JANUARY 16, 2019
Vol. 6, No. 1

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VIRTUOSO SURGICAL

NASHVILLE, TN

CONTACT

Richard Hendrick

richard.hendrick@virtuososurgical.net

YEAR FOUNDED

2016

WHO'S BEHIND IT

COO Richard Hendrick, PhD; President and CTO Robert J. Webster III, PhD, a co-founder of the Vanderbilt Institute in Surgery and Engineering (VISE); Chief Clinical Strategist Duke Herrell, MD, a urologic surgeon and director of the robotics committee at the Vanderbilt University Medical Center; and Chief Administrative Officer Mark Pickrell, JD

UNMET CLINICAL NEED

The range of motion for straight tools that pass through rigid endoscopes is limited, hindering surgeons' capability in procedures and forcing them to tilt the entire endoscope to move their tools to targets within their field of vision. This can complicate surgery, contribute to operation time, and greatly limits the surgeon's capabilities

SOLUTION

The Virtuoso system with two telescoping nitinol tube arms increases the dexterity and capacity for bimanual tool manipulation in endoscopic applications

FUNDING TO DATE

$3 million from individual angels as well as federal and state grants

Endoscopy

VIRTUOSO SURGICAL: EMPOWERING ENDOSCOPIC SURGERY

Virtuoso Surgical has developed a minimally invasive endoscopic robotic surgery system that enables doctors to surpass some of the limitations of traditional endoscopes. The Virtuoso system features a pair of instrument delivery arms made of concentric nitinol tools that mimic a surgeon's hands to offer unprecedented control, specificity, and variability to a full range of endoscopic applications.

by COLIN MILLER

When considering surgical options, endoscopy presents a notable advantage over open surgery: minimal disruption of tissue. This allows the impact of the procedure to be concise and it curbs patient discomfort. Unfortunately, some cases require more complex motion than today's rigid endoscopes permit without moving the entire device, a luxury that delicate areas of operation do not afford. As a further obstacle, the amount of open lumen is very limited, restricting the size of manipulation tools that can be fed through the endoscope and used to cut, grip, and move materials. Although robotic options are becoming more popular, the challenge of manipulator miniaturization has led to a focus on laparoscopic applications that require tools in the 5-8mm size range and involve multiple ports, increasing the relative ease of these procedures. In order for endoscopic applications to be equally effective anywhere in the body, they must be able to match the precision of a skilled surgeon on a vastly smaller scale.

> *"It's very difficult with the current surgical robotic architectures to scale down to the level you need for endoscopic tools."*
>
> *—Richard Hendrick, PhD*

Richard Hendrick, PhD, COO of **Virtuoso Surgical Inc.** explains that his company's system, which involves an 8mm endoscopic element with two independently movable nitinol tube arms, a rod lens mounted above them, and the ability to deliver fluid bidirectionally, incorporates more functionality in the ideal size limit than any before. "It's very difficult with the current surgical robotic architectures to scale down to the level you need for endoscopic tools," he says, adding that conventional non-robotic tools have a limited range of motion. "They can go in and out of the endoscope and spin," he explains, and notes that with conventional tools in rigid endoscopy, a surgeon's eyes and hands are "fundamentally tied together," meaning that for the surgeon to tilt their tool, they must tilt the entire endoscope. With traditional endoscopes, one can move the module containing the lens and tool in or out along the scope's trajectory but not vertically or horizontally. To achieve these adjustments, the whole endoscope must be tilted—a risky prospect in places like the brain or in internal organs that require special caution.

"From the surgeon's perspective, we can take highly specialized procedures that are also very difficult and make them much simpler," says Hendrick, citing the example of a tumor dissection that can be accomplished more precisely with the *Virtuoso* system than any other thanks to the dual arms that cut and hold tissue simultaneously. As another example, a laser-based benign prostatic hyperplasia (BPH) therapy's efficacy has been well proven clinically yet is utilized in only 2-3% of cases because it is extraordinarily challenging for the surgeon to learn. The *Virtuoso*

System can make this procedure much easier, encouraging more surgeons to adopt it. Since the arms are made of telescoping nitinol tubes, they can withstand extremely high strain and can be bent into any shape to conform to a particular case's requirements, eliminating the need for awkward movements during operation.

Even if an endoscope can accommodate two tools simultaneously, Hendrick notes that present technology only permits the tools to be oriented straight out and parallel to one another, prohibiting truly collaborative work between the two. Since surgeons are used to doing bimanual (or two-handed) procedures, this configuration is less than ideal. By contrast, the arms of Virtuoso's system are fully opposable, since the concentric nitinol tubes that comprise them are curved, highly elastic, and able to rotate with respect to one another, generating what Hendrick describes as a "tentacle-like motion." "Because our technology is small enough, we can give them two hands, and we can make those hands dexterous," he says.

Founded in 2016 and beginning full operation in 2017 Virtuoso Surgical can trace its roots back to 2009, when Robert Webster, PhD, and Duke Herrell, MD, started working together at Vanderbilt University. While in graduate school at Johns Hopkins, Webster developed Virtuoso's underlying concentric tube robot technology. Herrell, an expert in minimally invasive and robotic surgery, immediately saw the potential in Webster's prototype for an endoscopic application. At this point, Hendrick entered Vanderbilt to pursue his PhD under Webster's advisory and commenced working with him and Herrell over the next few years to develop the platform into the iteration seen today. Soon after, a lawyer named Mark Pickrell was recruited to help with contracts, IP, compliance, capital-raising, and administration. Going into this venture, Hendrick benefitted from a better understanding of the medical device field and the regulatory environment than some of his peers in academia because he had worked for orthopedic implant instrument manufacturer DJO Surgical while he was an undergraduate. Knowing that the regulatory burden of his nascent company would be high and that it would not be comparable to building a simple prototype the way other academics might, Hendrick ensured that understanding of design controls and implementing quality systems were key initial steps to Virtuoso's formation, giving it, he believes, a strategic edge from the front end.

Regulatory conversations are still ongoing, as the engineering, building, and benchtop testing phase for the device is actively underway. Hendrick suggests that there may be predicate devices to form a basis for 510(k) submission.

So far, the Virtuoso team has managed to implement a variety of tools into its system, which acts as a delivery channel due to the hollow structure of the innermost nitinol tube. Laser fibers, kidney stone baskets, electrodes, and forceps are just part of the growing list, as are irrigation and suction elements. Hendrick mentions that a major focus of development is trying to deviate as little as possible from the way endoscopic surgery is done today. "We want the surgeon standing in about the same place as they would if they were doing a manual endoscopic procedure, so there's not much of a need to reorganize the operating room," Hendrick says. The basic interface involves a joystick-like input for surgeons to convey their desired motions to the tubes on the device as well as a screen to observe the action captured by the endoscope lens.

Virtuoso's solution has been issued a licensed patent from Johns Hopkins for Webster's original concentric tube concept and is securing another from Vanderbilt submitted in the early stages of the founding members' collaboration. Regulatory conversations are still ongoing, as the engineering, building, and benchtop testing phase for the device is actively underway. Hendrick suggests that there may be predicate devices to form a basis for 510(k) submission. After FDA approval is secured, he expects to see a pilot rollout over a period of six to 12 months to gauge market reception and formulate further strategy based on the findings. The company's business model is based on of the device being disposable, with the main unit as a piece of capital equipment that Hendrick says, "will be much, much cheaper than what is normal in surgical robotics today." After extensive R&D testing, he believes Virtuoso is approaching a stable design that he's confident meets users' needs well.