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MEDTECH INNOVATOR
2019 MEDTECH INNOVATOR VALUE AWARD WINNER

OncoRes Medical

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YEAR FOUNDED

2016

WHO'S BEHIND IT

Katharine Giles, MBBS, medical doctor & assistant surgeon/ venture capitalist; CSO Brendan Kennedy, PhD, biomedical engineer, lead inventor of OncoRes' technology and a pioneer of micro-elastography; CMO Prof. Christobel Saunders AO, a cancer surgeon and also a professor at University of Western Australia

UNMET CLINICAL NEED

In order to fully resect a breast cancer tumor, the margins of the tumor must be ascertained at the risk of leaving cancerous tissue and requiring follow-up lumpectomy procedures or otherwise avoidable mastectomy. Currently, there is no suitably accurate, marketed device to scan the surgical cavity intraoperatively for remaining suspicious tissue once a tumor has been resected

SOLUTION

A handheld probe that combines optical coherence tomography and micro-elastography technologies (together "OCT-E") to detect malignant tissue with high accuracy and without using contrast agents or ionizing radiation

Breast Cancer

OncoRes: Shedding Light on Breast Cancer Tumor Removal

The treatment of breast cancer today commonly entails repeat breast conserving surgeries due to imprecise methods of locating and measuring tumors during surgery. These lead to unnecessary expenditures of over $1 billion across the US and Europe. To help surgeons reduce these follow-up surgeries, OncoRes Medical is developing a probe that detects residual tumor within the surgical cavity in real time using OCT-E.

by COLIN MILLER

Breast cancer is the most common type of cancer in women across the world, impacting nearly a quarter of a million women in the US annually and killing roughly 20% of those diagnosed, according to the CDC. Classifiable into several major types including ductal, lobular, and mucinous, tumors in the breasts can affect different areas of the tissue, and many of these tumors can be detected using elastography, a measurement of stiffness.

The technology penetrates tissue with near-infrared light, requires no harmful radiation or contrast agents, and provides image resolution on the micro-scale.

Sonographic elastography has been used in tumor diagnosis alongside standard ultrasound to compress the breast and take sequential ultrasound images to find portions of tissue with greater resistance. Pre-operative imaging is used by physicians to map the tumor size and location in preparation for a lumpectomy, however while the operation is in progress, surgeons lack a reliable means of ascertaining whether they have resected the entire tumor and may end up needing to perform follow-up lumpectomy procedures or otherwise avoidable mastectomies.

Australian start-up **OncoRes Medical Pty Ltd** is working to illuminate the intraoperative cavity with a handheld probe that combines optical coherence tomography (OCT) and micro-elastography (together "OCT-E") to intra-operatively assess the cavity for residual tumor in real time to a depth of 1mm. "Effectively what we're doing is translating the surgeon's sense of touch into a micro-scale image...it's enhancing something they already do, which is great in terms of integration into surgical workflow, training, and adoption," explains CEO Katharine Giles.

To the patients' benefit, the technology penetrates tissue with near-infrared light, requires no harmful radiation or contrast agents, and provides image resolution on the micro-scale. Giles first saw the technology in 2013 while

working for Brandon Capital, Australia's largest life sciences venture capital fund, searching for early-stage devices with a clear pathway to improving patient outcomes. After a Series A investment of AU$6 million by Brandon Capital in 2016, breast-conserving surgery was selected as OncoRes' first clinical indication, though the methodology could be applied to other cancers since variation in tissue stiffness is a common theme among cancers in other organs.

In a clinical study of 90 patients, the device in a benchtop setting identified cancer at the edge of lumpectomy specimens with 95% accuracy. Giles explains that such success is due to the combination of imaging techniques. While OCT is extremely useful for distinguishing dense tissue from adipose tissue in the breast on the micro-scale, healthy dense tissue and cancerous tissue may appear similar, and so overlaying micro-elastography, a quantitative measurement of tissue stiffness, improves the contrast between healthy dense tissue and cancerous tissue.

During a lumpectomy, the surgeon would use the probe inside the surgical cavity to identify tumor that has been missed, revealed by the resulting images on the attached console. This will enable the surgeon to decide if more tissue needs to be removed.

Although some devices exist in the same intraoperative market as OncoRes' probe, none analyzes the margin of resected samples and the cut edge of the surgical cavity, using micro-elastography, Giles says. Without a clear tumor margin, a second procedure will most likely be necessary, and this brings an increased risk of infection and other post-operative complications, including more extensive surgery. At present, Giles notes that around 40% of repeat lumpectomies become mastectomies.

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The team behind OncoRes is passionate about reducing the need for repeat surgeries. "It's incredibly important," Giles says, "for the patient to be set up with the best foundations, both emotionally and physically, for the battle they face ahead."

The research and development team at OncoRes has developed a broad intellectual property portfolio, currently totaling six patent families, including IP around various aspects of implementing OCT-E into a handheld probe. The patent families are form factor and indication agnostic and would provide additional value should the company eventually adapt the probe to other applications, either in specifically designed surgical tools or through retrofitting. To that end, the technology has been implemented in as small a form factor as a 19-gauge needle.

Having recently commenced *in vivo* human trials that should conclude by early next year, OncoRes will soon open a round of fundraising to see the company through to FDA clearance. (It recently received $25,000 as the 2019 MedTech Innovator Value Award winner.) Giles hopes to be able to run simultaneous trials for FDA and TGA (Australia's Therapeutic Goods Administration). Australia's R&D tax incentive program is helping support the necessary ongoing investment in research and development.

OncoRes plans to sell the device to hospitals and other surgical practices. The company is aware that the product will have to create value and address the needs of multiple stakeholders, including surgeons, payors, and hospital purchasing committees to enable market adoption. Having received strong positive feedback from the World Congress on Controversies in Breast Cancer in San Francisco where the device was previewed, it seems surgeons are as excited to use it as Giles is for its debut.