



MEDICAL INNOVATION: VACUUM-ASSISTED BREAST BIOPSY (VAB) (MEDICAL DEVICE: DIAGNOSTIC)

Physician: Fred Burbank
Industry: Biopsys, Johnson & Johnson

Situation

Invasive biopsies involving high costs and physical scars

Breast cancer represents one of the biggest threats to women's health worldwide. The disease strikes one in eight women in the U.S. alone, making it the most common form of cancer other than skin cancers, and more than 200,000 cases of invasive breast cancer are diagnosed each year nationally. Further, the National Institutes of Health estimates that breast cancer is the most expensive cancer each year, accounting for \$16.5 billion in medical costs in 2010.

While early detection in the form of mammogram screening over the last forty years has significantly lowered the death rate from breast cancer, mammograms don't always give a complete picture. Very often, lesions detected by a mammogram require additional analysis in the form of tissue biopsies in order to give physicians sufficient information to tell if the growths are cancerous. Until recently, however, biopsies required an invasive surgical procedure several hours in length, involving high costs and often producing substantial physical scars.

Physician-Industry Collaboration

A car-theft fighter turns his skills to medical innovation

In the late 1980s, an assistant clinical professor of radiology at Stanford, Fred Burbank, had an idea that would transform the way breast cancer biopsies would be conducted. He reasoned that a small, needle-shaped probe could be developed with vacuum capabilities, enabling it to take multiple tissue samples using just one incision. In Dr. Burbank's view, such a device could be used in place of invasive surgical sampling procedures on the one hand, and so-called "core needle" biopsies that involve multiple needle insertions, on the other.

While Dr. Burbank had never developed a medical device before, he was no stranger to inventions. Less than a decade before, after both he and his wife had their car stereos stolen, they designed a simple armored shield that would fit around the front of an in-dashboard car stereo and lock into place. They obtained a patent for their product and founded a small company, Audio-Safe, and later sold their product line to a company in Alabama.

With his experience as an entrepreneur, Dr. Burbank set to work realizing his idea for a vacuum-assisted breast biopsy device, and in 1993 founded a start-up company named Biopsys with the help of Dr. Tom Fogarty, an experienced medical device inventor colleague from Stanford. Biopsys gave Burbank the resources and funding to make his vision into reality, and the company developed the Mammotome® biopsy device, allowing for quick multiple captures of breast tissue samples through a very small (0.1") incision leaving women with hardly a scar.

With ultrasound guidance, a physician is able to insert the device probe through the small incision and position it near the lesion to be biopsied. The physician then presses a button on the device and vacuum power pulls a small sample of tissue and slices it for collection in the probe. The entire procedure takes less than an hour, and recovery is close to immediate.



Innovation Benefits

Over three million biopsies worldwide

Since its introduction in 1995, over three million women worldwide have undergone minimally invasive biopsies using so-called vacuum-assisted breast biopsy (VAB) devices. In a 2005 scientific [paper](#), 23 leading surgeons, radiologists, pathologists and oncologists said that when biopsies are required, minimally invasive biopsies should be the procedures of choice rather than open surgical biopsies. And, since only some 20% of breast biopsies register as positive, minimally invasive VAB procedures can help many women avoid open surgery altogether.

In addition, the VAB device and minimally invasive breast biopsy is cost-effective compared to traditional biopsy methods. A [study](#) comparing the total costs of VAB to open surgical biopsy found the overall cost advantage to the VAB procedure ranges from \$314 to \$843 per procedure, depending on the facility type.

Patient Benefits

A seasoned traveler grounded by a threat of cancer

As described in AdvaMed's [Profiles in Progress You Can See](#), Diane Dodge was a seasoned traveler and never let a thing stand in her way of seeing the world. But after she lost her sister-in-law to breast cancer, Diane was forced to pause and take her own health into consideration. She decided to have what she thought would be a routine mammogram, but when the procedure uncovered two lesions, Diane was suddenly grounded.

To determine if these were cancerous, Diane's physician immediately ordered several biopsies of her breast. One of the lesions, which turned out to be benign, was able to be biopsied with a minimally invasive technique known as core needle.

The other lesion was more problematic. Similar to nearly 50 percent of the 1.6 million breast tumors biopsied each year, it was hard and marble-like. Unable to penetrate it using a core needle device, her physician used a minimally invasive VAB biopsy device.

Using this device, Diane's physician was able to examine a section of the troublesome tumor, and thankfully pathology diagnosed it as benign. After her VAB procedure, Diane said, "It didn't hurt in the slightest, and it gave me peace of mind to know I was being treated with the best technology available."