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Assessing Tissue Dielectric Constant (TDC) Measurements to Differentiate Breast Cancer from Healthy Breasts

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Study Goals and Rationale

Measurement of the Tissue Dielectric Constant (TDC), also known as permittivity, has proven to be a valuable non-invasive method for rapidly assessing skin tissue properties in various physiological and pathophysiological conditions. One area of great interest that has not been adequately explored is whether differences in TDC values associated with cancerous tissue, assessed in situ, can provide valuable information when evaluated in vivo. Of specific interest to the present work is the potential utility of TDC measurements in differentiating a breast with a malignant tumor from one with either a non-malignant tumor or no tumor at all. Prior workers have examined breast tissue samples obtained from normal breasts with samples obtained from breast-reduction procedures and have compared malignant and non-malignant tissue. The conclusion was that the TDC of malignant tissue versus adipose-dominated tissues was extensive. In contrast, the differences between malignant tissue and normal glandular/fibroconnective tissues were minor, being no more than about 10%. More recent studies of breast tissue samples, spanning the range of 500 MHz to 2.5 GHz, indicate that permittivity values for malignant tissue are greater than those for non-malignant tumor tissue, which in turn are greater than those for normal breast tissue. The dielectric constant of normal breast tissue has also been assessed at 3.2 GHz but not at 300 MHz, which is an order of magnitude lower and is the planned test frequency. These workers reported TDC values for breast fat to range from 2.8 to 7.6, which is an expected value for low-water-content fat. The impact of water content and distribution on breast fat permittivity has been assessed via tissue models, which have shown a moderate interaction. Based on the above information, it is clear that there is a plausible expectation that measuring breast tissue in vivo may reveal significant differences in TDC values between breasts with malignant versus benign tumors. To our knowledge, such measurements have not been done by anyone or group. Such measurements and the analysis of the forthcoming data form the basis of this research study. The primary goal of this research is to address and answer the questions outlined in the following specific aims.

Specific Research Questions and Aims

(1) When measured directly over the tumor site, does TDC differ from that which would be measured on a healthy breast? And do such differences, if detected, depend on whether the tumor is malignant or benign? (2) When measured at a standardized anatomical site, does TDC differ from that which would be measured in a healthy breast at the exact location? And do such differences, if detected, depend on whether the tumor is malignant or benign? (3) When measured directly over the tumor site, does TDC differ between the presence of a malignant vs. benign tumor, as would be measured on the same breast? (4) If TDC differences between malignant and benign tumors are determined, in what way are such differences related to tumor parameters? (5) What is the normal variation in TDC values in healthy breasts?

Methods

The specific tests consist of the measurement of TDC values of women who are already scheduled to undergo an ultrasound-guided diagnostic biopsy of the breast performed by Dr. Weingrad. During all measurements, the participant will assume a supine position, with the head of the bed adjusted to a thirty-degree angle. Participants will lie comfortably with their arms positioned just behind their head throughout the measurements. A total of four sites will be measured, two on each breast: The first and second measurements will be made at the 12 o'clock position of the breast, with the probe lining up to the periphery of the subareolar region of each breast (see image in Data Collection Form). The third measurement will be taken at the site of the mass, with the probe contacting the skin directly superficial to the mass. The fourth measurement will be taken at the mirror-image location on the contralateral breast. Each of these four sites will be measured with the probe a total of three times, all in succession, alternating between each breast. Each measurement will be done by gently touching the probe to the skin for 10 seconds or less, before moving to the next site. All measurements will be completed in less than 5 minutes.

Study Population

Women over the age of 18 who have either non-palpable or palpable breast masses that have been identified as abnormal by mammographic, ultrasound, and/or MRI imaging modalities, who are planning to undergo surgical biopsy performed by Dr. Weingrad, MD, a breast cancer surgeon. The initial intention is to evaluate a maximum of 150 subjects.

Exclusion Criteria

Women with skin that is not intact, or those with lesions or ulcers over the anterior thoracic wall, will be excluded from the study. Women with a history of prior breast cancer or those who have received radiation/ or have had an exposure to radiation therapy throughout their lifetime, for any reason/medical condition, will be excluded from participating in the study. Women with a history of breast implants or those who have undergone unilateral breast augmentation or reconstructive surgery will be excluded from this study. Women with a pacemaker, Implantable Cardioverter Defibrillator (ICDs), and/or Left Ventricular Assist Device (LVAD), or any implantable wires will be excluded from this study. Women who are pregnant will be excluded from the study.

Analysis

The analysis will be directed toward answering the following fundamental questions: 1. At the mass site, does the TDC value differ from the healthy breast? 2. At the mass site, does the TDC value differ from the standard site? 3. What is the normal variation in TDC values of healthy breasts among women? 4. How does the TDC value vary by site in healthy breasts? 5. What difference can be seen in the TDC value in affected breasts with masses that are either malignant or benign? 6. Are there differences in TDC value that depend on the size and pathological type of mass? Statistical significance is judged by paired t-tests with a p-value of <0.01 ($0.05/5$) accepted as evidence of a breast-differential at the selected sites.