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Self-Expanding Nitinol Stents - Material and Design Considerations

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Self-Expanding Nitinol Stents — Material and Design Considerations

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Abstract:

Nitinol (Nickel-Titanium) alloys exhibit a combination of properties which make these alloys particularly suited for self-expanding stents. Some of these properties cannot be found in engineering materials used for stents today. The paper explains the fundamental mechanism of shape memory and superelasticity and how they relate to the characteristic performance of self-expanding stents. Nitinol stents are manufactured to a size slightly larger than the target vessel size and delivered constrained in a delivery system. After deployment they position themselves against the vessel wall with a low, chronic outward force. They resist outside forces with a significantly higher radial resistive force. Despite the high nickel content of Nitinol, its corrosion resistance and biocompatibility is equal to that of other implant materials. The most common Nitinol stents are listed and described.

Introduction

When Charles Dotter experimented with Nitinol wire coils as intra-arterial scaffolds back in the early nineteen eighties, Nitinol was known only for its unusual shape memory effect [1]. A coil wound to a small diameter and delivered through a catheter into the vessel, would expand to a larger diameter, e.g. the diameter of the vessel lumen, upon warming with 60°C saline solution (Fig. 1). Although the shape memory effect looked like ideally suited for the scaffolding of vessels, it took many more years for Nitinol stents to appear in the market. Dotter clearly was ahead of his time. The melting and processing of Nitinol, an intermetallic compound of titanium and nickel, had not been fully developed with consistent quality, nor had the properties of this material been fully understood. Today, twenty years after Dotter s experiments, Nitinol stents are self-expanding without the need for post-deployment heating. They are superelastic, i.e. crush recoverable, exert a gentle chronic outward force and are generally more physiologically compatible than balloon-expandable stents. All major medical device companies as well as

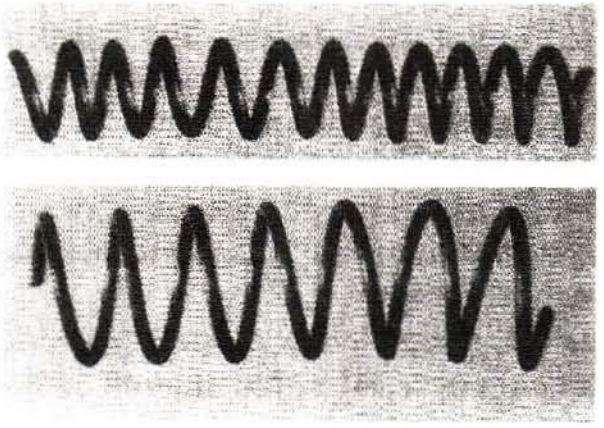

Fig.1 Nitinol coil stent used by Dotter [1], coiled for delivery and heat expanded

many smaller producers now offer Nitinol stents for (mainly peripheral) vascular and non-vascular indications.

In the following, after a brief explanation of the mechanisms of shape memory and superelasticity, we will describe the unique material properties of Nitinol and how they relate to the performance characteristics of Nitinol stents.

Superelasticity and Shape Memory in Nitinol

Conventional stent materials, like stainless steel or cobalt based alloys, exhibit a distinctly different elastic deformation behavior from that of the structural materials of the living body. The elastic deformation of these metals and alloys is limited to approx. 1% strain, and elongation typically increases and decreases linearly (proportionally) with the applied force. In contrast, natural materials, like hair, tendon and bone can be elastically deformed, in some cases, up to 10% strain in a non-linear way [2]. When the deforming stress is released, the strain is recovered at lower stresses. As shown in Fig. 2, the loading/unloading cycle is characterized by a pronounced hysteresis.

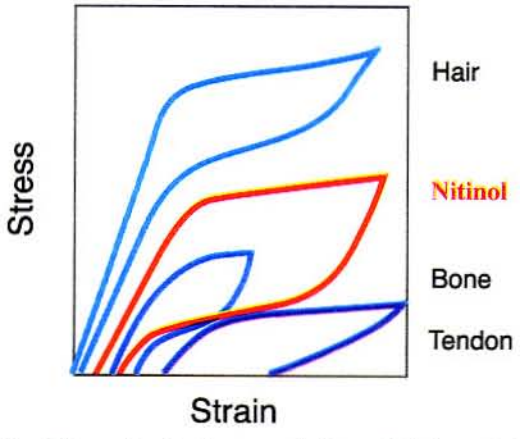

Fig. 2 Biomechanical compatibility of Nitinol: deformation characteristics of Nitinol and living tissues [2]

A similar behavior is found with Nitinol alloys, equiatomic or near-equiatomic intermetallic compounds of titanium and nickel. Fig. 3 shows a characteristic stress/strain curve for a Nitinol alloy wire at body temperature (as will be shown later, the properties of Nitinol alloys are strongly temperature dependent). As with natural materials, the loading and unloading curves show plateaus, along which large deflections (strains) can be accumulated on loading, or recovered on unloading, without significant increase, or decrease, respectively, in loads (stress). Because deformation of more than 10% strain can be elastically recovered, this behavior is called superelasticity .

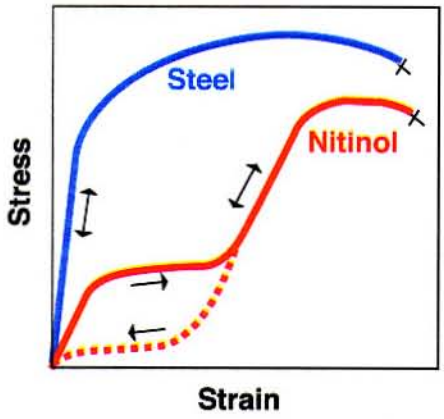

Fig. 3 Schematic stress-strain diagram for Nitinol and stainless steel

Superelastic Nitinol appears macroscopically to be simply very elastic. However, the mechanism of deformation is quite different from conventional elasticity, or simply stretching of atomic bonds. When a stress is applied to Nitinol, and after a rather modest elastic deformation, the material yields to the applied stress by changing its crystal structure. This stress induced phase transformation allows the material to change shape as a direct response to the applied stress. When the stresses are removed, the material reverts to the original structure and recovers its original shape. While superelasticity is the result of a stress induced phase transformation, shape memory is the result of a thermal phase transformation. In fact, when superelastic Nitinol is cooled to below a critical temperature (the transformation temperature, which is dependent on alloy composition and processing history), it also changes its crystal structure. If no force is applied, this phase change is not accompanied by a shape change. The material can be plastically deformed in the low temperature phase , but the original shape can be restored by heating above the transformation temperature [3].

Self-expanding Nitinol stents are manufactured with a diameter larger than that of the target vessel. Their transformation temperature is typically set to 30 degrees C. They can be easily crimped at or below room temperature and placed in a delivery system. To prevent premature

expansion during delivery into the body, the stent is constrained by a retractable sheath or other means. At the treatment site it is released from the delivery system and expands until it hits the vessel wall and conforms to it. Now at body temperature, the stent is superelastic.

Material Considerations

Nitinol is an alloy composed of 55 w.% nickel and balance titanium. It has found widespread acceptance as a material of choice for medical implants and devices [4]. It derives its unique properties from a solid state transformation, which can be triggered thermally or mechanically, and is dependent on the composition and processing history of the material. This adds another level of complexity to the material specification and may explain why ASTM specifications [5,6,7] describing material composition and test methods have only recently been issued. In addition to, or even instead of, the commonly known material characteristics like chemical composition, Young s modulus, yield strength, ultimate tensile strength and elongation to failure, properties like transformation temperature, upper and lower plateau stress, recoverable strain and permanent set have to be taken into account. As mentioned above, these properties are strongly dependent on the processing history and play an important role in the design and manufacturing of self-expanding stents.

Biocompatibility and Corrosion

It is now well understood that Nitinol requires controlled processing to achieve optimal shape memory and superelastic properties [8]. In the same way, surface processing is required in order to promote optimal corrosion resistance and biocompatibility. Properly treated Nitinol implants are very corrosion resistant and biocompatible [9]. Nitinol, like titanium and stainless steel a.o., is a self-passivating material, i.e. it forms a stable surface oxide layer that protects the base material from general corrosion [10]. Considering the high nickel content of the alloy, there are, understandably, concerns that nickel may dissolve from the material due to corrosion and cause adverse effects. On the other hand, other alloys that contain high levels of nickel, such as MP35N (a Co alloy with 35 weight % Ni), or 300 series stainless steel (approx. 10 w.% Ni) exhibit good biocompatibility, and have long been used as implants in orthodontics, orthopedics and cardiovascular applications [11]. Several studies have measured nickel release during the exposure of Nitinol implants to body fluids. During an *in vitro* dissolution study of Nitinol dental archwires in saliva [12], it was found that Nitinol appliances released an average of 13.05 mg/day nickel, which is significantly below the estimated average dietary intake of 200-300 mg/day. In another study [13], orthodontic patients with Nitinol appliances had Ni-concentration in their blood measured during a period of 5 months. Results showed no significant increase in the nickel blood level throughout the study.

A comparative *in vitro* cell culture study [14] measured nickel release from Nitinol and 316L stainless steel in fibroblast and osteoblast cell culture media. In both media, nickel levels were higher in the Nitinol group the first day and decreased rapidly with time to achieve similar levels as 316L after 8 days. It is important to highlight that even though higher levels of nickel were measured in the Nitinol group, nickel did not reach toxic values and cell proliferation or cell growth near the implant surface was not affected. Furthermore, in this study, Nitinol was only mechanically polished while stainless steel was electropolished. The authors speculated that passivation treatments, such as electropolishing, would decrease the nickel release from Nitinol. To evaluate the effect of different surface treatment methods on the Ni-ion release, Trepanier et al [15] immersed mechanically polished and electropolished samples of Nitinol, MP35N and 316L stainless steel in Hank s physiological solution at 37 degrees C for a period of greater than 1000 hours (Fig 4). It was found that samples that were prepared by mechanical polishing released higher amounts of Ni-ions than those prepared by electropolishing. Surface analysis data demonstrate that the electropolishing process removes excess nickel from the surface and forms a layer enriched in titanium (in the form of TiO_2). In contrast, the mechani-

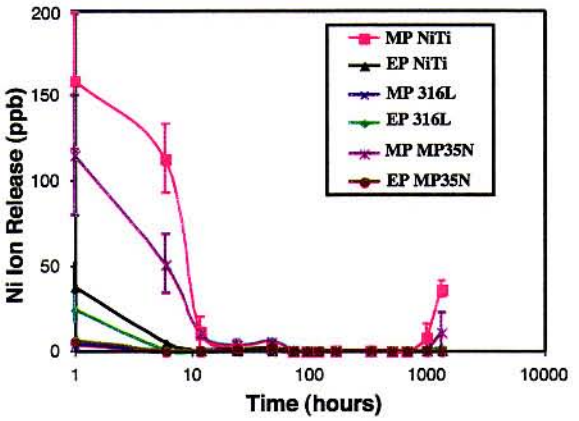

Fig 4: Ni ion release from Nitinol, MP35N and stainless steel (MP: mechanically polished, EP: electropolished)

Material	Surface Condition	Ni:Ti	Ni:Cr
Nitinol	Mech. Polished	0.18	
Nitinol	Electropolished	0.04	
MP35N	Mech. Polished		0.4
MP35N	passivated		0.08
316L SS	Mech. Polished		0.11
316L SS	Electropolished		0.07

Table 1: Ratio of Ni to Ti in the surface of mechanically, electropolished or passivated samples of Nitinol, MP35N and stainless steel

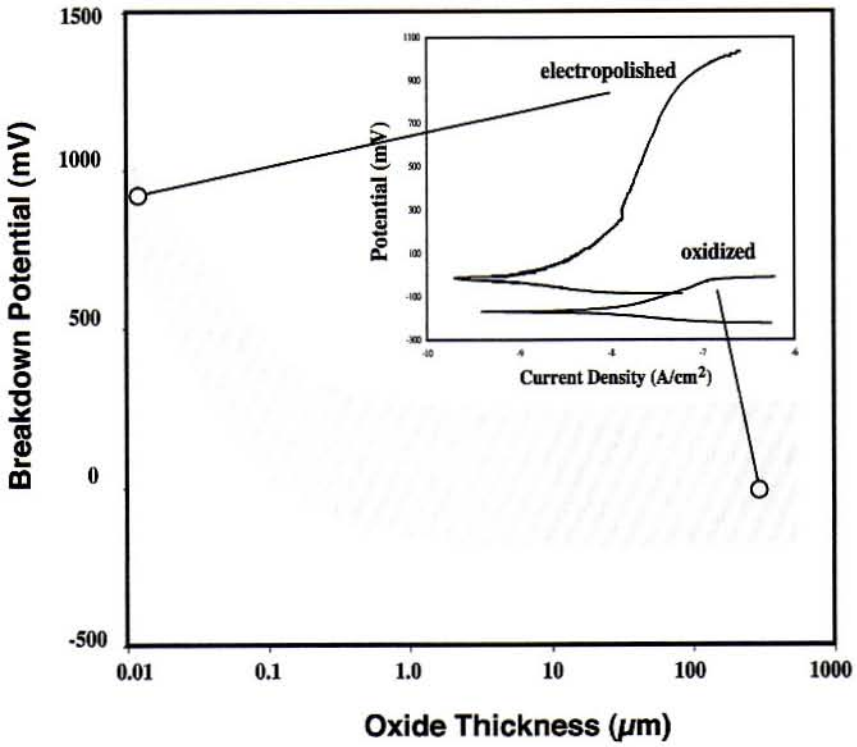

Fig. 5 Break-down potential as a function of oxide thickness on Nitinol (oxide created by varying heat treatment time and temperature); insert: results of potentiostatic corrosion tests of Nitinol samples with electropolished and oxidized surfaces

cally polished samples have a relatively high concentration of nickel in the surface (Table 1). Furthermore, the mechanically polished Nitinol and MP35N samples show an increase in Ni ion release after 1000 hours. This may be due to corrosion activity (pitting) after the initial 1000 hour time period in the non-passivated samples.

ASTM standard F2129 provides a quantitative method recognized by the FDA for the accelerated assessment of the corrosion resistance of implant materials [16]. The most relevant data derived from this test is the break-down potential E_{bd}, since most biomaterials corrode locally by pit formation. A high breakdown potential indicates that the material is very stable and resists pitting. Although no official limits have been established, materials with an E_{bd} =/> 500 mV are considered sufficiently corrosion resistant and safe for the use as implants. This value is used by Cordis, a Johnson & Johnson company, as the internal standard for all Nitinol implants. It corresponds with the corrosion resistance of the stainless steel Palmaz-Schatz stent as a predicative device, the stent with the longest implantation history.

Anodic polarization tests per ASTM F2129 have been used to evaluate the influence of surface preparation on the corrosion susceptibility of Nitinol stents. Trepanier at al. [17] have shown that electropolished Nitinol stents have excellent corrosion resistance with breakdown potentials (E_{bd}) greater than 800 mV, whereas the E_{bd} of non-electropolished stents was on the order of 200 mV. It was further shown that the breakdown potential of electropolished stents was degraded to less than 500 mV after thermal treatments in the 400ßC to 500ßC range. This led to the conclusion that optimal corrosion and biocompatibility results are obtained with a thin, titanium oxide (TiO_2) surface layer formed after electropolishing (passivation) treatments. It further appears that uniformity, rather than thickness, of the oxide is most important to protect the material from corrosion. More recent studies [18] correlate E_{bd} with the thickness of the oxide layer created by heat-treating electropolished Nitinol samples (Fig.5).

To improve the radiopacity of Nitinol stents, markers are often attached to the stent struts. However, when coupling Nitinol with dissimilar materials, galvanic corrosion effects have to be considered. Markers are typically made from high density materials like gold, platinum, or tantalum. Nitinol and tantalum are galvanically similar and thus, the combination has no significant effect on the corrosion resistance. In contrast, gold and platinum are more noble than Nitinol (or stainless steel) and can cause severe galvanic corrosion of the Nitinol (or stainless steel) stent. Therefore, the use of the noble metals as markers

requires either an insulating layer between the stent and the marker or the assembly has to be coated with a protective coating.

In 1999, the medical community as well as the device industry were alerted to the corrosion issue by reports by Riepe et al [19] on the observation of severely corroded Nitinol graft scaffolds from explanted Stentor aortic stent grafts after 5 months implantation (Fig. 6). It was preliminarily speculated that cell-induced electrochemical corrosion or active cellular destruction of the surfaces (e.g., osteo-clasts-bone) might have been responsible for the severe corrosion. However, subsequent cell culture testing with Nitinol test samples performed by Riepe s group did not induce any corrosion [20]. Further analysis of the failed components revealed an oxide thickness of 0.2-0.3 µm (determined by Auger analysis) and an E_{bd} of 280 mV (from anodic polarization tests). In contrast, 12 month explants of electropolished graft scaffolds examined by Pelton et al showed no signs of corrosion. The oxide thickness on these devices was approximately 0.01 µm and the E_{bd} > 900 mV. This highlights the importance of optimized surface preparation. Most Nitinol stents marketed today have electropolished surfaces. There have been no further reports on corrosion cases.

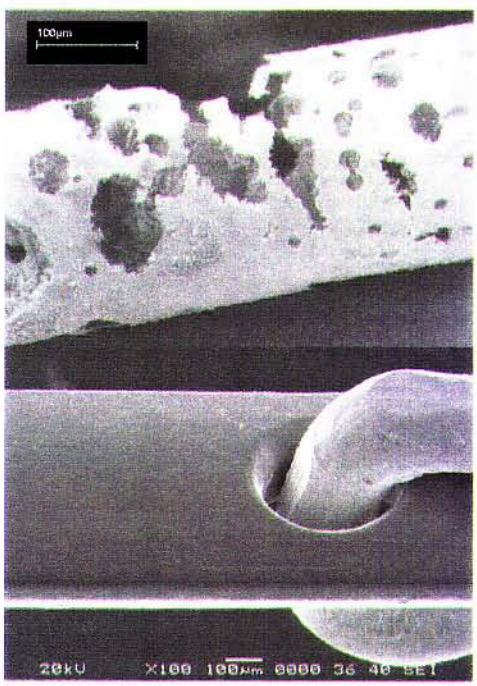

Fig 6: top: heavily corroded Nitinol explant (5 months [19]), bottom: electropolished Nitinol explant (12 months, with Ta marker attached)

Material Specific Device Characteristics

The most unusual property of Nitinol alloys is *stress hysteresis*. While in most engineering materials stress increases linearly with strain upon loading and decreases along the same path upon unloading (as shown in Fig. 3 with steel as an example), Nitinol exhibits a distinctly different behaviour. After an initial linear increase in stress with strain, large strains can be obtained with only a small further stress increase. This is called the loading plateau. The end of this plateau is reached at about 8% strain. Unloading from the end of the plateau region, causes the stress to decrease rapidly until a lower plateau (unloading plateau) is reached. Strain is recovered in this region with only a small decrease in stress. The last portion of the deforming strain is finally recovered in a linear fashion.

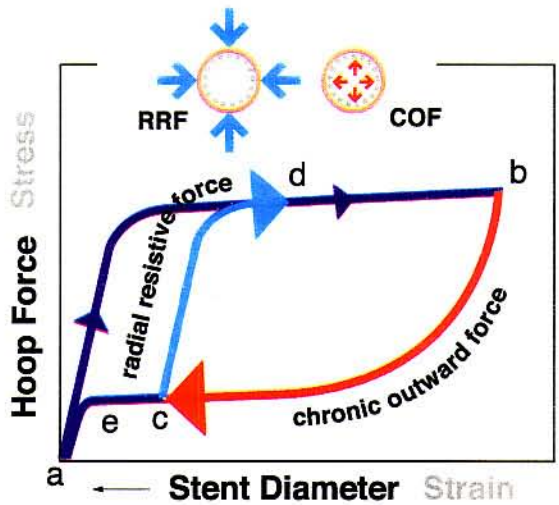

Fig. 7 Schematic stress hysteresis and concept of biased stiffness as demonstrated with the cycle insertion into delivery system/deployment/compression of a stent

The stress hysteresis or path dependence of Nitinol results in a device feature termed *biased stiffness* [21]. This concept is illustrated in Figure 7, which again shows a schematic superelastic stress-strain curve for Nitinol, illustrating both non-linear response and hysteresis. Using this graph, we will follow the cycle of crimping a stent into a delivery system, deploying it and have it expand and interact with the vessel. For this purpose, the axes have been changed from stress - strain to hoop force - stent diameter. A stent of a given size larger than the vessel (point a) is crimped into a delivery system (point b), then packaged, sterilized and shipped. After insertion to the target site, the stent is released into a vessel, expanding from b until movement is stopped by impingement with the vessel (point c). At this point, further expansion of the stent is prevented. Because the stent did not expand to its pre-set shape, it continues to exert a low outward force, termed *chronic outward force* or COF. However, it will resist recoil pressures or any other external compression forces with forces dictated by the loading curve from point c to d , which is substantially steeper (stif fer) than the unloading line (towards e). These forces are called *radial resistive forces* or RRF [22].

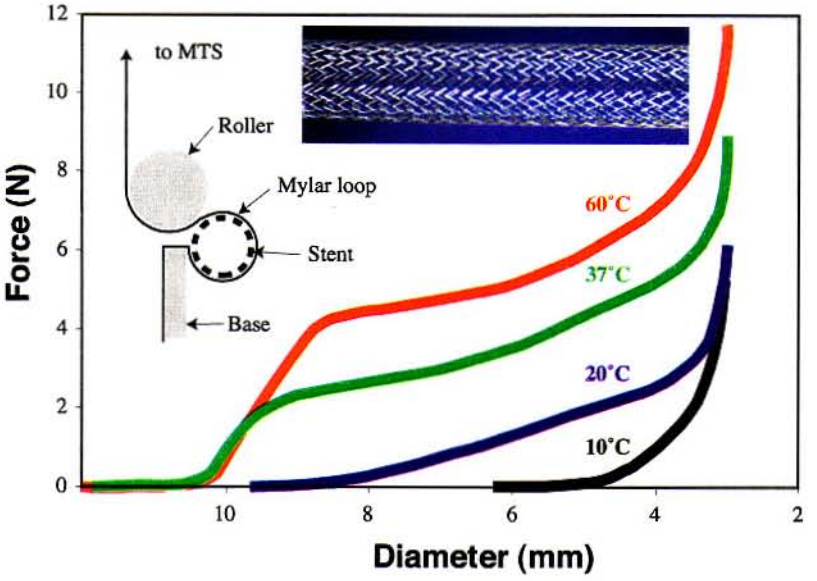

Fig. 8 Unloading curves of Nitinol stents (Cordis SMART) at different deployment temperatures; insert: radial force test set-up, schematic

The unusual elastic hysteresis of Nitinol allows the continuing opening force of the stent acting on the vessel wall, COF, to remain very low even through large deflections and oversizing of the stent. Meanwhile the forces generated by the stent to resist compression, RRF, increase rapidly with deflection until the plateau stress is reached. Although most self-expanding stent placements are preceded by a percutaneous transluminal balloon angioplasty, there are indications that the chronic outward force of a Nitinol stent placed without previous PTA causes the vessel to remodel with less intimal hyperplasia than if PTA is performed prior to stenting [23].

Another unusual feature of Nitinol stents is their *temperature dependent stiffness*. Stents with a transition temperature of 30 degrees C feel quite weak when squeezed or crushed at room or lower temperature. In contrast, they feel much stiffer when squeezed at temperatures above 30 degrees. Fig. 8 shows actual unloading curves of a Nitinol stent (Cordis SMART Stent) with a diameter of 10 mm at different temperatures. The test set-up (insert) is described in [24]. As can be seen from this graph, the chronic outward force actually doubles when the temperature is increased from 20 to 37 degrees C. As mentioned before, the transition temperature of the stent can be adjusted to a certain extent during processing. This gives the designer another option to increase or decrease the radial forces of the stent without changing the design or physical dimensions, as for each degree that the transition temperature is below body temperature, the loading and unloading forces increase by approximately 4 N/mm^2.

Kink resistance is an important feature of Nitinol for stents in superficial vessels that could be deformed through outside forces. The carotid artery is a prime example. There is a perceived risk for balloon-expandable stents in carotid arteries to be permanently deformed through outside pressure resulting in a partially or completely blocked vessel, once the buckling strength of the stent is exceeded. Although Nitinol stents typically don t have the buckling strength of stainless steel stents, they cannot be permanently deformed through outside forces. Nitinol stents can be completely compressed (crushed) flat and will return to their original diameter when the deforming force is removed (Fig. 9). A quantitative analysis of the forces relevant to the performance of superelastic stents can be found in [22].

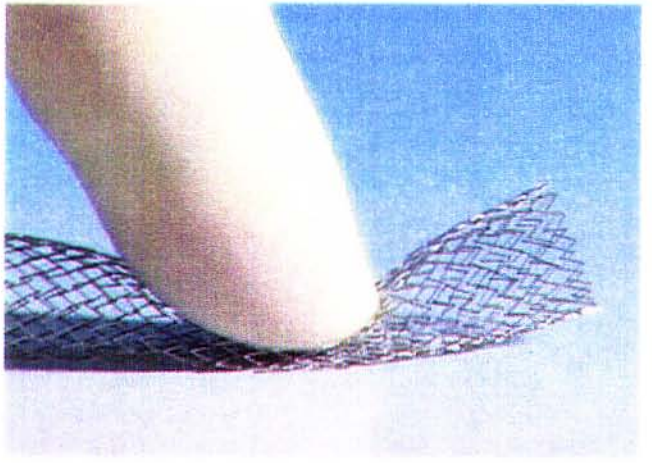

Fig. 9 Extrem deformation of a Nitinol stent (Cordis SMART); the stent will recover after the load is removed

Nitinol is non-ferromagnetic with a lower magnetic susceptibility than stainless steel. *MRI compatibility* is directly related to the susceptibility properties of a

material, relative to human tissue. Therefore, Nitinol produces less artifacts than stainless steel, similar to pure titanium. It has to be noted, however, that processing of the material can influence the quality of the MR image substantially.

Nitinol Stent Designs

In the following, we will try to list and describe the self-expanding Nitinol stents currently being marketed or in evaluation (Table 2). Designs included in this survey have been documented in brochures and company websites. Like others, this review is clearly not complete and may describe stents that are not yet, no longer, or not world-wide available.

Wire-based Stent Designs

The evolution of Nitinol stent designs is clearly linked to the development of the material itself. Early on, Nitinol was only available in wire form. Consequently, early Nitinol stents were wire coils, similar to Dotter s experimental device. Today, coil stents made from round or flat Nitinol wire are still available. They are mainly used for non-vascular applications (e.g. Endocare s Horizon Stent for the relief of bladder outlet obstruction), with the exception of the IntraCoil Stent (Intratherapeutics, Fig. 10), which is indicated for the treatment of patients with superficial femoral artery and popliteal artery lesions. One advantage of simple wire coils is their retrievability in certain applications. As described earlier, Nitinol looses its stiffness when cooled. The EndoCare Horizon or the D&E Memokath prostatic stents can be retrieved from the prostate by chilling the device with cold solution. The stents become soft and pliable and can be retrieved with a grasping forceps (Fig. 11).

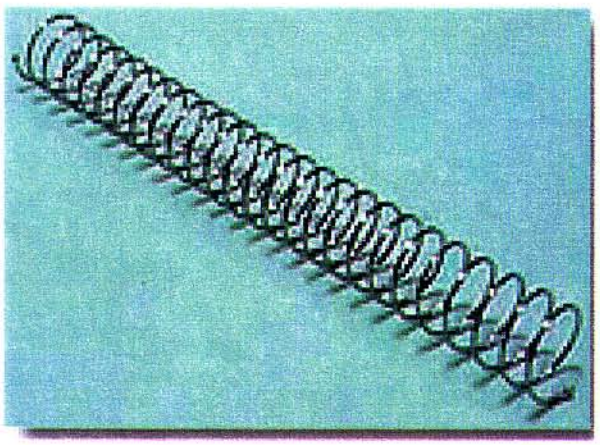

Fig. 10 Intracoil stent (IntraTherapeutics)

Other early wire based stent designs are the Cragg Stent (MinTec, Fig. 12), a sinusoidal coil with peak-to-valley suture connections for vascular and non-vascular applications, and the knitted Ultraflex Esophageal Stent (Microvasive, BSC). Newer designs are the ZA biliary Stent (Cook, Fig. 13), a modified knitted design, and the braided Expander Stent (Medicorp). The Boston Scientific Symphony Stent is a wire formed design with struts welded to form hexagonal cells. While wire based stents generally are very flexible, the Symphony Stent is quite rigid (Fig.14).

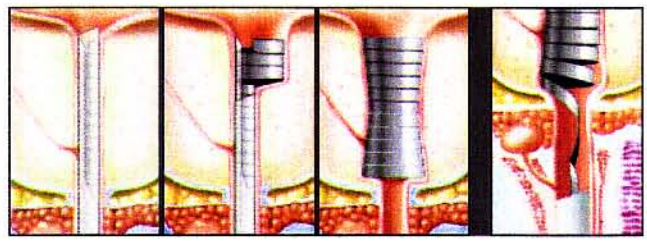

Fig. 11: Deployment and retreaval (far right) of the Horizon stent (EndoCare)

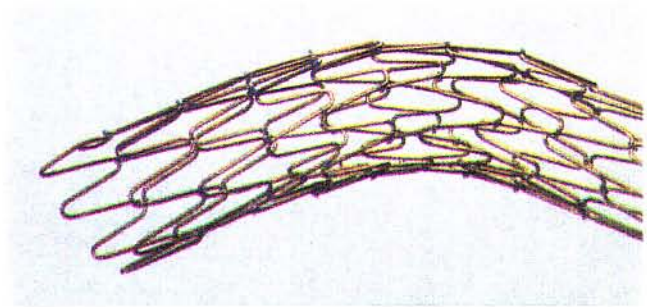

Fig. 12: Cragg Stent

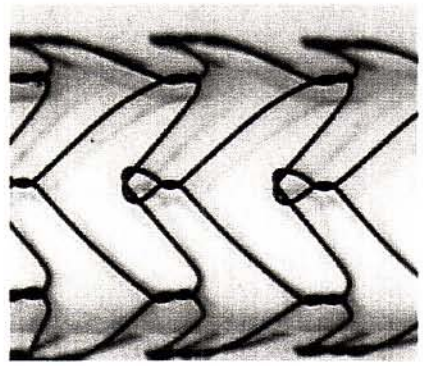

Fig. 13: Cook ZA knitted stent

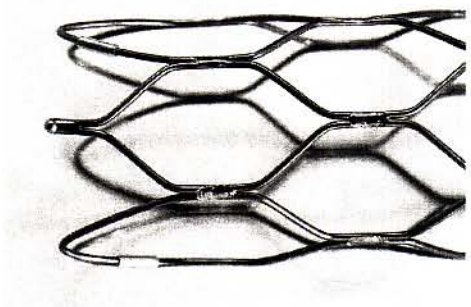

Fig. 14: Welded Symphony Stent (BSC)

Company Name	Product Name	Fabrication Method	Comments	
Bard	Memotherm	Laser cut tube		[25]
Bard	Memotherm-Flexx	Laser cut tube		
Bard	Luminexx	Laser cut tube	Welded Ta markers	[26]
BBraun	Vascuflex SE	Laser cut tube		[27]
Biotronik	Philon	Laser cut tube	SiC coated	[28]
BSC	Radius	Laser cut tube		
BSC	Symphony	Welded wire	Sleeve PtIr markers	[29]
BSC	Ultraflex	Knitted wire		
Bolton Medical	Sprinter	Braided wire		[30]
Campus	Campus	Laser cut tube		[31]
Cook	ZA	Knitted wire	Sleeve Au markers	[32]
Cook	Zilver	Laser cut tube	Coined Au markers	
Cordis	SMART	Laser cut tube		[33]
Cordis	SMARTeR	Laser cut tube	Coined Ta markers	
Cordis	SMARTControl	Laser cut tube	Coined Ta markers	
Cordis	Precise	Laser cut tube		
EndoCare	Horizon	Flat wire coil		[34]
EndoTex	NexStent	Laser cut tube		[35]
Engineers&Doctors	Memokath	Wire Coil		[36]
FlexStent Medical	FlexStent	Braided wire	Au coated	[37]
Guidant	Dynalink	Laser cut tube		[38]
Intratherapeutics	IntraCoil	Wire coil		[39]
Intratherapeutics	Prot g	Laser cut tube		
Intratherapeutics	Prot g GPS	Laser cut tube	Coined Ta markers	
Intratherapeutics	EndoCoil	Flat wire coil		
Intratherapeutics	EsophaCoil-SR	Flat wire coil		
Jomed	Jostent SelfX	Laser cut tube		[40]
Jotec	FlowStent Diamond	Laser cut tube	DLC coated	[41]
Medicorp	Expander	Braided wire		[42]
Medtronik AVE	Bridge SE	Laser cut tube		[43]
Optimed	Sinus	Laser cut tube		[44]
Optimed	Sinus-Aorta	Laser cut tube		
Optimed	Sinus-Flex	Laser cut tube	DLC coated (opt)	
Optimed	Sinus-TIPPS	Laser cut tube	Pre-shaped	
Optimed	Sinus-REPO	Laser cut tube	DLC coated (opt)	
Vascular Architects	Aspire	dual rail ladder coil	ePTFE covered	[45]

Table 2: List of popular Nitinol self-expanding stents

Sheet-based Stent Designs

A perceived disadvantage of braided or knitted wire-based stents is the crossing of the filaments. This increases the wall thickness of the stent and the delivery profile. Moreover, there are concerns about fretting corrosion or the wear of the Nitinol at the cross-over points. When Nitinol sheet became available, Angiomed (Bard) developed the first laser-cut Nitinol stent by cutting a pattern from sheet, rolling it up and welding at specific strut locations (Fig.15).
An interesting sheet based Nitinol stent is the experimental ratcheting EndoT ex stent, similar to the design suggested by Sigwart (Fig. 16) [46]. It is chemically etched from thin Nitinol sheet to produce a series of windows and a locking feature at one edge. It is rolled up to a small diameter roll and placed onto a PTCA balloon. The assembly is then placed into the vessel and the diameter of the stent is adjusted by inflating the balloon. As the balloon expands, the stent uncoils to the desired diameter to prop open the vessel. The stent is locked into place by unique tabs that slide into the stent windows upon baloon deflation. This design provides a wide range of diameters to custom fit for each treatment. It combines balloon expandability with the superelasticity after deployment. However, it has some of the perceived disadvantages of the knitted wire stents with non-uniform cross-section and potential fretting cross-over points.

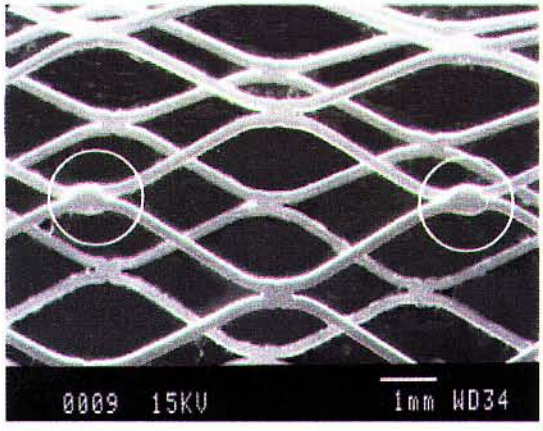

Fig. 15: Sheet-based Memotherm Stent with overlap welded struts

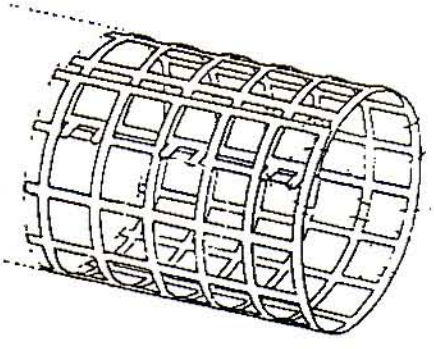

Fig. 16 Concept of a sizable superelastic stent [44]

Vascular Architect s aSpire stent uses a dual-rail ladder type frame that is also etched from Nitinol sheet and covered with ePFTFE. It is helically coiled onto a delivery system that allows deployment with a variable pitch to keep vessel sidebranches open.

Tube-based Stent Designs

In the mid 1990s, Nitinol seamless tubing appeared in the market in production quantities. With it came laser cutting of tubular Nitinol components. Today, by far most self-expanding Nitinol stents are produced by laser cutting of Nitinol tubing. Early examples are the Angiomed (Bard) Memotherm and the Scimed Radius stents. The Memotherm was a rigid, closed-cell design with a diamond shaped pattern similar to the original Palmaz balloon expandable stent. The Radius, on the other hand, is a flexible open-cell design with sequential rings and periodic peak-to-peak non-flex bridges. Most laser-cut Nitinol stents employ variations and/or combinations of these basic design features (Fig. 17, Fig. 18). There are Nitinol stents in the market that are coated with silicon carbide (SiC) or diamond like carbon (DLC). It is probably fair to state that these developments are more driven by product differentiation than actual scientific considerations [47].

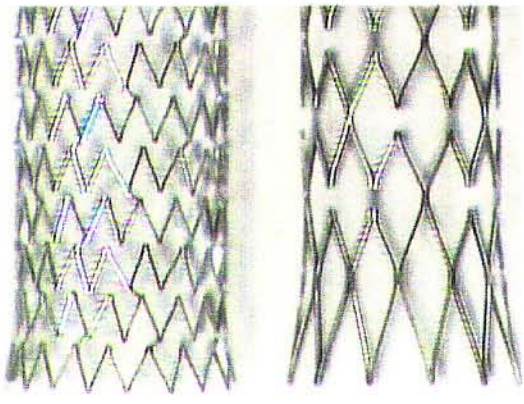

Fig. 17: Laser-cut tubular Nitinol stents, left: SMART Stent (Cordis), right: Memotherm Stent (Bard)

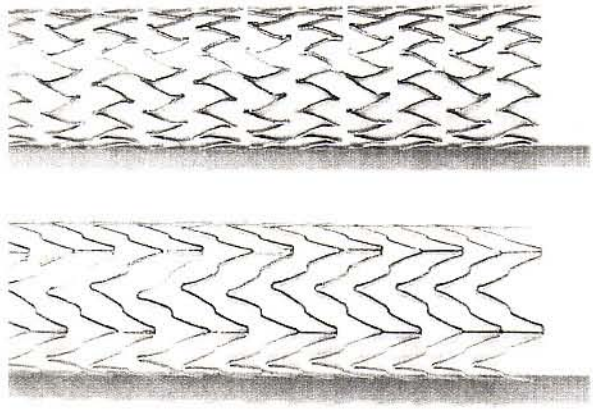

Fig. 18: Laser-cut tubular Nitinol stents, top: Jostent SelfX Stent (Jomed), bottom: Dynalink Stent (Guidant)

Radiopacity Enhancements

Theoretical calculations as well as experimental studies show that the radiopacity of Nitinol is similar to that of stainless steel for equivalent dimensions. However, as the stent profiles continue to shrink to accommodate smaller delivery systems, the cross section decreases with a concomitant decrease in x-ray visibility. Therefore, to improve the fluoroscopic visibility of the Nitinol stents, radiopaque markers are often attached or integrated into the design of the stent. The Optimed Sinus stent family, for example, features a set of tab markers at the stent ends that are integral parts of the stent cut out of the tubing (Fig. 19). The advantage of this approach is that there are no compatibility issues, as no dissimilar metals are involved. On the other hand, it allows only moderate visibility improvement. Tantalum markers are riveted or coined into eyelet-shaped tabs at the ends of the Cordis Smarter and SmartControl stents (Fig.20). As mentioned earlier, Tantalum and Nitinol are close together in the galvanic series of metals, i.e. galvanic corrosion is not a problem. The Cook Zilver stent is of similar design, but uses gold markers instead of Tantalum. It is assumed that the entire stent is coated with a thin polymer layer to protect it form galvanic corrosion.

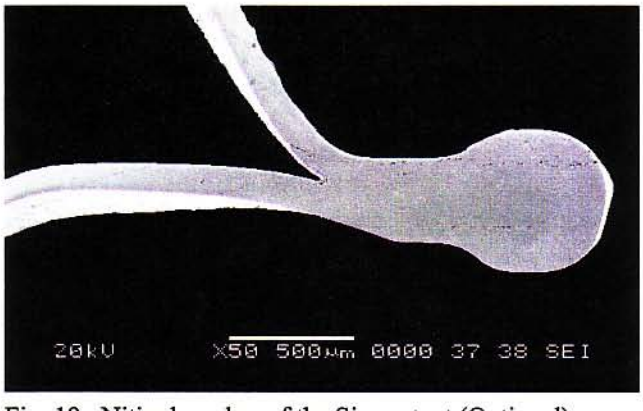

Fig. 19 Nitinol marker of the Sinus stent (Optimed)

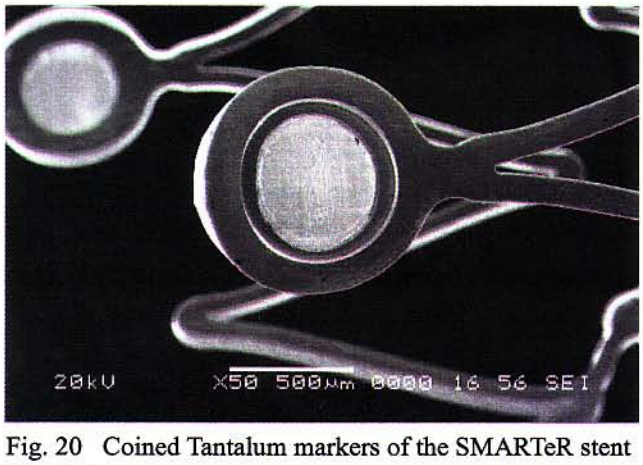

Fig. 20 Coined Tantalum markers of the SMARTeR stent (Cordis)

Tantalum tabs are welded to the ends of the Bard Luminexx stents (Fig. 21). Because of the large mass of these tabs, the X-ray visibility of this stent is very good. There are concerns, however, that brittle interface layers can be created during welding of Nitinol and Tantalum.

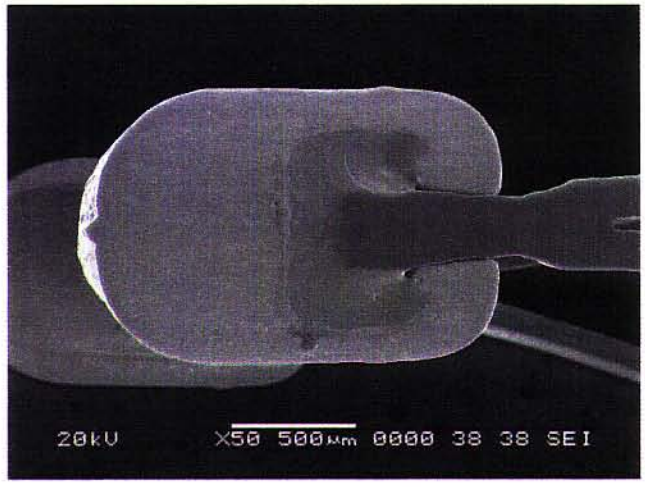

Fig. 21 Welded Tantalum markers of the Luminexx Stent (Bard)

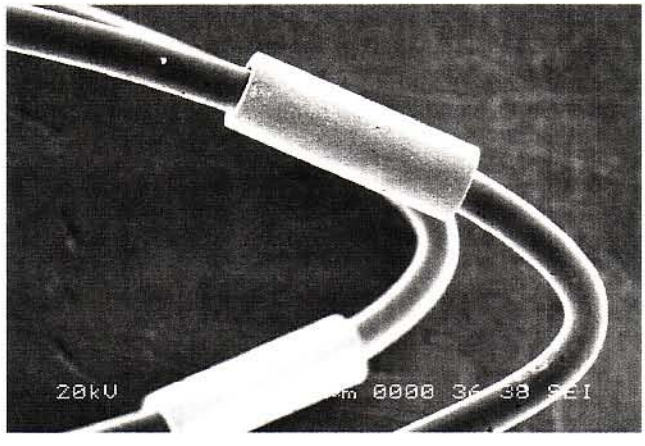

Fig. 22 Platinum-Iridium sleeve marker of the Symphony stent (Boston Scientific)

Platinum-Iridium sleeves are used as markers for the wire-based BSC Symphony stent (Fig. 22) while the Cook ZA knitted stent uses Gold sleeves. As mentioned above compatibility issues have to be considered when using these material combinations.

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