

## Breast Disease Management And Treatment: Prepare For A Paradigm Shift

by James Vetter, MD

The golden standard for breast disease treatment has lost its sheen. Physicians and patients desperately need minimally invasive procedures that provide better clinical outcomes and superior cosmetic results.

Each year, more than 1.6 million women have breast biopsies for suspicious lesions. Over one million of them will undergo invasive surgery to have a biopsy and/or to remove benign or malignant lesions. Compared to other areas of medicine that have adopted less time-consuming, technologically advanced percutaneous procedures, breast disease treatment is stuck in the dark ages.

But technological advances are taking shape. Medical device companies aim to alter the gold standard of open biopsy to percutaneous procedures with new technologies and tools. The upshot: Physicians will soon be able to perform breast disease procedures more precisely and with better results.

### New technologies revolutionize the breast care industry

The most common types of breast disease surgeries are lumpectomies (breast-conserving removal of malignant tissue) and mastectomies (whole breast removal). While studies show lumpectomy procedures – combined with radiation treatment – yield results comparable to mastectomy, some considerable shortcomings are associated with this 40-year-old surgical technique.

Physicians perform breast disease procedures without using ultrasound, making it impossible to visualize the lesion size and to accurately calculate how much tissue removal is needed to completely remove the lesion. As a result, approximately 30 percent of women who undergo breast cancer surgery need further surgery to remove additional cancerous tissue. Breast conserving therapy procedures are also time-con-

suming and require removing large volumes of breast tissue. For the patient, this can result in breast deformities and large scars.

However, an innovative, ultrasound-guided device developed by Rubicor Medical is attempting to change the results of open surgical breast biopsy and tissue removal procedures. The device uses an RF (radio frequency) powered loop that provides precise lesion capture, while significantly reducing procedure time and improving cosmetic outcomes.

The procedure, called Phantom Soft Tissue Excision, allows the breast surgeon to view the lesion under ultrasound, while excising the tissue. The surgeon makes a tiny incision in the breast, and inserts and positions the Phantom beneath the lesion.

Next, the surgeon rotates the device's RF-loop counter-clockwise around the lesion to excise it from healthy breast tissue. Another small incision is made to remove the excised tissue from the breast. This procedure may result in the removal of significantly smaller volumes of tissue and a potentially smaller incision than other standard procedures.

### Rubicor Medical's Phantom Flexible Loop Electrosurgical System

Recent case experience with the Phantom has shown up to a 76 percent reduction in procedure time (skin nick to incision closure) when compared to other tissue removal procedures (approximately 10 minutes using the Phantom compared to about 64 minutes).

In breast disease procedures like lumpectomies, surgeons use scalpels or electrocautery knives to cut through tissue. The extracted sample will have irregular, jagged edges often due to the inability to visualize and locate the lesion. The Phantom's uniformly shaped loop avoids this by cutting through tissue and creating a more uniform cavity in the breast once the tissue is

removed. By doing so, the Phantom may have the potential to optimize accelerated partial breast brachytherapy, a new post-surgery cancer treatment that uses localized, internal radiation in the cavity to prevent further cancer growth.

Since commercializing in May, surgeons have successfully completed more than 100 cases using the Phantom. This year, Rubicor plans to conduct a clinical trial and registry to collect clinical data and to publicize the results.

### Further advancements in breast disease management

Outside the operating room, major technological improvements are occurring in breast biopsy and benign tumor removal procedures. Breast biopsies can either be performed in a physician's office or in an operating room. Many patients may opt for biopsies to be performed in the physician's office under local anesthesia. Here the physician removes samples of tissue from an abnormal mass or lesion.

Often, the procedure involves multiple insertions of a biopsy needle to retrieve adequate tissue samples for pathology analysis. This usually requires several samples, and is potentially time-consuming, not to mention uncomfortable for the patient.

However, advances in technology are attempting to reduce procedure time and increase patient comfort. Rubicor is addressing the multi-insertion biopsy technique through development of a product called Flash. It's an FDA-approved, minimally invasive breast biopsy device that lets physicians take and view multiple samples of breast tissue with one insertion.

This single insertion capability and automated sampling may reduce procedure time, increase ease of use, and potentially yield better tissue samples for improved pathology analysis. In addition, unlike other biopsy devices on the market

that require expensive equipment, Flash does not require its own customized power generator. This can save physicians up to \$20,000 in capital costs.

### Rubicor Medical's Flash Breast Biopsy Device

Biopsy procedures generally find about 80 percent of all breast lumps harmless and 50 percent to be specific types of benign mass, known as a fibroadenoma. These types of tumors can grow over time and become uncomfortable. But they are usually not dangerous to the patient.

Often, in the physician's office, a small incision is made in the breast to remove the fibroadenoma piece by piece. As such, current excision devices might require removing as many as 20 individual pieces to remove the entire tumor.

Rubicor Medical has developed another minimally invasive device called the Halo Breast Biopsy Device, which enables the physician to percutaneously excise an intact tissue mass from the breast in an office setting. Like Phantom, the Halo device uses an RF-powered loop design to cut around the lesion. The physician makes a small puncture in the skin to insert the device and to remove the tumor, which is collected in a small bag attached to the loop and removed from the patient's body.

These tools may raise the bar in the advancement of biopsy and tissue excision treatments, and improve the care and comfort of patients faced with breast disease. Researchers are already at work developing other technologically advanced devices that will revolutionize the way breast care is currently managed and treated. ☺

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