An Overview of Superelastic Stent Design

Duerig, Pelton

Materials Science Forum
Vols. 394-395
pp. 1-8

2002

Materials Science Forum Vols. 394-395 (2002) pp. 1-8

An Overview of Superelastic Stent Design

T.W. Duerig and A.R. Pelton

Nitinol Devices and Components, 47533 Westinghouse Road, Fremont, CA 94539, USA

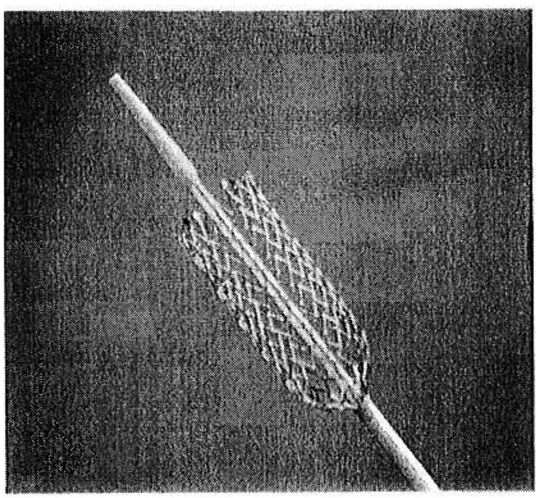
Keywords: Nitinol, Stents, Superelasticity

Abstract. This paper summarizes the key differences between self-expanding and balloon expanding stents, highlighting the advantages of Nitinol. Also summarized are many novel concepts and future directions in stenting, including neurovascular stents, distal protection during stenting, coronary stents, and balloon expanding superelastic devices.

Introduction

A stent is a device used to scaffold or brace a biological lumen, most commonly, diseased arteries after balloon angioplasty. Angioplasty is performed to expand a diseased and constricted vessel; the purpose of the stent is not to initially open the artery, but to prevent the restriction from returning with time (restenosis). The efficacy of stents in reducing the occurrence of this vascular restenosis has been proven beyond doubt. Such stents are inserted into the arterial system through a convenient superficial access point such as the femoral artery. A delivery system is used to transport the stent to the intended deployment site, at which time the stent expands to the vessel diameter. All stents can be classified as either Balloon eXpanding (BX) or Self eXpanding (SX) depending upon how this deployment is affected: BX stents are manufactured in the crimped state and expanded to the vessel diameter by inflating a balloon (thus plastically deforming the stent), while SX stents are manufactured at the vessel diameter (or slightly above) and are constrained to the smaller crimped diameter until the intended delivery site is reached, whereupon the constraint is removed and the stent deployed (Fig. 1). Accordingly, BX stents resist the balloon expansion process whereas SX stents assist the vessel expansion.

Fig.1 A 10mm self-expanding Nitinol SMART® stent superelastically deployed from its delivery system.



Balloon expandable stents were the first to be commercially available, and remain by far in the majority today. Interest in self-expanding stents, however, is increasing, and Nitinol is playing a key role in this growth. Initial interest in Nitinol centered upon superficial artery applications such as the internal carotid artery where the stainless steel BX stents had been observed to crush. Most, if not all, Nitinol stents can be crushed fully flat and still elastically recover their original shape without clinically relevant loss of lumen diameter. Since then, however, several other advantages of Nitinol stents have been identified, many significant enough to believe there will be substantial growth into the more traditional areas of stenting, including coronary.

Contrasting BX and SX Stents

Previous papers have described the forces, stiffness and key m echanical features of stents [1-3]. An analysis of these and other factors allows us to compare and contrast the use of superelastic SX stents with conventional BX stents. Below are tabulated the key features of a successful stent design, with discussions of the differences. It should be noted that while not all BX stents are stainless steel and not all SX stents are Nitinol, the exceptions are rare and largely unimportant and thus will be ignored unless otherwise noted.

Strength. BX stents have a predefined strength, or upper limit to the radial force which they can resist without incurring plastic deformation. If exceeded, BX stents can collapse or buckle having serious clinical implications. Superelastic SX stents have no such limitation, and elastically recover their shape even after complete flattening. One obvious advantage to SX stents, therefore, is that they are crush resistant, making them ideally suited to superficial locations such as the carotid and femoral arteries. A second advantage is that "radial strength" need not be considered in the design of an SE stent, thus removing a central and very limiting design requirement.

Stiffness. BX stents of the identical design as SX stents are stiffer simply because of the lower modulus of Nitinol. This difference is difficult to quantify due to the non-linear stress-strain curve of Nitinol, but will generally be a factor of at least 3 times. Further, since BX stents must be made to resist collapse, their designs tend to be of a stiffer nature. Stiffness by itself is neither an advantage nor a disadvantage, but there are several consequences of this stiffness difference that are discussed below.

Due to the lower stiffness of SX stents, the radial compliance of an SX stented vessel is much greater than for a typical BX stent. A healthy vessel with a 6 %/100mm-Hg compliance is generally 3-4 %/100mm-Hg after stenting with a typical SX stent, and less than 1% /100mm-Hg when stented with a BX stent in place. Most physicians intuitively feel it advantageous to preserve the natural, physiologically correct vessel properties as much as possible, but it is not clear whether there is a real clinical advantage in doing so.

Axial stiffness (bending resistance) is somewhat less clear than radial compliance since design also plays an important role in controlling bending stiffness, but again the lower modulus generally leads to a substantially more flexible device both during delivery and especially after deployment. Efforts by BX stent designers to match the bending compliance of SX stents have led to the use of flexible links, which can easily become plastically deformed and may be subject to fatigue damage. Even with such improvements, SX stents remain much more *conformable*, meaning that they adapt their shape to that of the vessel, rather than force the vessel to the shape of the stent.

Often neglected is the related fact that SE stents have much lower contact pressures than do BX stents. BX stents, by restricting vessel movement, produce higher metal-tissue contact forces. This is true in both straight vessels subjected only to systolic pulsation, but especially so in dynamic vessels such as the femoral, carotid, and subclavian vessels. It is possible that this lower contact pressure plays a role improving restenosis results in these areas.

Temperature Dependence. Of course stainless steel has no temperature dependence in the general range of body temperature, whereas the plateau stresses in Nitinol increase with temperature. Other than making it difficult to "feel" the behavior of the stent at room temperature, there is another complication that SX stent designers must consider: storage and sterilization. ETO sterilization exposes devices to 58°C, and shipping can at times reach higher temperatures than that. At these temperatures, the stent will certainly impart greater forces against the catheter, may develop some amnesia (reduction in recovered diameter), or may undergo an increase in A_f temperature that can have very serious clinical effects. It is therefore strongly advised that one extensively tests devices in this temperature range, and even to provide protection to assure product is not exposed to temperatures above which testing has been done.

Acute Recoil. BX stents recoil after balloon deflation, both when inside a vessel and when bare. SX stents assist balloon inflation and thus there is no recoil of the stent alone. The situation in a vessel, however, is much different, where both devices will generally recoil due to the springback forces of the vessel. Practice tells us that BX stent recoil will be less when they are placed in calcified lesions. This is one of the reasons that BX stents are still preferred in renal and coronary stenting. While it may be 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. A BX stent, once placed, can only become smaller in diameter over time (barring a second interventional procedure). Any time dependent closure of the stent is termed *chronic recoil*. Most modern BX stents are strong enough to make this negligible. A properly oversized 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*, meaning that they continue to open over time, often remodelling the vessel profile. It remains unclear how much negative chronic recoil occurs in more hardened arterial disease states. It is possible that if this were to be better defined, it might be possible to increase physician confidence in using SX stents in the large renal and coronary markets.

After 2-4 weeks it is common to find that stents have moved well into the wall of the artery, and now support the vessel from well within the smooth muscle layer, rather than from within the lumen itself. *Hyperplasia*, therefore, is not necessarily indicative of a problem in an SX stent: many SX stents show substantial "hyperplasia", or tissue within the stent lumen, yet preserve the vessel lumen diameter perfectly. Hyperplasia in a BX stent, however, is indicative of a constriction. Since endothelium grows quickly over both stainless steel and Nitinol, there does not appear to be a difference in the blood flow. This may, however, become an important issue with respect to drug or radiation coated stents that may retard endothelialization, or even cause the lumen to retreat, leaving the BX stent exposed to the flow of blood.

Wall Apposition. Wall apposition refers to the ability of a stent to "hug the wall" of a vessel around tortuous anatomy, and to hug the wall in eccentric lesions, tapers and bifurcations. While the conformability of SX stents is inherently better than BX stents, good conformability is not guaranteed, and results only from sound design principles.

Delivery Profile and Accuracy. The delivery profile of BX stents is dictated by the profile of the balloon upon which they are mounted. SX stent profiles are currently dictated by the strut dimensions required to achieve the desired mechanical performance. Current profiles of the two types are very similar (slightly over 4F for coronary stents, 6-7F for 6-10mm peripheral vascular stents), but clearly SX stents have the greater potential to reduce size. This will certainly play an important role in neurovascular stenting, where both delivery profile and flexibility are essential. Reduced profile is certainly an area that is key to the future of stenting, and which is receiving a great deal of attention by stent producers (Fig. 2).

Placement accuracy has historically favored BX stents. Early SX delivery systems compressed during delivery (thus moving the stent from its intended location) would often spring forward from expansion. Newer delivery systems are much improved and nearly as good as BX systems, but even so, the gold standard for placement accuracy are the new generation of flexible-link BX stents. These new stents exhibit no foreshortening, and only radial forces are imparted on the stent during deployment, thus minimizing axial movement. In certain areas, this is of little significance; in others, such as the renal arteries, it remains an important issue. It should be noted, however, 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.

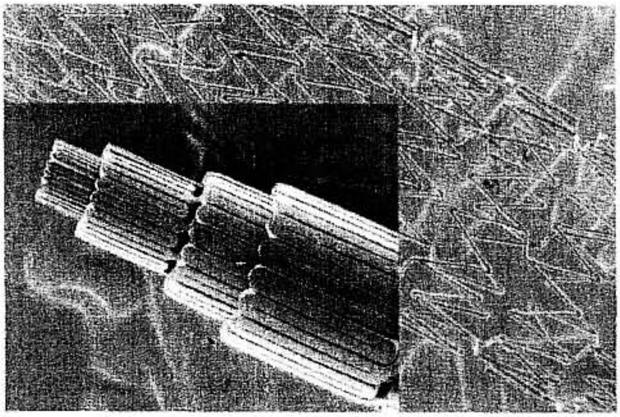


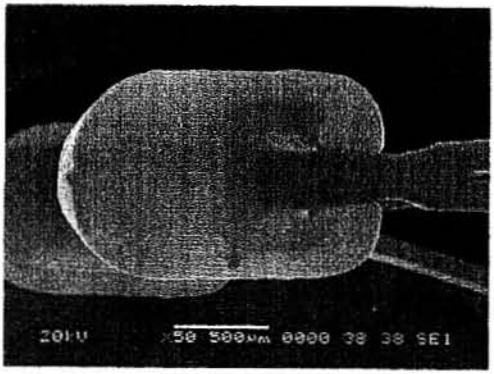
Fig.2 Progress of laser cutting technologies (inset) with the smallest cut tubing being of a diameter of 0.5mm. The resulting 3mm diameter stent is shown in the background.

Visibility. While the X-ray visibility of stainless steel and Nitinol is very similar, both are becoming inadequate as we learn to make scaffold with less and less metal. Gold plated versions of both exist, but there are both corrosion and clinical concerns with the use of gold [4]. A new group of SX stents instead uses Tantalum to "mark" the ends of the stent (Fig. 3). Until a reliable way is found to protect gold or platinum layers, or a robust method for applying a uniform coating of tantalum is found, this appears to be the best way to address the problem. It should be noted that the radiology equipment is steadily improving in resolution, and that too is improving visibility.

There is a great anticipation that magnetic resonance imaging will be used to place stents. 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. The balloon within a BX stent must open the vessel and plastically deform the stent; SX stents assist the balloon whereas BX stents resist the balloon. Thus balloon pressures in BX stenting are far higher than in SX stenting. In a straight vessel, this has no relevance except that the SX stent allows the use of a thinner, lower pressure balloon. In tortuous anatomy, however, the higher pressure balloon may cause damage to the vessel by temporarily forcing the vessel into a straight configuration. This can also knock-off plaque from the vessel walls, a particular threat in SVG and carotid interventions.

Direct stenting is becoming very 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 certainly do not have the strength to directly open calcified lesions. Either they must be pre or post dilated with a balloon,or the interventionalist must trust that the chronic outward growth of the stent will occur and will resolve the disease state by itself. Our knowledge of what will and what will not resolve itself, and how long it will take, is insufficient at present to allow extensive primary stenting with SX stents.



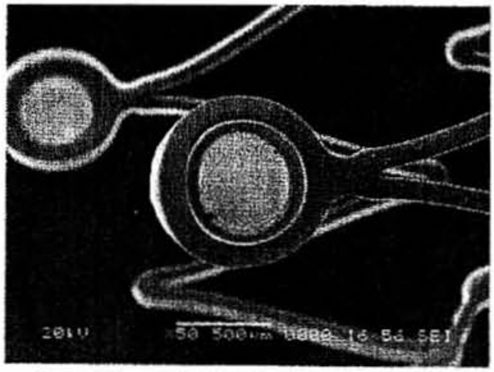


Fig.3 Two approaches to adding Ta markers to enhance the radiopacity of Nitinol stents. Left are welded Ta markers (2 mm in length), and right are shown Ta rivets (0.5mm in diameter). Below right cross-section shows the interlocking that assures that rivets are firmly retained.

Fatigue. Here we must consider two types of fatigue, pulsatile and flexural.

Native vessels undergo diameter changes of approximately 6% when subjected to a 100 mm-Hg pulse pressures [5]. A stent placed in these environments 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 juxtaposition. Stainless steel stents cannot survive such large diameter changes, but are sufficiently rigid to prevent the vessel from 'breathing' due to the pulse pressure. Vessels stented with BE stents generally pulse less than 1.0% of their diameter making fatigue essentially a stress-controlled problem. SX stents pulse with the vessel, and, are best considered a displacement-controlled fatigue problem.

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 FEA analyses require a great many assumptions regarding vessel behavior and stent-vessel interaction. Further, the consequences of a break are often unclear.

Bending/crushing fatigue is often ignored, but can be very important nonetheless. One extreme case is the popliteal artery (Fig. 4), but such issues can also be important in coronary vessels as a result 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. Nitinol performs far better than any other known metal in displacement-controlled environments such as these, and ultimately this may lead to advantages for the more fatigue resistant Nitinol in coronary applications.

Thrombogenicity and Biocompatibility. These attributes have been discussed in detail in other publications [6,7]. In short, both thrombogenicity and corrosion resistance of Nitinol are superior to stainless steel, but it appears unlikely that these differences are of clinical significance—or at least no viable evidence of this sort has been presented. One must be constantly aware, however, that the superior corrosion resistance of Nitinol is not automatic; its surface must be carefully treated through electropolishing and/or passivation, or other similar methods.

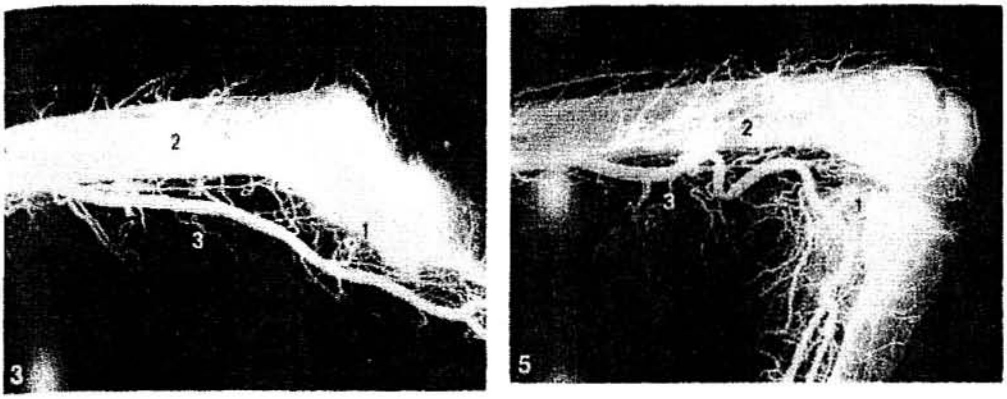


Fig 4 Radiograph of an extended and bent knee show highlight the severe fatigue environment to which implant can be exposed.

Other Uses of Nitinol in Stents

Martensitic Stents. While the vast majority of Nitinol stents are superelastic and self-expanding, three other types of Nitinol stents have been proposed: stents which are installed cold then thermally recover their specified shape when exposed to body temperature [8], stents that recover their desired diameter by heating above body temperature after insertion into the body [9], and BX Martensitic stents that can be later heated to cause shrinkage to assist in removal [10]. The last of these is probably the most interesting, but has still not been commercially successful. In addition to removability, these stents offer more uniform expansion, but at a price: Martensitic Nitinol is inherently weak and requires large, bulky structures. Moreover, Martensitic Nitinol is not superelastic and thus offers none of the typical advantages of Nitinol SE stents.

Balloon Expandable, Superelastic Stents. A variety of ways exist to make stents that are superelastic yet balloon expandable [11]: stents with break-away constraints, stents with plastically deformable constraints, stents with interlocking features and stents with two stable diameters (so-called "bi-stable" stents).

Stent Grafts. Several Nitinol-ePTFE and Nitinol-Dacron stent grafts have become available in recent years. One of the more novel devices, in both construction and delivery mode, is the Hemobahn® by Gore (Fig. 5). These devices bring about several new aspects of device design. Graft-stent interactions can dramatically change the flexibility and kink resistance of the devices, and increasing the flexibility of the stent does not necessarily imply a reduction in overall device flexibility. Corrosion is also changed, since grafts do not generally endothelialize, and thus the exposure of the metal is changed. The lack of endothelialization can also increase the severity of a fatigue break.

AAA Grafts. Several bifurcated Nitinol grafts exist for treatment of Abdominal Aortic Aneurysms (AAA). The market for these devices is potentially huge, yet none of the existing devices has an unblemished track record--even thought the surgical procedure is extremely invasive, it remains the gold standard treatment. The main problems appear to be sealing (requiring high radial forces), buckling and kinking around tortuous bends, and fatigue and corrosion breaks [12].

Distal Protection. It is known that all stenting procedures incur some risk that debris is knocked loose from the vessel wall, and that debris can carried downstream causing a host of clinical problems, including stroke. In order to increase the safety of these procedures, several companies are investigating the use of filters.

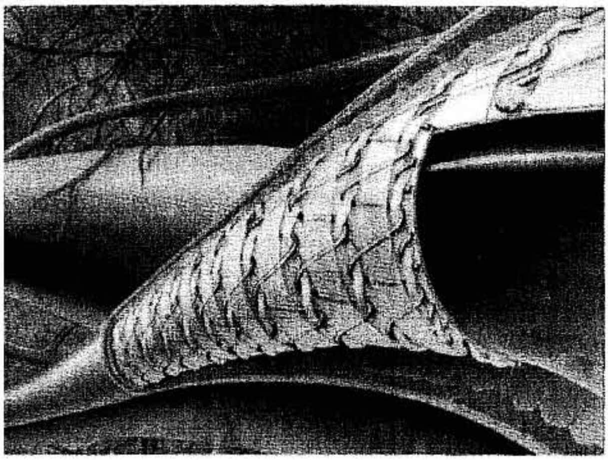


Fig. 5 The Hemobahn® by Gore uses an undulating Nitinol wire helix in a ePTFE graft to create a highly flexible stent-graft.

Coronary Stents. Coronary vascular disease remains by far the largest indication for stents, yet with very few exceptions, Nitinol remains unused and even untested in this field. Some of the cited reasons are that the vessels are static, and both placement accuracy and stiffness favor BX stents. The first of these, however, is not true; coronary vessels undergo substantial movement, and with placement accuracy now comparable, stiffness appears to be the only barrier to entry into this field. As stated earlier, however, the presence of negative chronic recoil may offset the need for high stiffness. Clearly more clinical experience is needed in this area.

Conclusions

SX and BX stents differ in many respects, but thematically summarizing, 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. SX stents assist, BX stents dictate. Clearly there is a place for both in radiology suites. Perhaps the most important unknown regarding SE stents concerns the effect of chronic outward growth of a stent. 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.

References

[1] T.W. Duerig, D.E. Tolomeo and M. Wholey: Proc. SMST-2000, in press.

[2] T.W. Duerig, D.E. Tolomeo and M. Wholey: Min. Invas. Ther.& Allied Technol. Vol. 9(3/4) (2000), p. 235.

[3] D.E. Tolomeo and T.W. Duerig: Criteria for Fatigue Resistant Design of Superelastic Stents, to be published.

[4] A. Kastrati, et al.: Circulation Vol. 101 (2000), p. 2478.

[5] K.W. Lau and U. Sigwart: J. Indian Heart Vol. 43(3) (1991), p. 127.

[6] R. Venugopalan and C. Trepanier: Proc. SMST-2000, in press.

[4] A. Kastrati, et al.: Circulation Vol. 101 (2000), p. 2478.

[5] K.W. Lau and U. Sigwart: J. Indian Heart Vol. 43(3) (1991), p. 127.

[6] R. Venugopalan and C. Trepanier: Proc. SMST-2000, in press.

[7] B. Thierry, Y. Merhi, C. Trepanier, L. Bilodeau, L'H. Yahia and M. Tabrizian: Proc. SMST-2000, in press.

[8] A. Balko, G.J. Piasecki, D.M. Shah, W.I. Carney, R.W. Hopkins and B.T. Jackson: J. Surgical Research Vol. 40 (1986), p. 305.

[9] R.J. Alfidi and W.B. Cross: Vessel Implantable Appliance and Method of Implanting It, US Patent: 3,868,956 (1975).

[10] R.L. Hess: Removable Heat-Recoverable Tissue Supporting Device, US patent 5,197,978 (1993).

[11] T.W. Duerig, and D. Stoeckel: Composite Self Expanding Stent Device Having a Restraining Element, US patent 6,086,610.

[12] B. Riepe, et al: Eur. J. Vasc. Endovasc. Surg. Vol.13 (1997), p. 540.