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“We want to give surgeons the ability to look through the patient’s skin and tissue and see the anatomy...the super hero’s ‘x-ray vision!’”

—Nissan Elimelech

Augmedics
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YEAR FOUNDED
2014

WHO’S BEHIND IT
Nissan Elimelech has a degree in biomedical engineering from the Ben-Gurion University of the Negev, and gained relevant experience as a spine surgery sales rep and technical consultant for Medtronic. Elimelech is also the co-founder and inventor behind Medizn Technologies, which has developed a novel biodegradable substance for hernia procedures.

UNMET CLINICAL NEED
Although the benefits of surgical navigation systems are well established, very few surgeons use them routinely because many feel that they don’t integrate well into surgical workflow.

SOLUTION
An augmented reality headset that allows surgeons to see the patient’s anatomy and the position of their instruments in real time as they look at the surgical site, rather than at a monitor across the room.

FUNDING TO DATE
$9.1 million ($800,000 seed funding, and $8.3 million Series A)

Surgical Navigation

AUGMEDICS:
AUGMENTED REALITY OFFERS INTUITIVE SURGICAL NAVIGATION

Despite the widespread installation of surgical navigation systems across North America and Europe, 85% of surgeons don’t use them routinely, chiefly because they’re not easy to use. Augmedics aims to get more spine surgeons to use these systems with an augmented reality headset and processor that allows surgeons to look at the patient rather than a monitor across the room.

Over the 20 year or so history of surgical navigation systems—computer assisted visualization systems that allow surgeons to track their instruments on a view of the patient’s anatomy during surgery—they’ve demonstrated many benefits. In orthopedics, for example, the use of such systems has enabled more minimally invasive procedures while cutting down on radiation exposure from intra-operative fluoroscopy; helped surgeons increase the precision with which they place screws, thereby avoiding revision surgeries, and boosted the safety of procedures overall. Despite these advantages, however, today only 15% of surgeons use surgical navigation systems routinely.

This underpenetrated market has every reason to grow in orthopedics because of the large volume of procedures required by an aging population and increasing rates of obesity, and also because the bundled and value-based payment models that are becoming a way of life reward therapeutic efficiency—the low revision rates that these technologies yield, for example.

Yet a recent report from iData Research describes the surgical navigation market as “mature, well penetrated and small.” (See “US Surgical Navigation markets: Growing Slowly and Steadily Despite Robotics,” MedTech Strategist, January 31, 2018.) iData estimates the compound annual growth rate for surgical navigation systems in the US at only 1.6% on sales of $118 million in 2016.

Nissan Elimelech, the founder of Augmedics Ltd. was a surgical sales rep and then a technical consultant for the spine surgery unit of Medtronic plc. After selling surgical navigation systems that required a long sales cycle and a substantial investment on the customer’s part, he was struck that these systems weren’t being used as much as one might expect. “I thought long and hard about what was missing in current navigation systems,” he says. Drawing on his experience with spine surgeons, he concluded “the systems aren’t intuitive, and that prevents surgeons from even trying to use them.”

Surgical navigation systems help surgeons see the location and path of their surgical instruments in the body as they operate. Generally, software is used to create, pre-operatively, a 3D model of the patient’s anatomy, based on CT scans (or other images) taken before the procedure. During the surgery, the instruments and anatomic landmarks are tracked using markers and tracking systems (optical or electromagnetic) and software aligns these locations and trajecto-
ries with the 3D reconstruction of the patient’s anatomy (a process known as registration). All of this information is displayed on a computer screen in the OR, located at some distance from the patient.

To Elimelech’s point, if you visited the OR of a spine surgeon using a navigation system, you would observe the surgeon with his hands and instruments in the patient’s body, but his head would be turned away from the patient and towards the monitor. “The surgeon may be drilling or putting in implants, but he is not looking directly at his hands. That lack of intuitiveness was a hurdle,” says Elimelech.

Accordingly, Elimelech set out to deliver a new surgical navigation system with all the functionality of the existing systems from the leaders in the field, but with one chief difference. The far monitor would be replaced with an augmented reality headset that would allow surgeons to see the anatomical reconstruction and the position of the instruments while looking at the surgical site on the patient. Elimelech says, “We want to give surgeons the ability to look through the patient’s skin and tissue and see the anatomy and organs that they want to operate on—the super hero’s ‘x-ray vision’.”

The company’s first product, xvision-spine augmented reality surgical navigation system, is based on a headset developed by Augmedics to accommodate the ergonomics of surgeons (who tilt their heads 30-40 degrees while looking down at the surgical site). It incorporates the reflective waveguide (the AR eyeglasses that project images onto the retina) of Lumus Optical (Ness Ziona, Israel). The intraoperative tracking system, including infrared cameras, projectors, filters, and algorithms, all reside in the headset, which uses an NVIDIA Tegra processor. The company offers a separate workstation, which preprocesses the patient’s CT, MRI, or other image data to create the anatomical model and register the images, and calibrates the surgical tools by placing markers. The workstation can be used for surgical preplanning—to determine the trajectory and placement of instruments, and it also sends processed data to the headset, which accomplishes all of the intraoperative functions—tracking, image registration, and displaying the images. “It looks completely different from all the other navigation systems; it is just a lightweight headset,” Elimelech says.

The headset offers several modes of visualization: 3D, 2D images of the axial or sagittal planes, depth peeling, a tip view, or a transparent view, permitting surgeons to “see” through bones or to “see” through skin and tissue so that only the bones are visible. The images can be zoomed in and out, flipped and rotated, and the contrast can be adjusted. As is customary with surgical navigation systems, the visual modes are controlled at the surgeon’s request by a technician at the workstation, because surgeons must maintain a sterile field.

The surgeon sees two little screens floating just above the patient (see Figure 1). “Without looking aside or up the surgeon can very intuitively see the 3D image, and when he inserts an instrument inside the patient, he can see the 2D planes to verify that the tool is inserted correctly,” says Elimelech.

xvision, which doesn’t yet have regulatory clearance, has been in the works for just about three years now. The company completed its second cadaver study earlier this year, a proof-of-concept study at Johns Hopkins Hospital (also involving two surgeons in Israel), in which surgeons used xvision to place 120 pedicle screws in five separate cadavers at spinal levels L5-T6, achieving a screw...
placement accuracy of 96.7% (according to the combined Heary-Gertzbein grading scheme). Surgeons responding to a questionnaire at the end of the study gave the system high marks for usability.

In August 2018 Augmedics began a first-in-human clinical trial of xvision-spine at Sheba Tel Hashomer Medical Center and Asaf Harofeh Medical Center, in Israel. Led by Co-Principal Investigators Ran Harel, MD, and Yigal Mirovsky, MD, the open label, prospective, single arm, multi-center study will evaluate the safety, performance, accuracy and usability of xvision-spine during spine fusion procedures involving pedicle screw placement. The number of subjects will range from eight to 22, depending on the number of screws placed in each subject, with a minimum of 85 total screws placed in the study.

Augmedics has designed into xvision-spine the same level of functionality as currently available surgical navigation systems, because, says Elimelech, “For regulatory reasons, we need to be very similar. Besides, there is no need to reinvent everything from scratch. The systems of Medtronic, BrainLab [BrainLab Inc.] and Stryker [Stryker Corp.] are all excellent. Surgeons trust these systems, and we want to be similar to the standards these companies have created over more than 20 years.”

However, while being largely similar, the small change the company has made in providing a near-eye—rather than far off—display has huge ramifications, Elimelech believes, because it “changes the whole touch and feel of the navigation system, and dramatically improves the usability.”

As noted, xvision-spine is not yet cleared for marketing, so the company hasn’t yet done studies to show whether it results in shorter procedures or better outcomes than those realized by other surgical navigation systems. But that’s not the point, says Elimelech, who emphasizes that the main problem Augmedics is trying to solve is the under-use of surgical navigation systems. “Surgical navigation systems improve accuracy, increase safety, shorten procedure times, and reduce radiation exposure. But those benefits can’t be realized unless surgeons use them!” he says.

Medtronic’s recent acquisition of Mazor Robotics for approximately $1.64 billion is evidence of the industry’s interest in increasing the precision and predictability of spine procedures, and that doesn’t only underscore Augmedics’ arguments in favor of surgical navigation, it also represents the next step for the company, once its first system is cleared and launched. “Our xvision system can be used to plan the screw positioning, and the robot can take over and provide a mechanical guide to help the surgeon place the screw.” There are multiple ways of integrating xvision with robotic arms, Elimelech says, and a solution that integrates the two technologies is in the proof-of-concept stage.

The company will focus on bringing out new technologies for the future of spine surgery, rather than spending its resources on building a sales force and selling. “We are trying to build strong partnerships where we will eventually integrate our xvision systems into partners’ devices.”

The universe of potential partners doesn’t just cover surgical navigation companies; companies offering other intraoperative imaging systems provide a good fit as well. “Our main strategy now is to pick our partners correctly so we can be in the hands of as many surgeons around the world as possible in the shortest amount of time,” Elimelech says.