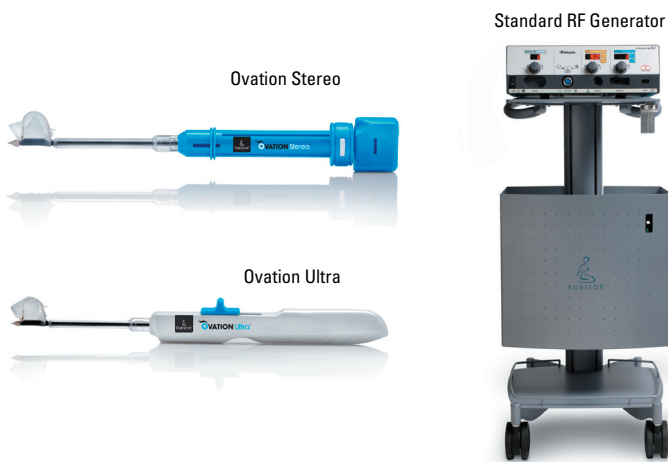


Large Intact Sample Device for a Non-surgical Alternative to Removal of Fibroadenomas; 6 Month Follow-up.

Richard E. Fine, MD, Beth A. Boyd, RN.
Advanced Breast Care, Marietta, Georgia

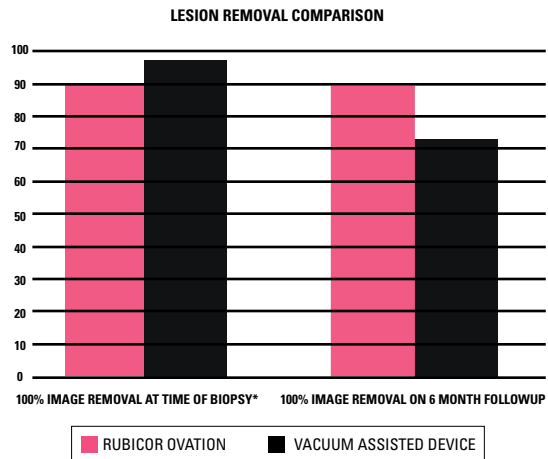
BACKGROUND

Fibroadenomas are the most common benign tumors of the female breast. They account for 50% of all breast biopsies performed. When offered the option of conservative management, most women will prefer excisional biopsy. As a result fibroadenomas account for a significant proportion of open surgical biopsies performed for benign breast disease. An alternative to excision with open surgery is acquiring a surgical quality sample using a percutaneous, office based procedure. This can be accomplished by using a biopsy device capable of excising, capturing and extracting an intact tissue sample through a small incision. We report our initial experience of fibroadenoma removal using the large intact specimen removal biopsy device.



RESULTS

All of the procedures were performed with image guidance. Thirty-one cases (79%) utilized ultrasound and 8 (21%) of the cases utilized stereotaxis. An ultrasound or mammogram was performed at the 6 month follow-up evaluation. Thirty-five (90%) of the cases completely removed the fibroadenomas at time of biopsy and showed no lesions during the 6 month post-biopsy evaluations. One case was lost to follow-up because the patient moved out of the country. Four of the thirty-nine (10%) fibroadenomas were not completely removed at time of biopsy, but showed stability at the 6 month follow-up.



MATERIALS AND METHODS

A large intact biopsy system, the Rubicor Ovation, was used to treat fibroadenomas in a nonrandomized fashion. Thirty-nine patients were treated and had follow-up evaluations at 6 months post-biopsy. Four early cases were treated with a 4g device. The remaining procedures were performed with a 14g device. This procedure is completely office-based using only local anesthetic.

CONCLUSIONS

The results at six months post-biopsy demonstrate the effectiveness of fibroadenoma removal utilizing a percutaneous approach. The Encapsule offers a quick, precise office-based alternative to surgical excision of fibroadenomas while maintaining the intact pathologic architecture. This study demonstrates an improvement in image absence at 6 months compared with other studies utilizing a vacuum-assisted biopsy device, taking multiple core samples to achieve removal of image evidence of the lesion.

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