.7	5.6
Maximum (N)	85.1	130.8	130.8	33.4	45.9	45.9	130.8

Table 2 Stent Models (Manufacturer) and Construction

Braided, bare (n = 8)		Braided, covered (n = 5)		Knitted, bare (n = 5)		Knitted, covered (n = 7)	
Enterella (Ella-CS)		Enterella (Ella-CS)		Egis (S&G Biotech)		Egis (S&G Biotech)	
Ella-BD (Ella-CS)*							
Wallstent (Boston)*		CCI (MI Tech)*		CNZ (MI Tech)		HRC (MI Tech)	
Wallflex (Boston)		CCBA (MI Tech)		NCS (MI Tech)		TLC (MI Tech)	
Niti-S S-stent (TaeWoong)				Niti-S D-stent (TaeWoong)		ComVi (TaeWoong)	
Evolution (Cook)						ComVi flare (TaeWoong)	
Colon stent (Micro-Tech Nanjing)		Colon stent (Micro-Tech Nanjing)		Hilzo straight (BCM)		Hilzo dog-bone, partially covered (BCM)	
Rectum stent (Micro-Tech Nanjing)		Rectum stent (Micro-Tech Nanjing)				Hilzo dog-bone, fully covered (BCM)	

All stents made from nitinol, except *biodegradable polydioxanone stent, †Elgiloy stent.

*CCI stent classified as ‘braided’ due to mechanical behavior as a consequence of the silicone covering, despite a knitted underlying wire construction.

Fig. 4. Distribution of expansion force (N). The two references covered esophageal stents are seen on the far right. 280: braided Ella-HV+ stent; 290: knitted Egis stent. The numbers on the X-axis identify the stents according to the test numbers in Table 1.

Fig. 5. Compression/expansion loop diagrams, demonstrating the wide range of forces. The graphs start on the right as the diameter of the stent is compressed. More or less ideal curves are seen in (A). (B, C) Some stents are starting to exceed the load of the test system (arrowheads) and the erratic behavior of the thick polymer skeleton of the biodegradable stent is seen (arrows).

tained. Their values were established as best as possible from the plateaus of the curves.

Compression of the biodegradable stent (sample 25) was somewhat erratic due to the higher friction on the thicker polydioxanone filaments. The graphs illustrating the range of forces are shown in Fig. 5.

Discussion

The primary purpose of a colonic stent is the expansion of luminal obstruction by tumor tissue. It would therefore be a natural assumption that there is consensus and guidance on what is an acceptable range of force required to dilate most malignant strictures. However, in an industry, which is otherwise heavily regulated, no such guidance exists, or indeed how this should be assessed. Consequently, there is a vast variation between individual devices, which has been demonstrated in esophageal and vascular stents.^{9,19–21} Mukai et al²² demonstrated that low axial force is preferable for placement within the biliary tree, and Freeman et al²³ suggested the same for vascular stents, but the ideal range has yet to be defined in any organ. In our study, the variation in expansion force was as much as 23-fold, where this could be measured. Some devices are so powerful, that commercial equipment designed for the purpose struggles to assess them, raising the question at which point the rigidity of the device becomes counterproductive, or even unsafe.

Stent development has taken place on a trial and error basis, often driven by perceived marketing advantages. The ideal expansion force might be correlated to pressure measurements obtained

at balloon dilatation. During pneumatic dilatation 2–4 bar of pressure will result in dilatation of most benign strictures, but it is difficult to relate this to forces applied by a self-expanding stent. It is reasonable to assume that the average force of approximately 30 N (median 24 N, mean 37 N) recorded in this study represents a sensible value, as most stents deliver the desired result. At that point the conformability of the stent to a flexure might become the primary factor for stent choice, especially as the majority of lesions occur in the tortuous recto-sigmoid colon.

The way in which stent coverings affect radial force as well as axial rigidity are not adequately understood. If stents are covered in the traditional way by application of liquid silicone, the resultant fixation of the stent wires against each other increases forces in the radial and axial direction. As an undesired effect, the stent becomes stiffer and less conformable, as well as easier to displace. Membranes applied as a loose covering do not have this effect. In addition, these constructions tend to have bare ends, resulting in better fixation against the mucosa, not only relying on fixation by friction against the bowel wall.

A higher expansion force tends to affect the speed of expansion more than the ultimate lumen achieved, because the relentless outward action of the shape-memory metal will try and re-establish maximum expansion. But it must be remembered that this is activated by the metal warming to body temperature, and does not occur straight away. While immediate expansion is not as critical in the bowel as in an artery, early decompression of the colon is often essential to avoid ischemia and perforation of the distended proximal bowel. Thus, a minimum immediate force on stent deployment is needed. The typical pattern of the expansion

curves indicated higher force at smaller diameter. This is important to understand: If after several minutes the stent does not show signs of adequate expansion allowing early bowel decompression, limited balloon dilatation (e.g., 50% of stent diameter) might need to be considered. The authors use 30%–40% expansion at 5 minutes plus endoscopic or radiologic signs of bowel decompression as a rule of thumb.

The average force of the examined colonic stents was clearly lower than the two esophageal stents used for reference. Those two stents represent the ends of the spectrum of forces for esophageal devices. The reason for this is the use of a larger wire gauge for esophageal stents, as they only need to fit into 18 Fr and 22 Fr delivery systems respectively, whereas most colonic stents are designed for 10 Fr delivery systems for through-the-scope application.

Individual manufacturers have tried to objectively measure their device characteristics, but with the complete lack of guidance and industry standardization, there is no uniformity in how this is undertaken and how the results should be represented. Without a comparable measure of stent characteristics, the physician is unable to make an informed decision about the most suitable device for the individual patient's condition and anatomy. Advertising and marketing are based on purely subjective interpretation of stent forces, instead of addressing the varying needs of different patients.

It is of concern that there is not even an industry standard defining how expansion force should be measured. Where tests are undertaken, they are performed in different ways using different units, making it impossible for the operator to compare device characteristics, even if the results were made available.

We suggest that a standard test procedure needs to be defined, using a radial compression tool as described above. Assessing expansion force over the length of the stent instead of a single point gives a much more realistic representation of the stent expanding against a segment of tumor. Expansion force should be measured in 'newton' as a universally accepted international system of units.

Nomenclature is also variable and inaccurate. Technically, the most appropriate measure for stent expansion over a segment is 'hoop force', reflecting the tension distribution across the circumference and the length of the compressed segment.²⁴ Radial force describes resistance against compression, whereas expansion force is the term that describes the stent's outward force during the expansion process. These parameters are related and which exact one is used is less important than uniformity across the industry.

A description of stent characteristics should be available on the stent boxes, as well as in the instructions for use to allow operators to make the best choices for different contexts. Some manufacturers already include tables for the degree of stent shortening during expansion from their compressed and elongated state. Depending on stent construction, there is a relation between expansion force and axial rigidity.⁶ The latter, which represents the stent's resistance to conform to a flexure is exaggerated by covering the stent in liquid silicone—a process which 'glues' the wires together and markedly increases the rigidity of the stent skeleton. This is not the case when a separate covering membrane is attached to the outside of the stent or sandwiched between two layers of metal wires in 'double' stents.

Additional information on stent expansion and straightening forces would allow better matching of the device characteristics with the specific patient's needs. Strictures with a small tumor bulk positioned in or near flexures have the best result with a conformable stent, in which case high expansion force is not a

priority. Stenoses with a large tumor bulk or surrounding fibrosis, e.g., recurrence after radiotherapy or anastomotic recurrences have a requirement for a higher expansion force in order to overcome the restriction by the associated scar tissue. However, the higher force exerted on the surrounding tissues by larger esophageal stents causes more complications²⁵ and at the same time previous treatment increases the risks in esophageal stenting,²⁶ which makes stent selection particularly difficult in the context of previous chemo-/radiotherapy.

The use of a single parameter might not be adequate to describe stent behavior,^{27,28} however, a uniform assessment would at least allow some form of comparison.

Due to the lack of clarity around current stent properties, it is not possible to identify the 'best' stent. Furthermore, the differing requirements between patients make it very hard to develop the ideal stent, which suits all patients, but interventionists need to understand their devices in order to achieve a good clinical result.

Regulators of the industry need to work with manufacturers and the interventionists to develop an agreed test standard and define an acceptable range of stent forces. Otherwise, best possible patient outcome will continue to be guesswork.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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