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Discussion

[BREAST: ORIGINAL ARTICLES: Discussion]

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As I grow older in our specialty, the value of credibility in plastic surgery comes with higher and higher premiums. Truthfully, real credibility, in either surgeons, industry, or organizations, seems the exception rather than the rule. In the end, it all comes down to one simple question: Does it help the patient? Dissecting marketing hype, media spins, and bureaucracy is often difficult, time consuming, and taxing.

I would first like to congratulate Dr. Wiener for stepping up to the plate, asking hard questions, generating data, and ultimately trying to benefit patients.

I have been close to this subject for 10 years. At the end of my residency I observed no fewer than five different breast pocket irrigation solutions being used by a variety of my faculty, yet there was no real scientific basis for any one solution over another. We took this question to the laboratory and applied the scientific method to determine what solutions provided the best broad-spectrum antibiotic coverage for the multiple organisms that have been implicated in breast implant capsular contracture. This study and subsequent ones¹⁻³ have made recommendations to optimize breast pocket irrigation.

ASKING THE HARD QUESTIONS

Similar to Dr. Wiener, I have been perplexed by the U.S. Food and Drug Administration's decision in 2000 to restrict the use of Betadine (povidone-iodine) for breast pocket irrigation. The reasons or, perhaps better said, the environment that would produce this decision became much clearer to me after I attended the silicone gel premarket approval hearings in April of 2005. As much as anyone wants to admit (or deny), the politics that cloud the science are clearly evident and factor heavily in decisions in that forum. I agree with Dr. Wiener's overview of the available data that existed to make this 2000 restriction, and anyone interested may review all of the details published in this *Journal* in 2001.²

Suffice it to say there are no data, even today, that implicate any negative implant shell effect of extraluminal Betadine. The logic that led to this decision remains an enigma, and clearly the Food and Drug Administration is implicated in the final decision; however, responsible parties also include the plastic surgeons, scientists, and manufacturers who allowed the cited information to end up as a restriction based on no real data.

GENERATING DATA

One does not need to step into any plastic surgery forum for long to hear countless opinions and recommendations being given based on no data. Dr. Wiener has taken a difficult step in taking the time, interest, and effort to generate data. Without data, his conclusions are useless, but he has given us some hard facts to support his position.

To be complete, it would be helpful to know what submuscular pocket plane was used in all cases in this study. I assume he meant a standard partial subpectoral technique with some degree of muscle division inferiorly. It would also be interesting to know why the contracture rates for groups I and III were different when the technique was similar.

Finally, it would have been best to have a minimum follow-up of 12 months in each group; however, capsular contracture related to the operative procedure almost always occurs by 6 to 12 months postoperatively. I would bet that Dr. Wiener's current data are no different as he continues to follow his patients.

Also salient is that these data and conclusions coincide with our recently published series demonstrating a similarly low contracture rate using appropriate breast pocket irrigation solutions.³

BENEFITTING THE PATIENT

Capsular contracture remains the most common complication of aesthetic and reconstructive breast surgery. This has been consistent across all studies for the past 45 years. This study and others³ have provided clinical guidelines that reduce this problem significantly. I cannot think of any logical reason why anyone using a breast implant would not adopt these practices to minimize peri-procedure implant contamination. The irrigating solution used in this study (50% Betadine) has been cited as an appropriate broad-spectrum solution in other studies as well.^{1,3-5} Other viable Betadine or non-Betadine-containing solutions have also been shown to have similar efficacy.¹⁻³

Interestingly, to date, I know of no known bacterial resistance that has developed to Betadine, and due to its low cost and widespread availability, I agree with Dr. Wiener's conclusion that the restriction on Betadine usage with breast implants should be reversed.

Clear benefits to patients using Betadine irrigation have been demonstrated by this study and others.³⁻⁵ I want to thank Dr. Wiener for his hard work and credibility in taking the difficult steps in the best interest of the patient. Now it is the Food and Drug Administration's turn; we can all wait and watch to see which road they will take.

DISCLOSURE

Dr. Adams serves as medical director of the Mentor Corporation's cohesive gel implant trial. He is an investigator for the Inamed and Mentor cohesive gel IDE trials; Inamed academy faculty; and an Ethicon Innovation Council member.

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