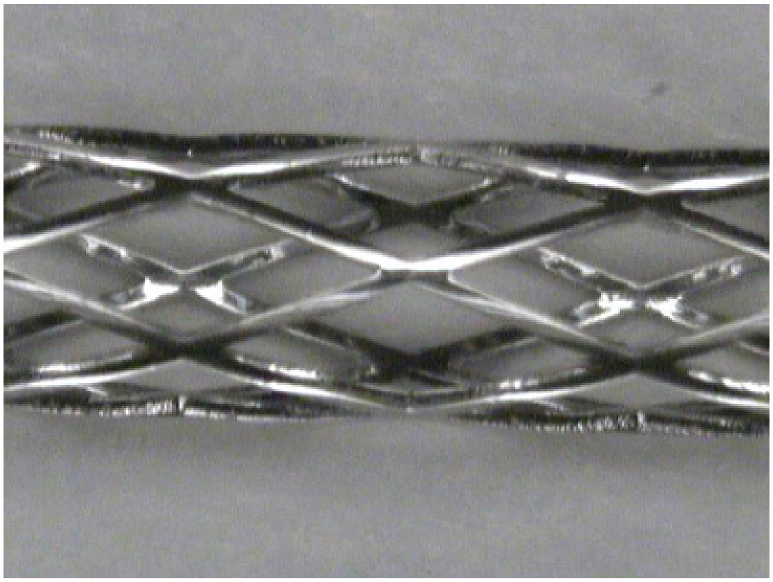
BOTM: August 2010

Nitinol



Nitinol (Nickel-titanium naval ordnance laboratory) alloy is a widely used "superelastic" material for vascular stents. Its attractiveness is based on its ability to retain its shape and elasticity—a quality called "shape memory"—at body temperature over relatively long periods without showing evidence of metal fatigue. Shape memory allows a nitinol stent to be deformed for easy implantation after which it assumes its functional or "austenitic" shape *in situ* after being warmed to body temperature.

While *in situ* the mesh-like stents display:

1. kink resistance due to an ability to partition strains to regions of lower stress,
2. constant unloading stress on host tissue in response to large strains by the latter due to its greater dependence on temperature than strain to develop an unloading force,
3. similar compliance to a variety of tissues as indicated by closely matching stress-strain hysteresis curves—a feature that can be adjusted by programmed processing,
4. ability to be imaged by MRI—unlike other metals,
5. for strains below 0.5% a better-than-other-metals fatigue strength *in vitro* and
6. a tendency to form a passivated TiO_2 layer that resists corrosion and protects the Ni component from same.

While nitinol has been primarily used for vascular stenting, it has also been used to make valve patches and orthodontic devices; and, particularly because of its elastic and non-kinking qualities, to make surgical tools such as a tumor locator, an ablator, a kidney/gall stone retriever and biopsy forceps.

Of particular concern to implant pathologists is host reaction to nitinol beyond its fulfillment of targeted goals for the implant. Certainly, the corrosion and kinking resistance as well as other superelastic behavior make it more attractive as a biomaterial than metals such as 316L steel, long used for stenting. An indicator of minimal implant pathology is a thin fibrous capsule at the host-implant interface, and this goal appears to be reached at least over three months in laboratory *in vivo*studies[1].

However, as noted by Haider et al.[2] at the 2010 SFB meeting, there remains concern over long-term leaching of Ni++. They have been investigating surface treatments such as magnetoeletropolishing to reduce corrosion. Yang et al.[3] at the same meeting reported an attempt to counteract the thrombogenic potential of vascular stents by coating them with organoselenium, a nitric oxide synthesis stimulant. Of course, one thrombogenic condition is abnormal flow in vascular tubes that creates stagnant regions where platelets aggregate. As well as the stress-strain hysteresis curves of programmed nitinol match those of host tissues, they are not exact fits. Moreover, fatigue over years of cyclic loading *in vivo* has apparently not been investigated. If significant, the change in mechanical characteristics would impact dynamic flow patterns in the vessel. More research is needed.

References

Almost the entire narrative preceding the last paragraph was summarized from reference 1.

1. Duerig T, A Pelton, D Stöckel (1999) "An overview of nitinol medical applications" *Mat. Sci. Engin.* A273-275: 149-160.
2. Haider W, N Munroe, V Tek, PKS Gill, C Pulletikurti, S Pandya (2010) "Effect of surface treatments on localized corrosion behavior of Nitinol alloys" *Trans. Soc. f. Biomat. 34th Ann. Mtng, Seattle*, 874
3. Yang J, Mirkazemi S, Cai W, Meyerhoff M (2010) "Catalytic Nitric Oxide Generation via Layer-by-Layer Assembly on Metal Surfaces" *Trans. Soc. f. Biomat. 34th Ann. Mtng, Seattle*, 507.