In the spring of 2000, the US Food and Drug Administration (FDA) issued a ban on the use of Betadine (Purdue Frederick, Stamford, Connecticut) with breast implants due to concern about an adverse effect on shell integrity that could lead to implant deflation or rupture. The ban was enacted primarily on the basis of 2 studies, the first of which was presented to the FDA by Mentor Corporation (Santa Barbara, California). This study tested Mentor saline implants with long-term intraluminal Betadine fill, and subsequent valve patch delamination was reported.1 This was the first published instance of Betadine being used intraluminally rather than as pocket irrigation, which may have contributed to negative results. The second study evaluated the effect of Betadine on silicone elastomer. Changes in elastomer strength and color were demonstrated, but this was the result of soaking the fill tube in Betadine and not the implant shell, which is manufactured differently.2 At that time, the FDA advisory panel did not recommend a prohibition on the use of Betadine with breast implants, however the FDA chairman went against the panel’s recommendation and the prohibition was put in place.3

In my own practice, I utilize Betadine irrigation because it offers ease of use, minimized medication error potential, decreased allergic risk (for patients who are allergic to Betadine, I use Adams’s triple antibiotic irrigation4), and cost-effectiveness. Furthermore, studies—including my own5 and those of Adams et al,4 Burkhardt and Eades,6 and many others—have shown not only no deleterious effect of Betadine on breast implants but also a significant decrease in the incidence of capsular contracture (CC). In fact, CC rates can be reduced to 1% or less with the use of Betadine,4,6 a significant finding considering that CC can result in significant patient morbidity and can require fairly extensive surgical correction with increased risks, including contracture recurrence.

The efficacy of irrigation with povidone-iodine (the generic form of Betadine) in reducing CC is most likely related to the infectious/biofilm theory of contracture origin.7-9 Cultures from breast tissue, ductal fluid, and explanted capsules have revealed bacterial growth,10,11 and in vitro studies have indicated the effectiveness of povidone-iodine in eliminating the implicated bacteria. An improved bactericidal effect of Adams’s antibiotic irrigation solutions with added povidone-iodine, as compared with antibiotic irrigation alone, has been demonstrated.12,13 It is thought that biofilm formation leads to greater potential for bacterial resistance, and therefore the key to controlling contracture is prevention of biofilm formation.

A theoretical risk of delamination with Betadine use would apply to both saline and silicone implants, textured and smooth. However, the deflations reported in the original Mentor reports resulted only from intraluminal application in saline implants. Many other studies reporting on shell integrity for all types of implants have shown no deleterious effects as a result of Betadine.4-6,14,15 Tensile strength analyses have demonstrated decreased strength of textured shells versus smooth shells, but this was attributed to the texturing rather than to Betadine.14,15

In further exploring the FDA’s decision to ban Betadine and reviewing the FDA panel transcripts for saline implant premarket approval from March 2000,16 it was apparent that all references in this matter were to the use of the specific Betadine brand and not generic povidone-iodine. A comprehensive review of all FDA recommendations and manufacturers’ saline and silicone gel breast implant labels17 revealed unanimous use of the Betadine brand, with 2 exceptions that I will discuss shortly.

In November 2005, I wrote a letter to the FDA and to the manufacturers regarding this issue, and in it I claimed that patient safety was being compromised because of this decision. I received a brief note of acknowledgment from Inamed (now Allergan, Irvine, California) and a fairly short response from the FDA stating that manufacturers must request any labeling change and that the FDA must approve any request to remove statements on breast implant labeling. Since then, there have been no updates from Allergan, Mentor, or the FDA regarding this issue. Explanations I received from both Allergan and Mentor (personal communication, October 27, 2012, and November 25, 2012) indicated that they believed plastic surgeons

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were using Betadine anyway and that it was too expensive and time-consuming to perform the FDA-required clinical studies for labeling change. I believe that this approach compromises patient safety because there are some surgeons who will abide by FDA policy and not use Betadine, even as others use Betadine “in secret.”

At this point, Betadine implant irrigation is the standard of care because it leads to greater patient safety, as indicated by extensive literature. Accordingly, on November 15, 2012, I sent an e-mail to the FDA, the manufacturers, and plastic surgery leadership, raising this issue once again. I suggested that the FDA and manufacturers come to an agreement to change the labeling, wherein the FDA would make an exception to the clinical study requirement and accept the existing clinical literature as evidence for the labeling change. I received a letter dated December 4, 2012, from the FDA Acting Director in the Division of Surgical Devices, Mark Melkerson, and this letter was almost identical to the one I received in 2005, stating,

To clarify, the statement above is not an FDA ban, it is identified in the labeling as a “Surgical practice in which product use is contraindicated due to compromise of product integrity.” Also, this labeling contraindication does not preclude the surgeon from irrigating the breast implant pocket with Betadine, it specifically contraindicates contact of the implant with Betadine. Thus, a surgeon who irrigates the breast implant pocket with Betadine and then rinses the pocket with saline to remove the Betadine would not be acting counter to the labeling. (personal communication)

Of note, my objection to rinsing the pocket with saline after irrigation is that I want prolonged tissue contact with the Betadine, as it takes time for the transected ducts to seal. I believe a longer contact time helps decrease contamination of the pocket that may occur prior to the ducts sealing, and this may help to explain the very low incidence of contracture. I have not received a response from other parties, most notably the manufacturers. This may be in part because most surgeons use Betadine pocket irrigation regardless of the FDA’s contraindication and the labeling protocol is not perceived as a concern. However, this practice is still contrary to federal policy. Some surgeons also might be concerned about potential legal implications in cases of implant deflation that is blamed on the use of Betadine, despite extensive literature suggesting the unlikelihood of this scenario. There are surgeons with whom I have had conversations who have suggested asking patients to sign an “off-label” consent regarding the use of Betadine, but I am against this policy because Betadine legitimacy should not be a patient decision; the science and literature are complex, and our expertise is the reason patients consult board-certified plastic surgeons. Additionally, on hearing the word deflation, many patients would be immediately concerned and would not realize the consequences, risks, and expense of contracture until it had already occurred. In the same vein, I would not ask a patient what setting to use on cautery or what suture to apply; these decisions are part of the technical aspect of surgery, and selecting an appropriate protocol to maximize safety and results is what we are trained to do.

Also of concern is the fact that the FDA’s transcripts, labeling, and contraindications all focus on the Betadine brand and not generic povidone-iodine, which leads to potential confusion. Including generic povidone-iodine in the “ban” would require an additional clinical study from the manufacturers and FDA approval. Therefore, although the ultimate solution is the removal of the Betadine ban from breast implant labeling, I propose that a “workaround” is to make sure that generic povidone-iodine is still applied in breast pocket irrigation and described in operative reports rather than the term “Betadine.”

Earlier, I referred to 2 studies that are exceptions to nearly unanimous manufacturer labeling of silicone gel breast implants with contraindication for the particular brand name, Betadine. Unlike the labeling for Mentor saline and silicone gel implants, Allergan silicone gel implants, and Sientra (Santa Barbara, California) silicone gel implants—all of which have labels that warn against use of the specific Betadine brand—Allergan saline implants bear labeling that contraindicates generic povidone-iodine. However, this is clearly a mistake, as it is in direct discord with the FDA’s instructions. Interestingly, the labeling for Allergan (then McGhan) saline implants in May 2000 specified Betadine, not generic povidone-iodine. There have been no additional clinical studies done on Betadine or povidone-iodine since that time and, as stated earlier, no additional label change requests made by manufacturers to the FDA. I have brought this error to the attention of Allergan.

The second exception is with Sientra. Their labeling states that, in addition to Betadine being contraindicated for pocket irrigation, “other iodine solution” should not be used to soak the implant. It is unlikely that Sientra performed specific clinical studies on Betadine or povidone-iodine; therefore, Sientra labeling may also be noncompliant regarding soaking the implant in “other iodine solution,” rather than just Betadine. In any case, the main concern is pocket irrigation, and Sientra labeling is specific for Betadine in that regard.

It is important to understand some specifics about the use of povidone-iodine for breast pocket irrigation. First, the variety of povidone-iodine used for surgery is the paint or solution, not the wash or scrub. The wash/scrub contains a detergent that is tissue toxic, and the paint/solution does not. There are concerns for tissue toxicity and cellular damage with povidone-iodine, but the data are conflicting and have not proven significant in clinical studies. Furthermore, cellular toxicity is part of the mechanism of action on bacterial cell walls. The paint comes in a 7% or 10% solution, and I dilute this 50:50 with normal saline. I apply approximately 50 cc per breast pocket, which I then suction out. I have chosen a 50:50 dilution based on clinical experience. In rare circumstances in years past when I had attempted implant salvage in a compromised augmentation by irrigating the pocket with full-strength povidone-iodine, I saw formation of a persistent seroma,
possibly due to irritation caused by the full-strength solution. I have not seen this with the 50:50 dilution, nor have I had a wound-healing problem attributed to the povidone-iodine. The causes of the small number of wound-healing problems I have seen were identifiable and were not povidone-iodine related. I want the purest solution possible while maintaining safety, and this dilution seems to achieve that goal without causing seromas or wound-healing problems. I do not rinse the breast pocket with saline afterward because, again, I want as much tissue contact with the povidone-iodine as possible, particularly in light of the biofilm theory. This is also acceptable in the labeling for silicone gel implants, as the manufacturers that have suggested rinsing with saline afterward specified the Betadine brand and not the generic povidone-iodine.

Our main concern as board-certified plastic surgeons should be patient safety. Extensive literature and clinical practice have clearly shown the value of using Betadine (or the generic povidone-iodine) to irrigate the breast pocket, and doing so results in the reduction of CC rates with no harmful effects on the breast implant or the patient. The FDA and the manufacturers are currently only treating policy, not patients. The federal government is not willing to intervene or compromise, and the manufacturers seem uninterested. Submitting to policy that is harmful to patients is against our training, and we must consistently defend and support our patients. As board-certified plastic surgeons, we must speak out against a needless policy that could be harming patients and is an intrusion on our ability to practice with patient safety as the primary concern. I would suggest that all of you contact your implant representatives and also the FDA, stating that the ban on Betadine statements should be removed from breast implant labeling.

Disclosures

Dr Wiener is a stockholder with the Ideal Implant Corp.

REFERENCES