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Hand-held RF probe from Dune ensures lumpectomy margins

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A hand-held surgical probe could help surgeons obtain a clear margin during a single lumpectomy procedure, according to a report issued at the annual scientific meeting of the **American Society of Breast Surgeons** (Columbia, Maryland) in Baltimore, which concluded on Sunday. Developed by **Dune Medical Devices** (Caesarea, Israel), the BP probe provides information in real time to detect differences in electrical waveforms reflected from fresh tissue specimens.

Gil Rosen, vice president of Dune, told *Medical Device Daily* in an e-mail that the probe device and accompanying console were designed specifically for intraoperative use and, if necessary, in the lumpectomy cavity, enabling what he called "data enhanced surgery."

"The heart of the disposable probe units is Dune's proprietary sensor," he wrote. "This electromagnetic fringe field sensor is capable of sensing minute differences in electromagnetic properties within its immediate vicinity, namely a 7 mm

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wide and 1 mm deep area of breast tissue which is in direct contact with the probe's tip, at the time of the measurement."

The probe, Rosen wrote, has an "automatic, self-regulating, gentle, sensor-to-tissue attachment mechanism that ensures each measurement is taken in good contact conditions." The accompanying console unit contains the control, data input, algorithm system and display elements.

The probe works using RF spectroscopy, or "spectrum measurement of the issue in the radio frequency range of 0-1 GHz," Rosen wrote. How the probe reacts depends on the pathology of the tissue.

"With each measurement, Dune's BP sensor is resonating with the tissue and the resonance frequency is changed depending on the tissue's properties," Rosen wrote.

Key to each measurement is the ability to "control and limit the interaction volume of the area from which the data is collected."

In the study, researchers intraoperatively applied the probe to the surface of 41 fresh lumpectomy specimens. Probe output and pathology data were separately evaluated by two pathologists and recorded as positive or negative for malignancy.

To assess potential clinical outcomes, researchers assumed that if the data had been available during the initial surgery, a detected positive margin would have been excised immediately.

According to the data, the probe would have identified positive margins in nine out of 12 patients, potentially eliminating the need for additional surgery. It would be equivalent to a 7.3% positive margin rate, the company said.

"Assessing margins without the probe, the projected positive margin rate would be 29.3%," the company said.

Going forward, the company will be "continuing [its] clinical trials – currently each measurement point is compared to a permanent pathology of the same spots." Surgeons involved in the company studies are blinded to the results in real-time, Rosen wrote. Later on, there will be "work with the device 'unblinded' – in which actual re-excision reduction will be measured."

The U.S. is the company's "main target" for the device, which it hopes to have cleared by the FDA by the end of 2007. The company expects to secure a CE mark within a few weeks.

Rosen wrote that the company hopes to be able to sell the console to the end-user for under \$30,000 and the disposable probe for under \$500.

"We are extremely excited about giving breast surgeons this tool," Rosen wrote. "Later on we hope to make the technology available to additional surgical oncology procedures, where real-time, easy-to-generate data can enable a more complete excision, and superior decision-making."

Lorraine Taft, MD, principal investigator of the study and director of the breast center at **Anne Arundel**

Medical Center (Annapolis, Maryland), said in a statement that surgeons “currently have no technology that allows us to determine in the operating room whether we have removed all the tumor from a woman’s breast, which is why we sometimes have to take the patient back to remove more.”

Linsey Gold, DO, Breast Fellow at Anne Arundel Medical Center Breast Center, who worked closely with Tafra on this study, said, “The device would be expected to help guide surgeons in identifying in real time those patients with positive margins intra-operatively so that they could perform a ‘precision mastectomy’ – removing the tumor with clear margins and taking the least amount of tissue, thus leaving the best cosmetic result.”

The only methods of intra-op evaluation, Gold wrote in an e-mail to *MDD*, are “gross margin assessment, frozen section, touch prep cytology, intra-operative ultrasound, specimen radiography, [and] margin shave technique.”

Gold said the device “would definitely be widely accepted by all surgeons performing breast surgery.”

“It is easy to use, gives rapid, real-time margin assessment, it is based on sound technology that correlates well with gold-standard histopathologic evaluation and gives easily reproducible results,” Gold wrote. “There is no extra training, skill or education that would be required to fully utilize this technology. To date, and as far as we can tell, it provides the best, most reliable, intra-operative assessment of lumpectomy margins.” ■