

FEBRUARY 2024 | Vol. 11, No. 2

MedTech STRATEGIST

**FIRE1: Marrying
Medtech and Digital
Tech to Transform Heart
Failure Treatment**

David Cassak

**A Data Strategist
Steers Northwell Health
to an AI-Driven Future**

Wendy Diller

**VUZE Medical:
Software-Based
Guidance for
MIS Spine Surgery
and Beyond**

Wendy Diller

**IS BETTER IVUS
THE MISSING
LINK IN PVD?**

Mary Stuart



[MYSTRATEGIST.COM/MEDTECH-STRATEGIST](https://mystrategist.com/medtech-strategist)

Sections

THE BRIEF

6

6 Patch-Pump Hopefuls Aim for a Piece of the Pie

Growing demand for insulin patch pumps in the US—a market currently dominated by Insulet and the *Omnipod 5*—has ignited a firestorm of activity among would-be competitors, including Medtronic, Tandem Diabetes Care, Roche, and embecta, along with innovative smaller companies such as PharmaSens, Modular Medical, and ViCentra—all aiming to shake up the status quo.

Mary Thompson

9 Precision Heart Care From Cleerly Transforms Cardiac Risk

Cleerly has been successful with a new cardiac care model that helps clinicians tailor medical care with the aid of its disease-staging system, to reduce future events. Now the start-up has launched an ambitious landmark trial called TRANSFORM, to advance evidence for evaluating and treating heart disease based on disease characteristics rather than surrogates.

Mary Stuart

START-UPS TO WATCH 36

36 Insight Medbotics: Operating Robotically Inside the MRI

Colin Miller

38 VUZE Medical: Software-Based Guidance for MIS Spine Surgery and Beyond

Wendy Diller

Features

Is Better IVUS the Missing Link in Peripheral Vascular Disease?

12

Intravascular ultrasound has been proven to make endovascular interventions safer, and good outcomes more durable, but only a minority of clinicians use it. Two device imaging start-ups—Provisio Medical and Evident Vascular—are innovating to address barriers to the use of IVUS, with an initial focus on peripheral vascular disease, the largest potential endovascular market, and the one most in need because of the complexity of the anatomy and disease.

Mary Stuart

FIRE1: Marrying Medtech and Digital Tech to Transform Heart Failure Treatment

20

Launched as a novel collaboration between The Foundry and a major strategic, Ireland-based FIRE1 hopes to revolutionize the way we treat heart failure by, in effect, treating patients as consumers and taking heart failure into an era of deeper patient engagement.

Measuring Patient Appeal

22

Gilde's Janke Dittmer on the factors that spurred his firm's investment in FIRE1.

David Cassak

A Data Strategist Steers Northwell Health to an AI-Driven Future

28

Marc d. Paradis is in charge of managing Northwell Health's data strategy—how it is organized, accessed and shared—at a time when the volume of healthcare data is increasing exponentially and new federal interoperability laws are starting to have teeth. Northwell's response is to open its doors to new kinds of external collaborations with investors, entrepreneurs, and vendors.

Marc d. Paradis on Generative AI

30

Paradis shares his views on how generative AI is changing healthcare systems.

Wendy Diller





Ra'anana, Israel

Contact: David Tolkowsky,
Founder and CEO

davidt@vuzemedical.com

VUZE Medical: Software-Based Guidance for MIS Spine Surgery and Beyond

Surgeons have been satisfied with short-segment X-ray-guided interventions for decades, but their needs are changing as more procedures move to minimally invasive, outpatient and ambulatory settings. VUZE Medical has developed a software-based guidance system for MIS spine surgery that meets the market's changing needs by adding capabilities to the X-ray guidance already in place.

► WENDY DILLER

In 2015, David Tolkowsky, an Israeli computer science-trained entrepreneur, was looking for new challenges in image-guided medical interventions, where he had built decades of product marketing expertise and also as an inventor had over 50 patents granted.

Tolkowsky had previously led as CEO two successful start-ups—superDimension for 10 years and Sync-Rx for 7 years—through concept generation, product development, clinical validation, regulatory clearance, and early commercialization. The former, a pioneer in electromagnetically navigated bronchoscopy, sold to Covidien (now **Medtronic**) in 2012 for more than \$300 million, several years after Tolkowsky had left the company. He was at the helm when the latter, a developer of a transcatheter cardiovascular image-guided intervention platform called *SyncVision*, was sold to Volcano Medical (now **Philips**), also in 2012. The products

of both have since become global standards of care in their fields.

After the sale of Sync-Rx, Tolkowsky stayed on for a short time at Volcano as general manager of its Israeli business, then left to explore other opportunities. When Nissan Elimelech, a co-founder of Augmedics, then an early-stage start-up, reached out for help in developing a navigation system for spine surgery based on augmented reality, he jumped at the opportunity to work as a consultant.

Israel in the mid-2000s was a hotbed of healthtech innovation, including pioneering robotic surgical systems that firms like **Mazor** were aggressively selling. Although Tolkowsky lacked experience in spine surgery, he set out to learn more about it. During his discussions with surgeons, he found that, while spine surgery navigation had been on the market for more than 20 years, it was being used primarily for large, inpatient procedures, which

account for 20% of spinal fixations and fusions. It offers surgeons enhanced accuracy and repeatability by utilizing (typically in-OR) CT/cone-beam CT (CBCT) 3D scanning, but at the cost of extensive hardware, a revised workflow, elaborate preparations, and modified vendor-specific surgical tools. For the remaining 80% of procedures, most of which are performed on short spinal segments, surgeons continued to rely on 2D X-ray guidance, which had not changed during that time. Additional categories of spinal interventions such as augmentation and pain therapy remained 100% X-ray guided. Tolkowsky thus felt that “the market was telling us something” and set out to discover what that was.

“In our conversations with surgeons, we found that the majority of the market was not being served and that there has been close to zero innovation in guiding those 80% of interventions in the past 20 or more years, even as procedure sites were moving from

inpatient to outpatient and ambulatory settings. Because of the short stay, surgery must be minimally invasive, and the surgeon has no direct sight of the treated vertebrae. The reliance on X-rays only increases in such transition," Tolkowsky says.

Although surgeons were content with basic X-rays and off-the-shelf tools already at their disposal, they told Tolkowsky that they were open to less ambitious "X-ray-plus" innovation, which would maintain familiar workflow simplicity, tool neutrality, and affordability while adding much needed cross-sectional imaging views to improve accuracy and consistency. "The surgeons were telling us that, while they did not desire large, expensive navigation systems, if during tool insertion they could get the axial and sagittal [vertebral] cross-section views that they lack today with their 2D C-arms, then that would be a clear winner," he says.

Much research had been done with the goal of co-registering 2D X-rays to 3D images of the same vertebra, but the computations took too long and technological progress never transitioned into products that could be used in real-world applications. Tolkowsky set out to overcome this challenge using software-only solutions. He was determined to avoid the extensive hardware used by the prior generation of surgical navigation, which in his view was "a necessary evil that no surgeon has ever asked for." Furthermore, software-only development projects tend to be better-focused and less expensive, thus more suitable for start-ups, he points out.

While developing the software algorithms can be difficult, computations that took hours years ago take only

seconds these days, thanks to the huge progress in graphic processing offered by off-the-shelf PCs. Driven by other industries such as gaming, this progress is clearly beneficial to the medtech industry.

"The surgeons were telling us that, while they did not desire large, expensive navigation systems, if during tool insertion they could get the axial and sagittal [vertebral] cross-section views that they lack today with their 2D C-arms, then that would be a clear winner."

—David Tolkowsky

A second algorithmic challenge is the combining of a standard preoperative CT scan, acquired at a different spinal position with the patient on their back, with 2D X-ray images acquired during surgery with the patient positioned on their stomach (or side). A third algorithmic challenge is detection of the surgical tools in the X-ray images to subsequently transform their positions to the CT's 3D space. Overall, Tolkowsky notes that "thanks to the software expertise of our own team, coupled with Nvidia's parallel progress in PC hardware, our processing time for each incoming X-ray image has gone down

from approximately one hour in 2017 to 2.5 seconds today."

Identification of these problems and the opportunities they presented led to the formation of **VUZE Medical** in 2017. The initial team comprised five of the founder's longtime colleagues, all with considerable domain expertise. VUZE aims to improve the standard of care for spinal stabilization cases, one of the most common surgical procedures. The system that it has developed offers preoperative surgical planning, including implant sizing, entry location, and trajectory determination, along with intra-operative guidance and tool trajectory/position confirmation. Using proprietary image processing, it overlays a graphical representation of unmodified surgical tools seen in intra-operative 2D images onto axial and sagittal views generated from the patient's standard preoperative 3D scan. In addition, there is no need for the lateral X-rays that are mandatory in the pre-VUZE X-ray-guided surgical workflow and that surgeons typically wish to avoid.

The hardware consists of just an on-cart, off-the-shelf PC, and the only imaging required in the OR is a standard 2D X-ray. The system provides the same images as more complex navigation platforms, but without additional sensors, cameras, or reference arrays, nor does it require any calibrations or lines of site. There is no need for additional 3D scans in the OR, eliminating the requirement for a setup costing possibly millions of dollars and available only with the use of proprietary tools. The flexible, simple approach is particularly important as more procedures move beyond the inpatient setting into outpatient and

ambulatory center settings. Additionally, it offers attractive financial scenarios to lower-volume and/or lower-budget inpatient ORs.

Unlike complex navigation systems that provide cross-sectional images continuously, the VUZE display is updated upon each newly acquired X-ray image. Although initially considered by the developers as a potential drawback, Tolkowsky notes that as it turns out, it fits very well into the existing X-ray-guided workflow, which is stepwise by nature.

Additionally, he points out that the VUZE solution is not susceptible to sources of potential error that typically exist in complex navigation systems. There are no concerns over bending of the surgical tool during its insertion (because VUZE tracks the tool's distal tip, as opposed to tracking its visible proximal portion and extrapolating where the tip presumably is), over a shift of the reference arrays relative to the treated vertebrae (because VUZE does not use man-made references), or over a shift of the treated spinal segment relative to neighboring vertebrae (because VUZE focuses on the treated area).

VUZE 1.0 received FDA 510(k) clearance in 2022 for use in minimally invasive thoracic-lumbar fixations and augmentations (spinal levels S1-T7). VUZE 2.0 with broader capabilities as well as interoperability with a wide range of X-rays from all major vendors, is under review at the FDA. The system is currently available at select sites on a pilot basis, with additional placements planned once the company receives the green light on VUZE 2.0.

While the company's immediate focus is on use of the system in spinal


stabilization by implants or cement injections, with 3 million applicable surgeries annually, other spinal and skeletal interventions are expected to follow. VUZE has 10 issued patents, with more pending.

The VUZE solution is not susceptible to sources of potential error that typically exist in complex navigation systems. There are no concerns over bending of the surgical tool during insertion, over a shift of the reference arrays relative to the treated vertebrae.

The Israeli-Hamas War that is now in its fifth month has created disruptions that are minor relative to other companies, in part because most of the 10 employees are above the mandatory service age in the Israeli reserves, Tolkowsky says. As of January 2024, the company has raised roughly \$10 million in funds from a dozen private investors, including the founder. The first-in-human clinical trial using the device was completed on 20 patients at the Rambam Health Campus in Israel, followed by its use post-trial on an additional 17 patients. While the company doesn't have a huge data set, accuracy so far, based on clinical and research work, has been excellent, he says, largely because the inaccuracies inherent in legacy systems do not

apply to what the VUZE system does. Cadaver work to extend applications beyond stabilizations and fixations is underway, including for sacral fusions, open surgeries, and pain therapies. Eventually, the start-up hopes to move beyond spine surgeries into other areas with similar needs.

As a serial entrepreneur, Tolkowsky has a perspective on what drives success. His experiences with superDimension and Sync-Rx have informed VUZE's current strategy. One of the biggest challenges is figuring out the problem, he notes. "You always try to go after a common procedure, where there are guidance and navigation issues that you think you can do something about." That was the reasoning behind both the superDimension and SyncVision (name of Sync-Rx system) solutions, with the former hardware-based and the latter (like VUZE) software-based. The CEO continues, "And then of course you need an excellent team, where your job as a leader is to make the most of everyone's individual talents, leverage the cumulative experience, and create a whole that exceeds the sum of its parts."

The plan for VUZE, as it was with Sync-Rx, is to look for partners or an acquirer for commercialization. Commercialization is "a different ballgame with capital needs of a different order of magnitude and therefore different types of investors," Tolkowsky points out. "When the end goal is to create an improved standard of care, the preferred means to get there include teaming up with an established player, combining the respective offerings into a superior solution, and then together taking it to market through that player's channels." 

Posted on MyStrategist.com Feb. 22, 2024