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A survey of stent designs

D. Stoeckel[1], C. Bonsignore[1] and S. Duda[2]

[1]*Nitinol Devices and Components, Fremont, CA USA*
[2]*Dept of Diagnostic Radiology, University of Tuebingen, Tuebingen, Germany*

Summary

Over 100 different stent designs are currently being marketed or are in evaluation for vascular and non-vascular indications. This paper attempts to differentiate stent designs by engineering aspects. A stent design pyramid is presented, which breaks the differentiating aspects into materials, raw material forms, fabrication methods, geometrical features, and additions. The primary distinguishing factor in all groups is balloon-expansion versus self-expandability. Typical examples for each category of the pyramid are shown.

Keywords

stents, materials, fabrication methods, geometrical features

Introduction

The 2002 *Handbook of Coronary Stents* edited by Serruys and Rensing [1] lists 43 coronary stents or stent families, and *Koronarstenting*, published in 2001 by Machraoui, Grewe and Fischer [2], brings the number of stents tabulated to 59. Neither book claims to be complete; each focuses on cardiology, excluding stents specifically marketed for peripheral or non-vascular indications. It is therefore probably safe to assume that there are close to 100 different stents currently being marketed or in evaluation worldwide, with most of them available in Europe. As a result of strict FDA regulations, the number of approved stents in the USA is not quite as high, but is still substantial. These stents compete for a market that is estimated to be near $3 billion, and is expected to double with the advent of drug eluting devices.

Most surveys differentiate stents by their clinical use, e.g. vascular or non-vascular, coronary or peripheral. This paper proposes classifications based on design and engineering characteristics of these structures, which are illustrated in the stent design pyramid in Figure 1. The chosen starting point is materials used, and distinguishes between balloon-expandable and self-expanding stents. From there, the classifications branch out into forms of materials used, such as sheet, wire or tube; manufacturing methods, such as laser-cutting, waterjet-cutting, photo-etching; and various wire-forming techniques. Next, the vast array of geometrical configurations that

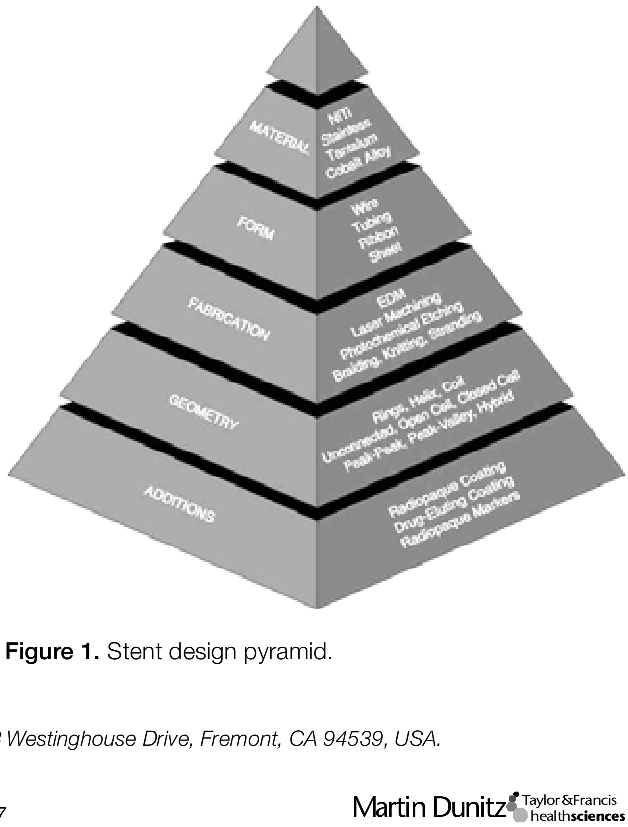

Figure 1. Stent design pyramid.

Correspondence: D. Stoeckel, *Nitinol Devices and Components, 47533 Westinghouse Drive, Fremont, CA 94539, USA.*

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have been explored in stent designs are considered. The classification ends with additions to stents, such as grafts, radiopaque markers and coatings. Throughout the text, each branch of a stent design map is presented that classifies nearly 100 commercialised stent designs. Designs included in this survey have been documented in texts [1,2], brochures, and company websites [3–25]. Like others, this review is probably not complete, and may describe stents that are not yet, or are no longer available.

Materials

Materials for metallic balloon-expandable or self-expanding stents must exhibit excellent corrosion resistance and biocompatibility (Figure 2). They should be adequately radiopaque, and create minimal artifacts during MRI.

Balloon-expandable stents are made from materials that can be plastically deformed through the inflation of a balloon. After the balloon is deflated the stent remains in its expanded shape, except for a slight recoil caused by the elastic portion of the deformation. The ideal material for these stents therefore has a low yield stress (to make it deformable at manageable balloon pressures), high elastic modulus (for minimal recoil), and is work hardened through expansion for high strength.

Balloon-expandable stents are manufactured in the 'small diameter', i.e. deliverable configuration, and balloon-dilated to the expanded shape at the target site inside the vessel. Self-expanding stents, on the other hand, are manufactured in the expanded shape, then compressed and constrained in a delivery system. Upon release from the delivery system they spring back, i.e. self-expand, to the preset diameter. Their function, therefore, is based on the elastic properties of the material used. Ideally, the material should have a low elastic modulus and a high yield stress for large elastic strains. Alternatively, the shape-memory effect of nitinol can be utilised. Here, large strains can be achieved either superelastically, or via the thermal memory of the material.

The most widely used material for stents is stainless steel, typically 316L, a particularly corrosion-resistant material with low carbon content and

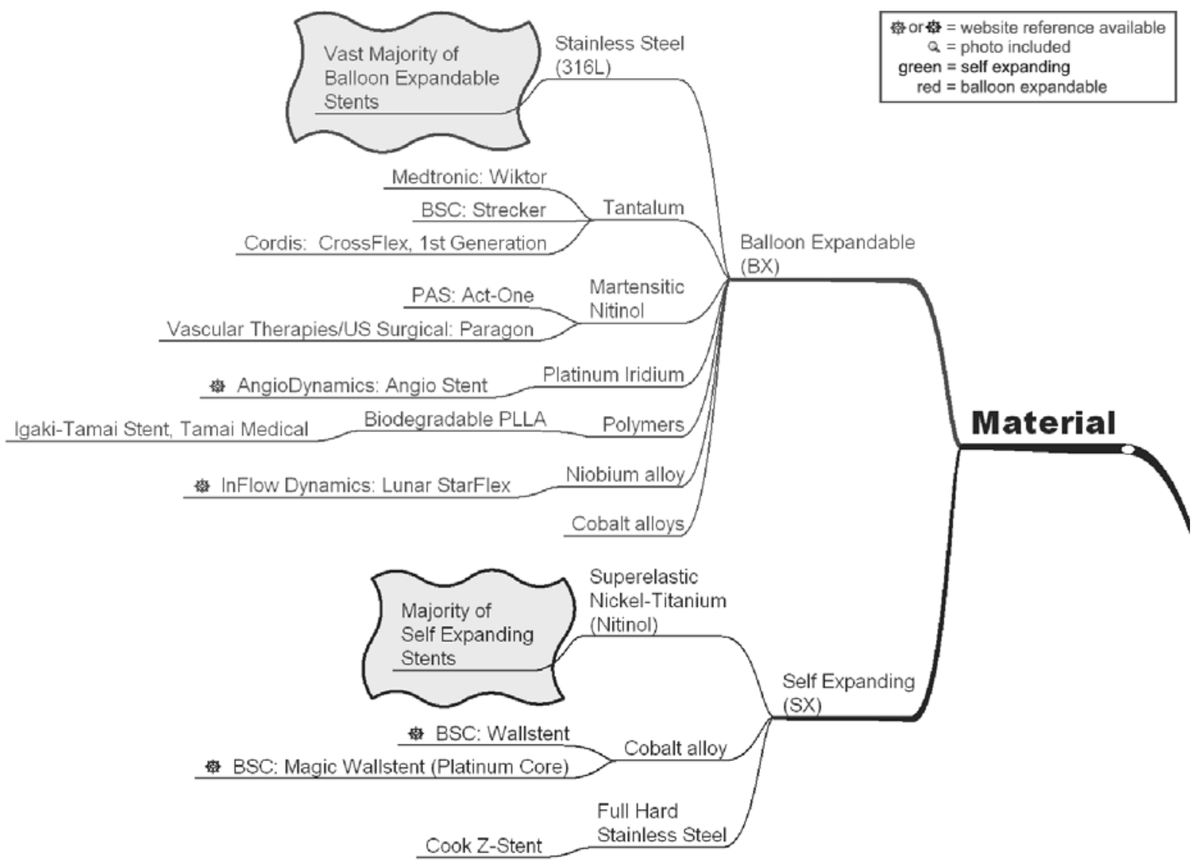

Figure 2. Overview of materials used in stent manufacture.

additions of molybdenum and niobium. In its fully annealed condition, stainless steel is easily deformable and, therefore, the standard material for balloon-expandable stents. In its full-hard condition, on the other hand, it exhibits enough elasticity for certain self-expanding stent designs.

Alternative materials for balloon-expandable stents are tantalum [BSC 'Strecker' (Figure 3), Cordis 'Crossflex', Medtronic 'Wiktor'], platinum alloys (AngioDynamics 'Angio Stent'), niobium alloys (Inflow Dynamics 'Lunar Starflex') and cobalt alloys. They are used for their better radiopacity, higher strength, improved corrosion resistance, better MR compatibility or the combination of all these features. Better radiopacity and higher strength allow the design of stents with smaller delivery profiles.

As mentioned above, materials for self-expanding stents should exhibit large elastic strains. The most widely used material is nitinol, a nickel–titanium alloy that can recover elastic deformations of up to 10%. This unusually large elastic range, commonly known as superelasticity, is the result of a thermo-elastic martensitic transformation. The limited elastic range of more conventional materials, such as stainless steel (Cook 'Z Stent') or certain cobalt-based alloys (BSC 'WallStent'), also limits design options. While the WallStent offers excellent wall coverage and flexibility, its shortcoming is its length change during deployment. The zig-zag configuration of the Z-Stent does not change length during deployment, but does not provide wall coverage in its bare configuration.

Raw material form

Stents can be made from sheet, wire (round or flat) or tubing (Figure 4). A big majority of the balloon-expandable and self-expanding stents are made from wire or tubing. A few exceptions are the BSC/Medinol 'NIR', the Navius 'ZR1', the EndoTex 'ratcheting' stent and the Cook 'GRII' (Figure 5), which are made from sheet metal. Stents made from sheet metal have to be rolled up to a tubular configuration after the pattern has been created. The NIR stent is then welded, while the ZR1 and the EndoTex use special mechanical locking features.

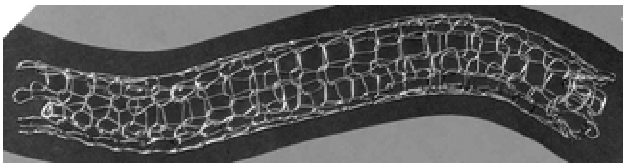

Figure 3. Strecker stent made of knitted tantalum wire.

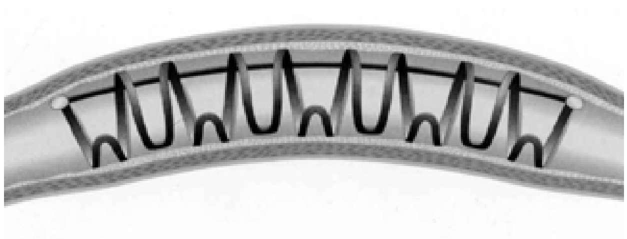

Figure 5. Cook GRII, formed from stainless steel sheet, featuring an axial backbone with integral gold markers.

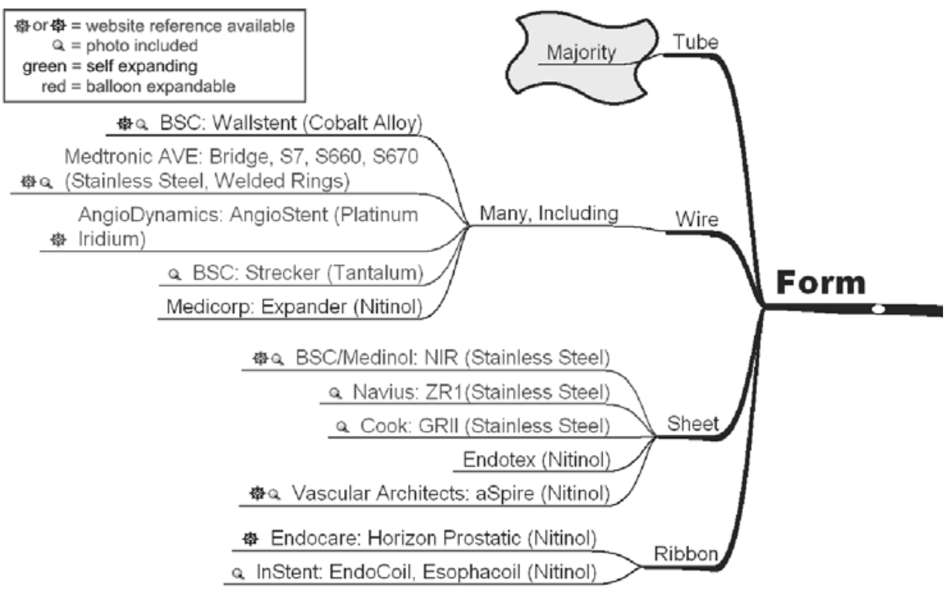

Figure 4. Overview of stent forms

Fabrication methods

The choice of fabrication method depends mainly on the raw material form used (Figure 6). Wires can be formed into stents in various ways using conventional wire-forming techniques, such as coiling, braiding, or knitting. The simplest shape of a wire stent is a coil, e.g. the IntraTherapeutics 'IntraCoil'. All coil stents marketed today are made from nitinol and are self-expanding. Welding at specific locations after wire-forming produces closed-cell wire stents [BSC 'Symphony' (Figure 7), self-expanding nitinol stent] or increases longitudinal stability (Cordis 'Crossflex', balloon-expandable SS stent). The most common wire-based self-expanding stent is the WallStent (BSC), a braided design using multiple elgiloy (cobalt-based alloy) wires (Figure 8). This allows continuous production, i.e. the stents can be cut to length from a long wire-mesh 'hose'. Knitting allows the production of flexible balloon-expandable and self-expanding wire stents. Examples are the BSC 'Strecker' tantalum stent and the Cook 'ZA' nitinol stent.

The vast majority of coronary stents, and probably the majority of peripheral vascular stents, are produced by laser cutting from tubing Typically, Nd:YAG lasers are used, allowing kerf widths of < 20 µm. Intricate patterns can be produced using tube sizes from 0.5 mm diameter. Balloon-expandable stents are cut in the crimped or near-crimped condition, and only require post-cutting deburring and surface treatment — typically electropolishing. They are marketed balloon-mounted, or unmounted for hand-crimping. Self-expanding nitinol stents, on the other hand, can be cut either in the 'small' configuration, requiring post-cutting expansion and shape-setting, or in the expanded condition. In either case, they have to be deburred and polished. Self-expanding stents have to be constrained in the delivery system and, therefore, are not available in an 'unmounted' configuration.

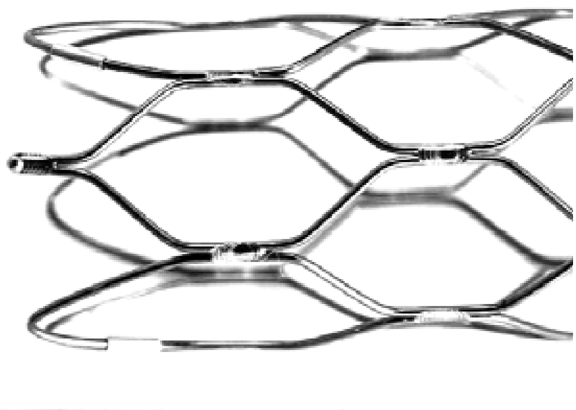

Figure 7. Symphony stent, nitinol wire welded to form a closed-cell structure.

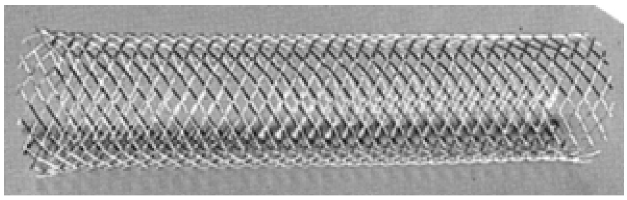

Figure 8. WallStent, braided stent fabricated from cobalt alloy wire.

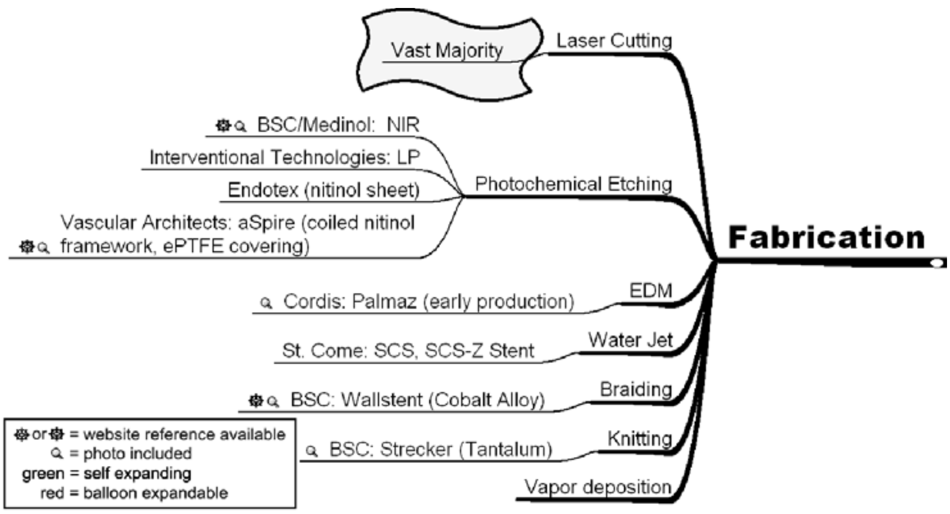

Figure 6. Overview of stent fabrication.

Laser cutting produces a heat-affected zone along the cut edge, which has to be removed for better performance. A cutting method that does not produce a heat-affected zone is waterjet cutting. A focussed jet of water with some abrasive additives is used to cut the pattern instead of a laser beam. Only one stent on the market has been produced by this method, the St Come ‘SCS’ stainless-steel stent.

Another interesting fabrication method is photochemical etching. Although this method is being used to produce stents from tubing (Interventional Technologies ‘LP’ stainless-steel stent), its real benefit is in sheet processing, when large numbers of parts can be processed in a single run. Examples are the BSC/Medinol ‘NIR’ stainless-steel stent and the Vascular Architects ‘aSpire’ nitinol stent frame (Figure 9).

Geometry

Early designs were generally classified as either slotted tube geometries, such as the Palmaz stents, or coil geometries, such as the Gianturco–Roubin Flex stent. While slotted-tube type designs had excellent radial strength, they lacked flexibility. The opposite was true of coil designs. Conflicting design imperatives spawned a rich variety of stent geometries competing in a very crowded marketplace, each seeking an optimal balance of strength and flexibility. The course of this evolution has been documented in the geometry branch of the design map, illustrated in Figures 10–12.

We have chosen to classify stent geometries into five high-level categories: coil, helical spiral, woven, individual rings, or sequential rings, each of which is further refined into appropriate sub-categories as described below.

Coil

Most common in non-vascular applications, as the coil design allows for retrievability after implantation. These designs are extremely flexible, but their strength is limited and their low expansion ratio results in high profile devices. Figure 13 shows an example of the InStent Esophacoil device.

Helical spiral

These designs are generally promoted for their flexibility. With no or minimal internal connection points, they are very flexible, but also lack longitudinal support. As such, they can be subject to elongation or compression during delivery and deployment and, consequently, irregular cell size. With internal connection points, some flexibility is sacrificed in exchange for longitudinal stability and additional control over cell size. The Crossflex stent depicted in Figure 14 is an example of a minimally connected helical spiral geometry.

Woven

This category includes a variety of designs constructed from one or more strands of wire. Braided designs are often used for self-expanding structures, such as the WallStent, as shown in Figure 8. While these designs offer excellent coverage, they typically shorten substantially during expansion. The radial strength of such a braided structure is also highly dependent on axial fixation of its ends. The Strecker stent (Figure 3) is an example of a balloon-expandable knitted tantalum stent, while the Cook ZA (Figure 15) stent demonstrates a self-expanding knitted nitinol wire design.

Individual rings

Single ‘Z’-shaped rings are commonly used to support grafts or similar prostheses; they can be

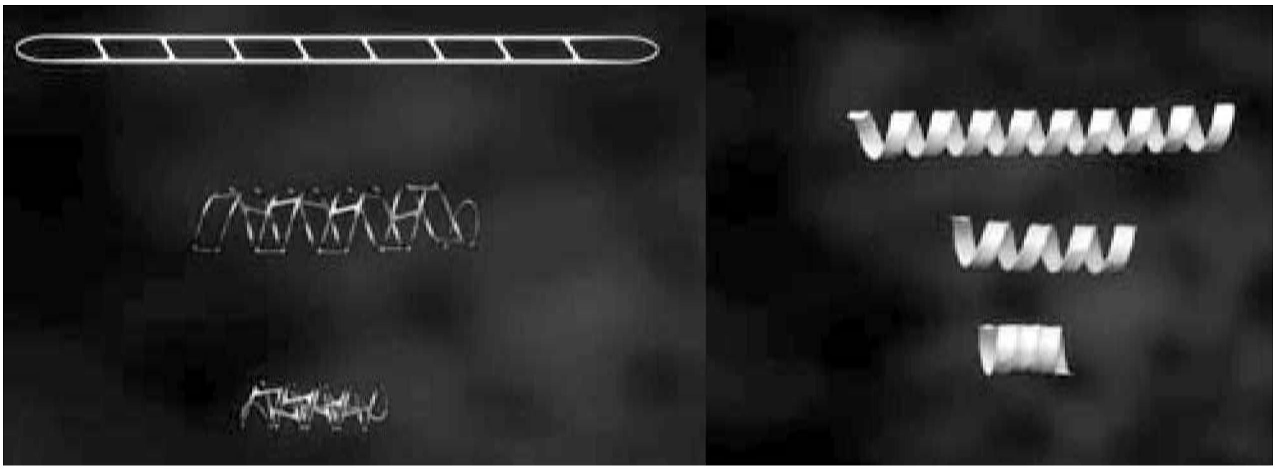

Figure 9. Vascular architect’s aSpire. Framework (left) is fabricated by photochemical etching of nitinol sheet and covered with ePTFE material (right).

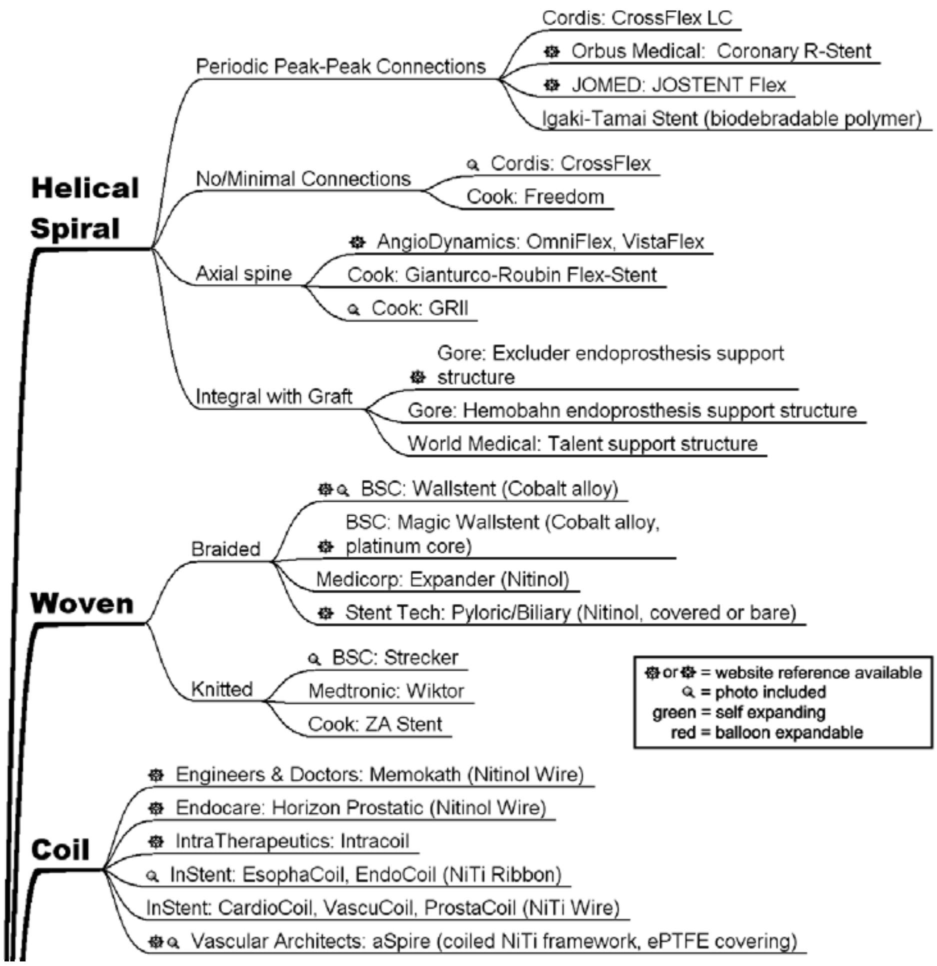

Figure 10. Stent geometry: helical spiral, woven, coil.

individually sutured or otherwise attached to the graft material during manufacture. These structures are not typically used alone as vascular stents.

Sequential rings

This category describes stents comprised of a series of expandable Z-shaped structural elements (known as 'struts') joined by connecting elements (known as 'bridges', 'hinges', or 'nodes'). This type of construction accounts for the majority of commercially available stents, and 70% of the designs included in this survey. This category can be further refined by describing the manner in which the structural elements are connected, and the nature of the resulting cells:

- *Regular connection* describes bridging elements that include connections to every inflection point around the circumference of a structural member.
- *Periodic connection* describes bridging elements that include connections to a subset of the inflection points around the circumference of a structural member. Connected inflection points alternate with unconnected inflection points in some defined pattern.
- *'Peak–peak connection' or 'peak–valley connection'* are terms used to describe the locations at which the bridging elements join adjacent structural members. 'Peak–peak' bridging elements join the outer radii, and 'peak–valley' bridging elements join outer radii to inner radii of the inflection points of adjacent structural members.

Closed cell

This describes sequential ring construction wherein all internal inflection points of the structural members are connected by bridging elements. Such a condition is typically only possible with regular peak-to-peak connections. Early slotted-tube type designs, such as the Palmaz stent (Figure 16), were strong, but inflexible. Later designs, such as the NIR stent (Figure 17), improved upon this concept by adding a flex-connector. These U-, V-, S-, or N-shaped elements plastically deform during bending, allowing adjacent

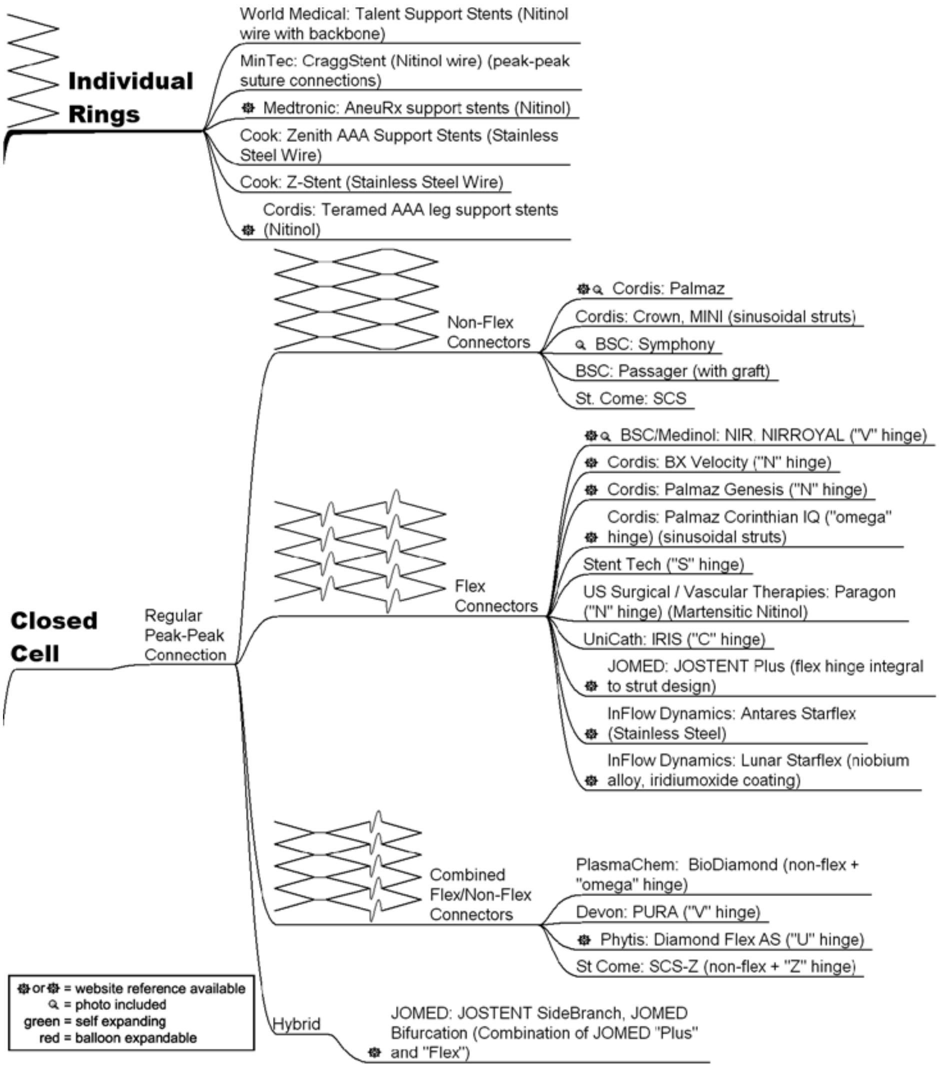

Figure 11. Geometry of stents manufactured as individual rings, sequential rings/closed cells.

structural members to separate or nest together, to more easily accommodate changes in shape. The primary advantages of closed-cell designs are optimal scaffolding and a uniform surface, regardless of the degree of bending. However, these advantages result in a structure that is typically less flexible than a similar open-cell design.

Open cell

This category describes construction wherein some or all the internal inflection points of the structural members are not connected by bridging elements. This allows periodic peak-to-peak connections, peak-to-valley connections, and mid-strut to mid-strut connections, as well as innumerable hybrid combinations. In open-cell designs, the unconnected structural elements contribute to longitudinal flexibility. Periodically connected peak-to-peak designs are common among self-expanding stents, such as the SMART stent (Figure 18), as well as balloon-expandable stents, such as the AVE S7 (Figure 19). The peak-to-valley connection of the ACS Multilink (Figure 20) virtually eliminates foreshortening and assures that adjacent structural peaks are aligned peak-to-valley throughout the expansion range of the stent, optimizing scaffolding characteristics. However, the peak-to-valley connectors take up material that could otherwise be used for structural members, consequently, structures with this type of peak-to-valley connection are generally not as strong as similar structures with peak-to-peak connections.

While these peak-to-peak and peak-to-valley connections are most common, there are also examples of other variations, such as the BeStent

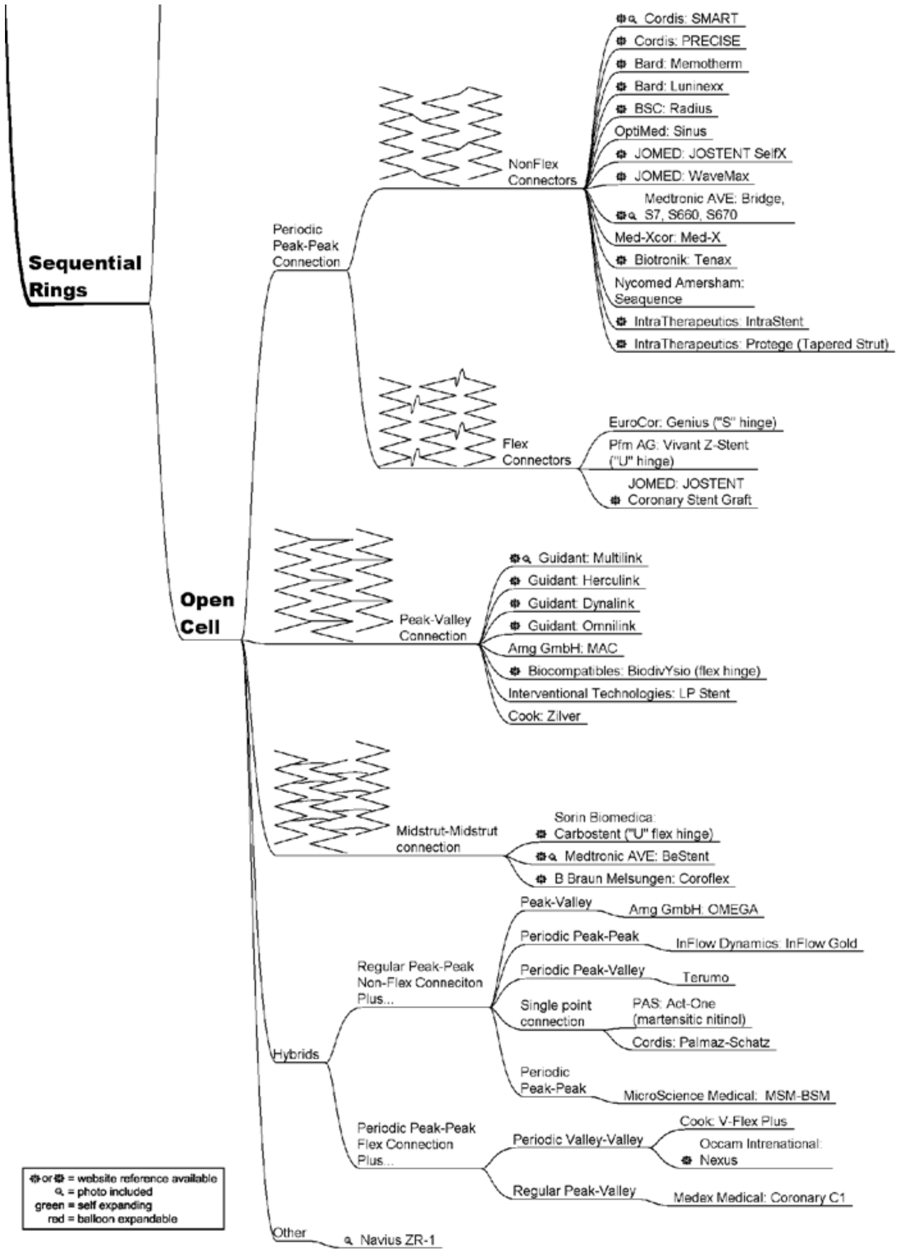

Figure 12. Geometry of sequential rings/open cells.

Figure 13. Esophacoil: coil stent fabricated from nitinol ribbon.

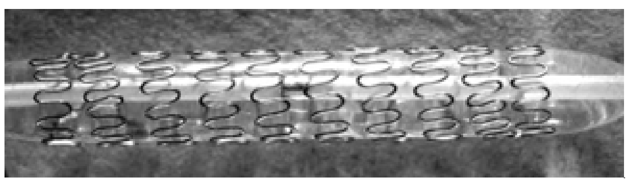

Figure 14. Crossflex: a minimally connected helical spiral stent fabricated from stainless-steel wire.

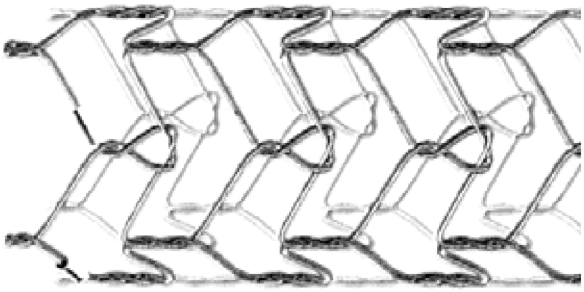

Figure 15. Cook ZA: knitted nitinol wire design, featuring sleeve-type gold markers.

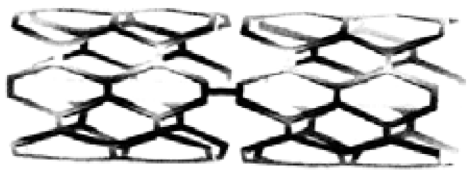

Figure 16. Palmaz–Schatz stent: each half represents a closed-cell slotted tube structure.

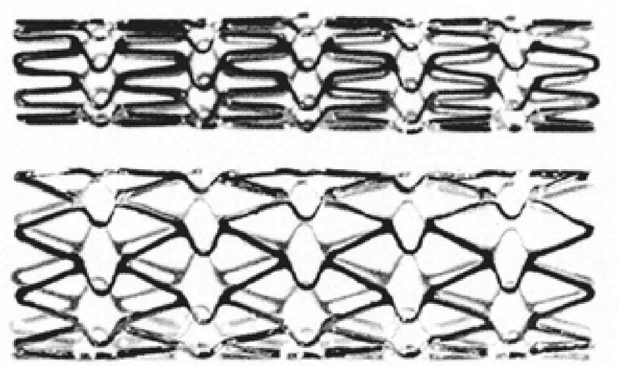

Figure 17. NIR stent: a closed-cell structure featuring 'V' flex-hinges.

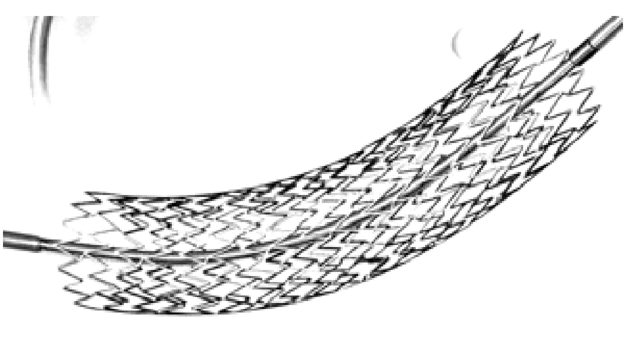

Figure 18. SMART stent: self-expanding open-cell sequential ring design with periodic peak-to-peak non-flex connections.

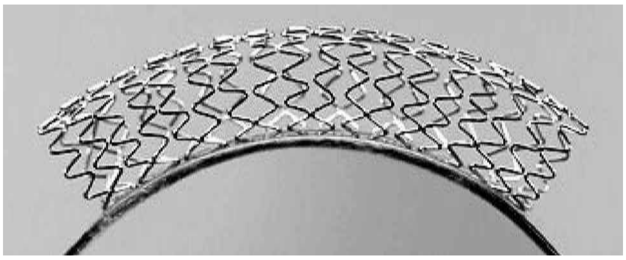

Figure 19. AVE S7 stent: balloon expandable open-cell sequential ring design with periodic peak-to-peak non-flex connections.

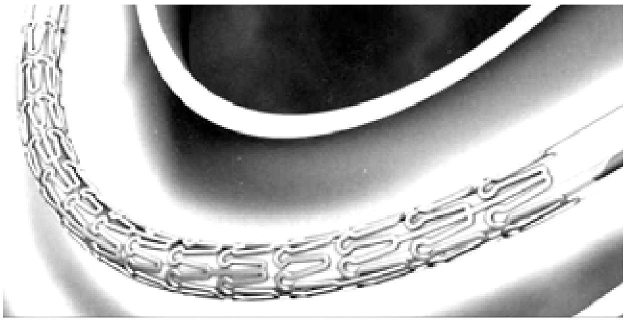

Figure 20. ACS Multilink: balloon expandable open-cell sequential ring design, with peak-to-valley connections.

(Figure 21), which feature mid-strut to mid-strut connectors. Finally, the Navius ZR1 (Figure 22) is a unique ratcheting design that defies categorisation.

Additions

Although the final layer of the stent design pyramid and the branch in Figure 23 covers a range of modifications to stent designs, it would exceed the scope of this review to comment on all options. Therefore, we will only comment on radiopacity enhancements. Stents made from stainless steel or nitinol are sometimes hard to see fluoroscopically, particularly if they are small and/or have thin and narrow struts. To improve X-ray visibility, markers are often attached to the stents. These additions are typically made from gold, platinum or tantalum, and can either be sleeves crimped around a strut (Cook 'ZA' nitinol stent with gold marker, BSC 'Symphony' nitinol stent with platinum marker); rivets coined into tabs at the end of the stent [Cook 'Zilver' nitinol stent with gold marker, Cordis 'SMARTeR' nitinol stent with tantalum marker (Figure 24)] or integrated in a strut (Medtronik 'BeStent' stainless steel with gold marker, Sorin 'Carbostent' stainless steel with platinum marker); or welded-on tabs [Bard 'Luminexx' Nitinol stent with tantalum tabs (Figure 25)].

Electroplating is also being used to enhance X-ray visibility. The Biotronik 'Tenax XR' stainless steel stent

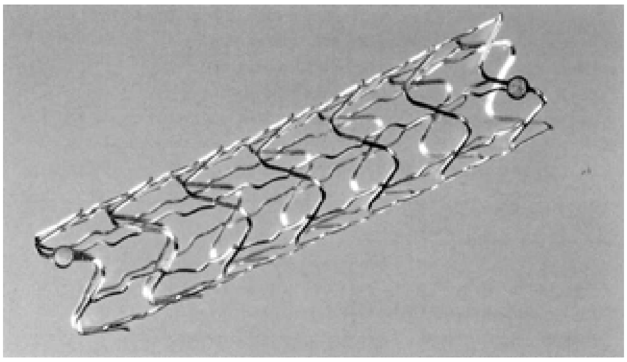

Figure 21. BeStent: balloon expandable open-cell sequential ring design, with midstrut-to-midstrut connections and integral gold markers.

Figure 22. Navius ZR1: ratcheting stent design fabricated from stainless-steel sheet.

has gold-plated end-segments, while the Inflow Dynamics 'Inflow Gold' and the BSC/Medinol 'NIR Royal' stainless steel stents were completely gold-plated.

Conclusions

In summary, we are confronted with more than 100 different stent designs. Why? This development has mainly been driven by patent and marketing issues rather than actual scientific considerations. Obviously, we do not need that many brands. Currently there are solid investigations underway testing biocompatibility, potentiodynamic polarization corrosion resistance, thrombogenicity, radiopacity, chronic fatigue behaviour in addition to more classic properties like flexibility, trackability and sheaf compatibility.

An example for such investigations is the evaluation of gold coatings on stainless steel stents. The modification of stent surfaces using metallic, ceramic or polymer (not drug-eluting) coatings is considered the next step in the evolution of stent designs. However, adding surface layers does not always improve the performance of a stent. Experimental evidence had suggested that coating stents with a gold layer may have a beneficial influence. However, clinical trials were not able to

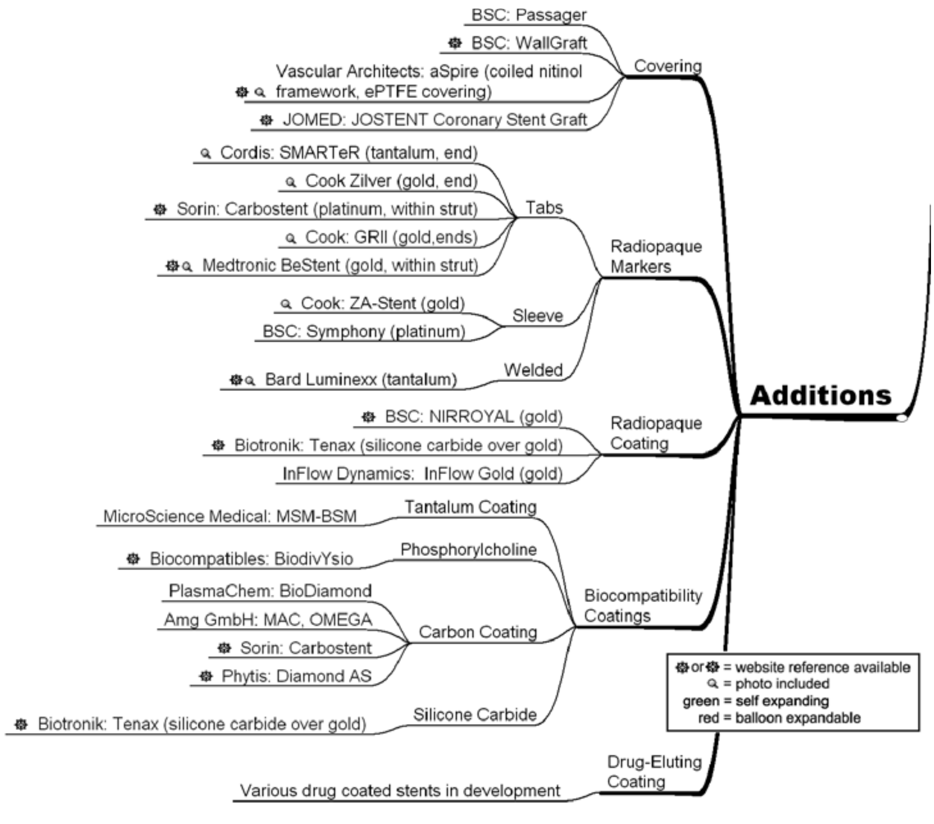

Figure 23. Overview of additions to stents.

prove this hypothesis. For example, in a randomized trial by Kastrati et al. patients with symptomatic coronary artery disease were randomly assigned to receive either a gold-coated Inflow stent (n = 367) or an uncoated Inflow stainless steel stent (n = 364) of identical design [26]. Follow-up angiography was routinely performed at 6 thrombotic events observed during the first 30 days after intervention. However, the gold-coated stents were associated with a considerable increase in the risk of restenosis over the first year after stenting (49.7% in the gold-stent group and 38.1% in the steel-stent group; P = 0.003). The same finding was reported from a Korean trail in 216 patients [27].

Trials like these may allow us to conclude that stent design, material and surface preparation may have a significant impact on long-term clinical outcome. We also have to take the stent design into account when we interpret results from trials that used different stent designs. This will certainly help us to discriminate actual achievements from 'me too' products and will enable us to get closer to the ideal stent.

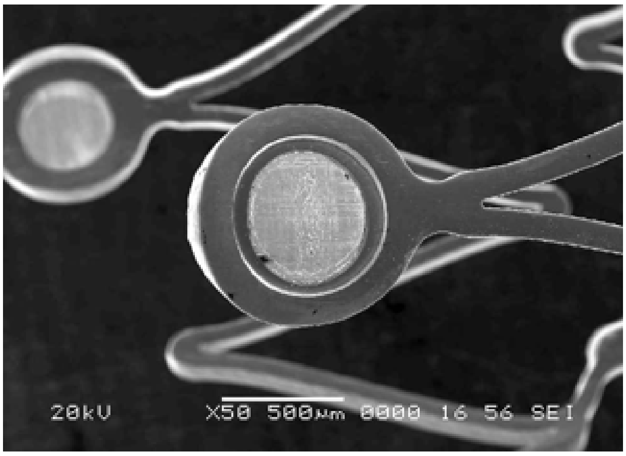

Figure 24. SMARTeR tantalum radiopaque marker in nitinol tab.

References

1 Serruys PW, Rensing BJ editors. *Handbook of coronary stents*. 4th edn. London: Martin Dunitz, 2002.
2 Machraoui A, Grewe P, Fischer A, editors. *Koronarstenting.* Darmstadt: Steinkopf, 2001.
3 www.aneurx.com visited on 6th July 2002.
4 www.angiodynamics.com visited on 6th July 2002.
5 www.bard.com visited on 6th July 2002.
6 www.barditalia.it visited on 6th July 2002.
7 www.bbraun.com visited on 6th July 2002.
8 www.biocompatibles.co.uk visited on 6th July 2002
9 www.biotronik.de visited on 6th July 2002
10 www.bostonscientific.com visited on 6th July 2002
11 www.endocare.com visited on 6th July 2002.
12 www.gore.com visited on 6th July 2002.
13 www.guidant.com visited on 6th July 2002.
14 www.inflowdynamics.com visited on 6th July 2002.
15 www.intratherapeutics.com visited on 6th July 2002.
16 www.jnjgateway.com visited on 6th July 2002
17 www.jomed.com visited on 6h July 2002.
18 www.medtronicave.com visited on 6th July 2002.
19 www.memokath.com visited on 6th July 2002.
20 www.occaminternational.com visited on 6th July 2002.
21 www.orbusmt.com visited on 6th July 2002.
22 www.phytis.com visited on 6th July 2002.
23 www.sorin-cid.com visited on 6th July 2002.
24 www.stenttech.com visited on 6th July 2002.
25 www.vasculararchitects.com visited on 6th July 2002.
26 Kastrati A, Schomig A, Dirschinger J *et al.* Increased risk of restenosis after placement of gold-coated stents: results of a randomized trial comparing gold-coated with uncoated steel stents in patients with coronary artery disease. *Circulation* 2000; 101: 2478–83.
27 Park SJ, Lee CW, Hang MK *et al*. Comparison of gold-coated NIR stents with uncoated NIR stents in patients with coronary artery disease. *Am J Cardiol* 2002; 89: 872–5.

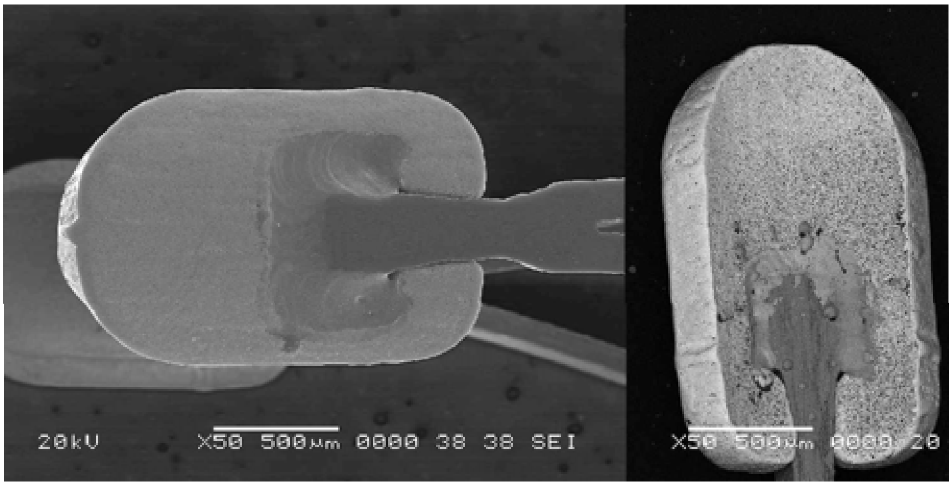

Figure 25. Luminexx radiopaque tantalum marker welded onto nitinol.