Weaving Flexibility and Strength into Stent Design

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Due to a societal increase in diabetes and obesity compounded by a growing population of aging baby boomers, stents are becoming a significant and necessary medical intervention. In fact, they represent a $1.4 billion market with a 15 percent increase per year. As a result, designers are constantly searching for ways to improve the device, which is designed to help blood flow bypass a section of artery that is restricted as a result of disease.

Though traditional laser-cut stents made from nitinol are effective, the design trades flexibility for strength, which means the stents are at risk for fracture, crushing, and kinking. This is a particular issue when the stents are used with patients suffering from femoropopliteal or proximal popliteal artery disease. Because the artery is located near the knee, it must be flexible enough to bend and rotate with the knee without fracturing, but also strong enough that it isn't crushed by the pressure. Increasing the flexibility, however, reduces the radial strength of the device. Obviously, a crushed or fractured stent must be replaced, which adds to the financial burden, and also adds stress onto the patient.

The solution to the flexibility versus strength paradox may exist in the creation of a stent that utilizes nitinol, a metal alloy of nickel and titanium, but differs from traditional stents in design, according to Christopher Owens, President and CEO of

IDEV [1], a company focused on the development and commercialization of minimally invasive medical technologies.

The nitinol-based stent, called SUPERA, is a woven wire designed to mimic and adapt to the patient’s natural anatomy, says Owens. The result is a stent that has maximum strength and flexibility, which opens up a wide variety of treatment options for patients and their providers. The design includes six pairs of interwoven, super-elastic nitinol wire; a back-braided design; and optimization of radial strength and flexibility—a radial strength that allows the stent to act as a comfortable scaffold, Owens says. Additionally, the diameter is natural to the reference vessel diameter.

The nininol-based with interwoven wire were shown to have four times the radial strength of a traditional stent and 360 percent more crush-resistance, according to studies performed by BDC Laboratories [2] in Wheatridge, CO and Medical Device Testing [3] in Minnetonka, MN. While the initial expense of the device is higher than a traditional stent, it eliminates the need for replacement or follow up surgery, lessening the financial impact of the stent.

If the product is in the legs, you don’t want the stent to be crushed by outside forces or movements, he says. These stents significantly improve flexibility, in addition to resistance to kinking, which happens when an artery bends with the natural movement of a knee, but the stent “kinks” and stops blood flow.

In a recent FDA Investigational Device Exemption clinical trial, 99.6 percent of the 264 participants met the primary safety endpoint of freedom from death, target lesion revascularization or amputations after 30 days post-procedure. After one year, the participants reported zero fractures and 90 percent reported no target lesion revascularization.

Links:
[1] http://www.idevmd.com/
[2] http://bdclabs.com/
[3] http://www.devicetesting.com/