ABSTRACT: The development of modern coronary stent platforms has transformed the landscape of interventional cardiology. Contemporary coronary stents are much more deliverable than older-generation stents. However, longitudinal deformation has emerged as a "new" complication in modern coronary stent platforms. Although most reported cases of longitudinal stent deformation involve mechanical or technical mishaps, it appears that it is more frequently associated with a particular stent design: the "offset peak-to-peak" stent design. This review summarizes the latest data around stent performance. Within this context, two clinical cases where longitudinal deformation was observed in the absence of any mechanical mishaps are also presented. Collectively, this evidence suggests that stent design may be a major determinant of stent performance.


Key words: longitudinal deformation, stent design, stent concertina, drug-eluting stent

Over the past decades, stent design and material has undergone significant evolution. The introduction of the drug-eluting stent (DES) has also made "drug delivery" another major determinant in modern stent design.1

Coronary stent design. The majority of early coronary stents were made of stainless steel. These designs were associated with variable basic manufacture, cell geometry, and strut thickness.2 Use of alloys such as cobalt chromium and platinum chromium has enabled stents to have thinner struts, while maintaining strength and radioopacity.3 Thin-strut stents improve deliverability and conformability. However, there is limited evidence suggesting that thinner struts may result in less vessel wall damage and hence less risk of restenosis.4-6 Although thin-strut DESs have never been shown to have lower restenosis rates than thick-strut DESs, the trend of thinner strut platforms has triggered innovative designs to maintain stent radial strength. The development of longer, thinner, more flexible, and easier-to-deliver stent platforms made percutaneous coronary intervention (PCI) possible even in the most tortuous anatomy and calcified vessels.7 However, longitudinal stent strength may be compromized with these modern designs.3 Stent design requires careful consideration of several performance characteristics, including crimped and expanded stent flexibility, shortening upon expansion, trackability, scaffolding, radioopacity, longitudinal strength, radial strength, and recoil.8

Stent longitudinal flexibility and deliverability prior to deployment, and vessel conformability after deployment, are widely dependent on the number, orientation, shape, thickness, and material of the crests and links.9 These parameters also determine the longitudinal strength of the stent, defined as maintenance of intact stent architecture upon exposure to compressing or elongating forces.9 Alteration of any one feature of a stent platform will undoubtedly impact other aspects of stent performance and may result in clinical complications. For instance, thinner struts improve deliverability, but reduce radioopacity of the cobalt chromium stents. In addition, reduction of the number of fixed links between cells or alteration of their geometry may enhance flexibility and conformability, but as a consequence may compromise longitudinal strength.7

Although stent flexibility may be influenced by a variety of factors, it has been shown that stent longitudinal integrity, defined by the number of links between hoops, correlates with stent stiffness. In addition, the alignment of the links with the long axis of the stent may also be an important factor for longitudinal integrity.9

Architectural design differences are major factors affecting resistance against longitudinal compression. The peak-to-peak or peak-to-valley strut architectures of platforms result in variation between the longitudinal stiffness and strength of stents. It is highly likely that the occurrence of longitudinal deformation is dependent on a particular stent design.10

Longitudinal stent deformation. Until recently, the longitudinal strength of coronary stents has never been considered a standard parameter of stent performance. However, recent evidence identified longitudinal compression, or postdeployment...
stent shortening, as a newly observed complication. Longitudinal stent deformation is defined as the distortion or shortening of a stent in the longitudinal axis following successful stent deployment.\(^3\) This phenomenon describes the effect of a longitudinal compression force on the stent rings, causing them to nest or concertinate.\(^8\)

PCI procedures involve multiple and complex techniques that may increase the risk for longitudinal stent compression. These include the use of extra-support guide catheters, aggressive guide catheter manipulation (deep-seat), mother and child catheter systems, multiple balloon postdilations, bifurcation stent techniques, and adjunctive devices such as intravascular ultrasound (IVUS), distal protection devices, etc.\(^7\) In a clinical setting, longitudinal compression may occur in various situations (Table 1),\(^8\) and it may simply represent an angiographic detection of an exceptional PCI complication. Protrusion of struts into the lumen and extensive malapposition of struts due to longitudinal deformation may result in disruption of flow and increasing the risk of stent thrombosis. Moreover, longitudinal deformation of a DES may result in uneven drug delivery and increase the risk for in-stent restenosis (ISR).\(^9\)

**Clinical reports of longitudinal deformation.** Hanratty and Walsh recently described 3 cases where longitudinal compression of a previously deployed stent resulted in stent deformation. Two cases were detected angiographically, while 1 was detected on adjunctive imaging. The complication was first reported with the Promus Element (Boston Scientific) platform. However, Hanratty and Walsh noted that this phenomenon has since been observed with all modern DES platforms. They concluded that such deformation could potentially result in a suboptimal technical result for the medium- to long-term and increase the risk for stent thrombosis and ISR if left undetected.\(^7\)

A recent retrospective analysis provided further valuable information on the frequency and mechanisms of longitudinal stent deformation. The study involved 4455 interventional cases performed during a 4-year period. Stent deformation occurred in a total of 9 cases (0.2%) and affected 0.097% of stents deployed. In 6 cases, the Promus Element stent was involved, and there was 1 case each involving Endeavor (Medtronic), Biomatrix (Biosensors Interventional Technologies), and Taxus Liberté (Boston Scientific) stents. Stent deformation varied from 0% in several stent types to 0.86% in the case of Promus Element.\(^3\) It was virtually unseen in the Cypher and Xience (Abbott Vascular) platforms. Longitudinal stent deformation is probably not a “class effect,” but highly dependent on a particular stent design.

**Bench testing of stent longitudinal integrity.** A recent investigation of the longitudinal compression behavior of the 4 contemporary coronary stent design families, using elaborate bench test methods, provided valuable information on the role of stent design. The study evaluated the longitudinal compression behavior of 14 commercialized stent platforms exposed to a longitudinal compression force determined to be 50 gram force (gf).\(^8\) The peak-to-peak, peak-to-valley, or mid-strut connect stent configurations, with 2-6 links connecting adjacent rings evaluated in this study, were in the relatively narrow compression range of 1.25 mm to 5.30 mm (4.46% to 18.93%, compared with the nominal expanded stent length). The two-link offset
peak-to-peak design demonstrated the lowest resistance to longitudinal compression by shortening 13.20 mm (47.07%, compared with the nominal expanded stent length). The study concluded that longitudinal compression or shortening is not associated with strut thickness, but is specific to the offset peak-to-peak stent design. If one draws a longitudinal axis/vessel axis along the stent, one would easily appreciate that there is virtually no “element” to resist any compression force in this particular design. The stent would simply concertina.

Another study compared the longitudinal strength of 7 currently available coronary stent platforms using standardized bench testing protocols. The study reported significant differences between the 7 stent designs exposed to a compression or elongation force. Stents with 2 links, such as the Promus Element and the Endeavor/Micro Driver, were more likely to distort under longitudinal forces than those with 3 or more links. Although these studies provided valuable information on the mechanical properties of the various coronary stent platforms available, the authors recognized that bench testing may not accurately mimic and predict stent behaviour in vivo.

Case Studies. Two cases of longitudinal stent deformation in the absence of any technical mishap are described below.

Case 1. A 53-year-old male, chronic smoker, presented with effort angina. MSCT coronary angiogram showed greater than 70% distal left circumflex artery (LCX) stenosis, subtotal LCX occlusion, coronary arteriovenous (AV) fistula from the left anterior descending coronary artery (LAD) to pulmonary artery (PA). Overlapping drug-eluting stent (DES) deployment (2.25 x 28 mm Promus Element distally at 10-16 atm; 2.5 x 24 mm Promus Element at proximal-mid LCX at 12-14 atm). Postdilation with non-compliant balloon (2.75 x 15 mm Quantum distally at 12-18 atm and 3.0 x 15 mm Quantum proximally at 16-18 atm). Stent deformation after postdilation (arrow). Further dilation with 3.5 x 15 mm Quantum at 18 atm. Deployment of a 3.0 x 12 mm Promus Element stent (arrow), postdilated with a 3.0 x 15 mm Quantum at 18-19 atm. Final angiogram.
catheter engaged the left main. A 2.25 x 28 mm Promus Element stent was deployed distally at 10-16 atm and a 2.5 x 24 mm Promus Element stent was deployed at the proximal-mid LCX overlapping the previous stent at 12-14 atm (Figure 1B). Postdilation with non-compliant balloon was carried out (Figure 1C). Stent deformation was observed after postdilation (Figure 1D). IVUS assessment showed suboptimal stent expansion. Further postdilation with 2.75 x 15 mm Quantum at 12-18 atm distally and 3.0 x 15 mm Quantum at 16-18 atm proximally was carried out (Figure 1E). However, following postdilation, stent deformation was observed on “Stent-Boost” and IVUS study (Figure 3), which failed to improve after further high-pressure balloon dilatation. Finally, a 3.0 x 12 mm Promus Element stent was deployed at the deformed proximal edge, and postdilated with a 3.0 x 15 mm Quantum at 18-19 atm (Figure 1F) to address the issue.

Case 2. An 84-year-old male presented with effort angina, hypertension, and high cholesterol. MSCT coronary angiogram showed triple-vessel disease (TVD). Transradial cardiac catheterization with coronary angiogram confirmed TVD (Figure 2A). RCA lesions were smoothly fixed with 2 DESs. There were critical ostial LAD and LCX lesions. The proximal-mid LAD lesion was fixed with a Promus Element stent. A 3.0 x 28 mm Promus Element stent was deployed to cover the left main and overlap the previous Promus Element stent in the LAD (Figure 2B). Delivery stent balloon was pulled back and inflated at 14 atm (Figure 2C). Left main stent shortening and deformation were observed (Figure 2D). There was no excessive manipulation of the guiding catheter. The ostial left main stent was serially dilated with a 2.0 mm Apex and then 3.5 mm Quantum balloons (Figure 2E) because the stent was “wrinkled” and the 3.5 mm balloon failed to cross directly. The procedure was accomplished by final kissing-balloon angioplasty with 3.0 mm Quantum at left main-LAD and 2.5 mm Apex at left main-LCX (Figure 2F). However, the proximal edge of the left main stent was shortened.

Discussion. According to Hanratty and Walsh, resistance encountered during the delivery of postdilation balloons or imaging catheters is an indicator of possible entanglement (usually related to guidewire bias or under-expanded stents) that could result in stent deformation. Radiographic assessment of the stented segment, preferably with “Stent-Boost” or equivalent image-enhancement program should be carried out. IVUS or optical coherence tomography (OCT) can help to confirm the diagnosis of stent deformity. OCT is particularly useful in detecting stent deformity of the less radioopaque stents and biodegradable vascular scaffolds. Operators should exercise extreme care during PCI for ostial lesions involving deep intubation with guiding catheters or extension systems through already stented segments. Moreover, caution is also advised following deliberate underexpansion of the proximal portion of a very-long stent in a tapered vessel.

The Williams et al study identified several additional mechanisms through which stent deformation may occur and provided further data on the frequency of occurrence associated with various DES platforms. The 9 reported cases occurred with 6 different operators, which reduced the likelihood of incidence due to procedural techniques. Williams et al described 2 cases of ostial stents crushed by the guide catheter. However, of the remaining 7 stents reported, 2 were crushed by guide catheter extensions and 5 were crushed by uninflated balloons.3 Despite the low number of cases reported, it is likely that the number of longitudinal stent deformation cases is underestimated and underdiagnosed. This study reported stent deformation in 0.86% of Promus Element stents (2 links) compared with 0.01%-0.02% for other stent platforms. There were no cases reported with the XIENCE V/Promus (Abbott Vascular) (3 links) or Cypher stents (6 links). Although the thin strut/open-cell design of the Promus Element stent offers increased flexibility, conformability, and deliverability, it may be associated with reduced longitudinal strength and a higher risk of longitudinal deformation due to its flawed stent design. Williams et al suggested that the increased radioopacity of the
platinum chromium Promus Element stent compared with other DESs may explain the increased detection of deformations observed. However, this increased frequency was not matched with other relatively radioopaque stent platforms such as the Cypher stent. Williams et al concluded that longitudinal stent deformation may occur secondary to a variety of mechanisms and emphasized the importance of identification because, if left untreated, it may be associated with higher risk of stent thrombosis.3

Despite the cases reported in these studies, accidental longitudinal deformation does not seem to affect the clinical safety of patients. Only 2 out of 12 cases reported adverse events. In the cases reported by Hanratty and Walsh, there were no adverse events observed, whereas in the cases discussed by Williams et al, 2 stent thromboses were reported. Moreover, evidence from a prospective single-blind randomized trial (PLATINUM; n = 1530 patients) comparing a platinum chromium everolimus stent to a cobalt-chromium everolimus stent showed no significant difference in safety and efficacy at the end of a 12-month follow-up after PCI.13 However, Pitney et al reported that patients with detected Endeavor/Micro Driver deformation had a 36% incidence of major adverse cardiac events, demonstrating that longitudinal deformation may potentially have adverse clinical consequences.12

Clinical observations on the association of the Promus Element design with an increased likelihood of longitudinal deformation are corroborated by evidence from studies evaluating the longitudinal strength of stent platforms using bench testing methods. These studies provide useful information on the structural and mechanical properties of these devices and recognized stent design as the key factor in determining the longitudinal strength and compression resistance of a stent. Prabhu et al concluded that there was no correlation between the amount of longitudinal compression and the stent strut thickness or stent material, but reported a moderate correlation between the amount of longitudinal compression and the number of links.9 Ormiston et al also showed that stents with 2 links, such as the Promus Element and the Endeavor/Micro Driver, were more likely to distort under longitudinal forces than those with 3 or more links.9 According to the study, the angulation of the links in the Promus Element stent design may result in decreased resistance to longitudinal deformation.9

Cases discussed in this report did not involve any operator mishap or mechanical incident such as guiding catheter deep-seating, rough handling of IVUS catheter, or difficulty in passing the postdilation balloons. However, despite the absence of mechanical complications, deformation on the stent edge was observed. Further dilation resulted in further collapse of the

Figure 4. (A) Coronary computed tomography angiography (CTA) showing triple-vessel disease (TVD). (B) Deployment of a 3.0 x 28 mm Promus Element stent to cover the left main stem (LMS) artery and overlap the distal Promus Element stent. (C) Delivery stent balloon inflation at 14 atm. (D) LMS stent shortening and deformation. (E) Ostial LMS stent dilation with 2.0 mm Apex and 3.5 mm Quantum. (F) Angiogram after final kissing balloon angioplasty: 3.0 mm Quantum at LMS-left anterior descending artery and 2.5 mm Apex at LMS-left circumflex artery.
stent. Although this deformation may be related to the curvature of the vessel, the stent design must have an impact on the longitudinal weakness of the stent in the absence of a mechanical incident. Operators should have in-depth knowledge of different stent designs and understand the behavior of different stents. They should meticulously look for stent deformity with the use of Stent-Boost and/or IVUS. Gentle handling of hardware is essential. It is important to “stop and think” whenever resistance is encountered during advancement and removal of balloon catheters or IVUS catheters. In the real world, there have been incidents of stent concertina of full metal jacket during IVUS catheter removal, which resulted in serious adverse events. The guiding catheter will “dive in” if the IVUS catheter is caught by the stent struts (usually at the underexpanded distal stent edge with guidewire bias) or calcification. The operators may consider advancing the system, rotating the system, and trying again. In some cases, buddy wire or buddy balloon may help to resolve the guidewire bias. Another guiding catheter system (from another vascular access site) may be necessary to bail out the situation if the original system was getting stuck.

Collectively, recent evidence from various studies and the cases presented in this report highlight several points regarding longitudinal deformation of coronary stents. First, accidental longitudinal deformation during PCI occurs in 0.2% of cases, primarily due to a variety of mechanical complications associated with endovascular tools. Deformations may also occur in new-generation stent platforms, raising issues about the role of stent strut thickness, materials, and three-dimensional stent design. Longitudinal deformation incidences are more frequently reported with the Promus Element stent. The offset peak-to-peak design of this coronary stent may be responsible for greater longitudinal deformation (4.7 times) compared with the deformations observed in 13 other stent products evaluated.13 Finally, longitudinal deformation may occur even in the absence of a causative mechanical incident, thus highlighting the important role of design in stent performance.

Conclusion. Longitudinal deformation incidences are more frequently reported with the offset peak-to-peak design as compared with other available stents. Although longitudinal deformation is a rare complication, it may adversely affect immediate and long-term clinical outcomes of PCI. The low number of cases reported thus far is probably the tip of the iceberg. If left undetected, this deformation could result in life-threatening complications. Understanding longitudinal stent integrity is essential for future design of stent platforms. Stent manufacturers may also consider reporting longitudinal stent strength, percentage foreshortening, or compressibility as a standard piece of information in addition to the current data provided for each product and adopting a consensus industry standard to assess this parameter.3,7,9,10 Perhaps, modifying the angulations and number of links at the proximal “crowns” may reduce the chance of stent concertina, as most reported cases of longitudinal stent compression occurred at the proximal stent edge.

References