

Title: Initial experience with a radiofrequency (RF), circumferential, vacuum assisted biopsy device for ultrasound-guided breast biopsies.

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Background: We evaluated the efficacy, ease of procedure and safety of a new co-axial biopsy needle (SenoCor 360, SenoRx, Aliso Viejo, CA) using RF energy to target and biopsy breast lesions with ultrasound guidance.

Materials and Methods: Following IRB approval, 20 patients scheduled for ultrasound-guided biopsy gave informed consent and were prospectively enrolled between October 2001 and March 2002. The biopsy device is comprised of a co-axial guiding cannula and a biopsy probe that incorporates an RF cutting tip, circumferential cutting ring and a 360 degree vacuum. The RF is used to penetrate breast tissue and cut lesion specimens. Parameters evaluated included breast composition, procedure time and number and weight of samples. Ease of positioning, penetrating and sampling breast tissue were assessed on a 5 point scale from 1 (very easy) to 5 (very difficult). Pathologists evaluated the adequacy of the specimen for histological diagnosis. Patient adverse effects were assessed during the procedure and 7-10 days following the procedure.

Results: Of 20 attempted biopsies, 18 were successfully completed and 2 had malfunctions precluding use during biopsy. In 82% of cases, the breast composition was moderately dense. Procedure time (from skin insertion to removal of device after the final specimen) was 1:32 to 17:00 minutes (mean 7:31 minutes). Lesions were all masses ranging in size from 7-28mm (mean 15mm). An average of 4 (range 2-7) specimens were obtained, which included complete excision of the ultrasound imaging features of 6 fibroadenomas. The average specimen weight was 85mg with a range of 50-180mg. Concordant histological diagnosis was rendered in all cases. The device was judged very easy (1 on the 5 point scale) to hold and penetrate breast tissue in 90% of cases. Lesion penetration and sampling were rated very easy in 70-80% of cases. There were no significant complications.

Discussion: Initial results demonstrated that the SenoCor 360 breast biopsy device was ergonomic, easy to use and provided excellent operator control of positioning during targeting and sampling. The samples, acquired quickly, were significantly larger (approximately 6 times) than those obtained from standard spring-loaded core needle devices.