

Rethinking Silicone vs. Saline Breast Implants

BY BRUCE JANCIN

SCOTTSDALE, ARIZ. — Silicone or saline?

With 550,000 breast augmentations performed each year in the United States, it's a question physicians and surgeons get asked a lot.

Today, most women choose silicone. Indeed, silicone gel breast implants have dominated the marketplace since November 2006, when the Food and Drug Administration lifted its moratorium on their primary cosmetic use. Silicone gel now accounts for 56% of all breast implants; saline implants, for 44%. But many women who opt for silicone gel implants don't fully appreciate the higher long-term complication rate, one expert said at the annual meeting of the American Academy of Cosmetic Surgery.

"It's really important for these young ladies to understand what they're getting in for 10-20 years from now, because often the complications are not reversible," explained Dr. Erik J. Nuveen, an Oklahoma City cosmetic surgeon who has performed more than 4,000 breast augmentations.

Dr. Nuveen uses both silicone and saline implants. In presurgical counseling, he has witnessed how the tactile experience of handling the silicone devices in the consultation room can influence the selection. This makes it all the more critical, he stressed, that a woman fully understands the pros and cons of both implant types before making her decision.

"The silicone gel implants are softer, more natural feeling. It's alluring to place one on the table and then put it in the patient's hand. You put a saline [implant] in the other hand and, sure enough, 99% of patients say, 'I've got to get that silicone gel,'" the surgeon said.

Silicone breast implants' purported association with connective tissue diseases—the debunked controversy that prompted the former FDA moratorium—has dis-

tracted attention from other, very real problems with silicone gel implants, he said.

An estimated 45% of women receiving silicone implants undergo reoperations within 10 years. In practical terms, this means that among women receiving silicone gel breast implants this year, there will be 138,600 reoperations for device rupture, contracture, pain, or loss of shape within the coming decade.

In contrast, the 10-year reoperation rate with saline implants is 20%-26%—roughly half the rate for silicone gel implants.

"These numbers are really important to me. They directly impact how I advise patients in order to minimize complications in their lives at 10 years," Dr. Nuveen continued.

Extracapsular rupture of a silicone gel implant with resultant migration of a silicone stream is a major problem. The silicone must be surgically removed before it can reach the lungs or other vital organs—and that involves a lumpectomy or mastectomy. The extracapsular rupture rate is 1% at the time of implantation, 7% at 5 years, and estimated at 10% at 10 years.

In contrast, rupture of a saline implant is less problematic. Implant deflation is immediately apparent, and the saline is readily absorbed by surrounding tissue. There is no need to remove substantial breast tissue. The rupture rate with saline implants is 3%-10% at 10 years, depending largely on surgeon expertise.

The reoperation rate for capsular contraction is substantially lower with saline implants than silicone gel.

Silicone gel implants require a larger placement incision—a minimum of 5 cm—because they go in full. The implants themselves are more expensive than saline ones. Moreover, silicone gel recipients have to bear a continuing lifelong expense for FDA-mandated



An estimated 45% of women who receive silicone gel breast implants (above) undergo reoperations within 10 years.

MRI evaluation in order to detect silent rupture. The initial MRI is required at 3 years, then every 2 years thereafter. It's not covered by insurance.

MRI has an 89% sensitivity for detection of implant rupture. In contrast, physical examination of the breast has only 10%-30% sensitivity. Mammography is quite poor at detecting silicone implant rupture while it's still intracapsular and more easily treated. Moreover, mammography is the No. 1 cause of implant shell failure.

These days the clinical situation in which Dr. Nuveen said he is most comfortable in recommending silicone gel is in the thinnest patients, who are more likely to find saline implants uncomfortable.

Dr. Nuveen said the future of breast augmentation may be a highly cohesive silicone gel called style 410. Widely used in Europe, it remains investigational in the United States, where clinical trials are underway.

Dr. Nuveen said he had no conflicts of interest. ■

CA 125 Level Predicts Survival in Ovarian Cancer Patients

BY JANE SALODOF MACNEIL

SAN ANTONIO — Elevated cancer antigen 125 levels measured after surgery but before chemotherapy are an independent prognostic indicator of recurrence and worse survival in women with high-risk, early-stage epithelial ovarian cancer, according to results of a Gynecologic Oncology Group study.

Moreover, the highest recurrence and worst 5-year survival rates were seen in a subgroup of women whose high post-surgery CA 125 levels persisted after they started treatment, perhaps suggesting a poor response to chemotherapy, Dr. Joshua P. Kesterson reported at the annual meeting of the Society of Gynecologic Oncologists.

Serum CA 125 levels are used to assess response to therapy and to detect recurrences, mainly in advanced epithelial ovarian cancer. Some studies have looked at CA 125 levels before chemotherapy in stage I disease. The current study, in 350 women, is the first to look at CA 125 levels after surgery but before chemotherapy, said Dr. Kesterson of a cancer research and treatment center in Buffalo, N.Y.

Looking at the primary end points, Dr. Kesterson reported 5-year recurrence-free survival rates of 86% in women who had normal CA 125 levels after surgery, and 75% in those with high lev-

els at that point. The 5-year overall survival rate was likewise higher when women had normal CA 125 levels before chemotherapy, compared with those who had high levels (88% vs. 82%).

Information for the current analysis came from a phase III clinical trial (GOG-157) that compared three vs. six cycles of adjuvant chemotherapy with paclitaxel and carboplatin in surgically staged women with stage IA/B grade 3 or stage IC or stage II epithelial ovarian cancer. Investigators deemed CA 125 levels that

were 35 U/mL or lower to be normal.

Preclinical data were available on 350 of 427 eligible patients: 110 women (31%) who had a normal CA 125 level before chemotherapy, and 240 (69%) with elevated CA 125 at that point. The median level was 65 U/mL after primary surgery.

White women were more likely to have elevated CA 125 than were non-whites, but this difference was not statistically significant. Nor were any significant differences observed in comparisons by performance status grade (0 vs. 1 or 2), tumor stage (I vs. II), cell type, cytology, rupture, or patient age.

Ascites was associated with a trend toward elevated CA 125 after surgery; it was present in 76% of women with elevated levels vs. 24% with normal levels.

The investigators observed that about three-fourths of patients had normal CA 125 levels after the first cycle of chemotherapy. This led to a stratification of the population into the following three groups based on CA 125 levels:

► **Normal before and after chemotherapy.** The best outcomes were seen in women who had normal levels before and after one cycle of chemotherapy; in all, 87% were recurrence free, and 92% were alive 5 years later.

► **Elevated before and normal after chemotherapy.** In comparison, the women who had elevated levels and fell

into the normal range after one cycle fared not quite as well, with 5-year recurrence and overall survival rates of 80% and 88%, respectively.

► **Elevated before and after chemotherapy.** When high CA 125 levels remained elevated after the start of chemotherapy, only 68% of women stayed recurrence free, and just 77% were alive 5 years later. These differences were statistically significant.

Dr. Kesterson said the study's limitations included a lack of information on how recurrences were treated and possible selection bias in that all cases were high risk. Among its strengths was that all patients were treated by gynecologic oncologists with comprehensive staging, central pathology review, standardized adjuvant treatment, and extended follow-up of a large number of patients.

In response to questions, he said the researchers found that whether patients received three or six cycles of chemotherapy did not affect the conclusion that an elevated CA 125 level after surgery is a significant prognostic factor for recurrence and for survival. Still to be examined, he said, is whether the interval between surgery and the start of chemotherapy could have influenced the findings.

The study was funded by the Society of Gynecologic Oncologists and the Ovarian Cancer Research Foundation. ■

