

Intact Specimen Capture and Collection of Image Detected Breast Lesions via Percutaneous Radiofrequency Device.

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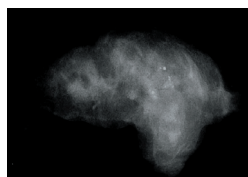
Intact Specimen Capture and Collection of Image Detected Breast Lesions via Percutaneous Radiofrequency Device
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OBJECTIVE:

The number of stereotactic and ultrasound guided breast biopsies has steadily increased over the past several years accompanied more recently by a surge in large core and vacuum assisted biopsy devices. This is largely based on the concept that complete removal of the imaged abnormality will be more efficacious and allow for a more complete diagnosis in most patients. While this seems reasonable, removing the abnormality in numerous pieces does not allow for optimal pathologic assessment especially of size and margin status and does not allow for specimen orientation. We evaluated the ability of a new core biopsy device, the Rubicor Ovation, which is capable of removing large intact samples. Approximately 100 specimens have been performed with this device to date. Early specimens were obtained to verify the safety and efficacy of the device. Once this was established, twenty-five consecutive samples were obtained from seven different sites in an effort to document sample size, pathological variables and patient comfort.



Specimen sample removed by biopsy device



Radiographic image of specimen post-biopsy



Cross sectional ultrasound view of extended loop encapsulating targeted lesion

METHOD:

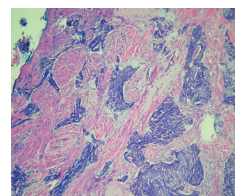
Seven sites participated in this trial. 25 consecutive patients who consented for the new procedure and who presented with a palpable mass or an image detected lesion measuring less than 2.0 cm in maximal size, were biopsied with the Ovation device. Specimens were sent to the routine pathology laboratories which normally processed specimens for the individual sites. Pathology reports were collected and assessed for pathologic diagnosis, ability to estimate lesional size, radiofrequency induced artifacts, ability to perform prognostic markers and ability to assess margins if appropriate. Patient comfort was assessed on a 1-10 scale.

RESULTS:

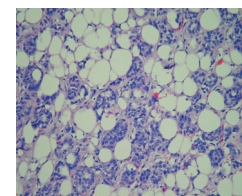
All procedure were performed with image guidance. Sixteen cases utilized ultrasound and 9 cases utilized stereotaxis. Local anesthesia was used in 22 cases and general anesthesia was used in 3 cases. The average sample size was 2.1 x 1.0 x 0.6 cm. The average patient comfort score was 1.27 with 1 representing no discomfort. Pathologic diagnosis was achieved in all cases. Lesional size was easily assessed. RF artifacts were related to the amount of energy utilized and averaged approximately 1mm around the margin of the specimen. Prognostic markers were assessed in only a subset of cases but correlated with the results of the lumpectomy specimen.

CONCLUSION:

The Ovation device can obtain large and intact specimens that allow for complete pathological analysis. This technology, which may be performed under ultrasound or stereotactic guidance, is promising and may have significant advantages over multiple core biopsies.



Thermal artifact at the edge of specimen



Well preserved tumor in center of specimen

INTRODUCTION

Today it is projected that more than 1.5 million biopsies are performed annually in the United States. More than half of these are open surgical biopsy procedures. Open surgical biopsy is still considered the gold standard because, compared to the majority of minimally invasive procedures, the open procedure provides a single, large biopsy specimen. The single biopsy specimen provides physicians with the information necessary to make a diagnosis and reduces the likelihood of re-operation or upgrading at the time of a cancer operation.

PROCEDURE

The percutaneous Ovation breast biopsy Device is designed to perform a breast biopsy by removing a single contiguous mass of tissue through a small incision. The system is comprised of a 6mm diameter biopsy device capable of excising, capturing and extracting an intact 2.5 cm diameter tissue sample. The collection mechanism is a combination of bag and RF scalpel deployed in-vivo that cuts, captures and completely isolates the targeted lesion or abnormality and, in some cases, its surrounding margin.

The Ovation device is unique in that it obtains a single contiguous specimen similar to that provided by open surgical biopsy. In the event that cancer is found, important prognostic information is preserved with this approach which makes it easier for oncologists to formulate recommendations. This novel device is compatible with either stereotactic or ultrasound imaging and has received 510(k) clearance from the Food and Drug Administration.

CLINICAL UPDATE

Since submission of the abstract, this device has been used clinically over 100 times. Approximately 30% of these cases were stereotactic and the remainder were ultrasound guided. Pathology was performed by 10 different pathology labs. Most of the lesions were benign however 5 reports detail capture of carcinomas with clear margins, the largest being 2 cm in diameter. While each of these patients were subjected to a follow up lumpectomy, the expectation is that clinical study will validate the ability of this device to excised small cancers with clean margins.

CONCLUSIONS

Image guided core biopsy is a major advancement in the treatment of breast abnormalities.

There has been a general trend towards using large core and vacuum assisted biopsy devices for ill defined lesions and microcalcifications since they acquire significantly more tissue than conventional spring loaded biopsy devices.

These devices remove the lesion in pieces compromising the pathologic assessment of size and margin status as well as specimen orientation.

Intact removal of these abnormalities is possible with the use of an RF wire loop with collection of the specimen in an attached bag that can be easily removed.

Minimal thermal artifact is noted at the edge of the specimen and is directly correlated with the amount of energy delivered. The device allows for the intact removal of image detected abnormalities with preservation of specimen orientation, and the ability to assess size and margin status when tumor is present.

Further studies need to be performed to determine the maximum amount of breast tissue that can be safely removed as an intact specimen and the optimal amount of RF energy that balances easy cutting and thermal artifact.