FDA: Silicone Breast Implants Seem Safe

Implant use does not appear to trigger connective tissue diseases or rheumatoid arthritis.

BY KERRI WACHTER

Preliminary safety data from postmarketing studies confirm that silicone gel–filled breast implants are safe and effective when used as intended, but women should fully understand the risks prior to considering the implants.

The data come from a report released by the Food and Drug Administration that updates the clinical and scientific information for silicone implants.

"Our review … continues to support the safety and effectiveness of silicone gel–filled implants when used as intended," Dr. Jeffrey Shuren, director of FDA's Center for Devices and Radiological Health, said in a press briefing. "We also want women to fully understand the risks and complications associated with these implants prior to considering them for breast augmentation or reconstruction."

As part of the FDA's November 2006 approval of two silicone gel–filled breast implants (the Allergan Natrelle and the Mentor MemoryGel), each manufacturer was required to conduct postapproval studies to characterize the long-term performance and safety of the devices.

In January 2011, the agency issued a statement about a possible but small association between silicone implants and anaplastic large cell lymphoma (ALCL).

The FDA's new "Update on the Safety of Silicone Gel-Filled Breast Implants" provides a clinical update on the two silicone gel–filled breast implants available in the United States.

The updated information includes preliminary data from the postapproval studies, a summary and analysis of adverse events reported to the FDA since approval, and a review and analysis of recent clinical publications about the safety and effectiveness of silicone gel–filled breast implants.

"I do want to emphasize today [that these data are] preliminary and that there are many more years of data collection needed to complete the required 10-year studies," said Dr. Shuren.

The report is not intended to provide a comprehensive clinical update about the safety of saline-filled breast implants.

Based on this report, according to the FDA news release, women should know the following:

► Breast implants are not lifetime devices. The longer a woman has silicone gel–filled breast implants, the more likely she is to experience complications. One in five patients who receive implants for breast augmentation will need them removed within 10 years. For patients who receive implants for breast reconstruction, as many as one in two will require removal 10 years after implantation.

► The most frequently observed complications and outcomes are capsular contracture (hardening of the area around the implant), reoperation (additional surgeries), and implant removal. Other common complications include implant rupture, wrinkling, asymmetry, scarring, pain, and infection.

► The complications that existed for women who received breast implants at the time of approval are similar to the complications observed today.

► Preliminary data do not indicate that silicone gel–filled breast implants cause breast cancer, reproductive problems, or connective tissue disease, such as rheumatoid arthritis. However, in order to rule out these and other rare complications, studies would need to enroll more women and be longer in duration than those conducted thus far.

The FDA will be holding an expert advisory panel in the next few months to discuss how postapproval studies on breast implants can be more effective. For now, the agency is recommending that health care professionals and women who have silicone gel–filled breast implants do the following:

► **Follow up.** Women should continue to routinely follow up with their health care professionals. This includes getting routine MRIs to detect silent rupture. Dr. Shuren noted that the first MRI should occur at 3 years post implantation and every 2 years after that.

► **Be aware.** Breast implants are not lifetime devices. Breast implants are associated with significant local complications and outcomes, including capsular contracture, reoperation, removal, and implant rupture. Some women also experience breast pain, wrinkling, asymmetry, scarring, and infection.

► **Pay attention to changes.** Women should notify their health care professionals if they develop any unusual symptoms. All serious side effects should be reported to the breast implant manufacturer and to Medwatch, the FDA's safety information and adverse event reporting program.

► **Stay in touch.** If a woman has enrolled in a manufacturer-sponsored postapproval study, she should continue to participate.

These studies are the best way to collect information about the long-term rates of complications.

The agency also redesigned its website to include comprehensive information on silicone gel–filled and saline-filled breast implants. ■