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Novel Intraoperative Probe Effective in Assessing Lumpectomy Margins, Elusive DCIS

Dune Medical Device Holds Promise for Reducing Re-Excision Surgeries According to Two Studies Presented at ASBS

Phoenix, May 7, 2007--A novel intraoperative breast cancer probe demonstrated significant potential for reducing positive surgical margins in lumpectomy patients—including those with hard-to-detect, pre-invasive, ductal carcinoma in situ (DCIS)—according to two separate studies presented here at the American Society of Breast Surgeons (ASBS) Annual Meeting. A cancer patient with positive margins typically requires a second surgery, with accompanying trauma and expense, to re-shave tumor sites for adequate tissue removal. The Dune Medical (Caesarea, Israel) probe uses Radio Frequency Spectroscopy to characterize breast tissue in real-time during surgery to determine margin malignancy status and holds promise to reduce re-excision procedures.

Selected for oral presentation at the 2007 ASBS conference, the first study found that the device fully detected 86% of positive margin patients during surgery, potentially converting them to negative status during this initial procedure. In the study, intact lumpectomy specimens were sampled immediately following excision by applying the Dune probe to multiple measurement sites on each margin examined. The probe readings were compared with post-operative pathology results on the same precisely identified margin areas. Conducted at two medical centers, the trial analyzed 314 breast tumor margins with approximately 3600 measurement points.

The second study, presented as an ASBS poster, found that the Dune device was able to identify 20 out of 21 DCIS sites post-operatively on freshly excised breast cancer tissue as verified by pathology reports. This study involved 46 lumpectomy specimens and 282 measurement sites, which were carefully selected to exclude tumor-concentrated sites. The Dune device also identified pathologies for a full range of additional breast tumor types with complete or high degree accuracy.

According to lead study author Dr. Tami Karni of the Sackler School of Medicine, Tel Aviv University, Israel, and the Breast Care Institute, Assaf Harofe Medical Center, Israel, the primary objective of breast conservation surgery today is to achieve complete excision of tumors surrounded by a rim of pathology-free tissue. However, a large percentage of women must undergo re-excision surgeries because post-operative pathology reports show margin disease.

“Today, no accurate method exists for determining margin malignancy status intraoperatively. Given this, the Dune device could spare a significant percentage of women additional surgeries by enabling highly accurate tissue classification while patients are still in the operating room and appropriate interventions can be made,” said Dr. Karni. She also points out that positive DCIS margins are especially difficult to detect intraoperatively. “The Dune probe holds tremendous promise for enabling treatment of DCIS in a single surgery, minimizing cosmetic impact and physical and emotional trauma of follow-up procedures.”

Both studies were carefully designed to maximize accuracy, with device readings and pathology reports focusing precisely on the same sites. In the intraoperative study, each margin was uniquely defined in orientation and marked with color coded ink to ensure histological analysis of the same surface. The study assumed that a clinically safe margin is 0.1 cm. However, data was analyzed for additional margin depths from 0 to 0.4 cm and showed a similar degree of accuracy.

“Accurate tissue characterization during surgery has clear and significant benefits but has long challenged medical science. The Dune intraoperative margin assessment probe promises to have an important impact in helping surgeons to achieve that goal,” said Dr. Dan Hashimshony, Dune Medical CEO.

The Dune margin assessment device consists of a sterile, hand-held probe and portable console. When the probe tip is applied to an excised lumpectomy segment, radio frequency signals are transmitted into the tissue and reflected back to the console where they are analyzed using a specialized algorithm to determine tissue status. With easy manipulation and instantaneous results, the technology is designed for easy integration into existing surgical workflow. The device is currently undergoing additional studies in the U.S. and Israel.

About Dune Medical Devices, Ltd.

Founded in 2002 and headquartered in Caeserea, Israel, Dune Medical Devices, Ltd. is a privately owned venture-funded medical device company, backed by Apax Partners. Dune is engaged in the development and commercialization of devices for real-time tissue characterization. Dune Medical’s devices facilitate complete, therapeutic excisions in surgical and interventional oncology procedures. The RF Spectroscopy probe system described above is undergoing extensive clinical trials in Israel. Preparations for additional U.S. trials are currently underway.

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