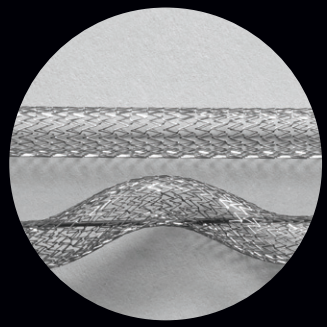
Mechanical Properties of Nitinol Stents and Stent-grafts

Comparison of 6 mm Diameter Devices



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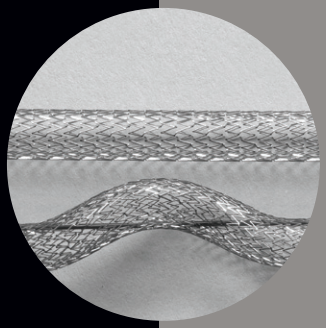
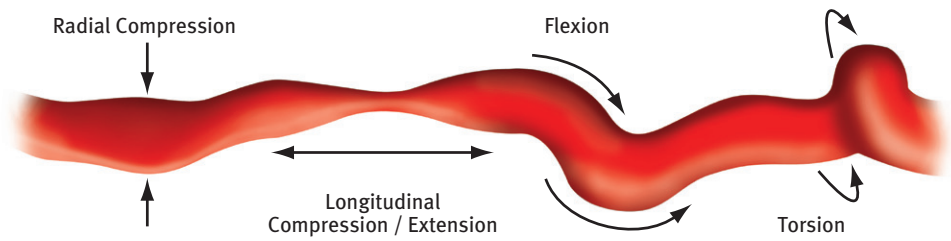


Purpose

The association of target vessel restenosis with stent fractures has led to an emergence of interest in the mechanical properties of nitinol stents and stent-grafts [1]. Reduction of these fractures requires an understanding of the biomechanical forces at the implantation site and the mechanical properties of the stent. Published comparisons between self-expanding stents have been sparse [2 – 5], limiting the physician's ability to select the optimal stent for the intervention. The testing presented in this report is intended to provide a comparison of 6 mm diameter nitinol stents and stent-grafts from various manufacturers (see *Table 1*) under four physiologically relevant strain conditions: longitudinal compression, radial compression, bending / flexion, and torsion (*Figure 1*). The choice of stents was not intended to be comprehensive, but instead representative of commercially available devices. As standards for this testing do not exist, every attempt was made to design fair and relevant tests. However, different tests are applicable to different applications and results may vary under other test conditions. No claim or evaluation with regard to product appropriateness for any indication is intended or implied.

FIGURE 1. *Forces simulated in stent comparison.*



Materials and Methods

Devices and Testing Equipment

The devices used in the study are presented in *Table 1*. Prior to testing, the devices were deployed and the stent removed. Each test was performed in triplicate using three separate stents. An INSTRON® Universal Tensile Tester (Instron Corporation, Norwood, MA) was used for all mechanical testing. Testing was done in a temperature controlled chamber at 37°C.

TABLE 1. *Nitinol stents and stent-grafts included in study.*

Tradename	Material	Size
PROTÉGÉ® GPS Device (ev3)	Nitinol	6 mm x 80 mm
LIFESTENT NT35 Stent (Bard)	Nitinol	6 mm x 80 mm
ABSOLUTE Stent (Guidant)	Nitinol	6 mm x 80 mm, 6 mm x 100 mm
S.M.A.R.T.® Control Stent (Cordis)	Nitinol	6 mm x 80 mm
GORE® VIABAHN® Endoprosthesis (Gore)	Nitinol / ePTFE	6 mm x 100 mm
FLUENCY® Plus Stent (Bard)	Nitinol / ePTFE	6 mm x 80 mm

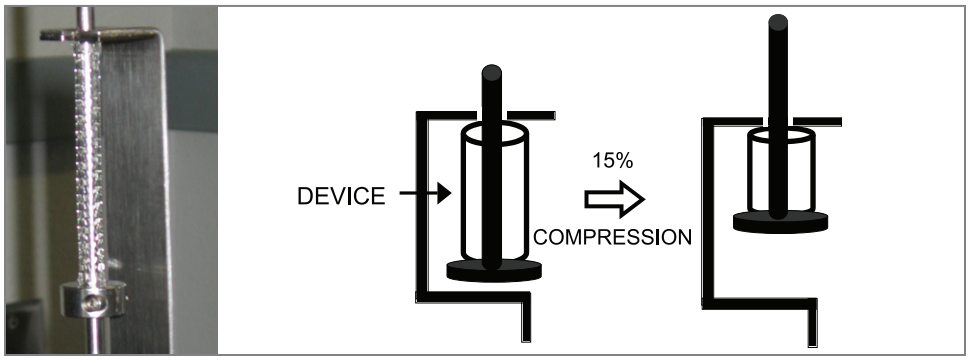
Data Analysis
For each device and mechanical force tested, data were collected for load (kgf, y-axis) vs. compression (mm, x-axis). To calculate the load at a specific compression, load values were averaged for ± 0.5 mm of the target compression value.

Longitudinal Compression
Stent samples were placed in a custom longitudinal grip and placed in the INSTRON® Tester (*Figure 2*). The grip has a central rod, a flat surface attached to the rod, and an upper flat surface with an opening to allow the rod (but not the stent) to move freely through the surface. The stent is placed on the rod and rests on the bottom flat surface. As the rod is advanced up through the upper flat plate, the stent contacts the upper flat plate and is compressed.

For quantitative analysis, the central rod was advanced until the device had compressed 15% longitudinally (12 mm for 80 mm length stents, 15 mm for 100 mm length stents) between the upper and lower surfaces. The force required to achieve this compression was measured for each stent.

As a qualitative assessment of the performance of these stents under longitudinal compression conditions without axial constraint, a 25% compression level was used. Pins were set such that the stent would be compressed 25% when positioned between them (*Figure 4*). A central guidewire was used to keep the stents between the pins.

FIGURE 2. *Photo and schematic of longitudinal compression testing fixture.*



Results
To mimic potential *in vivo* longitudinal compression forces [6, 7], all stents were compressed longitudinally by 15% and the corresponding force measured (*Figure 3*). The GORE® VIABAHN® Endoprosthesis was the most compliant stent, with the least force required for a 15% compression.

It was 3x more compliant than the next closest stent (LIFESTENT NT35 Stent) and 28x more compliant that the other stent-graft included in the study (FLUENCY® Plus Stent). The statistical analysis is presented in *Table 2*.

FIGURE 3. *Force (grams-force) required for 15% longitudinal compression.*

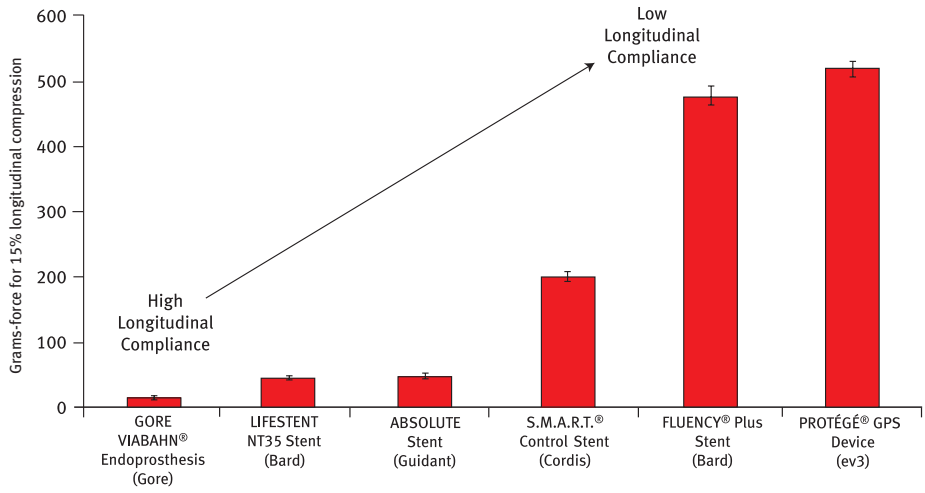
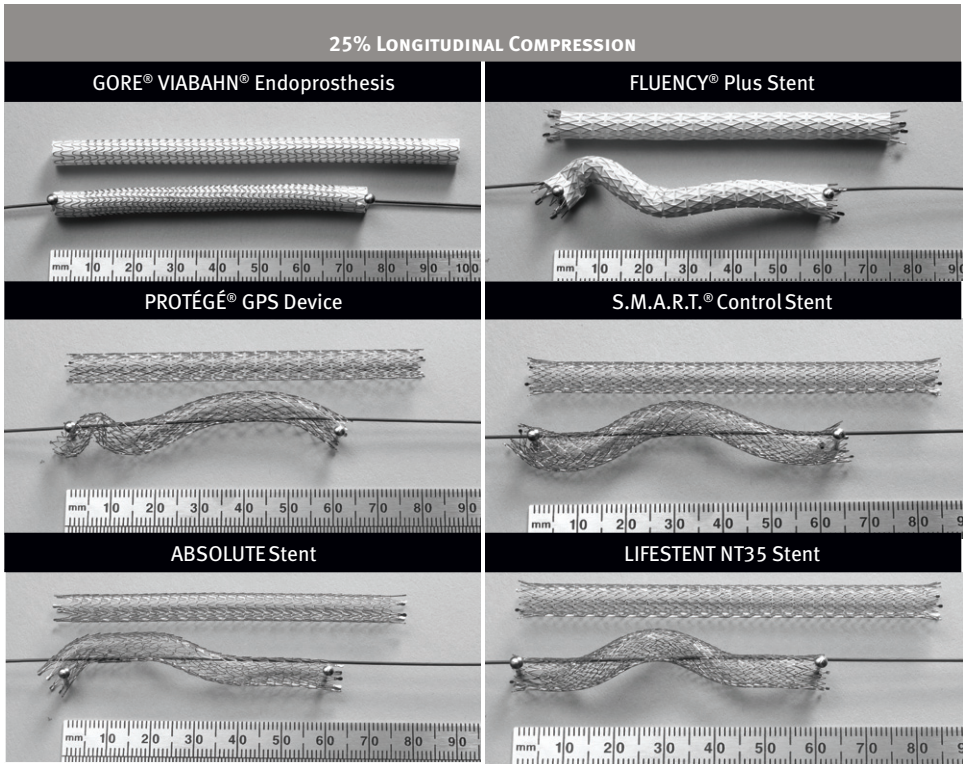


TABLE 2. *Statistical analysis of longitudinal compression data.*

Stent	Stents Connected by Same Letter Are Not Significantly Different (P < 0.05)				Mean (gm-force)
PROTÉGÉ® GPS Device	A				539
FLUENCY® Plus Stent		B			477
S.M.A.R.T.® Control Stent			C		203
ABSOLUTE Stent				D	55
LIFESTENT NT35 Stent				D	54
GORE® VIABAHN® Endoprosthesis				D	17

To visually represent the response of the stent samples to longitudinal compression, photographs were taken of the stent samples compressed by 25% (*Figure 4*). It is interesting to note that the GORE® VIABAHN® Endoprosthesis could be longitudinally compressed without introducing curves in the stent to compensate for decreased length. The S.M.A.R.T.® Stent, ABSOLUTE Stent, and LIFESTENT NT35 Stent showed compensating curvature, but did not show evidence of kinking. The FLUENCY® Plus Stent and PROTÉGÉ® Stent had both compensating curves and evidence of stent kinking.

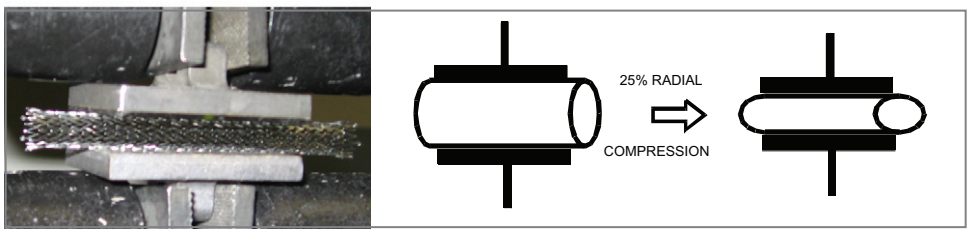
FIGURE 4. *Images of stents longitudinally compressed by 25%.*



Radial Compression

Each stent was situated between two flat plates (2" wide) attached to the INSTRON® Tester and the plates were advanced toward each other (*Figure 5*). The force required to compress the stent radially by 25% (1.5 mm) was measured.

FIGURE 5. *Photo and schematic of radial compression testing*



Results

To test radial compressive strength, all stents were placed between two flat plates and the force to compress the devices radially by 25% was measured. As seen in *Figure 6*, the stents showed similar radial strength, with only a 2.6 x difference observed from highest (Bard FLUENCY® Plus Stent) to lowest (Guidant ABSOLUTE Stent). The statistical analysis is presented in *Table 3*.

FIGURE 6. *Force (grams-force) required to compress stent radially by 25%.*

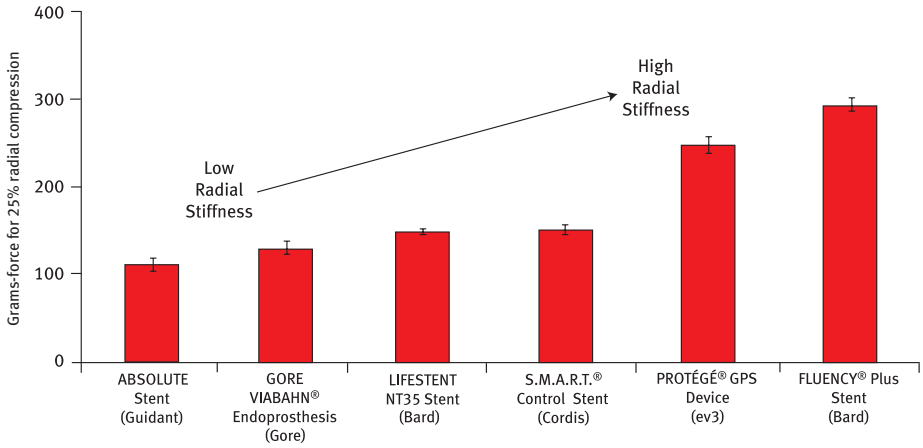


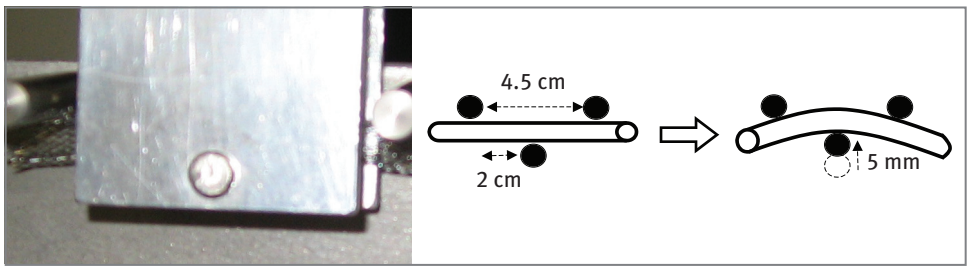
TABLE 3. *Statistical analysis of radial compression data.*

Stent	Stents Connected by Same Letter Are Not Significantly Different ($p < 0.05$)				Mean (gm-force)
FLUENCY® Plus Stent	A				296
PROTÉGÉ® GPS Device		B			242
S.M.A.R.T.® Control Stent			C		153
LIFESTENT NT35 Stent			C		150
GORE® VIABAHN® Endoprosthesis				D	125
ABSOLUTE™ Stent				D	115

3-point Bending

To quantitatively measure 3-point bending, a custom INSTRON® Tester grip was built with three support rods. The stent was placed with the outer support rods in contact with the upper surface of the sample and the middle rod supporting the bottom of the sample (*Figure 7*). The middle rod was pulled up 5 mm, thereby placing the stent sample in a 3-point bend. The force resulting from a 5 mm displacement of the middle rod was measured. Stent samples were also bent around various pin configurations and photographed to qualitatively assess bending performance.

FIGURE 7. *Photo and schematic of 3-point bending fixture*



Results

Quantitative comparison of the bending compliance of stent samples was evaluated using a 3-point bending test and the force to achieve a 5 mm bend displacement over a 4.5 cm length was measured for each stent. This displacement is within the range of physiological environments [8]. As seen in *Figure 8*, the FLUENCY® Plus Stent showed the lowest bending compliance of all stents. The GORE® VIABAHN® Endoprosthesis had the highest bending compliance, almost 4 x more than the next stent (ABSOLUTE Stent) and 108 x more compliant than the FLUENCY® Plus Stent. Statistical analysis is shown in *Table 4*.

FIGURE 8. *Force required for 5 mm displacement in 3-point bend test.*

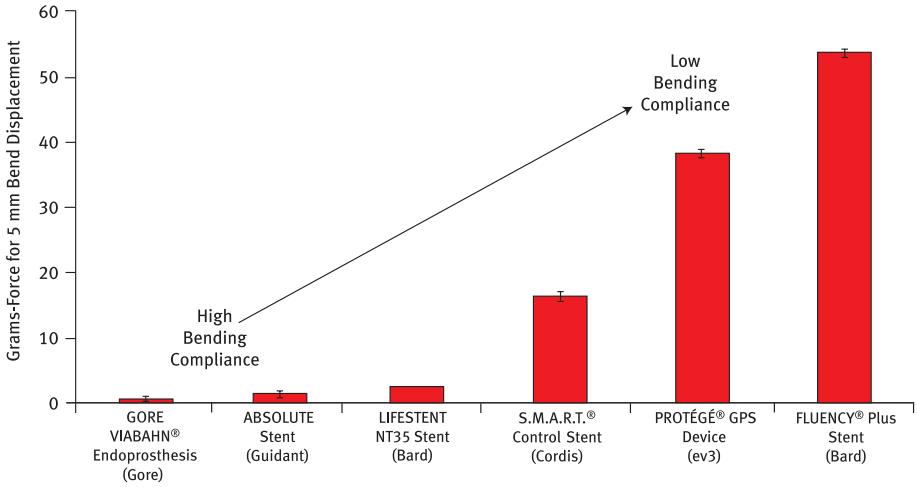


TABLE 4. *Statistical analysis of 3-point bending data.*

Stent	Stents Connected by Same Letter Are Not Significantly Different (p < 0.05)						Mean (gm-force)
FLUENCY® Plus Stent	A						54
PROTÉGÉ® GPS Device		B					38
S.M.A.R.T.® Control Stent			C				17
LIFESTENT NT35 Stent					D		2.2
ABSOLUTE Stent					D		1.9
GORE® VIABAHN® Endoprosthesis					D		0.5

To obtain a visual representation of the stent samples in extreme bending configurations, the stents were bent around pins arranged in two different configurations and photographed (see *Figures 9 and 10*). The stents with high quantitative bending compliance seem to show better conformability in the extreme conditions shown in *Figures 9 and 10*.

FIGURE 9. *Images of stents in various bending configurations.*

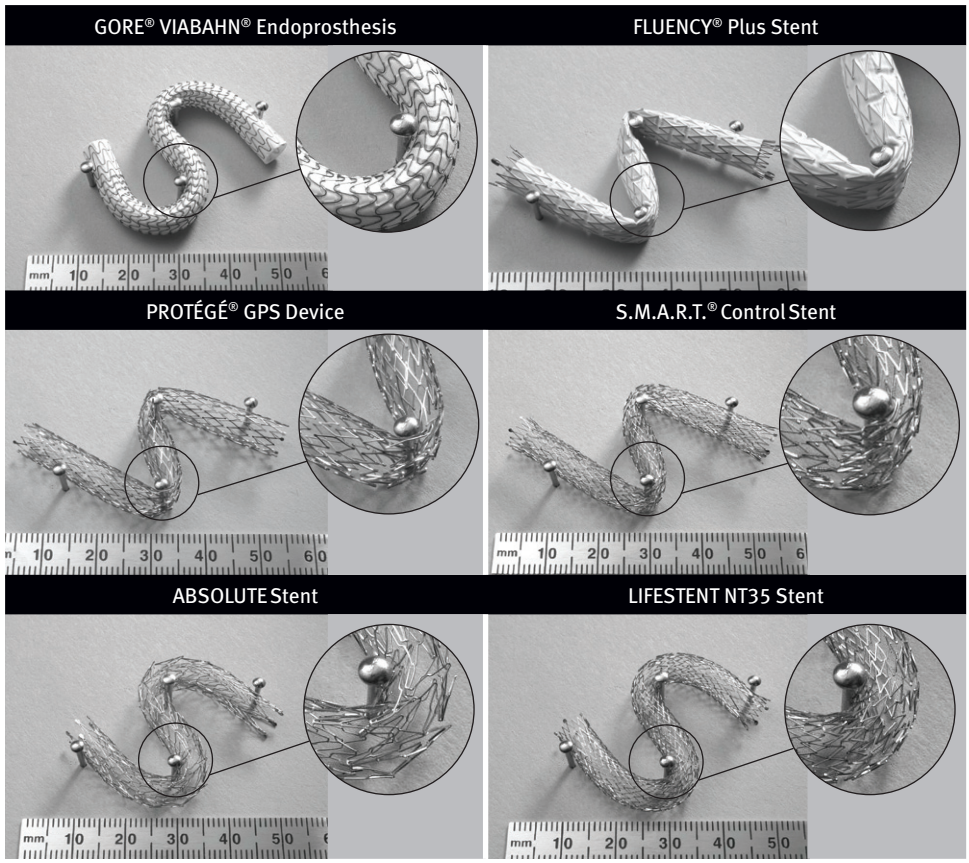
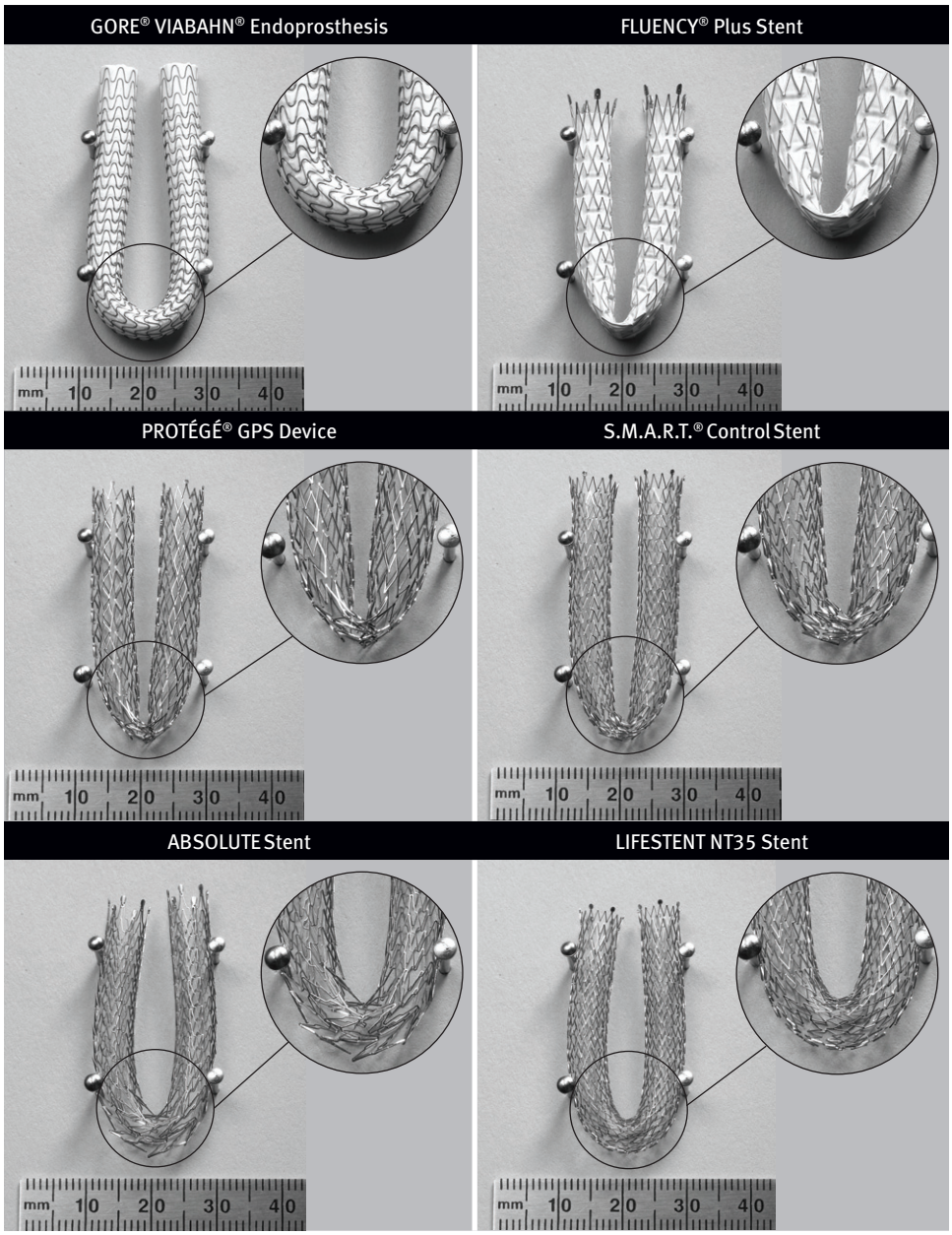


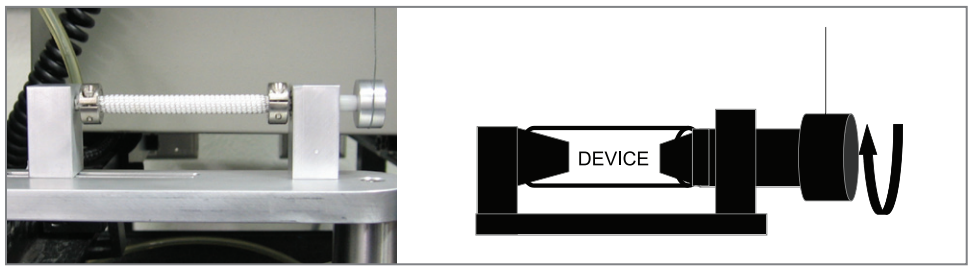
FIGURE 10. *Images of stents in various bending configurations.*



Torsion

A custom INSTRON® Tester grip was used to translate longitudinal movement of a pull string to angular deflection of the graft (*Figure 11*). Stents were secured in the grip with a known distance between attachment points. Tension was applied to the pull string causing one attachment point to rotate. The torsional force was measured at a 3° / cm twist.

FIGURE 11. *Photo and schematic of torsion testing fixture.*



Statistical Analysis

Statistical comparisons for each test were done using an ANOVA with a Tukey's post-hoc and significance set at $p < 0.05$.

Results

A comparison of measured torsional forces for a 3° / cm twist on the stent was evaluated (*Figure 12*). This 3° / cm twist is considered to be within the range of potential physiologic environments [6]. This twist was 24° and 30° for the 8 and 10 cm devices, respectively. The ABSOLUTE Stent showed the highest torsional compliance, while the FLUENCY® Plus Stent was extremely stiff (~23-fold difference compared to ABSOLUTE Stent). Statistical analysis is shown in *Table 5*.

FIGURE 12. *Force required for a 3° / cm twist.*

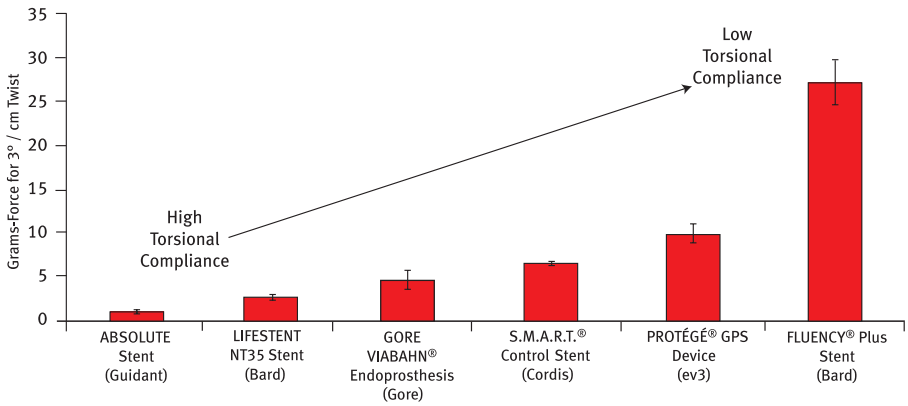


TABLE 5. *Statistical analysis of torsion data.*

Stent	Stents Connected by Same Letter Are Not Significantly Different ($p < 0.05$)			Mean (gm-force)
FLUENCY® Plus Stent	A			27.1
PROTÉGÉ® GPS Device		B		9.6
S.M.A.R.T.® Control Stent		B	C	6.2
GORE® VIABAHN® Endoprosthesis		B	C	4.3
LIFESTENT NT35 Stent			C	2.5
ABSOLUTE Stent			C	1.2

Flexibility and Stent Fracture Relationship

When comparing the compliance of the stents to stent fractures reported in the literature, there is a correlation with the more compliant stents having fewer fractures. GORE® VIABAHN® Endoprosthesis was the most compliant stent in 3-point bending and longitudinal compression. Of over 100,000 devices sold, the reported fracture rate of the GORE® VIABAHN® Endoprosthesis is less than 0.01%. Two other compliant stents, LIFESTENT NT35 Stent and ABSOLUTE Stent, have literature-reported fracture rates of 3.7% and 2%, respectively [9, 10]. The S.M.A.R.T.® Control Stent was less compliant in the studies above and has higher stent fracture rates (27 – 28%) reported in the literature [1, 9]. Although fracture data was not found on the PROTEGE GPS Device, fracture rates of the more flexible PROTEGE EverFlex stent were reported to be 8.1% at one year [11].

Conclusions

As shown in this document, there are stark differences between the performance of 6 mm self-expanding stents and stent-grafts under mechanical stresses. In some instances, the difference between stents was greater than 100 x (GORE® VIABAHN® Endoprosthesis vs. FLUENCY® Plus Stent in 3-point bending). Mechanical properties as evaluated in this paper correlate with literature reported fracture rates. With more information on the mechanical characteristics of the stents, the physician will be better able to make an educated choice for the end use application.

References

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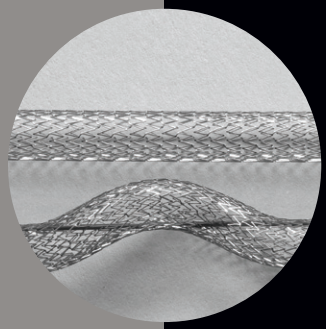

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