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Longitudinal stent distortion in clinical practice. How common is the problem and does stent design matter?

Introduction

Coronary stents represent the single most important advance in percutaneous coronary intervention (PCI) since the first angioplasty procedure by Andreas Gruentzig in 1977. The first generation designs were primitive:¹ the Palmaz-Schatz stent, cut from a stainless steel tube, was stiff and could be difficult to deliver, whereas the Gianturco–Roubin stent, made from a coiled wire, was more flexible but provided limited lesion coverage and radial support. Examples of early stents can be seen in figure 1. A tendency for the struts of wire stents to distort, by either collapsing like a concertina or unravelling when deployment and balloon withdrawal was attempted in challenging lesions and vessels, was noted soon after their introduction.^{2,3} However, the last 20 years has seen steady and impressive improvements in stent design, leading to better acute performance and long-term clinical outcomes.

Stent design

"...every human benefit and enjoyment, every virtue, and every prudent act, is founded on compromise..."
EDMUND BURKE (1729–1797)

The complex technical requirements that stents must fulfil has influenced their mechanical design. Over the last decade, drug-eluting stents (DES), which release various anti-proliferative agents, have allowed PCI to be undertaken in patients

with more severe and extensive coronary disease, often in heavily calcified and tortuous vessels. This has driven the development of low profile, highly flexible stent/balloon systems to facilitate delivery to the lesion site. Such design has, in turn, required a trade-off in terms of reduced longitudinal strength.

Indeed, all coronary stent designs are a result of compromise (fig. 2), and a major challenge in stent design is achieving the optimal balance between different stent properties. Balloon expandable coronary stents must be able to be crimped down securely onto their delivery balloon. Once crimped, the stent and delivery balloon combination must have a low profile and be flexible to facilitate stent deliverability to the lesion site. This commonly entails traversing highly tortuous and calcified coronary arteries. During deployment, the stent struts must exert sufficient radial force on the vessel wall to overcome lesion resistance and vessel recoil. To achieve an optimal lumen diameter post-placement, the vessel wall must be uniformly and adequately scaffolded, with minimal tissue prolapse between stent struts. At the same time, side branch access between struts must also be possible, so that bifurcation disease can be treated. The deployed stent must conform to the vessel curvature adjacent to the lesion, to minimize vessel distortion at the stent edge. Radio-opacity is also important to aid positioning and appropriate delivery in the vessel, to guide post-dilation, and to assess optimal stent expansion. However, the stent lumen must also be readily visible upon radiographic imaging.

In some instances, however, maximizing one desirable feature, for example vessel wall coverage, can only be achieved by compromising another characteristic, in this instance side branch access.

In terms of mechanical properties, the longitudinal strength of a stent can be defined as its ability to resist a longitudinal distorting force, whereas radial strength is its ability to resist a compressing force. There are a number of design characteristics that

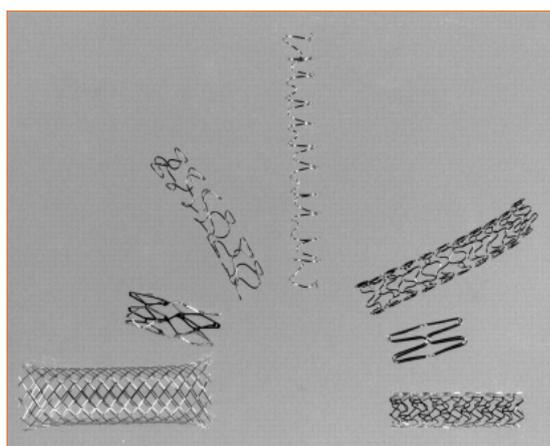


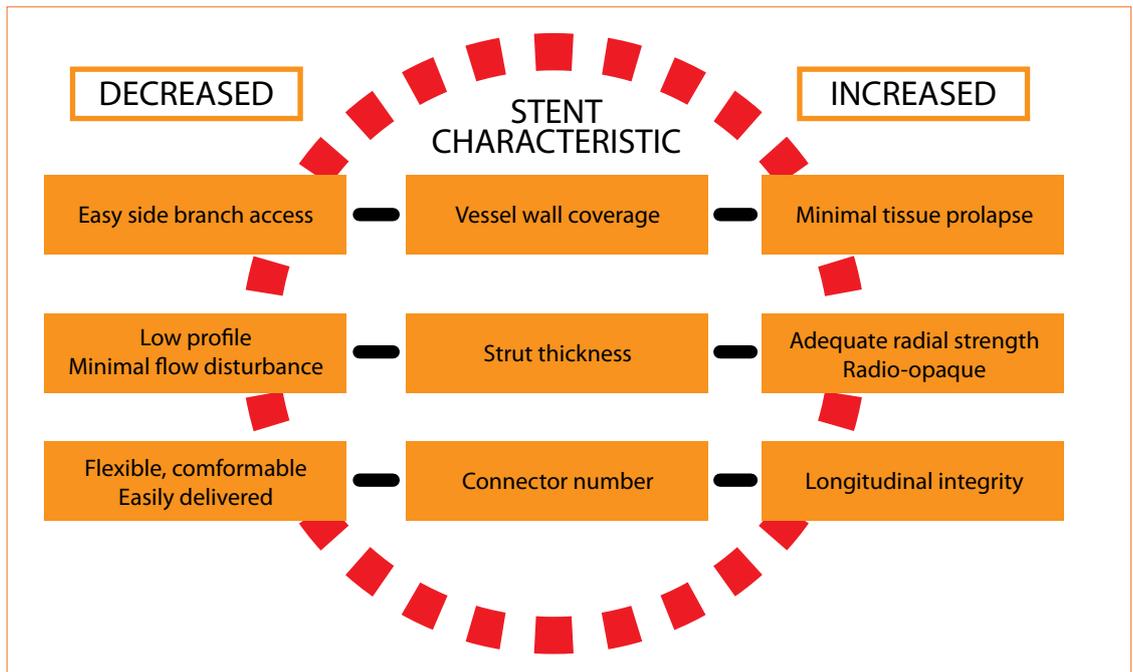
fig. 1

Early generation coronary stents. Many were made from a single coiled wire, and were prone to unravelling, compared with more recent designs.

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fig. 2

The effects of various compromises in coronary stent design on stent characteristics



influence the longitudinal and radial strength of a stent: strength of the stent hoops and the number and design of connectors between adjacent stent hoops.

The radial strength of the stent hoops is largely determined by three factors: the metal alloy (or polymer) chosen, the strut thickness and the stent design. First generation stents were mostly manufactured from 316L stainless steel. More recently, newer metal alloys, such as cobalt chrome and platinum chrome, have largely replaced stainless steel because they allow for reduced strut thickness, while maintaining radial strength and radio-opacity. Thinner struts provide a lower crimped profile and, at least in theory, better stent deliverability. There is also some evidence that, at least with bare metal stents, patients undergoing PCI with thinner strut stents have lower restenosis rates and better clinical outcomes than those treated with thicker strut designs.^{4,6} While the explanation for this finding is uncertain, thinner strut designs may cause less wall injury and less disturbance to blood flow. The reduction in strut thickness achieved over the last decade has been marked. Compared with the stainless steel BX Velocity/Cypher (Cordis Corporation) stent at 140µm, strut thickness has been reduced to 112µm with Nobori/Biomatrix (Biosensors International), to 91µm with the Resolute (Medtronic, Inc) stent, and to around 81µm with the Vision/Xience (Abbott Laboratories)

and Omega/Promus Element (Boston Scientific) stents. Further reductions in strut thickness are currently being explored; for example, the next generation Synergy stent (Boston Scientific) has a strut thickness of 74µm.

The number and design of connectors between adjacent stent hoops is also an important predictor of longitudinal stent integrity and has a major influence on stent flexibility and deliverability. In recent years, there has been a reduction in the number of connectors in widely-used coronary stents. Compared with the BX Velocity/Cypher stent, which had 6, most current stents have either 2 or 3 connectors (fig. 3).

In addition to the number of connectors, other important factors include whether adjacent sinusoidal hoops are aligned in-phase (peak to trough) or out-of-phase (peak to peak), whether peaks or troughs are linked, whether the connectors are straight or curved, and how each connector is aligned relative to the long axis of the stent. The pattern of connectors over the length of the stent is also important; if in a row, the connectors may increase longitudinal integrity by effectively forming a "spine".

Bench-top testing of longitudinal compression and elongation

Bench-top testing provides a standardized evaluation of various stent characteristics, and allows comparisons to be made between different

fig. 3

Different stent designs showing the sinusoidal hoop configuration, and the number and shape of the connectors between adjacent hoops. Those stents with the fewest connectors tend to be highly flexible and have excellent side branch access between the stent struts.

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Cypher Select	Liberté	Vision Xience V	MultiLink 8 Xience Prime	Driver Endeavor	Integrity Resolute	Omega ION Element
Stainless steel	Stainless steel	Cobalt Chromium	Cobalt Chromium	Cobalt Chromium	Cobalt Chromium	Platinum Chromium
140µ	100µ	81µ	81µ	91µ	91µ	81µ
6 connectors	3 connectors	3 connectors	3 connectors	2 connectors	2 (3) connectors	2 connectors

stent designs. For example, there are considerable differences between stents in terms of flexibility, both crimped on the delivery balloon and after expansion.⁷ Bench-top testing can also provide unique insights into more complex procedural techniques. For example, when evaluating strategies for treating bifurcation lesions, bench-top testing showed the importance of kissing balloon inflation to optimize strut apposition to the vessel wall.⁸

We have previously assessed stent longitudinal integrity in a bench analysis of seven different stents: Cypher (Cordis Corporation), Driver and Integrity (Medtronic, Inc.); Omega and Liberté (Boston Scientific); Vision and MultiLink (Abbott Vascular) stents.⁹ The degree of compression in 10mL of exposed stent after the application of a force of 0.5 Newtons (N) is depicted in figure 4. There were clear differences between stents, with the Promus Element and Driver (Medtronic, Inc.) stents being the most likely to be compressed. Elongation was assessed by clamping the stent with 8 mm exposed, and applying traction with a hook through the stent struts at a force of 0.5 N (fig. 5). The results were similar to those of compression testing; the stents more easily compressed were also more easily elongated. Analysis of the distorted stents showed that their ends were frequently folded in on themselves causing the vessel lumen to become markedly compromised. The 6-connector, thick-strut Cypher

stent was the least likely to be distorted, the 2-connector Promus Element and Driver stents the most likely, and the remaining 3-connector stents tested somewhere in between. Despite excellent resistance to longitudinal distortion, the Cypher stent is no longer widely used, in part because it is less flexible, deliverable and conformable than other stents.

Similar findings were described in another study comparing 14 examples from four families of stent designs.¹⁰ This work confirmed that the number of connectors predicted the degree of compression, but also suggested that whether or not connectors were peak-to-peak or peak-to-trough (which largely determines connector angle) was also of major importance.

Clinical longitudinal stent distortion

There have been several recent reports indicating that some of the newer generation stents may, in certain circumstances, be also prone to longitudinal compression and/or other distortion. However, this is not a new phenomenon: those who practised interventional cardiology late last century may recall similar complications occurring with many early stent designs, particularly those woven from a single wire. For example, shortening and elongation of the Wiktor stent (Medtronic, Inc) was described in 1994,^{2,3} with associated adverse clinical events including the need for coronary bypass graft surgery.

fig. 4

Stent compression under a fixed load of 0.5 N. The least compressible stent was the 6-connector Cypher, and the most easily compressed were the 2-connector Promus Element and Driver stents.

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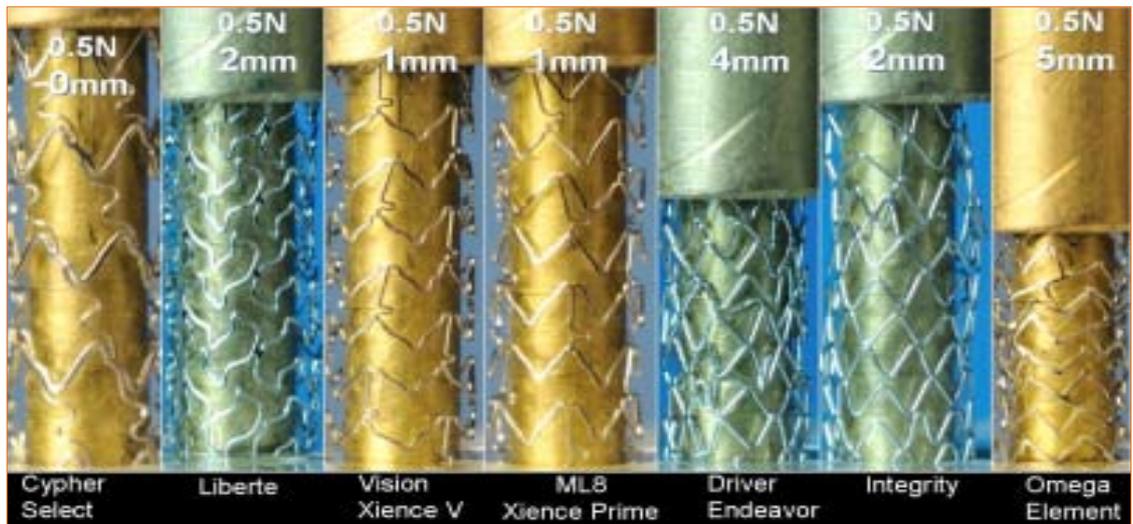
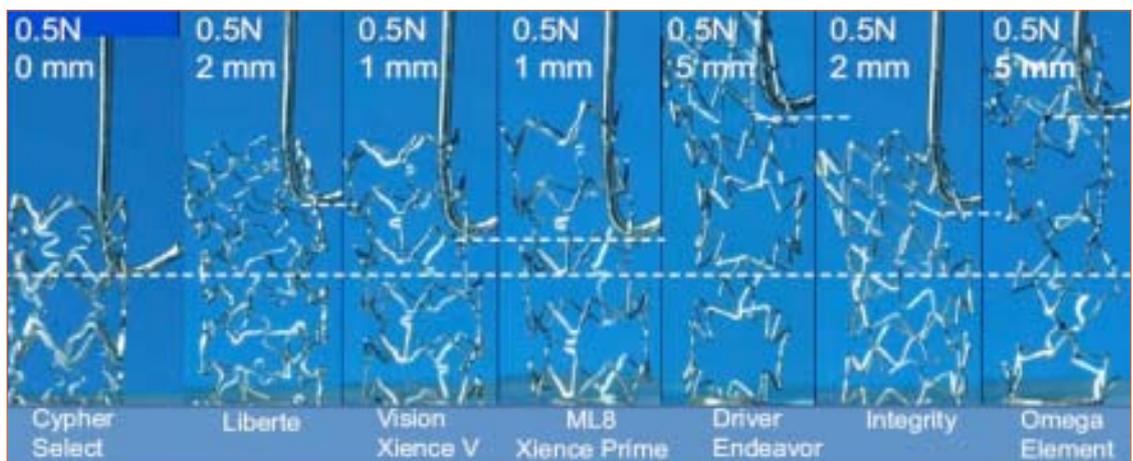


fig. 5

Stent elongation testing showed similar, but reciprocal, findings to the compression test results.

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The first indication that there was a problem with recent-generation stents came from Pitney and colleagues from Sydney, Australia, who described 14 cases of major stent deformation in 1,000 consecutive procedures using the 2-connector Endeavor/Driver (Medtronic, Inc) stents.¹¹ Distortion occurred in 1.8% of the 775 stents that were post-dilated. In those patients who experienced stent distortion, re-stenting was required in 9 patients and there were major adverse clinical sequelae in 5 patients (36%). They also noted that stent distortion could easily be mistaken for strut fracture. Distortion occurs at the index procedure and can be corrected if recognised, whereas strut fracture usually occurs later. However, both complications likely predispose the patient to stent thrombosis.

Hanratty and Walsh recently reported 3 cases of stent distortion occurring with ostial deployment of Promus Element, Biomatrix and Resolute Integrity stents, respectively.¹²

Soon after, 9 instances of stent distortion from approximately 9,400 stent deployments in 4,500 cases, giving a procedure occurrence rate of about 0.2%.¹³ It is clear, however, that stent distortion is a rare occurrence. Six of the 9 were with the Promus Element stent, and one each with Endeavor, Biomatrix and Taxus (Boston Scientific). There were multiple causes of stent distortion including the guide catheter, guide catheter extensions (Guideliner, Vascular Solutions; and Proxis, Velocimed) and post-dilation balloons. Two patients subsequently developed stent thrombosis, in both cases 2 months post-procedure, highlighting the importance of achieving satisfactory stent deployment.

The FDA Manufacturer and User Facility Device Experience (MAUDE) device-focused, adverse event database has recently been interrogated with regard to longitudinal stent deformation. Although there will be reporting biases in voluntary registries, the incidence of longitudinal

stent deformation appears to have increased in the last two years, with most recently-reported cases occurring in stents using the Element platform.¹⁴

Similar findings have been observed in carotid artery stenting, where stent deformation is more likely to occur in stents with an open cell as opposed to a closed cell design.¹⁵ Guidewire induced stent damage has also been noted in iliac vessels after stenting.¹⁶

Although it is difficult to precisely determine the incidence of stent distortion in the real world, available clinical data indicate the figure is likely to be low. However, awareness of the problem has only recently re-emerged, so conclusive data have yet to be prospectively collected. Furthermore, there is likely to be a spectrum with respect to the severity of the distortion, with more subtle deformation being easily missed during clinical and angiographic assessment. Although stent distortion almost certainly predisposes the patient to stent thrombosis, the magnitude of increased risk is difficult to assess from the case series reported to date.

Few centres or interventional cardiologists are likely to use all current generation stents in equal proportion. This, combined with the low overall incidence, makes it difficult to be certain about the relative likelihood of longitudinal distortion occurring with current-generation stents. To our knowledge, longitudinal distortion has not been reported in patients treated with a Cypher stent. While this may be due to its excellent resistance to longitudinal shortening and elongation noted in bench-top testing, it is also possible that a decline in use of the stent coincided with re-emergence of recognition of the problem. Furthermore, distortion in highly visible stents, such as Promus Element, is more likely to be detected angiographically than that in less visible stents. Despite these caveats, we believe that some stents are more likely to suffer distortion than others, and that the bench-top testing results usefully predict the likelihood of distortion occurring in clinical practice.

Prevention of longitudinal distortion

Most longitudinal distortion is a consequence of interventional equipment catching on the proximal end of a stent and there are a number of situations where the risk of longitudinal distortion is increased. For example, equipment can become

stuck on stents with struts that are separated from the vessel wall. These so-called unapposed struts can occur in tapered vessels where initial sizing and deployment is matched to the distal reference diameter. Stents deployed around a tight bend may also be at increased risk because wire bias directs the nose of balloons or other devices against the edge of the stent, causing the devices to become stuck against struts. Balloons are the most common device used which re-cross the proximal stent struts; they should be advanced slowly and gently under fluoroscopic imaging. If the balloon does not cross easily, altering tension on the guide wire may change the angle of approach. Previously inflated balloons, particularly if non-compliant, tend to develop “winging” and may be prone to catching on the proximal struts. If such a balloon is used and meets resistance, changing to a new, compliant balloon – perhaps with a smaller inflated diameter as these are less likely to catch on struts – is advisable. Care with procedural technique can therefore, in some cases, lessen the likelihood of longitudinal stent distortion.

Distortion appears most likely to occur in stents deployed in ostial or very proximal coronary lesions. Damage from the guide catheter, which is often pulled into the coronary artery as balloons are withdrawn, is a likely cause. This can be prevented by ensuring complete balloon deflation, applying forward pressure on the guidewire, and imaging the guide catheter tip when withdrawing the balloon from the coronary artery. If necessary, the guide can be disengaged from the coronary ostium before balloon withdrawal. The Guideliner has proven to be a very useful device to facilitate stent delivery through challenging anatomy, but should not be advanced through previously-deployed stents unless absolutely necessary, as it may catch on the proximal stent edge. Choosing a stent less prone to distortion might be prudent when treating very proximal disease. A guide catheter shape which provides good support without the need for deep engagement is also important.

Whilst distortion is more likely at the proximal end of a stent it can also occur at the distal stent edge. One situation where particular care is needed is withdrawing a Boston Scientific intravascular ultrasound (IVUS) catheter from the distal vessel beyond a stent. The catheter has a very short

rapid exchange segment; if the wire separates from the catheter shaft proximal to this segment the 'v' created between the two may catch on distal stent struts. If there is any resistance to IVUS catheter withdrawal through a stent, the IVUS catheter should be re-advanced, guidewire movement checked, and both the IVUS catheter and wire withdrawn together, at least until the IVUS catheter is back across the stent. As a general rule, if multiple lesions in the same vessel need treatment it is best to start distally and work back, rather than crossing and recrossing previously deployed stents.

Distortion in the mid-portion of the stent can also occur and usually happens during intervention for bifurcation lesions. When stenting across a bifurcation, there is often a size mismatch between the proximal and distal vessel, which can lead to initial underdeployment of the proximal portion of the stent. The proximal end of the stent should be post-dilated as soon as possible during the procedure to optimally appose stent struts to the vessel wall. Deep guide engagement and proximal stent damage may occur during the removal of a guidewire that has been deliberately trapped outside a stent to protect a side branch. If disengaging the guide catheter does not work, advancing a microcatheter over the wire to provide counter-traction might help prevent the guide being drawn down the vessel.

Recognition and management of longitudinal distortion

Longitudinal stent distortion should always be considered if there is any difficulty advancing balloons or additional stents during an interventional procedure. If a radio-opaque stent, such as Promus Element, has been distorted, there is a very characteristic but subtle "brightening" of the end of the stent evident on angiography, presumably due to the stent struts becoming more visible as they are bunched together. It may, however, be more difficult to recognize distortion in less radio-dense stents.

Once recognized, balloon re-dilation is the mainstay of treatment. It is often necessary to use very small balloons initially, and to increase balloon diameter from there on. If the smallest diameter balloons will not cross, advancing a Guideliner almost to the stent may help by changing the angle of approach and increasing

the forward force able to be applied to the balloon. Deploying an additional stent, partially overlapping the distorted portion of the first stent, is often also necessary. Intravascular imaging with IVUS or optical coherence tomography may provide additional useful insights, albeit with a risk of causing further distortion.

Case example

The characteristic angiographic features of longitudinal stent distortion are shown in the following case from our unit. The management of this patient is also described.

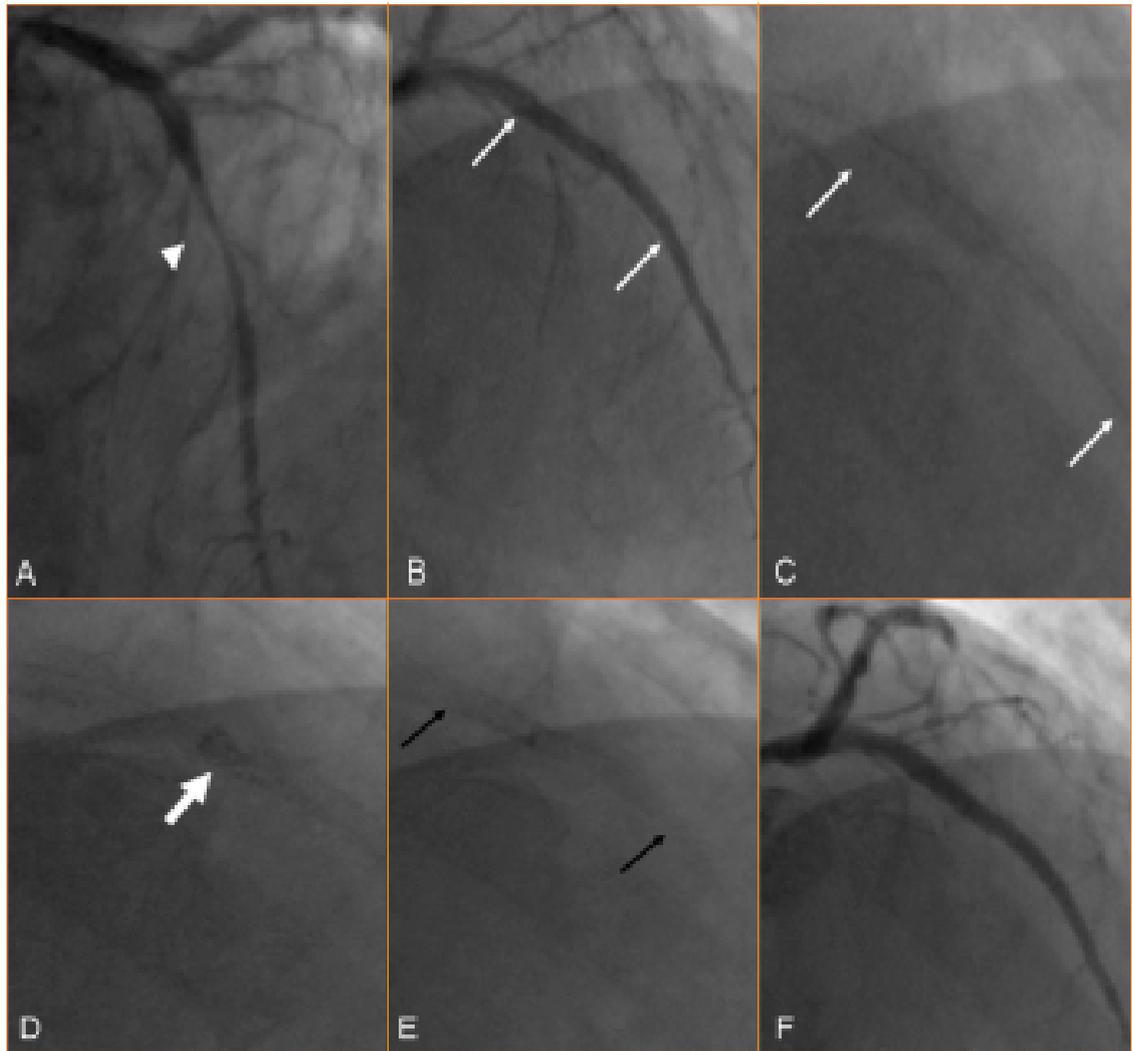
A 61-year-old man presented with ischaemic chest pain of acute onset, intermittent ECG ST elevation in leads V2-V3, and an elevated high-sensitivity troponin level. Coronary angiography demonstrated diffuse atheroma with a critical distal right coronary lesion and a severe non-calcified proximal-mid left anterior descending artery (LAD) stenosis (fig. 6). Given uncertainty around the culprit lesion, the right coronary stenosis was first successfully treated with a 3.5 x 12 mm Promus Element stent. The LAD lesion was then pre-dilated and a 2.75 x 24 mm Promus Element stent was deployed at 18 atmospheres. A 3.0 x 15 mm non-compliant balloon was easily advanced into the stent for post-dilatation. However, when a further inflation was attempted the balloon would not re-advance into the stent. Repeat angiography revealed distal displacement and "brightening" of the proximal end of the stent, indicating that the proximal hoops had been distorted and bunched together. A new 1.5 mm diameter balloon was needed to regain access to the stent, followed by further inflations with larger diameter balloons. After deployment of a second 3.5 x 8 mm Promus Element stent, partially overlapping the proximal end of the first stent, the final angiographic appearances were satisfactory. The patient remains well 12 months later.

Conclusions

Efforts to improve stent deliverability by reducing strut thickness and removing connectors between adjacent hoops has led to stents with less longitudinal integrity than those of the past. Longitudinal stent distortion, an old problem, has subsequently re-emerged as an infrequent but worrying complication of contemporary PCI. Stent manufacturers need to consider longitudinal integrity as an important stent characteristic

fig. 6

A mid-left anterior descending stenosis (A) is treated with a Promus Element 2.75 x 24 mm stent (B). The excellent radio-opacity of this stent allows the proximal and distal edges to be clearly seen, highlighted with white arrows (C). Characteristic brightening of the proximal edge of the stent is seen after distortion has occurred, highlighted with the white arrow (D). A second Promus element 3.5 x 8 mm was then deployed overlapping the proximal portion of the original stent (E). An excellent angiographic result was obtained (F)



that should be maintained when refining other desirable features. Some current stent designs appear to excessively favour stent deliverability and flexibility over longitudinal integrity.

Interventional cardiologists should be aware that longitudinal distortion can happen, and should incorporate simple strategies into their routine

practice to lessen the likelihood of it occurring. Stents with better longitudinal integrity should be considered for higher-risk lesions, such as those near coronary ostia. Clinicians should also be aware of the clinical and angiographic signs that indicate there is a problem, and understand the strategies needed to resolve it.

DISCLOSURES: The opinions and factual claims herein are solely those of the authors and do not necessarily reflect those of the publisher, editor-in-chief, editorial board and supporting company. JAO is on the advisory boards of, and has received honoraria from, Boston Scientific and Abbott Vascular. PAH, MWIW, FDV, TW, JTS and PNR have no relevant disclosures to declare.

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