FEBRUARY 2024 | Vol. 11, No. 2

# MedTech STRATEGIST

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## Start-Ups to Watch



Fazila Seker, CEO

Mehran Anvari, PhD, Co-founder and Scientific Advisor

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In 2009, the Canadian Centre for Surgical Invention and Innovation (CSii) was granted Can\$15 million by the Network Centres of Excellence's CECR program to establish a not-forprofit research incubator that would leverage Canadian investment in space exploration technology and pivot it to medical applications. Led by CEO and seasoned telerobotic surgeon Mehran Anvari, PhD, CSii partnered with MDA, creator of the Canadarm space station maintenance robot, to begin development of the Image-Guided Automated Robotics (IGAR) system for conducting breast biopsies and other operations inside the bore of an MRI machine (See Figure 1). Early prototypes of IGAR were created using components of the Canadarm, Canadarm2, and Dextre devices, as they were designed to function remotely under extreme conditions.

In 2015, CSii experienced déjà vu when it was awarded a Can\$625,000 contract with the Department of Public Works and Government Services through the Build in Canada

### **Insight Medbotics:** Operating Robotically Inside the MRI

The extreme magnetic field generated by an MRI scanner has largely precluded biopsies and surgeries from taking place while the machine is in use. Now, using robots built from non-magnetic materials and inspired by the rigors of outer space, Insight Medbotics is giving radiologists and surgeons access to unprecedented image-guided accuracy.

COLIN MILLER

Innovation Program, this time to test the teleoperative capabilities of *IGAR*. Two years later, Anvari and his partners officially founded **Insight Medbotics** to increase access to MRI as the best imaging modality for soft tissue where precision and accuracy are crucial, and to commercialize the *IGAR* system, which received FDA 510(k) clearance for breast biopsy as its first clinical indication in 2023.

Fazila Seker, a co-founder and previous CEO of MOLLI Surgical, joined Insight Medbotics as CEO last May. (See "MOLLI Surgical: Restoring Safety and Dignity to Tumor Marking," MedTech Strategist," October 4, 2023.) From working with physicians to help breast cancer patients, Seker learned to place patients first and foremost in the provision of care. "We need to understand the patient's experience and work in tandem with physicians and hospitals to deliver better quality care that also recognizes patient diversity in different settings," says Seker. While device companies often prioritize their technology and find themselves hunting for a problem to

solve, the CEO explains, her focus is set on the patient in a movement away from systemic therapy and toward targeted medicine.

Anvari, who serves as Insight Medbotics' scientific advisor, is a tenured professor of surgery at McMaster University and has been involved in the adoption of robotic technology since the 1980s. His work in robotic laparoscopic procedures has been recognized internationally, and he has delved into remote surgery with the Canadian Space Agency, NASA, and the US military in regions with high signal latency. After seeing the potential of AI in the mid-aughts, Anvari grew the concept for IGAR into a series of robots specialized for targeted treatments for spinal, intracranial, and other applications. The next objective after that was early detection and treatment of solid cancers, with the breast as the first area of focus since other cancer indications such as prostate, kidney, and liver would require IGAR to operate deeper inside the body and closer to other sensitive anatomy. Having demonstrated safety

and efficacy with FDA 510(k) clearance for the breast biopsy device, *IGAR* serves as a technology platform from which to develop the technology for other indications.

Breast biopsy was a natural first regulatory indication for *IGAR* since it is an easily accessible area that facilitates development of complex technology. Insight Medbotics plans to expand development of the breast biopsy product to targeted therapy delivery for breast cancer, which aligns with its ultimate vision of advancing precision medicine and reducing reliance on systemic therapies that may come with toxicity for patients.

According to Seker, bringing medical devices and procedures into an active MRI has always been a challenge because of the high magnetic field strength and tight spatial confines. Anvari adds that several researchers have tried to develop MRI-friendly surgical systems but did not succeed in obtaining FDA clearance because of image degradation, an issue that MDA's advanced engineering team was able to help Insight bypass. A testament to their durability, MDA's robots deployed in space can operate for 20-plus years without repairs while withstanding dramatic temperature changes. IGAR's MR-safe construction mitigates the risk of potential projectiles in the MRI field. The company intends to design future iterations of IGAR to be capital equipment-agnostic, allowing it to attach any MRI table.

Insight Medbotics has been approached by MR manufacturers who have expressed interest in taking future *IGAR* models into hospitals using their capital equipment. The company is actively developing these partnerships as an avenue to accelerate distribution and adoption of *IGAR* systems. The CEO also mentions that pharmaceutical companies have expressed interest in using *IGAR* for drug delivery, and she sees such strategic partnerships as a means of accelerating accessibility for patients.

Currently, some practices fuse magnetic resonance and ultrasound imaging to perform biopsies using ultrasound, though this fusion has its limitations. Targeting cancers early in their life cycle can open treatment options to include local antibody injections before surgery is necessary, and IGAR shows as much promise for therapeutic delivery as it does for biopsy. "Our robotics standardize physician skill level by reducing variability from clinician to clinician because the robot takes over once the procedural plan is approved," says Seker before explaining that the technology may also reduce training time for new physicians.

To date, the start-up has completed a 30-patient breast biopsy study and plans to enroll future studies to investigate more indications, though modifications

#### Figure 1 IGAR System



Source: Insight Medbotics

to the technology would be necessary to optimize it for procedures in the abdominal cavity or other anatomical regions. Insight Medbotics' long-term goal is to build out a modular platform that will allow for easy customization with procedure-specific attachments while simultaneously centering on ease of use and minimizing both clutter and storage space demands.

While MR-guided breast biopsy is well addressed by existing methods, other biopsy procedures could leverage IGAR's 1 mm accuracy and automation to help more physicians see cancers earlier and target them with confidence. Seker therefore anticipates commercially launching a future version of IGAR in the next three to five years as a prostate biopsy system, an area where existing methods have known shortcomings, most notably for catching small or deep lesions in large prostates. In such cases, missed targets contribute greatly to patient anxiety. The technology's IP, including issued and pending patents, is under an exclusive worldwide license from CSii and MDA.

> The company expects to utilize existing image-guided procedural codes for reimbursement, since they do not preclude a robotic approach to qualify. Currently raising a Series A with a goal of \$24 million, Insight Medbotics has been supported by grant funding from the McMaster Seed Foundation as well as by individuals in the company's home of Hamilton, Ontario, which Seker calls "a very tightly knit community with lots of great resources for early-stage ventures." MTS

Posted on MyStrategist.com Feb. 7, 2024