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Title: Multi-center evaluation of a new coaxial, vacuum-assisted biopsy device for ultrasound-guided breast biopsies

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Purpose: To evaluate performance and ergonomics of a new vacuum-assisted ultrasound-guided breast biopsy device (SenoCor 360™, SenoRx, Aliso Viejo, CA.).

Methods: 74 patients were biopsied at 4 centers from 12/2002 – 4/2003. The device has a radiofrequency tipped probe to access the lesion, 360 degree vacuum, a circumferential cutter to acquire samples and a coaxial cannula for multiple sampling. Patient and procedural data included breast composition, lesion characteristics, complications, number of samples, procedure time and histologic diagnosis. Quality of samples, lesion access and ergonomic features were assessed qualitatively and compared to prior experience with other devices.

Results: 78 of 79 biopsies were completed in patients from 20 to 83 years old. Breast composition was dense in 68% and lesions were assessed as dense or fibrotic in 58%. Lesions measured 4 to 110 mm with 94% masses. On average, 4.8 circumferential specimens (range 2-19) were obtained in 2-20 minutes (median 6). Safety and patient comfort were rated comparable to other devices. Sample quality, breast and lesion penetration, and positioning ease/accuracy were rated superior ($p<0.01$, Wilcoxon sign-rank test). 31 cancers, 43 benign lesions and 1 ADH were diagnosed without upgrades or discordant diagnoses at surgery. No complications required intervention.

Conclusions: Ultrasound-guided SenoCor 360 breast biopsies are safe, ergonomic and provide large diagnostic samples. Compared to other biopsy devices, it is easier to target lesions and position for sampling, particularly in dense tissue.