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A comparison of balloon- and self-expanding stents

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Summary

This paper summarizes some of the key differences between self-expanding and balloon-expanding stents, aligning engineering and design differences with clinical performance. While neither type of stent can be considered universally superior, the differences are significant enough to make each type more appropriate in specific circumstances. Many of the differences concern long-term outcome, for which there is still insufficient data.

Keywords

self-expanding stents, balloon-expanding stents, Nitinol

Introduction

Stents are classified as either balloon-expanding (BX) or self-expanding (SX), depending upon how deployment is effected. BX stents are manufactured in the crimped state and expanded to the vessel diameter by inflating a balloon, thus plastically deforming the stent (Figure 1). SX stents are manufactured at the vessel diameter (or slightly above) and are crimped and constrained to the smaller diameter until the intended delivery site is reached, where the constraint is removed and the stent deployed (Figure 2). Accordingly, BX stents resist the balloon expansion process, whereas SX stents assist vessel expansion.

BX stents were the first to be commercially distributed and, even though SX stents have captured a significant share of the peripheral vascular market, BX stents remain dominant in the much larger coronary arena. Previous papers have described the forces, stiffness and key mechanical features of stents [1–4]. An analysis of these and other factors allows comparison and contrast between the use of the two and the tabulation of some of the key differences. It should be noted that, while not all BX stents are stainless steel, and not all SX stents are nitinol, deviations from this are rare and largely unimportant. One important exception is one of the oldest SX stents, the braided WallStent, which is not superelastic, but technically still falls in the SX-stent family. The WallStent has represented the SX stent family in many of the clinical comparisons that have been made between SX and BX stents [5–6]. However, because of its unusual nature it is not clear that these clinical comparisons are universally relevant to the newer nitinol-based stents.

Radial strength

Radial strength describes the external pressure that a stent is able to withstand without incurring 'clinically significant damage'. It is not always clear how 'clinically significant damage' should be defined, but it is usually significant permanent reduction in the vessel lumen. BX stents can collapse if a critical external pressure is exceeded, potentially having serious clinical implications. It should be noted that this collapse is usually a buckling phenomenon (essentially flattening to a half-moon shape, rather than a uniform diameter constriction). This means that the resistance to collapse is highly dependent upon lesion eccentricity, localised irregularities etc.

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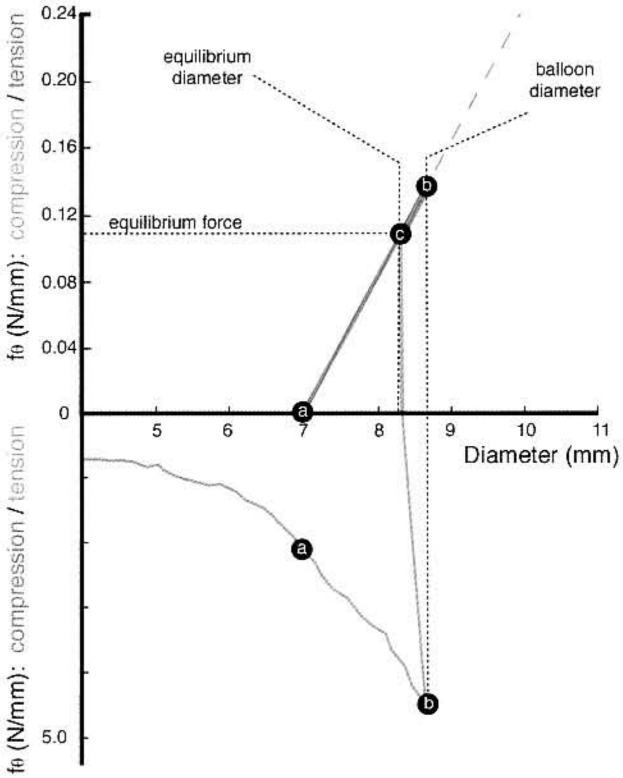

Figure 1. A force analysis of a BX stent is shown as it is expanded from 4 mm to 9 mm in a 7 mm vessel. The tensile hoop stress required to expand a typical coronary stent is shown by the blue curve from 4 mm until point 'b'. During inflation, the vessel is contacted at point 'a' and is expanded with the balloon to 9 mm, at which point, both stent and vessel are placed in tension by the balloon. *Note the scale of the vertical axix is much less sensitive below the axis than above*; the stent is more than 10 times the stiffness of the vessel. Upon deflation, the stent reverses its loads and is placed in compression, reaching a stress equilibrium with the vessel at point 'c'. In this case, the *in situ* acute recoil is 0.75 mm.

On the other hand, superelastic SX stents have no strength limitation and elastically recover even after complete flattening or radial crushing. Thus, SX stents are ideally suited to superficial locations, such as the carotid and femoral arteries. A second very important advantage of SX stents is that 'radial strength' need not be considered in their design, thus removing a central and very limiting design constraint. 'Ignoring' strength allows SX stent designers to favour other elements of design, for example, smaller cell size, or improved flexibility.

It should be noted that SX stents can be susceptible to buckling in certain circumstances (see Figure 3). Even though this buckling is elastic, and recovers immediately upon the release of stress, there can be certain situations where buckling can be clinically problematic (particularly with highly oversized stents). As with BX stents, it is important to note that designs which maximise radial stiffness do not minimise buckling. It is a common error to blame a buckled stent on insufficient radial strength or stiffness.

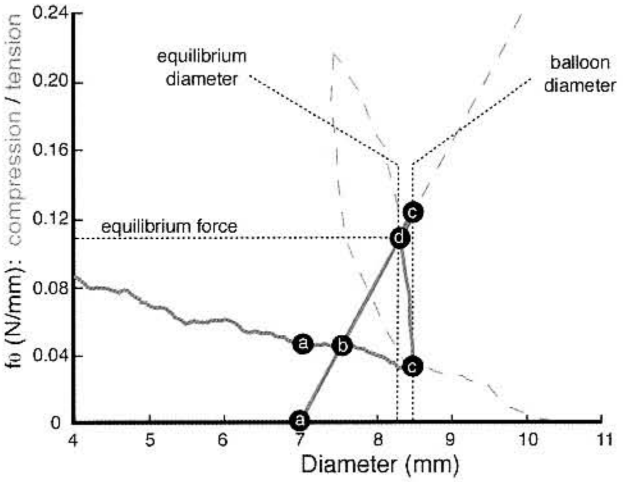

Figure 2. The life cycle of a 10 mm self-expanding stent in a 7 mm vessel is illustrated by examining the hoop forces in the vessel and stent. The stent unloads as its expands until it impinges the vessel (illustrated by the green curve to point 'a'). Upon contact, the vessel begins to expand (red curve). At point 'b', the stent and the vessel reach a stress equilibrium (the stent in compression, the vessel in tension). Balloon expansion to 8.5 mm further unloads the stent to point 'c', meanwhile increasing the tensile stress in the vessel to point 'c'. Deflating the balloon establishes the final stress equilibrium between stent and vessel at 'd'. Note that if the unloading stiffness were not biased (i.e. stiffer in loading than in unloading [2]), the vessel would recoil all the way back to point 'b' after balloon deflation, and balloon dilatation would have been only temporary.

Radial stiffness

Stiffness is defined as how much the diameter of a stent is reduced by the application of external pressure. A BX stent will be stiffer than an SX stent of identical design, because of the lower elastic modulus of nitinol. This difference is difficult to quantify, due to the non-linear stress–strain curve of nitinol, but the identical BX design will be at least three times stiffer. Since BX stents must be designed with a high radial strength, their designs tend to be of a stiffer nature as well. The stiffness of BX and SX stents are contrasted in Figures 1 and 2, which illustrate force–diameter measurements made on successful and typical commercially available stents. Stent stiffness by itself is neither an advantage nor a disadvantage, although there are several consequences of this stiffness difference that should be considered by both designer and clinician.

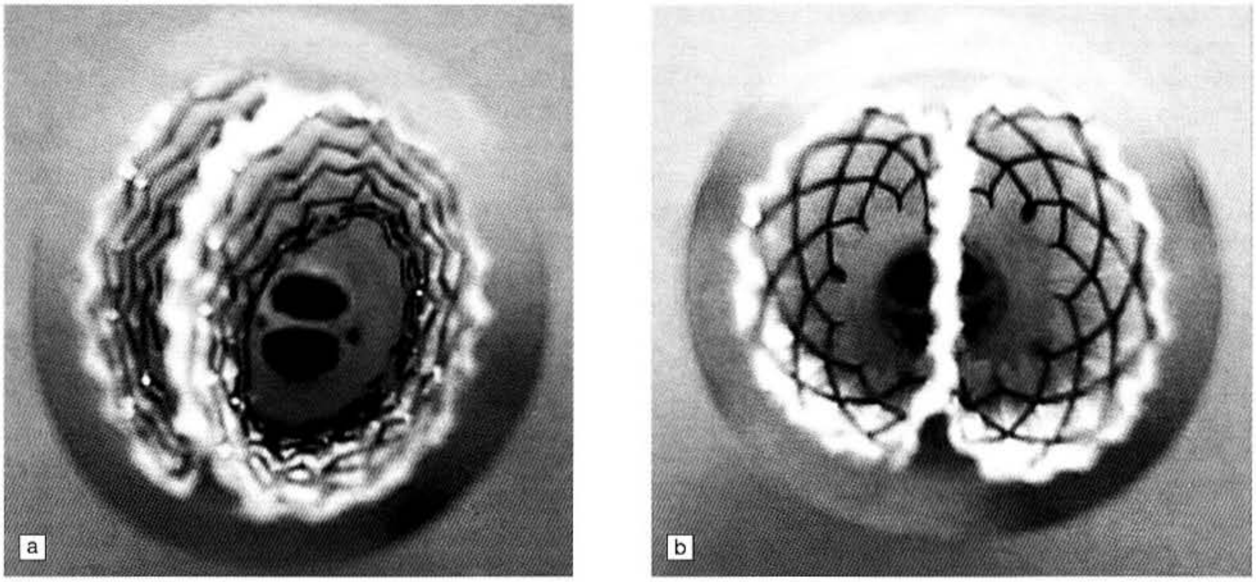

Figure 3. Buckling resistance, or strength, represents the true strength limitation of a BX stent, not radial strength. Even though SX stents cannot permanently buckle, (a) shows that certain superelastic stent designs can still buckle if pressured focally, in this case by a second, 'kissing' stent. Note that the design in (b), which as not buckled, actually has the greater radial stiffness — buckling resistance has little to do with radial stiffness or strength.

The radial compliance of an SX stented vessel is much greater than that of a typical BX stented vessel, due to the lower stiffness of the SX stent; i.e. a BX stent will significantly decrease the compliance of a vessel. A healthy vessel with a 6%/100 mmHg compliance is generally 3–4%/100 mmHg after stenting with a typical SX stent, and < 1%/100 mmHg when stented with a BX stent. Most physicians intuitively feel it advantageous to preserve the native, physiologically correct vessel properties as far as possible, but it is not clear that this provides any tangible clinical advantage. An oft-neglected consequence of this is that SE stents have much lower pulsatile contact pressures than do BX stents. BX stents, by restricting vessel movement, produce higher metal–tissue contact forces. Again, it is unclear if these tissue contact pressures are of clinical significance.

Axial stiffness, which is directly reflected in bending compliance, is also different, with SX stents being again much more compliant than BX stents of identical design; this applies both in delivery and deployment. Efforts by BX stent designers to match the bending compliance of SX stents have led to the use of very thin flexible links (Figure 4), which plastically deform with very little force. Even with such improvements, SX stents remain more *conformable* — they adapt their shape to that of the vessel, rather than force the vessel to the shape of the stent. Forcing a vessel into an unnatural shape, even if straight and aesthetically pleasing, can lead to high contact forces at the ends of the stent. There are additional implications in stenting dynamic vessels, such as the femoral, carotid and subclavian vessels. Flexible links that are plastically deformed during bending accumulate damage and can fracture quickly as a result of fatigue. It is not clear, however, whether fractures of this sort (in a link that is not intended to provide structural integrity) are deleterious to performance and long-term outcome.

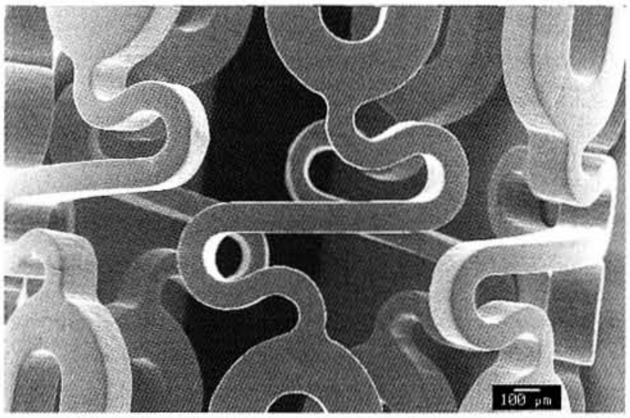

Figure 4. Very thin, easily deformed flexible links in the new generation of SS BX stents allows greatly improved flexibility and deliverability, rivaling that of SX stents.

Acute recoil

Acute recoil refers to the reduction in diameter immediately observed upon deflation of a balloon. A bare BX stent recoils after balloon deflation, whereas

SX stents assist balloon inflation and thus there is no recoil of the bare SX stent. The situation in a vessel, however, is very different, and both devices will generally recoil due to the springback forces of the vessel (see Figures 1 and 2). Experience has shown that BX stents recoil less than SX stents when placed in calcified lesions. This is one of the reasons that BX stents are still preferred in renal and coronary stenting. While it is certainly possible to design SX stents that are as stiff as commercially available BX stents, many of the advantages of SX stents would then be lost.

Chronic recoil and hyperplasia

Without subsequent balloon dilatation, a BX stent can only become smaller in diameter over time (*chronic recoil*). Most modern BX stents are strong enough to make this effect negligible. A properly over-sized SX stent, however, continues to apply a force acting to expand the vessel, and there is extensive evidence that they undergo a *negative chronic recoil*, which means that they continue to open over time, often remodeling the vessel profile. It remains unclear how much negative chronic recoil (or chronic expansion) occurs in more hardened arterial disease states. A fuller and more quantitative understanding of this might lead to a greater usage of SX stents in the renal and coronary markets.

It is common to find that after 2–4 weeks SX stents have moved well into the wall of the artery, and now support the vessel from within the smooth-muscle layer, rather than from within the lumen. *Hyperplasia*, therefore, is not necessarily indicative of a problem in an SX stent; it is, rather, an expected outcome. Hyperplasia in a BX stent, however, is indicative of a constriction since the stent has not moved outwards, but the vessel wall has moved inwards. Since endothelium grows quickly over both stainless steel and nitinol, there does not appear to be a difference in the blood flow due to protrusion of the struts into the lumen. Nevertheless, it remains true that SX stents generally reside near and scaffold the outside of the vessel wall, while BX stents remain near the lumen. The negative recoil of SX stents may become an important advantage with drug eluting or irradiated stents, in which the lumen may actually increase with time, leaving the BX stent exposed to the flow of blood — again, the SX stent will maintain apposition to the retreating wall.

Delivery profile and placement accuracy

The delivery profile of a BX stent is dictated by the profile of the balloon upon which it is mounted. SX-stent profiles are currently dictated by the strut dimensions (specifically the width) required to achieve the desired mechanical performance. Current minimum profiles of the two types are very similar, but SX stents would seem to have the greater potential to reduce in size. This is expected to play an important role in neurovascular stenting, where both delivery profile and flexibility are essential.

Placement accuracy has historically favoured BX stents. Early SX stents foreshortened significantly during expansion, or would spring forward from the delivery system once deployment began. Newer SX delivery systems are much improved and nearly as accurate as BX systems, but even so, the 'gold standard' for placement accuracy is the new generation of flexible-link BX stents, which exhibit virtually no foreshortening. In certain indications this degree of accuracy is of little significance, in others, such as in the renal arteries, it remains important.

It should also be noted that stent retention is only an issue with BX stents; SX stents are completely housed in delivery catheters, while BX stents are crimped onto a balloon and can be dislodged during delivery. Again, the adherence of BX stents to balloons has improved dramatically during recent years, and this appears to be more of a historical concern.

Visibility

The X-ray visibility of stainless steel and nitinol is very similar, however, both visibilities are becoming inadequate as designers learn to scaffold with less metal. Gold-plated versions of both exist, but there are corrosion and clinical concerns with the use of gold [7]. Some newer SX stents instead use tantalum to 'mark' the ends of the stent. Until a reliable way is found to protect gold or platinum layers, or a robust method of applying other radiopaque coatings is found, this appears to be the best way to address the problem. There is a great anticipation that MRI will be used in stent placement. While both stainless steel and nitinol are 'safe' in MR fields, nitinol provides a cleaner, more accurate image. It should be noted, however, that this depends strongly upon the surface finish of the stent.

Balloon trauma and direct stenting

As pointed out earlier, SX stents assist the balloon, whereas BX stents resist the balloon; balloon pressures during BX stenting are therefore far greater than in SX stenting (compare Figures 1 and 2). It is a myth that this results in lower forces against the vessel wall. Forces are dictated by the vessel compliance rather than the balloon, balloon pressure therefore has no relevance in a straight vessel, except that the SX stent allows the use of thinner, lower-pressure balloons. In tortuous anatomy, however, higher-pressure balloons may cause damage to the vessel by temporarily forcing the vessel into a straight configuration. This can also knock plaque from the vessel walls, a particular threat during SVG and carotid interventions. Direct stenting is becoming common with BX stents. In these cases, there is no pre-dilation of the vessel; the stent is simply advanced to the site and expanded. SX stents do not generally have sufficient stiffness to directly open calcified lesions; they must be pre- or post-dilated, or the interventionalist must trust that chronic outward growth of the stent will occur and will resolve the disease-state over time. Our knowledge of what will and will not resolve itself, and how long it will take, is insufficient at present to allow extensive primary stenting with SX stents.

Fatigue and long-term mechanical integrity

Two types of fatigue should be considered: pulsatile and axial. Native vessels undergo diameter changes of approximately 6% when subjected to 100 mmHg pulse pressures [8]. A stent placed in this environment is usually expected to remain patent for 10 years, or 400 million systolic cycles. This is no easy task, and again BX and SX stent-design philosophies are in opposition. Stainless-steel stents cannot survive even very modest diameter changes, but are sufficiently rigid to prevent the vessel from 'breathing' due to pulse pressure. SX stents, on the other hand, are too compliant to prevent diameter pulsation but, fortunately, are able to survive exceptionally large strain levels due to their superelastic properties. Fatigue analyses such as these are complex and beyond the scope of this paper. They generally involve a combination of physical testing and finite element stress analysis. Unfortunately, both are somewhat inadequate: physical testing systems are not able to operate reliably at high frequencies, and finite element analyses require a great many assumptions regarding vessel behavior and stent–vessel interaction. Furthermore, the consequences of a break are often unclear.

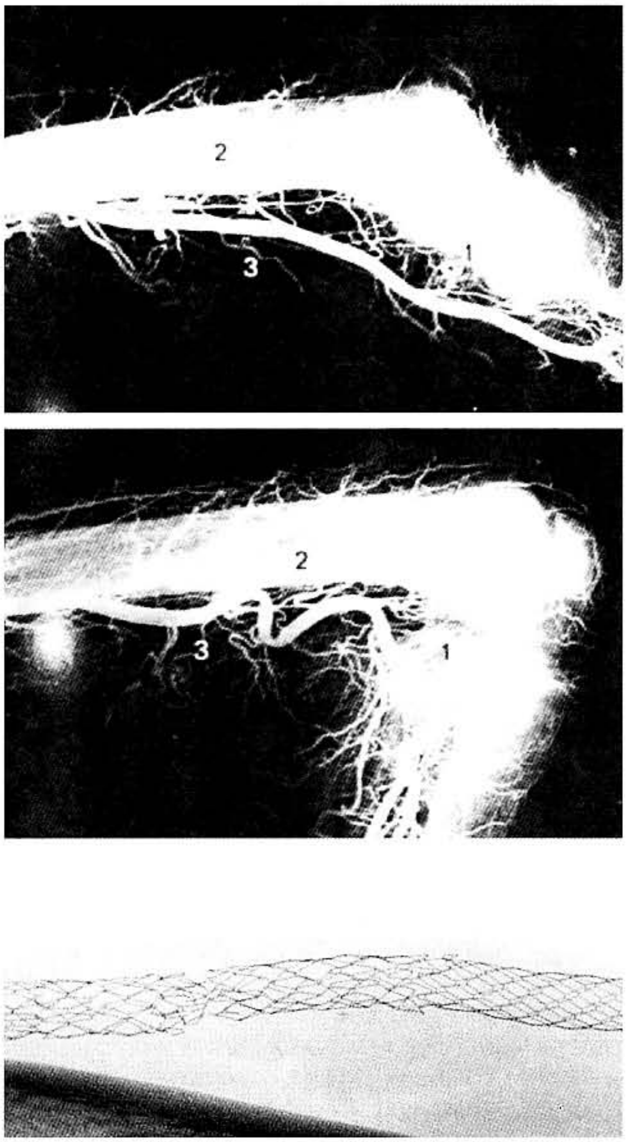

Figure 5. The popliteal is an example of a very dynamic artery, presenting a tremendous mechanical challenge for stent designers. Below is a fractured stent in the lower-central superficial femoral artery; the primary defomation mode in this case appears to be axial fatigue, caused by cyclic flexing in the knee. Such fractures appear to be common, but it is unclear what clinical impact they have, if any.

Bending/crushing/stretching fatigue is often ignored, but can be very important in certain indications. One extreme case is the popliteal artery (Figure 5), but such issues can also be important in coronary vessels because of the systolic expansion of the heart (thus stretching the stent). This later challenge is a new one in the sense that older generations of coronary stents were very rigid in the axial direction and not subject to axial fatigue. The newer, more flexible generations, however, can experience axial deformations and may be prone to fatigue damage. Nitinol performs far better than any other known metal in displacement-controlled environments such as these, which ultimately may mean that this more fatigue-resistant metal offers further advantages under these circumstances.

Thrombogenicity and biocompatibility

These attributes have been discussed in detail in other publications [9,10]. In short, both the thrombogenicity and corrosion resistance of nitinol are very slightly superior to stainless steel, but it appears unlikely that these differences will be of clinical significance — or at least no evidence of this has yet been presented. However, clinicians should be aware that the superior corrosion resistance of nitinol is not automatic; the surface must be carefully treated by electropolishing and/or passivation, or other similar methods. It is easier to make stainless steel corrosion-safe.

Balloon-expandable superelastic stents

Efforts have been made to combine some of the advantages of BX and SX stents by creating balloon-expandable, superelastic stents: that is, stents that are superelastic and that are unloaded during expansion (like SX stents), yet are placed by inflating a balloon. These devices would have the high compliance/low stiffness common to all nitinol devices, so would still require time to become efficacious in highly calcified areas.

At least two approaches have been proposed. The first adds a constraint to an SX stent that firmly compresses the stent onto a balloon. When the balloon is inflated, the constraint is either broken or plastically deformed and the stent is freed to expand [11]. The second is the 'BiFlex' concept [12], which again uses a Nitinol SX stent, but in which the design is modified to produce two 'stable' states, one closed and one open — again, a balloon is used to 'destabilize' the constrained shape so that the stent snaps to its open configuration. Early animal testing has indicated that premature deployment might be a problem with these stents when passed around a tortuous bend. Both concepts are still in their infancy and it is far too early to determine their potential. However, it is important to be aware that possibilities do exist which combine attributes of both BX and SX stents.

Conclusions

SX and BX stents differ in many respects, but can be thematically summarised, SX stents become part of the anatomy and act in harmony with native vessels, while BX stents change the geometry and properties of the anatomy: i.e. SX stents assist, BX stents dictate. Clearly, there will always be a place for both in radiology suites. Perhaps the most important unknown regarding SX stents concerns the effects of chronic outward growth. Physicians are beginning to experiment with eliminating post-dilation, and relying on chronic outward force to slowly remodel the vessel to the desired diameter. While acute results may not be as good, the lessened trauma may lead to a better chronic outcome. Unfortunately, very few data exist regarding the long-term outcome of BX versus nitinol SX stents made from tubing.

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