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Cardio Conversations: AVS' Talks About Starting A Company In A Pandemic, Cracking Peripheral Plaques And More

by Reed Miller

In this edition of Cardio Conversations, *Medtech Insight* editor Reed Miller talked to Robert Chisena, the co-founder and CTO of AVS (Amplitude Vascular Systems) where leads research and product development. He talked about his company's novel interventional technology for calcified peripheral arterial disease and how the company came together despite the pandemic.

Use the player below to hear the entire interview.

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AVS (Amplitude Vascular Systems) was born out of research at the University of Michigan about six years ago.

Robert Chisena, then a mechanical engineering PhD student at the university, and Hitinder Gurm, an interventional cardiologist who serves as the university's chief clinical officer, began developing a new approach to safely cracking calcium in peripheral vessels.

"Pretty early on, when I started to look at the number of people affected by this, I knew that it was a major issue, but I didn't know how big of an issue it was until we started putting it in front of other people," Chisena told *Medtech Insight*.

AVS's balloon-based intravascular lithotripsy technology generates a rapid, high-frequency, low-intensity pulse from outside the body to deliver a pressure wave into the vessel through a balloon catheter.

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"The high-impact force that is momentary – and the oscillation of that momentary force – is what cracks the calcium," he explained. "If you can impact [the calcium] in such a way that the solid mass breaks up over time without damaging the surrounding tissue, you get a good treatment effect."

ROBERT CHISENA

AVS' system is designed to be a minimally invasive technology that gently shatters calcium and opens the artery using a single device, requiring only a "small footprint" in the catheterization lab in hospitals. "You cross the lesion, you shatter the calcium, you expand the vessel, and then remove the device, all with one system – one balloon."

At the Transcatheter Therapeutics (TCT) conference in October, the company reported results from nine patients in the first-in-human *POWER PAD I* study.

The study enrolled moderate-to-severely calcified superficial femoral and popliteal arteries. The average treated lesion was 250mm long. Treatment with AVS' pulse intravascular lithotripsy system was successful in all nine patients with no major adverse events.

"We walked away from this trial with some incredible results in some not-so-easy-to-treat patients," Chisena said. "[The study] definitely helped solidify our trust in the technology. It is easy to use, but offers a lot of benefits to the patient and the physician using it."

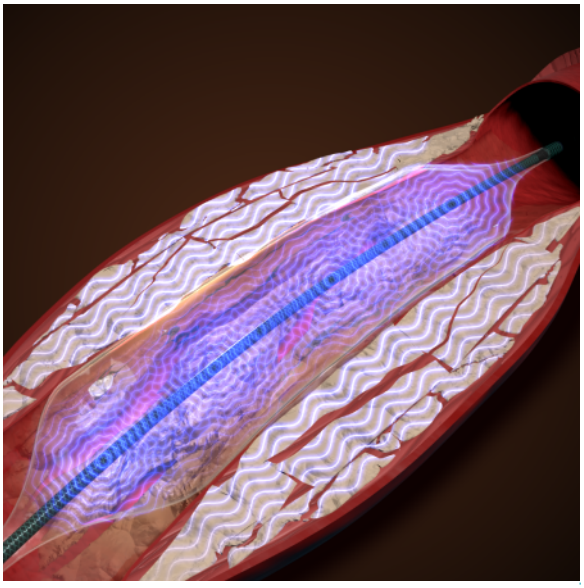
Crowded Field

AVS may eventually expand into other indications, including the coronary vessels, but it is now focused on peripheral disease because it is a largely unmet need. "Peripheral vessels are notoriously tough to treat when calcium is present," Chisena said. "Typically, these vessels are diffusely diseased, the calcium is eccentric, and difficult to access. And, when you treat it, there's a lot of recoil."

Shockwave Medical has already demonstrated the market potential for an interventional solution to calcified vascular lesions, which will certain attract more competitors. The company expects to record about $730m in revenue this year, representing year-over-year growth around 49%. Shockwave's market cap is nearly $7.4bn (Also see "*Shockwave Buys Neovasc, Hoping Reducer Angina Device Complements Coronary Lithotripsy*" - Medtech Insight, 18 Jan, 2023.)

AVS is confident it can be successful in the market, even as it becomes more crowded. "Even having a product that is 'just as good' as Shockwave's [devices] will be successful, but – without

going into too much detail – we have a few things up our sleeve at AVS that will really offer a lot of advantages to the doctors in treating these vessels."



AVS PULSE CRACKING VASCULAR PLAQUE

The company is led by executive chairman Mark Toland, an industry veteran who once led Boston Scientific's US cardiovascular commercial team. He came to AVS through Biostar Capital, which recently led AVS' $28.8m series B funding round along with CUE Growth Partners.

Sean Gilligan, formerly the vice president of program management and R&D at Boston Scientific, joined AVS as its chief operating officer in April and the company moved into its new offices in Boston in September.

After an eventful 2023, the company is now looking forward to starting a pivotal trial. "Since the series B, we're rolling right along with development, building out the company, and we expect to initiate that peripheral trial shortly – probably the next six months or so," Chisena said.

Use the player above, or find Medtech Insight's Cardio Conversations *on your favorite podcast platform, to hear the complete interview with Robert Chisena.*

Editor's Note: *In the interview, Chisena alluded to New York Times investigation of physicians marketing unncessary and potentially harmful peripheral atherectomy procedures. Some investors expected that negative publicity to slow the growth of peripheral interventions overall and Shockwave's stock price dropped throughout most of late 2023.*

"[Shockwave] will recover from that and that market segment will continue to grow," Chisena said. "There are really sick patients that require this type of treatment."

Shockwave has told analysts that those reports have had little impact on the demand for its intravascular lithotripsy technology. "We're not seeing any procedure change," Shockwave CEO Douglas Godshall said in response to a question about the Times' *report at the Wells Fargo Healthcare Conference in September.*

Further Reading

Shockwave Begins First All-Female Study Of Coronary Interventions

Reimbursement For Shockwave's IVL Device May Pose Quandary For CMS

Abbott Buys CSI To Add Peripheral And Coronary Atherectomy Technologies

Shockwave Buys Neovasc, Hoping Reducer Angina Device Complements Coronary Lithotripsy

FDA Approves Shockwave Coronary Intravascular Lithotripsy System

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