# **EXPEDITED PUBLICATION: CLINICAL RESEARCH**

# **Stent Longitudinal Integrity**

### **Bench Insights Into a Clinical Problem**

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**Objectives** Standardized bench-top compression and elongation testing was undertaken to assess the longitudinal strength of contemporary stents. Insights gained may improve clinical stent choice and deployment techniques, and facilitate future stent design improvements.

**Background** The hoops of coronary stents provide radial support, and connectors hold hoops together. Strut material, shape, and thickness, along with connector number and configuration, provide the balance between stent flexibility and longitudinal integrity. Longitudinal distortion manifests as length change, strut overlap, strut separation, malapposition, and luminal obstruction. These may predispose to restenosis and stent thrombosis, obstruct passage of devices, be misinterpreted as strut fracture, and require additional stenting.

**Methods** The force required to compress and to elongate 7 contemporary stents was measured with an Instron universal testing machine (Norwood, Massachusetts). Stents deployed in a silicone phantom damaged by a balloon or guide catheter were imaged by microcomputed tomography to understand better the appearances and effects of longitudinal distortion.

**Results** Stents with 2 connectors (Boston Scientific [Natick, Massachusetts] Omega and Medtronic [Santa Rosa, California] Driver) required significantly less force to be compressed up to 5 mm and elongated by 1 mm than designs with more connectors. The 6-connector Cypher Select required significantly more force to be elongated 5 mm than other designs.

**Conclusions** Stents with 2 connectors between hoops have less longitudinal strength when exposed to compressing or elongating forces than those with more connectors. This independent, standardized study may assist stent selection in clinical situations where longitudinal integrity is important, and may aid future design improvements. Stent longitudinal strength, the resistance to shortening or elongation, appears related to the number of connectors between hoops. Using a standardized testing protocol, designs with 2 connectors were more likely to shorten or elongate than those with more connectors. Distortion may be recognized clinically as bunching or separation of struts, and may be confused with strut fracture. Without post-dilation or further stent deployment, the patient may be at increased risk for adverse clinical events. A stent design change ensuring 3 connectors, especially at the proximal end of a stent, should increase longitudinal integrity, but perhaps at the expense of stent flexibility. (J Am Coll Cardiol Intv 2011;4:1310–7) © 2011 by the American College of Cardiology Foundation

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Balloon-expandable coronary stents generally have a series of hoops to provide the radial strength when scaffolding the vessel wall, with connectors between the hoops to hold the stent together. The sinusoidal hoops many be in phase or out of phase. The number, orientation, shape, thickness, and material of the connectors are major contributors to stent longitudinal flexibility and deliverability before deployment, and to vessel conformability and cell size and shape (for branch vessel access) after deployment (1). They also contribute to the "longitudinal strength" of the stent, which can be defined as maintenance of stent architecture without distortion when the stent is exposed to compressing or elongating forces.

Design changes that improve 1 stent feature often lead to a worsening of another desirable feature, with optimal stent design balancing tradeoffs between performance characteristics. The development of newer metal alloys such as cobalt chrome and platinum chrome has allowed stent strut thickness to be reduced with maintained radial strength. Reducing strut thickness without change in metal composition improves stent flexibility and crossing profile. There is evidence that thinner struts cause less vessel wall damage and hence less stimulus for restenosis (2). The number of connectors between hoops has also been reduced to improve stent flexibility, deliverability, conformability to the artery, and side-branch access (1).

The combination of fewer connectors and, to a lesser extent, thinner struts may adversely affect stent longitudinal integrity. We and others have observed shortening or elongation of stents due to the struts being pushed together or pulled apart (3,4). Stent distortion usually occurs after initial deployment, during positioning of a post-dilation balloon or intravascular ultrasound catheter. Similar problems have been reported to the U.S. Food and Drug Administration MAUDE (Manufacturer and User Facility Device Experience) Registry.

This study evaluated stent longitudinal strength using standardized bench testing protocols, comparing 7 currently available coronary stent platforms. Rigorous bench-top studies can improve understanding of clinically important stent characteristics and guide design improvements.

### **Methods**

Stent platforms. The stents tested were the Cypher Select (Cordis, Miami, Florida), Liberte (Boston Scientific, Natick, Massachusetts), Vision (Abbott Vascular, Santa Clara, California), MultiLink 8 (Abbott Vascular), Driver (Medtronic, Santa Rosa, California), Integrity (Medtronic), and the Omega (Boston Scientific). The drug-eluting version of Vision is Xience V, of MultiLink 8 is Xience Prime, of Driver is Endeavor, of Integrity is Resolute, and of Omega is Promus Element and Taxus Element (called ION in the United States). Three examples of the 3-mm diameter stent

of each platform design were tested. Drug coating does not alter the longitudinal integrity of a metallic stent platform. Figure 1 summarizes the key characteristics of each design, including strut thickness, stent material, and number of connectors between hoops.

**Stent compression and elongation tests.** Figure 2 depicts how the tests were performed using an Instron universal testing machine (Norwood, Massachusetts) to measure the force needed to compress or elongate stents more than 5 mm. For the compression test, each stent was clamped to the mandrel so that 10 mm of stent was exposed to the compressing force. For elongation, the clamp allowed 8 mm of stent to be exposed. Photographs were recorded at each millimeter of compression or elongation.

**Deployed stent longitudinal distortion test.** To study further the mechanism and appearance of longitudinal distortion, stents were deployed in a curved silicone phantom in a water bath under fluoroscopic control at 6 atm pressure. The deploying balloon was advanced and inflated to 20 atm so that the distal struts were fully apposed to the mock arterial wall but leaving the proximal struts malapposed and more likely to be distorted. A deflated, but previously used, noncompliant balloon was passed through the stent lumen on multiple occasions with different wire tension until resistance was encountered. Stent

deformation was observed on fluoroscopy. In a separate experiment, a guide catheter was advanced into the phantom to contact the deployed stent to mimic

# Abbreviation and Acronym N = Newtons

clinical stent compression by a deeply engaged guide. Micro-computed tomographic images of distorted stents were acquired (5,6).

**Statistics.** Descriptive statistics of the data were provided as mean  $\pm$  SD. The stents were compared using 1-way analysis of variance. Tukey's HSD multiple comparison test was used to make all pair-wise comparisons. Statistical analyses were performed using SAS statistical software, version 9.2 (SAS Institute, Cary, North Carolina). All p values resulted from 2-sided tests, and a p value of <0.05 was considered statistically significant.

## Results

When a compressive force was applied to the stents, they shortened (Fig. 3). The most easily compressed were the Omega (Element) and Driver (Endeavor) stents, where the force to shorten by 1 mm was similar at 0.16  $\pm$  0.01 N and 0.19  $\pm$  0.02 N (p = 0.9), respectively. The force to compress the Liberte by 1 mm (0.37  $\pm$  0.3 N) was similar to that for the Integrity (0.40  $\pm$  0.04 N, p = 0.94) but significantly more than the Driver (p = 0.001). The force required to compress by 1 mm the Vision (0.50  $\pm$  0.02 N) was



#### Figure 1. Design of the Stents Tested

Shown are photographs of the stent designs, their names, the metal they are constructed from, strut thickness in microns, and the number of connectors between hoops for each design. The Cypher Select, cut from a stainless steel tube, has a strut thickness of 140  $\mu$ m. Its design is out-of-phase sinusoidal hoops linked by 6 sinusoidal bridges that are orientated about 30° from the stent long axis. The Liberte, cut from a stainless steel tube, has struts100  $\mu$ m thick. Its apparently complex design is fundamentally out-of-phase hoops (yellow line) that are joined directly by 3 links (red arrows). The Vision and MultiLink 8 and their drug-eluting counterparts, Xience V and Xience Prime, are cut from a cobalt chromium tube and have struts 81  $\mu$ m thick. The design is in-phase sinusoidal hoops linked by 3 bridges that are aligned with the stent long axis. Each connector has a U-shaped loop to improve flexibility. The 3-mm Driver (and the drug-eluting version, Endeavor or Resolute) has sinusoidal, largely out-of-phase hoops linked by 2 welds (red arrows). The lotter with 2 welds between adjacent "hoops" (red arrows). The Omega (bare-metal version) and Promus Element (everolimus-eluting version) and the paclitaxel-eluting version (Taxus Element, called "loop" in the United States) have sinusoidal hoops made from platinum chromium. These are linked by 2 straight bridges per hoop that are aligned at an angle of about 45° from the stent long axis (red arrows).

similar to Cypher Select (0.51  $\pm$  0.04 N) and the MultiLink 8 (0.53  $\pm$  0.08 N) but more than the Liberte (p = 0.01).

For 5-mm shortening (Fig. 3), the least force was required for the Omega (0.40  $\pm$  0.06 N) and Driver (0.71  $\pm$  0.13 N, p = 0.4) stents. The greatest force was required for the Cypher Select, requiring 1.33 N, which was significantly more than for the Omega and Driver stents (p = 0.001 and p = 0.013, respectively). The Integrity (1.08  $\pm$  0.027 N), Liberte (1.10  $\pm$ 0.27 N), Vision (1.12  $\pm$  0.16 N), and MultiLink 8 (1.10  $\pm$ 0.16 N), all required significantly more force to be compressed 5 mm than the Omega (p = 0.013 to 0.004).

With 0.5 N of compressive force, the Cypher Select (Fig. 4) did not shorten. There was little shortening with the Vision and MultiLink 8 platforms. The most shortening and distortion occurred with the Driver and Omega platforms (Fig. 4).

The stent alterations that occurred with 5-mm shortening were demonstrated by micro-computed tomography (Fig. 5).

When an elongating force was applied to the stents, the most easily deformed stents were the Omega and Driver (Fig. 6). The force in Newtons to elongate stents by 1 mm was least for the Omega (0.19  $\pm$  0.01 N) and Driver (0.20  $\pm$  0.03 mm, p = NS). That to elongate the Liberte (0.36  $\pm$  0.07 N) was not different from the Integrity (0.37  $\pm$  0.04 N) but

significantly more than for the Driver (p = 0.023). The force to elongate the MultiLink 8 (0.54  $\pm$  0.02 N) by 1 mm was not different from the Vision (0.56  $\pm$  0.08 N) but significantly more than for Integrity (p = 0.02) and significantly less than the Cypher Select (0.8  $\pm$  0.08 N, p < 0.001).

For elongation of 5 mm (Fig. 6), although strong trends existed, the force required did not differ significantly between Driver (0.43  $\pm$  0.01 N), Omega (0.72  $\pm$  0.01 N), Liberte (0.80  $\pm$  0.11 N), Integrity (0.81  $\pm$  0.11 N), Vision (1.32  $\pm$  0.11 N), and MultiLink 8 (1.34  $\pm$  0.12 N). However, the force for the Cypher Select (5.7  $\pm$  3.46 N) was significantly more than for the other stents (p values ranged between 0.015 and 0.006).

With an elongating force of 0.5 N, those stents with the greatest longitudinal stability stretched the least, and those with the least longitudinal stability elongated the most (Fig. 7). The Cypher Select with 6 connectors between hoops was not elongated by 0.5 N force. The Liberte elongated 2 mm. The Vision/Xience and MultiLink 8/Xience Prime elongated 1 mm with minimal distortion (Fig. 7). The Driver/ Endeavor elongated 5 mm with the 0.5 N force, and there was severe distortion, with separation of hoops and reduction in scaffolding and drug application. In contrast, the



Figure 2. Compression and Elongation Tests

In **A**, for the compression test, the expanded stent was placed over a 2.60-mm diameter mandrel (m) and clamped so that 10 mm of stent was exposed. In **B**, a donut-shaped component (d) attached to an Instron universal testing machine was lowered over the mandrel to make contact with the stent. The force required to compress the stent 5 mm was plotted against compression distance. In **C**, for the elongation test, a stent was clamped so that 8 mm was exposed. In **D**, a hook attached to the Instron was passed through the side of a stent below the third hoop. The force to elongate the stent 4 mm was plotted against elongation distance.

Integrity, which is constructed from the same metal (CoCr, sometimes called CoNi), and has the same strut thickness (91  $\mu$ m) and number of connectors (2 connectors) but a different design in which a sinusoidal strut winds from one end to the other in a helical fashion was much more resistant to distortion elongating only 2 mm with the 0.5-N force. The Omega/Element with 2 connectors between hoops elongated 5 mm, with major disruption of stent architecture (Fig. 7).

Examination of bench distortions can facilitate understanding of clinical appearances after stent longitudinal distortion (Fig. 8). Devices such as a post-dilating balloon can catch on struts, deforming the stent, pushing the struts together, causing luminal obstruction (Fig. 8A). This obstruction may hinder the passage of devices across the deployed stent. Besides bunching of struts, there may be separation of struts (3) that may reduce scaffolding and drug application, and appear as a radiolucent area because of absence of struts sometimes misinterpreted as strut fracture (Fig. 8B). Stent malapposition occurs with these scenarios. Longitudinal distortion can occur when a guide catheter impinges on struts, shunting them distally (Fig. 8C).

### **Discussion**

This study sheds light on the increasingly recognized clinical problem of disruption of stent longitudinal integrity leading to distortion that can be marked (3,4,7-9). There

were significant differences between 7 contemporary stent designs subjected to a standardized compression or elongation force. Those stents with only 2 connectors, the Element and the Driver, were more likely to distort under longitudinal loads than those with 3 or more connectors. In addition, this study shows the bench appearance of disrupted stents to aid clinical recognition.

Longitudinal integrity is only 1 desirable characteristic on which to base stent selection. Although many factors influence stent flexibility, we have previously shown that the number of connectors between hoops, and hence, longitudinal integrity, correlates with stent stiffness, the reciprocal of flexibility (1). Stent deliverability, strongly influenced by flexibility, is the property that cardiologists desire most (1,10), and designs that have high longitudinal integrity may not have high flexibility and deliverability. We show that the earlier generation Cypher Select, a 6-connector design, had the greatest resistance to longitudinal distorting forces. This stent is no longer widely used because other designs have better flexibility, deliverability, crossing profile, radio-opacity, side-branch access, and freedom from strut fracture.

Besides connector number, the alignment of the connectors with the long axis of the stent may also be important for longitudinal integrity. The angulation of the connectors in the Element design (Fig. 1) where the connectors link the offset, in-phase hoop peaks may contribute to the lesser resistance to longitudinal distortion.

Longitudinal distortion was recognized in the early days of coronary stenting, particularly with stents made from a single wire. The Wiktor stent (Medtronic), a tantalum wire coiled in a sinusoidal fashion without connectors, was highly flexible (1) but prone to unraveling or uncoiling in complex anatomy or ostial positions (7–9). This potential for defor-



Figure 3. Compressive Force and Stent Shortening

Plotted is stent shortening (millimeters) against force (Newtons) for 3 examples of the 7 stent designs. Compression graphs are not smooth but are complicated because of strut collision and over-ride.



mation likely contributed to a restenosis rate higher than the contemporaneous slotted-tube stent designs (7,8). For some years following this, design trends swung away from coiled wire stents to designs that were laser cut from stainless steel tubes that had higher radial strength, and multiple connectors between hoops with greater longitudinal integrity but

lower flexibility (1). Subsequently, flexibility has been improved by designs with fewer connectors and thinner struts. Although reducing the number of connectors improves flexibility, the tradeoff can be reduced longitudinal integrity.

The analysis of 40 reports to the MAUDE registry provides insights into the nature and causes of longitudinal



Shown are micro-computed tomographic images cut electronically longitudinally after the stents had been compressed by 5 mm. Of course, different magnitudes of force were required to compress different designs by 5 mm. The lower portions of the stents below the **broken line** were clamped, hence were not subjected to compressive forces, and serve as normal stent comparitors for insights into mechanisms of shortening. For the Cypher Select the hoops were able to bunch as the wavelength of the sinusoidal connectors shortened and the connectors angulated and became less aligned with the long axis. For the Vision and MultiLink 8 designs, the hoops were pushed together where there are no connectors. In addition, the connectors became angulated and less aligned with the long axis of the stent. Furthermore, especially with the MultiLink 8, the U-shaped loop in the connector closed up. The Liberte, Driver, and Integrity designs have only 2 connectors between hoops, and these are direct connections so there was little to prevent struts bunching and overlapping in response to compressive forces. With only 2 connectors between hoops, there is again little to prevent Omega/Element struts being pushed together. Additionally, connector orientation changed, becoming more aligned with the stent long axis.



#### Figure 6. Stent Lengthening in Millimeters With Increasing Elongating Force in Newtons

The most easily deformed stents were the Omega and Driver. The force in Newtons to elongate stents by 1 mm was least for the Omega (0.19  $\pm$  0.01 N) and Driver (0.20  $\pm$  0.03 mm, p = NS). That to elongate Liberte (0.36  $\pm$ 0.07 N) was not different from the Integrity (0.37  $\pm$  0.04 N) but significantly more than for the Driver (p = 0.023). Force to elongate the MultiLink 8 (0.54  $\pm$  0.02 N) by 1 mm was not different from the Vision (0.56  $\pm$ 0.08 N), but significantly more than for Integrity (p = 0.02) and significantly less than the Cypher Select (0.8  $\pm$  0.08 N, p < 0.001). For elongation of 5 mm, the force required did not differ between Driver (0.43  $\pm$  0.01 N), Omega (0.72  $\pm$  0.01 N), Liberte (0.80  $\pm$  0.1 1N), Integrity (0.81  $\pm$  0.11 N), Vision (1.32  $\pm$  0.11 N), and Multilink 8 (1.34  $\pm$  0.12 N). However, the force for the Cypher Select (5.7  $\pm$  3.46 N) was significantly more that for the other stents (p values ranged between 0.015 and 0.006).

distortion, but not incidence because of under-recognition (3). Under-recognition is partly because cardiologists are not attuned to recognize distortions (3). Disruption may be difficult to recognize with the more radiolucent stents



headed arrows). In C, a deeply engaged guide catheter has shunted hoops distally, crowding them together, causing strut overlap, and causing the connectors between hoops to be aligned more horizontally (yellow arrows).

compared with a more radio-opaque stents such as the Element platinum chromium platform (11). Both stent shortening and elongation were reported. Deformation with



stent was secured by clamping the portion of stent below the broken line onto the mandrel so this portion was not exposed to disruptive forces. The Cypher Select had the greatest longitudinal stability with no elongation in response to 0.5-N force, and the Driver/Endeavor and Omega/Element had the least longitudinal stability, with 5-mm elongation in response to 0.5-N force.

separation or bunching of struts or both was most common in the proximal end of the stent, and less common at the distal end or in the middle of the stent. Shortening has been described as "concertina," "accordion," folded, squeezed together, pushed together, shrinkage, closing rings together, compression, wrinkling, deformation. Elongation has been described as stretching, elongation, or separation. Causes of shortening include the post-dilating balloon, intravascular ultrasound catheter, guide catheter, another stent delivery system, thrombectomy catheter, and wire entanglement. In some instances, cardiologists described disruption after resistance to crossing, a catheter catching in a deployed stent, or entanglement or entrapment of devices or wires in a deployed stent.

There are potential adverse consequences of longitudinal deformation. Patients with recognized MicroDriver distortion had a 38% incidence of major adverse cardiac events (3). When struts of a deployed stent are pushed together or pulled apart, longitudinally deforming a stent, there are regions of artery that are no longer fully scaffolded and where drug delivery may be reduced, with a potential for restenosis. Our clinical experience and our bench testing (Fig. 8) suggest that longitudinal deformation is often accompanied by protrusion of struts into the lumen leading to obstruction of passage of a device such as a post-dilating balloon. In addition, there may be significant malapposition of struts along with disrupted flow that may predispose to stent thrombosis (Fig. 8). Additional stenting may be judged necessary (3). Correction of stent deformation by post-dilation has been recognized for many years (12). We believe that when stent longitudinal deformation is recognized, post-dilation should be carried out to overcome luminal obstruction and appose struts. If a noncompliant balloon will not cross a deformed stent for post-dilation, then a compliant, more flexible or lower profile balloon may cross. Although intravascular ultrasound or optical coherence tomography may provide useful information, there is a risk that they will cause further deformation if they interact with the struts of a deformed stent.

Stent design is a balance of desirable characteristics. The alteration of 1 characteristic aimed at improving stent performance may lead to tradeoffs so that a desirable characteristic is lost or an undesirable characteristic appears. The reduction in number of connectors between stent hoops and, to a lesser extent, reduction in strut thickness have successfully improved stent flexibility and deliverability, with the unanticipated consequence of potential for longitudinal distortion (1). Although the Driver and Integrity stents have 2 connections between hoops (or hoop-like structures), the Integrity has greater longitudinal integrity, perhaps because the helical single wire winding from 1 end of the stent to the other behaves like a third connector. Bench testing provides independent, objective data to assist in understanding and recognition of stent properties such as

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distortion (1,6,12). It illuminates the design components that predispose to longitudinal distortion and can compare the potential for longitudinal distortion of different contemporary stent platforms so that we can provide recommendations to limit or avoid this deformation. Understanding longitudinal stent integrity may influence future stent designs. The testing data can provide and assist the interventional cardiologist in rational stent selection. We think there should be national recommendations for standardized nonclinical testing to evaluate longitudinal stability in addition to the recommendations for evaluating other stent characteristics. In this way, the longitudinal stability of new stent designs can be compared allowing more rational stent selection.

**Study limitations.** Bench testing may not accurately predict stent behavior in humans. Not all stent designs have been tested. Only 3 examples of each design were tested, although the narrow standard deviation of results argues for uniformity of response to testing. Testing was limited to 7 contemporary stent platform designs. We did not attempt to evaluate distortion in curved vessels.

### Conclusions

Stent designs with 2 connectors between hoops have less longitudinal stability and are more susceptible to longitudinal distortion than those with more connectors. Distortion may involve bunching or separation of struts and protrusion of struts into the lumen with malapposition and potential obstruction of passage of devices such as a post-dilating balloon through the stent. It may be misinterpreted as strut fracture and can cause adverse events. We believe that careful post-dilation should be considered if longitudinal distortion is recognized. For scenarios where distortion is more likely, such as ostial locations, the interventional cardiologist may chose to select a stent with higher longitudinal strength. Future stent designs are likely to be more mindful of longitudinal integrity. We think that standardized testing of longitudinal strength should be available to cardiologists to aid in stent selection.

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