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A NEW OPTION FOR BREAST TISSUE EXPANSION

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Breast cancer, commonly considered one of the most dreaded diagnoses a woman can receive, affects millions of women in the United States. Breast cancer is the second most frequently diagnosed form of cancer in US women (skin cancer is No. 1). According to the American Cancer Society, 226,870 new cases of invasive breast cancer and 63,300 new cases of in situ breast cancer will be diagnosed in US women in 2012.[1] In addition, 39,510 women are expected to die of this disease this year. The 5-year survival rate for female breast cancer has risen from 63% in the early 1960s to 90% today, meaning that the vast majority of women who develop breast cancer will enjoy many years of life after treatment for this disease.

Treatment for breast cancer is tailored to each woman's needs, and depends on tumor size, extent of spread, and other factors such as patient preference. Most women undergo a lumpectomy (surgical removal of the tumor and surrounding tissue) or a mastectomy (surgical removal of the breast). For women who undergo mastectomy, one decision that must be made is whether or not to undergo breast reconstruction, which can be done or started at the time of the mastectomy or at a later date.[1] Breast reconstruction typically involves use of permanent implants filled with saline or silicone or use of tissue from other parts of a woman's own body.[2] The American Society of Plastic Surgeons reports that 93,083 breast reconstruction surgeries were performed in 2010, representing an increase of 8% from the previous year.[3]

BREAST TISSUE EXPANSION

Many women undergoing breast reconstruction require tissue expansion prior to placement of the permanent breast implant.[4] Tissue expansion allows use of the patient's own skin from the breast area instead of using skin grafted from another area of the body or re-engineered tissue products to cover the implant. In conventional tissue expansion, an unfilled silicone bag is placed under the remaining skin of the chest wall in the surgical pocket under the pectoral muscle. The bag is then partially filled with saline at the time of surgery—allowing the surgical pocket to be filled while avoiding putting pressure on the incision. The incision then heals for about 3 weeks, at which point the process of inflating the expander begins.

A bolus of saline is injected through a magnetic port located on the surface of the expander, just under the patient's skin. Gradual inflation with saline

injections is continued on a weekly or biweekly basis. The rate at which the expander is filled depends on the preference of the surgeon and the condition of the patient's skin; a typical case takes several months. The needle-based saline injections are done under sterile conditions in the surgeon's office. Care is taken to avoid overfilling the expander, which can result in ischemia of the tissue. This procedure is repeated until the tissue is expanded to the desired size of the permanent implant. Of note: Saline expanders distend the skin in all directions; the resulting shape may not resemble the natural shape of a breast.

Hershman et al[5] used the Perspective database to identify 106,988 women with breast cancer who underwent mastectomy between 2000 and 2010. Fewer than one-fourth of these women (22.6%) were found to have undergone immediate breast reconstruction. The investigators were able to assess only those factors listed in the database. For example, they found that reconstruction was less likely with increasing age, black race (odds ratio [OR], 0.66), rural hospital location (OR, 0.48), a non-teaching hospital (OR, 0.82), and the presence of more than two comorbid conditions (OR, 0.72).

AeroForm™

A new type of breast tissue expander called AeroForm™ has been developed for use in post-mastectomy patients who are undergoing reconstructive surgery (Figure). Last fall, AirXpanders, the company developing AeroForm, received an investigational device exemption from the US Food and Drug Administration to proceed with a clinical trial to evaluate the new technology. This pivotal phase II, prospective, randomized, controlled, open-label study is designed to compare the performance and safety of AeroForm with a traditional saline breast tissue expander in an estimated 138 patients, who will be randomized in a 2:1 ratio. Final enrollment in the trial is planned for this summer.

FIGURE. AeroForm™ WITH DOSAGE CONTROLLER

AeroForm is a fully implantable self-contained tissue expander that contains a reservoir of compressed carbon dioxide (CO_2) gas. The expander consists of an outer silicone shell with an anatomically shaped inner chamber that emphasizes the lower pole of the breast, producing a natural-looking breast shape as it expands. The expander is available in four sizes: small, 400 cc; medium, 650 cc; large, 850 cc; and full, 1100 cc. The size of the expander is selected based on preoperative measurements of the chest wall and the desired size of the permanent implant. The second element in the AeroForm system is a handheld wireless dosage controller that activates release of CO_2 gas through a microvalve in the extender. The remote controller is specifically bonded to its particular expander, which has no internal power source, thereby ensuring that the expander cannot be activated by another controller or an outside power source. The controller is passed over the implant area to allow it to communicate with the expander. With one press of a button, a tiny dose of CO_2 is released.

The AeroForm expander releases CO_2 in 10-cc increments no more often than every 3 hours; a patient safety limit of 3 doses per day is built into the system. The dosage controller does not allow the expander to be filled beyond its proper volume. Patients, guided by their level of comfort, gradually inflate the expander. Patients' ability to accomplish tissue expansion at home with AeroForm eliminates the need for multiple office visits and percutaneous needle injections of saline.

The current study has been discussed on national television. The first volunteer treated in the study reported that she completed the expansion process in less than a week. She noted that some women have required up to 20 days, which compares favorably with the several months required for traditional breast tissue expansion.[6]

PILOT STUDY

Connell[4] conducted a preliminary feasibility study of the CO_2-based tissue expander in Australia in 2009. The study included immediate or delayed implantation of 10 tissue expanders in 7 women who had undergone a single or double mastectomy. Active expansion time in these patients ranged from 5 to 22 days (mean, 15 days). Time to achieve full volume was described as being about one-third that required with a saline expander. Women rapidly reached the desired volume during active expansion and had the option of slowing down if desired, such as when undergoing chemotherapy.

All the patients in this published study reported that the CO_2-based tissue expansion system was easy to use and produced satisfactory results. The surgeon rated his satisfaction with the device as good to excellent in all cases. Two patients experienced delayed wound healing. In one case, the delay occurred at a site that had been previously irradiated; the second event followed a nipple-sparing mastectomy. Both of the wounds healed well within 2 weeks, with no long-term effects. None of the patients developed infections or other serious adverse events.

CONCLUSION

One of the decisions facing women who have undergone a mastectomy for breast cancer is whether to pursue breast reconstruction surgery. Many women opting for this surgery first require tissue expansion. With the conventional procedure, tissue expansion takes several months and requires multiple visits to a surgeon's office. A new tissue-expansion system—AeroForm—is being evaluated in a multisite study. If approved, this system will allow patients to control their own rate of tissue expansion within safe limits from home and achieve a more natural-looking breast shape. The shorter time needed for CO_2-based tissue expansion will speed a woman's access to her reconstruction surgery.

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FINANCIAL DISCLOSURE STATEMENT

Susan Wysocki reports that she serves on the Advisory Board for Bayer HealthCare Pharmaceuticals, Church & Dwight Co., Inc., Merck, Novo Nordisk, Teva, and Watson Pharmaceuticals and on the Speakers' Bureau for Bayer HealthCare Pharmaceuticals, Merck, Novo Nordisk, Pfizer, Teva, and Watson Pharmaceuticals.

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