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Title: Breast-Conserving Surgery using NaviKnife Technology: Pilot Study on Non-Palpable Tumors

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Abstract:

Positive margins in breast-conserving surgery are associated with a higher risk for local recurrence despite adjuvant therapy. Current surgical strategies have a reexcision rate for positive margins as high as 25%. We have developed NaviKnife, a real-time electromagnetic navigation system, which defines (contours) the desired tumor resection margins using ultrasound and allows tumor movement to be followed in real-time during surgery. Our initial study done on breast phantoms showed NaviKnife decreased the positive margin rate from 42.9% (wire-localization alone) to 19.0% (NaviKnife). Our study on palpable tumors revealed that tumor contouring time takes an average of 8.44 minutes and that NaviKnife was safe and easy to use intraoperatively.

Twenty-five patients with a single non-palpable breast tumor will be recruited in this pilot study to assess the use of NaviKnife technology in breast-conserving surgery for non-palpable tumors. Feasibility will be assessed by demonstration of safety and sterility, acceptable duration of the operation and tumor contouring time, as well as positive margin rate.

To date, 9 patients (mean age 65.1 years) have been recruited and have undergone a partial mastectomy using the NaviKnife technique. The mean operative time was 81.75 minutes for partial mastectomy with sentinel node biopsy (from skin incision to closure). The mean tumor contouring time was 4.99 minutes. All margins were clear of invasive carcinoma. One specimen had a positive margin for ductal carcinoma in situ (positive margin rate of 11.1%). There were no complications or breaches in sterility during surgery. Feedback questionnaires stated that NaviKnife navigation was easy to use and a useful guide to surgical excision of non-palpable tumors.

NaviKnife provides useful real-time feedback to surgeons. This pilot study suggests that NaviKnife technology could reduce the incidence of positive margins and improve treatment outcomes in breast-conserving surgery.