Stent Longitudinal Strength Assessed Using Point Compression: Insights From a Second-Generation, Clinically Related Bench Test

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Background—Stent longitudinal distortion, while infrequent, can lead to adverse clinical events. Our first bench comparison of susceptibility of different stent designs to distortion applied force to the entire circumference of the proximal stent hoop. The test increased understanding of stent design and led to recommendations for design change in some. Our second-generation test more closely mimics clinical scenarios by applying force to a point on the proximal hoop of a malposed stent.

Methods and Results—Each 3-mm-diameter stent was secured in a test apparatus so that its proximal 5 mm was malposed in a 3.5-mm tube. An instron applied force to the proximal hoop of each of 5 examples of each of 6 stent designs using a narrow rod so that force applied and distance compressed could be measured. Hoops on the side of the force were pushed together, became malposed, and obstructed the lumen. In addition, the proximal stent hoop tilted causing malapposition, the contralateral side of the stent from the applied force causing lumen obstruction.

Conclusions—This second-generation, more clinically relevant test showed the Biomatrix Flex was the most resistant to deformation and the Element the most easily deformed. The addition of more connectors between the proximal hoops in the Promus Premier design has reduced the potential for distortion when compared with the Element, so that distortion was similar to the Vision, Multi-Link 8, and Integrity designs. The test also provided insight into the way in which stents are likely to distort in clinical practice. (Circ Cardiovasc Interv. 2014;7:62-69.)

Key Words: drug-eluting stents ■ stents

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Stents

Stent longitudinal deformation is an infrequent complication of percutaneous coronary interventional procedures but associated with an increased likelihood of adverse clinical events.1-6 Although it can occasionally involve the distal end or the body of a stent, it is much more likely to occur at the proximal end, especially if struts are malposed.1-3 Forward pressure on an angioplasty balloon or guide catheter, particularly when not coaxial with the stent, applies a force to a localized point on the proximal circumference of the stent rather than pressure over a broad front.4 The most common result is the pushing of stent hoops together and distortion of the proximal end of the stent with lumen compromise. The appearance has been described as like a concertina or accordion, struts compressed, squeezed or pushed together, or stent shrinkage, folding or wrinkling.5-7

We previously compared longitudinal strength (the ability of a stent to resist longitudinal distorting forces) for 7 different stent designs using compression and elongation bench tests.7 The compression test involved relating the force applied to the circumference of the proximal hoop of a stent to the extent of stent compression. Other investigators used a similar test but with a greater length of stent exposed to compression.8 These tests enabled comparison of stent designs in a standardized, reproducible way and provided novel insights into stent design and performance.7 The test led to the recommendation of additional connectors between the proximal hoops of the element design to improve longitudinal strength.7

The basic design of all stents, hoops that provide radial strength and connectors that hold the hoops together, is a balance of desirable characteristics. A consequence of reducing the number of connectors between hoops to improve flexibility and side-branch access has been to reduce longitudinal strength and increase the likelihood of longitudinal distortion.7 Those stent designs with fewer connectors had the greatest propensity to longitudinal distortion. The Element design (Boston Scientific, Nattick, MA), with only 2 connectors between hoops, had the least longitudinal strength on our bench testing. Although longitudinal stent deformation probably occurs with all stents, in recent years the majority of clinical reports of the problem have been with the Element design.
WHAT IS KNOWN

- Stent distortion is an infrequent clinical problem usually caused by a device applying force to the most proximal stent hoop.
- Our first-generation longitudinal strength test applied force to the full circumference of the proximal hoop.
- A relationship between connector number and the likelihood of stent distortion was identified, leading to a recommendation that additional connectors be added to some stent designs.

WHAT THE STUDY ADDS

- This second-generation test more closely mimics clinical conditions by applying force to a single point on the proximal hoop.
- Point compression not only pushed the stent hoops together, but also caused the proximal end of the stent to fold over and compromise the vessel lumen, explaining why it is often difficult to recross a distorted stent.
- Additional connectors between the proximal hoops of contemporary stents have reduced the potential for distortion.

Although our first-generation compression test provided insights into stent design and performance, and led to recommendations on stent design improvements, a shortcoming of the test was that it did not replicate the manner in which stent distortion most often occurs clinically.\(^6,7\) Other investigators have observed that longitudinal compression is most commonly caused by application of a localized force, for instance by a postdilatation catheter or stent delivery systems.\(^5\) We developed a second-generation, more clinically related test simulating the usual clinical scenario, in which a localized force is applied to 1 portion of the circumference of a malpositioned proximal stent.

Methods

Stent Platforms Tested

The 6 stent designs tested (Figure 1) were the Vision (Abbott Vascular, Santa Clara, CA), Multi-Link 8 (Abbott), Biomatrix Flex (Biosensors, Singapore), Integrity (Medtronic, Santa Rosa, CA), Omega or Element (Boston Scientific), and the Promus Premier (Boston Scientific). The drug-eluting version of Vision is Xience V, of Multi-Link 8 is Xience Prime and Xience Xpedition, of Integrity is Resolute Integrity, and of Omega is Promus Element, Promus Element Plus, and Taxus Element (called Ion in the United States). Five examples of the 3-mm-diameter stent of each design were tested. Drug coating does not alter the longitudinal integrity of the stent platform. The same length of each stent design (5 mm) was exposed to the compressive force by securing the distal end of each stent.

Test Apparatus and Test Method

The test apparatus was constructed by placing a 20-mm length of silicon tubing (internal diameter of 2.75 mm; Figure 2) inside the

Figure 1. Characteristics of stent designs tested. Depicted are Vision scans of the 3.0-mm-diameter examples of 6 stent designs and listed are the stent names and design characteristics. The Vision and Multi-Link 8 have in-phase sinusoidal hoops linked by 3 bridges that join peaks and troughs and are aligned with the stent long axis. Each connector has a U-shaped loop to increase flexibility. The Biomatrix Flex has out-of-phase sinusoidal hoops with peaks linked by 2 S-shaped connectors. The Element design has sinusoidal hoops with off-set peaks linked by 2 straight bridges per hoop. The Promus Premier has the same design as the Element except that the proximal 3 hoops are linked by 4 connectors, in contrast to 2 connectors in the Element. The red arrows indicate the connectors. The Integrity design has a single sinusoidal component that winds helically from 1 end of the stent to the other, with 2 or 3 welds between adjacent hoops. CoCr indicates cobalt chromium; CoNi, cobalt nickel; and PtCr, platinum chromium.
distal end of a polytetrafluoroethylene (PTFE) tube (internal diameter of 3.5 mm; Figure 2). A stent was advanced into the tubes, so that the proximal 5 mm of stent (measured with a microscope) lay within the 3.5-mm tubing. The stent was deployed at nominal pressure, thereby leaving the proximal 5-mm malapposed. The deploying balloon was advanced and inflated at high pressure within the distal portion of stent (inside the 2.75-mm tube) to secure firmly the distal portion of the stent, so that there was no distal movement of any stent during compression. A 0.51-mm-diameter rod representing the tip of a post-dilatation catheter attached to an Instron universal testing machine was lowered to contact the proximal hoop of the stent at 1 point in the lumen that differed according to stent design (Figure 3). The force needed to compress the different stent designs was compressed by a 0.5 N force are shown in Figure 5. The least compression was seen with the Biomatrix Flex and Integrity designs. The Vision, Multi-Link 8, and Promus Premier designs were compressed a similar distance. The greatest compression was seen with the Element design, and in fact most examples of the Element were compressed the maximum distance of 4 mm with <0.5 N force.

When a 0.5 N force was applied to a point on the proximal hoop, there was tilting of this hoop that caused narrowing of the lumen that differed according to stent design (Figure 6). The greater the tilting, the greater was the narrowing. The relationship of % area loss (\( y \)) to angle of tilt (\( x \)) is described by the equation \( y=0.0002x^2 \) with \( R^2=0.97 \). The narrowing was caused by struts on the contralateral side from the point of force application becoming malapposed and protruding into the lumen. In addition, the struts on the same side as the point force in some instances became overlapped and protruded into the lumen. The force needed to compress the different stent designs by 4 mm was greatest for the Biomatrix Flex and the Integrity (Figure 7). Similar forces are required to compress the Vision, Multi-Link 8, and Premier designs by 4 mm. The least force was required to compress the Element design.

The stents were well secured in the apparatus so were no instances of the entire stent moving distally.

Statistics

Descriptive statistics of the data are provided as mean±SD. The strength between the different stent designs was compared using 1-way ANOVA. Tukey honest significant different multiple comparison test was used for all pair-wise comparisons. The relationship between force applied to the stent and compression distance was plotted. Images of the different stent designs are assembled in plots. Plots were created in Microsoft Excel or Microsoft PowerPoint (Microsoft, Redmond, WA). Statistical analyses were performed using SAS statistical software, version 9.2 (SAS Institute, Cary, NC). All \( P \) values resulted from 2-sided tests, and a \( P \) value of <0.05 was considered statistically significant.

Results

With force applied to a point on the circumference of the proximal hoop, hoops were pushed closer together. However, the extent of compression was greatest below the point of force application and least on the opposite side. This commonly lead to the portions of hoops on the maximally compressed side overlapping, becoming malapposed, and then protruding into and obstructing the stent lumen (Figure 3). The opposite side of the stent tilted and was lifted off the tubing, causing further strut malapposition and lumen obstruction.

When compression distance was plotted against force applied by the Instron (Figure 4), the least force was required to compress the Element design and the greatest force required to compress the Biomatrix Flex at least up to 3 mm of compression. The forces required to compress the Integrity, Multi-Link 8, Promus Premier, and Vision designs are similar.

The distances that the 6 different stent designs were compressed by a 0.5 N force are shown in Figure 5. The least compression was seen with the Biomatrix Flex and Integrity designs. The Vision, Multi-Link 8, and Promus Premier designs were compressed a similar distance. The greatest compression was seen with the Element design, and in fact most examples of the Element were compressed the maximum distance of 4 mm with <0.5 N force.

Discussion

The principal findings of this study are that when a longitudinally compressive force was applied to a point on the proximal hoop of amalapposed stent in a mock artery, the deformation that occurred differed according to stent design and the
magnitude of the force. With sufficient force to compress the stent by 4 mm, hoops were pushed together on the side of the stent beneath the compressing force. All stents developed some strut overlap and there was protrusion of struts into the lumen (Figure 7). The proximal hoops were tilted to the side of the compressing force, and the struts on the opposite side were pulled away from the phantom arterial wall, causing malapposition and further lumen obstruction (Figure 7). When a 0.5 N force was applied, the compression was less marked. Only the Element design developed strut overlap and with layers of struts (Figure 6). With this 0.5 N force, the Biomatrix Flex showed the least compression and luminal obstruction. The Premier design is the same as the Element but with additional connectors between the proximal hoops. The addition of connectors has improved longitudinal strength in the proximal end where most deformation occurs.

We previously compared longitudinal strength in 7 stent designs using compression and elongation tests. The compression test applied force to the circumference of the proximal end of each stent. It enabled comparison of stent designs in a standardized, reproducible way and provided useful insights into stent design and performance. The test lead us to recommend that a stent design change ensuring 3 connectors, especially at the proximal end of a stent (that) should increase longitudinal integrity, but perhaps at the expense of stent flexibility. Boston Scientific subsequently modified the design of the Element platform by the addition of connectors between the proximal hoops to enhance...
longitudinal strength at the proximal end of the stent for the Promus Premier design.

The main limitation of this test was that it did not replicate the common clinical situation in which guide catheter alignment, vessel angulation, and guidewire bias result in a balloon catheter or other intracoronary device catching and applying force to 1 side of the proximal end of a stent.\(^5\),\(^7\) Ex vivo attempts to develop a comparative test using noncompliant balloons were unsatisfactory because of poor reproducibility.\(^1\) Our new test apparatus used a 3-mm nominal diameter stent deployed, so that its distal portion was fixed and the proximal portion malapposed in tubing of 3.5-mm diameter. The 5-mm malapposition length we used is similar to malapposition reported clinically.\(^9\),\(^10\) A decrease in length of malapposition decreases distortion potential and an increase in length increases distortion potential. An important insight from the single point test, not apparent when force is applied evenly to the end of the stent, is the manner in which stent distortion and lumen compromise occur. On the side where force is applied, the struts bunch together, overlap and protrude into the vessel lumen. Perhaps even more important is the pulling away of stent struts from the opposite vessel wall. The combination of effects may markedly compromise the vessel lumen and provide a nidus for other equipment to catch if advanced into the stent. This has a clinical correlation in that when stent distortion occurs in for instance a 3.5-mm-diameter stent, it is sometimes only possible to advance a narrow caliber balloon, such as a new 1.25- or 1.5-mm-diameter balloon into the stent. A series of balloons, of sequentially increasing diameter, may then be needed to restore a navigable stent lumen. The patterns of deformation fit with what we see clinically supporting the clinical relevance of the test method.

The test clearly shows that once stent deformation starts to develop, further force applied to the stent only makes matters worse. The interventional cardiologist needs to be aware of this risk and the need to take great care if there is resistance when advancing a balloon or other catheter into a fully or partially deployed stent. Changing to a smaller diameter compliant balloon, changing the angle of entry into the stent by guide catheter or guidewire manipulation, or using a buddy guidewire is maneuvers that may assist crossing without causing or worsening stent damage.

Besides luminal obstruction, longitudinally distorted stents have been associated with restenosis, stent thrombosis, geographical miss with need for additional stenting and emergent revascularization surgery.\(^1\),\(^3\),\(^5\),\(^11\)

Although the mechanism and patterns of distortion observed in this study were different from those in our first-generation test, in general, the relative susceptibility of different stents to distortion was similar to that in the previous study.

There are a number of reasons that we chose a compressive force of 0.5 N for testing. In our first study, 0.5 N force gave the best separation of longitudinal distortion between designs tested. This was also true with the current testing.
In addition, there is evidence that 0.5 N force is clinically relevant. Prabhu et al reports that 2 interventional cardiologists were asked to push the balloon dilatation catheter against the constriction with the force that they would generally apply in a clinical situation when a catheter tip is caught while trying to cross a freshly deployed stent. Each of the cardiologists was asked to repeat the experiment 3×. This testing was performed using 6-Fr and 7-Fr guide catheters. The average force applied using the 6-Fr guide catheter was 45±12.5 gf, and the average force applied using the 7 Fr guide catheter was 57±12.4 gf. A clinically relevant force of 50 gf was chosen to encompass both clinical scenarios. There were only 5 stents tested for each design, the resulting sample size is small. Although the ANOVA assumptions of normality, independence and equal variances were met by the data, the 1-way ANOVA may not be the most powerful test because of the small sample size. This should be taken into consideration when interpreting the results.

Testing was limited to 6 contemporary stent platform designs. We tested only the 3.0-mm-diameter examples of each platform. Comparative results are likely to be similar for different stent diameters if the designs are similar. Comparative results will be changed if different sizes have dissimilar designs, such as altered number of connectors. This testing model assesses compression of the proximal 3 or 4 hoops, with the remainder of the stent fixed to the tubing (or simulated vessel wall). Resistance to longitudinal compression may be influenced by the type, number, and pattern of connectors for a longer length of the stent, even if compression only develops at the end. Unlike most other stents, the Premier design changes over the length of the stent. The proximal 5 mm of stent was assessed with this model because this is where distortion most commonly occurs.
Conclusions
A second-generation bench test was designed to mimic more closely the clinical problem of longitudinal stent distortion. Unlike our previous test, the distorting force was applied to a single point on the proximal stent hoop rather than to the full circumference of the hoop. The Biomatrix Flex was the most resistant to deformation and the Element the most easily deformed. The test supports a potential mechanism by which asymmetrical applied longitudinal forces may distort stents in clinical practice.

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Disclosures
J. Ormiston is an advisory board member for Abbott Vascular and Boston Scientific and has received minor honoraria from them. The other authors report no conflicts.

References


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