

**Use of biopsy marker in patients undergoing neoadjuvant chemotherapy.**

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**Background:** Biopsy site markers serve as surrogate surgical targets for small cancers occult to imaging after image-guided biopsy. Patients with a favorable response to pre-operative neoadjuvant therapy may also require a surrogate surgical target. Using serial sonography, we assessed the longevity and usefulness of a mammo- and sonographically visible marker in patients undergoing pre-operative therapy.

**Methods and Materials:** Cancer patients in a study protocol gave informed consent for marker placement and follow-up sonography during their neoadjuvant therapy. Prior to therapy, patients had a marker placed after ultrasound-guided harvesting of protocol defined tissue. Markers were placed through an 11 gauge (6 patients) or an 8 gauge (4 patients) directional vacuum-assisted biopsy device. The marker (Gel Mark™ Ultra, SenoRx, Aliso Viejo, CA) is composed of 11 synthetic bioresorbable pellets and an embedded stainless steel wireform providing sonographic and radiographic visibility. Response to therapy and sonographic visibility of the marker were assessed on follow-up exams at 3-5 and 6-10 weeks following marker placement.

**Results:** From 4/8/02 through 11/14/02, 10 patients (aged 34-67) diagnosed with invasive cancer consented to this study. The marker was visualized sonographically during deployment in all cases and in the biopsy cavity on mammography in all cases (except in one chest wall tumor too posterior to be imaged by mammography, the marker was visualized in the specimen radiograph). The marker was visualized by ultrasound in 9 cases at 3-5 weeks and in 7 cases at 6-10 weeks. Of the 10 patients, 8 responded to therapy, with no definitive residual tumor seen by ultrasound in 2 patients (at 7 and 9 weeks). Of the six patients who underwent breast conserving therapy, the marker was identified in all six lumpectomy specimens.

**Discussion:** A new tissue marker for breast biopsies, the Gel Mark Ultra, was sonographically visible up to 9 weeks after placement (the marker wireform is visible mammographically). Placement of a biopsy site marker prior to neoadjuvant chemotherapy facilitates breast conserving therapy in patients with no imaging evidence of residual tumor.