CARDIOVASCULAR DEVICES

Intact Vascular Inc.

Optimizing balloon angioplasty for peripheral arterial disease

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Contact: Bruce Shook, President & CEO
Business: Minimally invasive repair of arterial dissections following angioplasty
Founded: August 2011
Founders: Peter Schneider, MD, CMO; Robert Giasolli; Carol Burns
Employees: 17
Financing To Date: $19.9 million
Investors: Quaker Partners Management LP; HIG BioVentures LLC; Angel investors
Board Of Directors: Bruce Shook; Peter Schneider; Douglas Evans (Lungpacer Inc.); Dennis Wahr, MD (Holaira Inc.); P. Sherrill Neff (Quaker Partners Management); Aaron Davidson (HIG BioVentures); Kathy Crothall, PhD (Aspire Bariatrics Inc.)
Scientific Advisory Board: Michael Dake, MD (Stanford University School of Medicine); David Deaton, MD (Endologix Inc.); William Gray, MD (Columbia University Medical Center); John Laird, MD (University of California, Davis, Medical Center); Alan Lumsden, MD (Methodist DeBakey Heart Center, Houston); Jihad Mustapha, MD (Metro Health Hospital, Wyoming, MI); Rodney White, MD (Los Angeles County-Harbor-UCLA Medical Center)

The eureka moment for Peter Schneider, chief of vascular therapy at Kaiser Permanente Moanalua Medical Center in Honolulu, HI, occurred in 2007 while he was tacking Christmas lights to his home. He thought how great it would be to have a new solution to repair tears or dissections in arteries following balloon angioplasty, in a focused manner, similar to tacks for holiday lights.

Schneider has brought his idea to fruition as co-founder of Pennsylvania-based **Intact Vascular Inc**. Instead of relying on traditional stents, the company's *Tack Endovascular System* uses multiple, small nitinol *Tack* implants to reduce metal exposure when treating peripheral arterial disease (PAD).

When a diseased artery is dilated using a balloon, the diseased portion of the artery is stretched. However, in up to 80% of cases, the plaque that lines the artery is actually dissected or torn. The artery wall is also at risk. "These tears create tissue flaps, which frequently protrude into the lumen of the artery," says Bruce Shook, president and CEO of Intact Vascular. "This is a problem because it increases the risk of reocclusion."

The Tack system not only dramatically minimizes the metal that is left in the artery compared with a stent, but also decreases the vessel inflammation associated with stents. And in cases of vessels with low to moderate levels of calcification, "stenting those arteries to repair the dissection is really overkill in many ways," Shook notes.

Take the example of performing angioplasty in the superficial femoral artery, resulting in two dissections in the treated area, spaced 50 mm apart. Repairing those dissections with a stent requires a stent that covers that entire length of the artery, plus about an additional 10 mm on either side. "Although the clinician only has two discreet areas that need repairing, he or she lines the entire length of artery with metal," Shook explains. "All that metal irritates the vessel. It also prevents the vessel from flexing normally."

Shook also points out that stents are designed to produce a great amount of radial (outward) force on the vessel wall, which over time causes the vessel wall to thicken. "As that process continues, the lumen of the vessel closes down and the stents can re-narrow (in-stent restenosis) or block completely, causing a whole new challenge for the patient and the doctor," Shook says.

The greatest technical challenge in developing the Tack system was for the Tack implants themselves to adapt to a range of vessel diameters, which stents cannot do. "With a stent, you have to actually size the stent to the vessel diameter," Shook explains. "But the way the struts are designed and joined together in the Tack implant allows it to conform to vessels of different diameters."

There are about one million patients worldwide who receive an endovascular procedure in the leg each year, of whom roughly 300,000 would benefit from the Tack system. These are patients who have just undergone reasonably successful angioplasty for opening the artery, but then dissections are detected that must be managed. The annual market potential for the device exceeds $500 million.

Intact Vascular has two versions of the product. One is for use in arteries above the knee (in the thigh) and the other for below-the-knee arteries (in the calf). CE mark for the above-the-knee product was granted in 2012, with below-the-knee approval expected at the end of the year. However, PMA approval is not anticipated until late 2018 for the above-the-knee version, followed one year later for the below-the-knee product.

Shook has been a medtech executive for more than 30 years. Most recently, he was co-founder, president, and CEO of Neuronetics Inc. (noninvasive brain stimulation technology to treat depression) from 2003 to 2014. Before then, he was co-founder, president, and CEO at Neuron Therapeutics Inc. (a drug/device product for treating CNS disorders) from 1998 to 2002. Shook also held various management positions, including president, at Abiomed Inc. (the first FDA-approved ventricular assist device) between 1987 and 1997. Earlier on, he served in a variety of engineering and research positions at Cordis Corp. (developing cardiac pacing products) from 1984 to 1987.

Intact Vascular has two issued and eight pending US patents with multiple foreign filings, and does not share royalties/revenues with another entity.

The Tack Endovascular System consists of a single-use, disposable delivery catheter that comes in a variety of lengths, ranging from 80 cm to 135 cm, depending on the physician's approach. The catheter is also preloaded with six compressible Tack implants, similar to a staple gun containing staples. Above-the-knee Tack implants treat vessels ranging in diameter from 2.5 mm to 6 mm, whereas below-the-knee Tack implants accommodate vessels from 1.5 mm to 4.5 mm.

After standard angioplasty is performed

by either an interventional cardiologist, vascular surgeon, or interventional radiologist, dissections become visible on angiography. Then under fluoroscopy, the Tack delivery catheter is passed over the same guidewire already in the patient and advanced to the most distal dissection. The outer sheath of the catheter is then retracted to expose and deploy the first Tack implant, which self-expands to appose the dissected tissue against the vessel wall where it can heal. Each Tack implant is also surrounded by six sets of two tiny anchors that grip the vessel and prevent migration.

Next, the operator moves the delivery catheter back to the second most distal dissection and similarly deploys the second Tack implant. The same steps are repeated for a third or more dissections.

Once all the Tack implants are in place, a balloon is inserted over the guidewire and inflated to set the Tack implants into the artery wall. On average, it takes three to four minutes to insert three or four Tack implants. "The amount of nitinol in contact with the vessel is 70% to 80% less than for a traditional stent," Shook states. "Our Tack implant also has a fraction of the radial force relative to a stent, so it produces much less irritation of the vessel." Moreover, the vessel is able to flex normally because the vessel is no longer entirely lined with metal. "We provide for very focal treatment," says Shook, who notes that the learning curve is short for any clinician who performs angioplasty and stenting. "We use the same techniques as are involved in deploying a stent."

The Tack system is also ideal for use with drug-coated balloons, according to Shook. Since October, the FDA has approved two drug-coated balloons from **CR Bard Inc.** and **Medtronic PLC**, respectively. "Although these balloons elute paclitaxel into the vessel wall and reduce inflammation, they still produce dissections," he says. "Our system is the ideal solution for repairing these dissections and aligns beautifully with a key goal of drug-coated balloons: reducing vessel inflammation."

Over the past four years, Intact Vascular has completed three clinical studies involving a total of 173 patients, mostly for above-the-knee procedures. Combined, the studies demonstrated excellent 12-month patency of about 80%, a rate that is competitive with the best stents from such companies as Bard, **Abbott Laboratories Inc.**, Medtronic, and **Boston Scientific Corp.** Shook says. There was also no migration of any Tack implant, "which is critical," he reports.

He says that another advantage the Tack system has over stents is preserving future treatment options. Use of the Tack implant does not preclude future stenting and makes bypass surgery easier by leaving more native vessel available to the surgeon.

The Tack system is expected to start selling in both the US and internationally in early 2019 and will fit into the existing reimbursement infrastructure.

So far, the company has raised $19.9 million, comprising angel funding and a $16.6 million Series A round led by Quaker Partners and HIG BioVentures that closed in 2012. Shook declines to comment on future fundraising.

The most likely exit strategy for Intact Vascular is an eventual acquisition by a player in the peripheral vascular market or one that seeks to enter the space. A potential future application of the Tack system is following atherectomy. **SU**

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– Bob Kronemyer