Evaluate Vantage

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Interview – Rox Medical thrives under pressure

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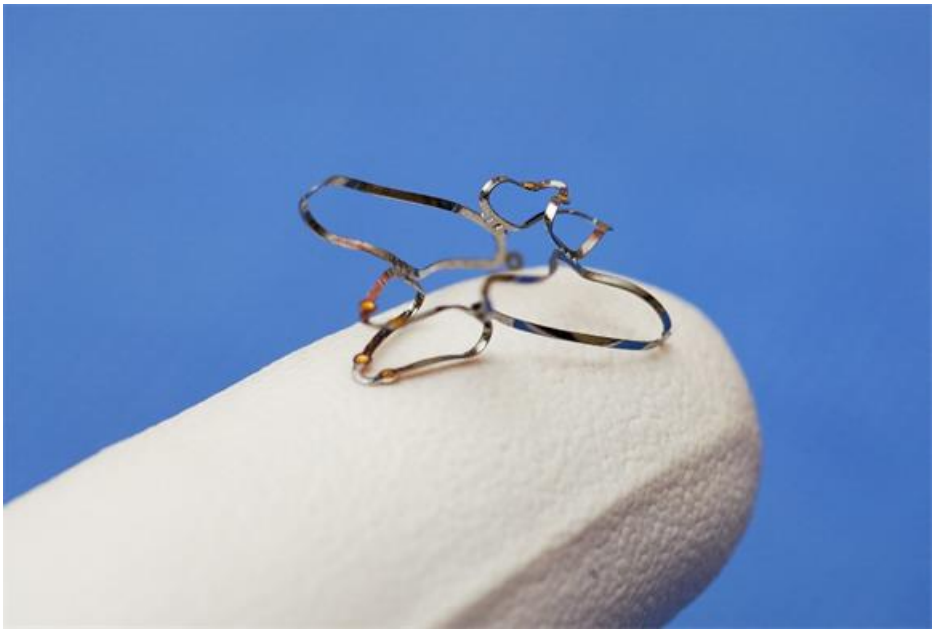
Three years ago treating uncontrolled hypertension with a medical device meant one thing: renal denervation. The shock failure of this much-vaunted technology in a US trial back in 2014 has allowed Rox Medical to step into the spotlight. The group has just closed a $40m series E round to fund development of an entirely different technology.

“Frankly it was hard for us to get attention at a time when everyone was clamouring for renal denervation, because it was going to solve all the problems,” says Rodney Brenneman, the company’s chief executive. But the data reported on its Coupler device were so strong that the company managed to hook VCs in a big way.

The stent-like device is implanted in the upper leg to create an anastomosis and allow blood to flow from the femoral artery into the femoral vein. This causes a fast and durable drop in arterial pressure. It is intended to treat isolated systolic hypertension – a disease of ageing in which loss of collagen causes the blood vessels to stiffen.

It was initially developed as a therapy for chronic obstructive pulmonary disease – arteriovenous anastomosis has been shown to increase exercise capacity in patients with the disorder – and is CE marked for this indication. Hypertensive patients who received the Coupler in this context had sharply lowered blood pressure, so the company conducted an eight-patient feasibility study in hypertension and went from there.



The CE mark might not assuage the doubts of those who watched the previous technology come to nothing; after all, several renal denervation devices had also been CE marked. The $40m Rox has just obtained will go towards a US approval trial – crunch time, given that this is where renal denervation hit the buffers (*Failure of Medtronic’s Symplicity trial exacerbates concerns over renal denervation, January 9, 2014*).

The trial will enrol about 250 patients, Mr Brenneman says, although a listing on Clinicaltrials.gov suggests a headcount of 500. The endpoint will be reduction in ambulatory blood pressure from baseline at six months; patients in the control group will undergo a sham procedure, and all patients will be given drug therapy.

As well as providing evidence for US approval, the study should help Rox obtain European reimbursement.

Immediate effect

The data will take a few years to come through, but the interventional cardiologists performing the implantation procedures ought to have a fairly good idea of the device’s efficacy long before that.

“One of the challenges of renal denervation still is [that] you do a procedure and the doctors don’t know if they did a good job,” Mr Brenneman says. “With Rox Medical, you do the procedure in the cath lab, the blood pressure goes down and you can see it. That’s satisfying for the doctors and patients, but it’s also very reassuring for the investors.”

Largest series E rounds in medtech, 2016 to date

Date	Company	Investment ($m)	Focus
May 20	Heartflow	64.0	Cardiology
September 6	Rox Medical	40.0	Anaesthesia & Respiratory
January 5	Pathway Genomics	40.0	Cardiology; In vitro diagnostics
May 17	Mitralign	39.8	Cardiology
June 21	Miramar Labs	33.6	General & plastic surgery

Those investors include Apple Tree Partners, Versant Ventures and Domain Associates, as well as Novartis’s venture arm.

The market for the Coupler is sizeable, particularly as there is nothing similar on the market or in development. Around 70 million people in the US and a similar number in Europe have high blood pressure, half of whom find that their condition is poorly controlled by medication. Mr Brenneman says at least half of these fit into this isolated systolic hypertension category and are therefore candidates for treatment with the Coupler.

If investors have seen the technology’s potential, Mr Brenneman hopes acquirers will, too.

“There are a lot of large med device companies that have been watching us, that have already indicated an interest in [hypertension]. They have made an investment or some sort of acquisition in this area, but always in the renal denervation arena,” he says, naming Medtronic, Boston Scientific and Abbott as examples of groups that have looked into devices to treat high blood pressure.

“When we finish enrolment in our US trial at least by that point I think this will be an extremely attractive technology for a large company to take on,” Mr Brenneman says. “We’d be right in line with whatever they’re doing in heart disease or stroke.”

Rox Medical Coupler trials

Phase	Study name	Description	Enrolment	Trial ID
Phase II	RH-01	European pilot study in resistant hypertension	8	NCT01682057
Phase III	RH-02	European pivotal study in resistant hypertension	100	NCT01642498
Phase III	RH-03	European post-approval registry in hypertension	100	NCT01885390
Phase III	US HTN-01	US pivotal study in resistant hypertension	500	NCT02895386

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