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 malapposed.5–7 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.5 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

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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, Natick, 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...
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.

stent.6,7 The new Promus Premier design (Boston Scientific) is the same as Element, except with additional connectors linking the proximal 3 hoops (Figure 1).

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.5,7 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 malaposed 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 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 proximal 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 valley next to rather than above a connector (Figure 2). This rod had a concave foot that prevented the rod slipping off the stent strut in all tests (Figure 2). The probe attached to the Instron universal testing machine was advanced at a rate of 0.1 mm/s. The Instron recorded both force and displacement data at 0.01-mm intervals and plotted a force–displacement curve. The Instron was programmed to shorten each stent by 1.0 mm, with stent changes recorded using a Nikon 700D camera. The Instron then shortened the stent a further 1 mm, another photograph was taken, and the process was repeated until the stent was shortened by 4 mm. The rate of shortening was 0.1 mm/s and the Instron recorded data at 0.01-mm intervals. The force required to shorten 5 examples of each of the 6 different stent designs was plotted against the distance shortened. In addition, the stents were photographed after a 0.5 N compressive force was applied. One example of each design compressed by 4 mm and another example after compression with a 0.5 N force were imaged by microcomputed tomography (microCT). The 4-mm compression distance was chosen to mimic malaposition lengths that have been reported clinically.9,10

Figure 2. The test apparatus was constructed by placing a polytetrafluoroethylene (PTFE) tube (internal diameter, 2.75 mm) within a silicon tube (internal diameter 3.5 mm) as in A. Each 3-mm test stent was deployed, so that the distal portion (below the red line) was fixed in the 2.75-mm PTFE tube. The proximal 5 mm of the 3-mm-diameter stent deployed at nominal pressure lay malapposed within the 3.5-mm silicon tube. B, A rod (R) with a concave foot connected to an Instron universal testing machine was in contact with the proximal end of a Biomatrix Flex stent. C, The R has been withdrawn after it had compressed the stent by 4 mm.

Discussion

The principal findings of this study are that when a longitudinally compressive force was applied to a point on the proximal hoop of a malapposed 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 to 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.
method. 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×. The stents are viewed from the proximal end with the lumen depicted in red. This shows visually that the greater the tilt of the proximal hoop, the greater was the luminal obstruction. The greatest tilt and lumen obstruction were with the Element design and the least with the BMX Flex. Addition of connectors proximally creating the Premier design has strengthened the proximal end of the stent, so that tilt and obstruction were less than with the Element design.

Limitations
Bench testing may not accurately predict stent behavior in humans. Not all stent designs have been tested. Only 5 examples of each design were tested although the narrow SD of results argues for uniformity of response to testing. Because 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.5,6
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


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