

# Breast Augmentation Roundtable

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**T**his roundtable was conducted live at the American Society of Plastic Surgeons meeting in Chicago, Illinois, in 2005. Dr. Spear was not present for the roundtable, and his comments were formulated and added after the completion of the roundtable. For this reason, his comments have been placed in italics.

**Adams:** On behalf of my co-editor for this supplement, Dr. Spear, *Plastic and Reconstructive Surgery*, and myself, we would like to welcome each of you and thank you for your participation. All of you were selected because this is a roundtable on reoperations in breast augmentation. This is thought to be a significant problem currently in breast augmentation, and you all have experience and insight into potential solutions.

As far as the rules of this roundtable, they are written down in front of you. Basically, there is not going to be any content added post-roundtable other than grammar. There are five questions listed at the bottom. Each question will be discussed for a total of 12.5 minutes. The initial question response, which each of you will have time to respond to, will be 1.5 minutes, and the first participant to respond will be rotated. We will have an open discussion for 5 minutes or up to the 12.5-minute time limit, which Dr. Teitelbaum will facilitate. Any questions? I'd like to introduce Steve Teitelbaum, who is going to moderate this. Steve, I'll turn it over to you.

## QUESTION 1

**Teitelbaum:** I'll start with my left and we will just go around taking the first question. We'll start with you, Brad. *Are reoperations in breast augmentation a problem?*

**Bengtson:** Nationwide and internationally, I believe that they are. A significant part of it is that

each surgeon really desires to get the best result possible, to use the best implant that they deem is out and available to them, and to decrease uncorrectable deformities and problems in the future. I think they are a problem, and I think our goal should be to do everything we can to limit reoperations in the future.

**Jewell:** I agree. I think a reoperation problem exists. It's a quality marker, and I think we need to approach this in a fashion to help define why reoperations are occurring and what we can do to improve outcomes for patients. We need to ask and answer the question, What are we doing to prevent implants from giving us the outcome that we believe they are capable of? What decisions are we making that are wrong, that predictably produce a reoperative scenario, whether it's implant malposition, stretch deformity, things of this nature? Granted, we can't control the biologic response to an implant or the healing or scarring, but we certainly can control the decisions we make on the front end, which should lower the reoperation rate.

**Tebbetts:** Reoperations, in my opinion, are the number one problem for breast augmentation patients. Any reoperation subjects the patient to risks and costs that she would not have encountered had that reoperation not been necessary. A two-and-a-half decade history of 15 to 20 percent reoperation rates within just 3 years in sequential [premarket approval (PMA)] studies is difficult, to say the least, to explain to the public, especially considering that this is a totally medically unnecessary operation. This unenviable track record sends a clear public message that the processes we use for surgeon education, patient education, clinical evaluation, and decision making are flawed and ineffective.

**Adams:** I would agree with other roundtable participants, what they've alluded to. If you look at the best data that we have collectively from consecutive PMA studies that would indicate reoperation rates of 15 to 20 percent, which I think are

*Date of roundtable September 25, 2005; accepted for publication March 20, 2006.*

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DOI: 10.1097/01.prs.0000247288.70207.24

excessive, there are good data to support that much lower reoperation rates are attainable.

**Spear:** *Reoperations are a problem, but the problem needs some explanation. To begin with, there is a difference between reoperations and revisions. Reoperations might encompass any event that transpires in the vicinity of the patient's breast augmentation. This might include breast biopsies, scar revisions, change of implant size, subsequent mastopexy, and so on. So before looking at the problem of reoperation, it is important to clear up the ambiguity among the reasons for reoperation, some of which are out of the control of the surgeon and the patient, some of which are naturally occurring events, some of which are implant-related problems, and some of which are surgery-related problems. So while it is an appropriate goal to reduce the frequency of reoperations, the reoperations we really want to reduce are the reoperations that are revisions because of problems such as capsular contracture, implant malposition, infection, and extrusion. While it might be desirable to eliminate reoperations because of the patient's desire for a larger or smaller implant, many of those issues are less surgical issues and more whether or not the surgeon is willing to let the patient electively adjust her result later. It is interesting that when reoperations are looked at in prospective blinded trials that include any and all events after breast augmentation surgery, the numbers tend to be fairly consistent at 15 percent to 20 percent at 3 years in several studies, all of which were initiated after 1995. Yet when you ask surgeons what their reoperation rate is, very few will admit to a reoperation rate higher than 5 percent. It is important, therefore, to remember that multicenter, controlled studies probably provide more accurate information than individual surgeons' reporting of their events, no matter how well intended. In summary, then, while it is a desirable goal to reduce the frequency of revisions or reoperations after breast augmentation, the more important goal is to reduce the frequency of revisions because of unsatisfactory results.*

**Teitelbaum:** Does anyone else have any comments on what others have said in this discussion so far?

**Jewell:** I think that the reoperation rate can be lowered. It's no different from Jimmy Doolittle getting a B-25 to take off from the deck of a carrier; it's a process, it's a project, it's a mindset, and it's important that we do this.

**Tebbetts:** And not only can they be lowered, but there is a clear body of peer-reviewed and published data that proves that they can be lowered and goes further to specify exactly how they can be lowered.

**Teitelbaum:** Can anybody comment more about the specific reasons that reoperations

should be reduced? Dr. Tebbetts spoke about the risks to the health of the patient and the costs to the patient. Are there other reasons that you can mention, any of you? Why is it important to reduce it? We know about patient health and safety and costs. Are there any other reasons anybody can comment on?

**Jewell:** Prevent irreversible changes and damage to tissue.

**Bengtson:** Pain, deformities, decreased sensation, patient dissatisfaction.

**Tebbetts:** Those all come under the categories of risk, and certainly all those things can happen.

**Adams:** I think that certainly, ultimately, we are all here to deliver the best optimal care to these patients, and I think that minimizing reoperation rates is going to serve that purpose best. Other things include litigation issues. As patients have more and more reoperations, the chance for litigation is higher, and that's another reason to consider what we are talking about.

**Bengtson:** The reoperation patient, particularly if it's not my patient, is one of the most difficult patients to deal with, because they come to you for another opinion and we have the option of either not seeing them or just not seeing them in consultation or offering anything or choosing not to operate on them. But generally they come with extremely high expectations. They want you to fix the problem, and they typically have not been adequately educated previously. Typically, some major principles at the time of the first breast augmentation have been violated and have produced, a lot of times, some problems that are just not correctable.

**Adams:** The other thing that struck me when we were talking is that in a primary augmentation patient, everything is better in that patient. The tissues are better, and the psychological well-being of the patient is better. So, certainly, the fewer reoperations we have to do, the better it's going to be for the patient, the surgeon, everybody involved.

**Spear:** *No question that with each subsequent operation on a patient, the risk increases and the likelihood of success decreases. For that reason, it is certainly desirable to reduce the frequency of reoperations as much as possible. Ideally, each patient should only need one operation, but on the other hand, the longer these patients are followed, the more likely there will be a reoperation for one reason or another.*

**Teitelbaum:** Does anyone have any comment about the rate of reoperations and how that is perceived by the [Food and Drug Administration

(FDA)] and by women advocacy groups and the media?

**Tebbetts:** I think that's a very simple question. Ask yourself. If you put yourself in the patient's place, or if it was your wife, or if you were an advocate, how do you explain a 20 percent 3-year reoperation rate for a totally medically unnecessary operation? I can't fathom how you'd explain that.

**Jewell:** Yes. The implication is, we either aren't getting it right or haven't figured it out. Something's wrong here. For, as John said, a medically unnecessary, elective operation in healthy patients with good tissue, we should be able to figure it out and deliver a consistency in outcomes. I mean, this is a manufacturing concept. The *Harvard Business Review* article that I sent you that Steven Spear talks about is Toyota's concept of manufacturing. How do we learn as we do to get better? How do we make improvements versus making the same mistake? John Tebbetts and I share this quote by Einstein that insanity is doing the same thing time and time again and expecting different outcomes.

**Tebbetts:** Further, I can just imagine any of us sitting in a [morbidity and mortality] conference when we were general surgery residents and trying to explain to any faculty member this kind of reoperation rate for a totally elective procedure.

**Adams:** Steve, you asked specifically about the FDA. One thing I do remember from attending the last silicone implant PMA hearings in April of 2004 is that the number one term that you heard at that hearing was implant rupture, but the second thing was reoperation. That was something the FDA and the breast implant women's advocacy groups consistently mentioned. So it's clearly a major issue raised by those groups.

**Spear:** *I would state that reoperations were one of the many things that women's advocacy groups and the media were inclined to use as a weapon against the implant manufacturers and plastic surgeons. For that reason, they were quite prone to lump together all the various causes of reoperation and assign them the same level of complicity in terms of danger or risk. Reoperations for such things as a staged mastopexy or a breast biopsy are a totally different matter than a reoperation because of capsular contracture or implant malposition or implant rupture. So, for those who are opposed to breast implants on any basis, it was convenient to use the biggest number possible for reoperations. In my opinion, although it is desirable to lower the reoperation rate, this has become as much a political issue as a medical one.*

**Teitelbaum:** One last question on this issue before we move to topic 2. I've heard well-known

plastic surgeons at the podium at national meetings say that since this is an elective operation to start with and was done for unclear medical reasons in the beginning, it's just like redecorating your living room. It's justifiable to have a high reoperation rate because it's all about patient request. What do you say to that person?

**Jewell:** I think that we should be able to get this right. It's an operation that delivers value to patients—positive psychological outcomes with regard to quality of life and body image. We should be able to deliver this operation in a way that's safe and predictable.

**Tebbetts:** Well, patients' wishes are directly affected by the level of education that every patient has. Just because a patient wants something doesn't mean in any sense that it's medically reasonable to deliver that. So to me that is a completely illogical and lame excuse.

## QUESTION 2

**Teitelbaum:** We need to move on, but we may revisit this later if there is time. Question 2: Dr. Jewell, *have you changed your position on reoperations from years past, and why?*

**Jewell:** I have, yes. With the ability to put insight into the process, to control each step of the process, reoperation rates can be improved, versus doing it the way that it always has been done, accepting poor outcomes, dissatisfied patients, and reoperation. What I'm saying is I think my position certainly has done a dramatic change since I took a process-oriented approach to this and realized, from years of experience, that by making good decisions on the front end, problems were prevented from occurring later.

**Tebbetts:** I certainly agree with Dr. Jewell, and I would add that my opinions about reoperations changed somewhere after the first decade that I'd been in practice. Until that time, I really didn't realize, based on my resident education and my early surgical experience, that reoperations are largely totally preventable by logical processes to which Dr. Jewell alluded. Once we know that a process exists, and once we have solid scientific data that are peer-reviewed in this *Journal* and that show us that there are ways to do this, then certainly I have problems saying that it can't be done. So yes, my opinions have changed.

**Teitelbaum:** Dr. Adams, have your opinions changed?

**Adams:** I think my opinions have changed in the regard that I've been in practice 10 years, and when I first started in practice I don't think I was educated enough that reoperations were a prob-



lem and that there was an answer to that issue. Through good mentorship, I think, I've learned, first of all, that reoperations are a problem and that there are good methods and data out there to lower that rate. Now, in the past 5 years, I have implemented the processes and seen that it's really possible to do in your practice. There has definitely been an evolution, but it's been more at my end, of educating myself to show that there is a method that works.

**Bengtson:** I think that surgeons, including myself, previously tend to overestimate the number of surgeries they perform. They tend to overestimate the quality of the results, and they tend to underestimate the complications and reoperations. So what really changed for me is when I actually started documenting and tracking things very specifically, not only with the measurements and changes that occurred in the breast over time but also very specifically tracking the patients and getting very, very good follow-up and being brutally honest with myself, including some accountability with my partners. That really has changed things a lot, because for reasons that I am sure we are going to get into, for reoperations, I think we may vary a little bit on this with the people here, but I think it's important to look at what specifically we are reoperating for. If it's an elective reoperation, and the patient is desiring an implant change, I think that's a failure in education, in the preoperative planning, in the measurements, and all that can be done up front, from the surgeon's standpoint. If it's a technical complication or whatever, I think we can learn from that and decrease our reoperations over time, so that the only things that are left are things that really we can't control, ultimately. We can do as much as we can to decrease capsular contraction, that sort of thing, but ultimately there is going to be a distillation of things down to, it is hoped, a very low percentage, in my practice probably less than 1 percent, of complications that truly are medically necessary that we need to correct.

**Spear:** *I must admit that I have thought about the issue of reoperations frequently over the last several years. Although I probably do not consider it as much an issue as some of the other panelists do, I have been inclined to rethink my approach to revision surgery and reoperations. In light of the thoughts of my fellow panelists, as well as some introspective thinking, I have tried to be somewhat more conservative and cautious in agreeing to perform reoperations on patients where the risk/benefit ratio was less inviting. For example, adjusting one or the other inframammary folds by some small amount to improve symmetry is some-*

*thing that I would have been quite willing to do several years ago, but am now less willing to do. Similarly, for mild degrees of capsular contracture, where one breast is a little firmer than the other, this is something where I would probably be somewhat less willing to reoperate today as compared with several years ago. Perhaps the most important area where I have learned to be more cautious in terms of reoperation is on the issue of symmetry. I have been truly impressed that breast asymmetry is a natural condition that exists in at least 80 percent to 90 percent of women. While breast augmentation can enlarge both breasts and improve the appearance of the patient, there is certainly no guarantee or even likelihood that the asymmetry will be corrected. I now tell all patients—in fact, I will guarantee them—that their breast asymmetry will not be solved by breast augmentation, although it might be improved in some cases. Just as likely or more likely, the degree of asymmetry may actually be magnified by the presence of the implants. In general, although I do not perceive reoperation as being as serious an issue as my fellow panelists do, I have nevertheless tried to reduce my frequency of reoperation, not just in my patients but in any patient who comes to me, because of the increased risk of reoperation as well as the decreased likelihood of success in terms of whatever the presenting problem is.*

**Teitelbaum:** Any comments?

**Jewell:** A few more comments. Unfortunately, plastic surgery does have a culture of reoperation, from our reconstructive heritage. With that in mind, that mindset needs to be changed in terms of the aesthetic procedures. We should be able to get it right. We should be able to do lipoplasty right the first time around, or a breast reduction, or other procedures. I agree with Brad that we need to define better, each of us, why we are reoperating and what the situations are. All of us in this roundtable have totally transparent data with [institutional review board] oversight that demonstrate the approaches that we use here, as opposed to anything otherwise.

**Tebbetts:** I think that Dr. Bengtson alluded to the accountability factor, and Dr. Jewell mentions the fact that I think everyone at this table is involved in PMA studies. That, in fact, as Dr. Jewell said, makes our data totally transparent, and I think the experience of being an investigator in a PMA study and having clinical review organizations come in and review your data on a regular basis is quite enlightening. It's almost brow-beating for me.

**Jewell:** Not to mention the FDA.

### QUESTION 3

**Teitelbaum:** I am going to move on to the third question, and this will go to you, Dr. Tebbetts. *What do you say to people who say that reoperations are not a problem?*

**Tebbetts:** If anyone thinks that reoperation in breast augmentation is not a problem, I suggest that they ask any patient who has had a reoperation, or who requires a reoperation, if she thinks that reoperation is a problem. Further, I think that for surgeons who really think that reoperations are not a problem, I respectfully suggest that all surgeons' reoperation rates be documented in a registry that is transparent to patients and to patient advocate groups. With transparency and surgeon accountability, perhaps patients and patient advocates might change the perspective of surgeons who don't see reoperations as a problem.

**Adams:** If people believe that reoperations are not a problem, I'd say to them that they either don't know the data or they are disregarding the data. In the data that we have, that has been alluded to before, there are PMA studies and multiple ones over time, and they all show the same things. Anybody who feels that reoperations are not a problem is just disregarding that or choosing to disregard that. I also think that some comments were made earlier that nobody seems to think they have a high reoperation rate; very few people have it. I think, again, I would echo some of the earlier comments: that's just a fallacy. In the transparent studies, the reoperation rates are 20 percent, so there have to be surgeons with 20 percent reoperation rates. I should mention, in fairness, that for the reoperation rates we are quoting, some of these are for other procedures, such as breast biopsy, but get counted as a reoperation. Nevertheless, when one accounts for these subgroups, the overall reoperation rate is still excessive.

**Tebbetts:** I think, in fairness, we are throwing around the number 20 percent. It could be 15 to 20 percent. In different studies it's ranged, really, between 15 percent and 20 percent, and what we are talking about here are data from PMA studies over the past 2½ decades. In my opinion, data from a PMA study are the best data, period, available in any aspect of plastic surgery with respect to scientific methodology and peer review.

**Teitelbaum:** Dr. Bengtson, earlier you mentioned that your opinion changed after you started looking at your data carefully and realized what your true rate of successes was and was not. So

when you meet a surgeon who says that reoperations are not a problem, what is it that you would say to that surgeon?

**Bengtson:** Well, my comment would be that you haven't asked the question, or you haven't asked the right question, and/or you are not being honest with yourself. I am continuously surprised, particularly at national meetings, that there is an inherent lack of follow-up and documentation of actual complication rates and problems and those sorts of things. To me, it took me a long time to figure it out, but a half-truth is a lie. I think we each need to be extremely honest and, as John said, transparent. Otherwise, you can't learn. You don't learn from your successes; that's a great result. You learn from the problems and complications that you have. It's kind of human nature to not want to deal with those things, or not really recognize those things, but you don't excel or get better without that.

The second thing I would say to them is that, and it's a question that we may deal with a little bit later but, if they are going to blast through some of the basic principles at the first operation and they really don't feel reoperations are a problem, then I really would like for these surgeons to have patients sign additional consents that they will stay with that surgeon for life, so that I don't have to deal with them in my office and their problems and baggage. People have talked about in the past in the journals that we need to deal with patients with large implants, because I don't. If they are going to do those things and intentionally blast through what the breast and the body can take, then they should stick with that patient for life, so that maybe they will see that reoperations may be a problem then.

**Jewell:** I agree pretty much with everything that has been said so far, in terms of many surgeons lacking the insight to ask the question of what was not done to make this process optimal. I also think there is the issue of patient selection, where high-risk scenarios are willfully operated on time and time again. I am talking about patients with augmentations, mastopexies, tubular breasts, small breast diameters that will produce a double-bubble deformity, and so on. In other words, there are a lot of scenarios where you can see a reoperation coming. In that case, it may be better to say to the patient, "You don't meet my criteria for this operation," versus saying, "Well, it's going to take multiple operations to get you where you need to go," and that may not be the case.

**Spear:** *In regard to surgeons who might say the reoperations are not a problem, most likely they are saying*

that, in their hands, reoperations are not a problem. It is possible that for some surgeons, their reoperation rate or their perception of their reoperation rate is low and, therefore, they believe it is not a problem for them. I would return to some of my earlier comments, where I said that reoperations that are, in fact, revisions for true postoperative problems are an issue if the rate is high. Reoperations for insignificant events, such as a breast biopsy or a planned mastopexy, are really not a problem in terms of the original surgery. Obviously, one way to avoid having a high reoperation rate is simply to refuse to reoperate on your patients. In other words, to say to patients, for mild capsular contracture, malposition, or size dissatisfaction, that you refuse to reoperate on them. Refusing to reoperate on those patients might reduce your reoperation rate, but it does not necessarily make for a better surgical outcome or a happier patient. So I would simply say that the goal is to provide high-quality surgery by doing the best possible operation that is appropriate for the patient, with the fewest complications or need for medically necessary reoperations. Again, all of the emphasis on reoperations over the last several years has made me look at my own data and to make the effort to keep that number as low as possible while still providing responsive and high-quality surgical care. I did find it interesting in my own data that my reoperation rate for primary breast augmentation over the last 3 years is 1 percent, and that was in a patient who sought a change from saline to silicone implants. My reoperation rate for revision augmentation mastopexy was more like 15 percent, where I was dealing with more complex problems. So we do need to be careful when we look at reoperations in terms of looking at what the patient's initial problem was before surgery.

#### QUESTION 4

**Teitelbaum:** Any other comments on this topic? Okay, then I'll move to the next one. Dr. Adams, reoperations: how do you address the problem and, specifically, what is the single most important factor to be addressed?

**Adams:** Well, I think it's fairly easy to address the problem. You just go and look and see what's worked. The single most important thing is to institute a logical decision-making process in this endeavor. What I mean by that is, the process involves four things in my mind: education; tissue-based clinical analysis; a refined surgical technique; and a refined postoperative surgical management plan. That's not something that I have personally invented, but it's something that I've taken from my mentors—things that are published, peer-reviewed, proven processes. I even mentioned today to some of my colleagues here at this roundtable that we (Bengston, Jewell, Tebbetts, Adams) have more than 2500 cases now in peer-reviewed published articles or presented at national meetings, 2500 breast augmentations with a reoperation rate of less than 3 percent. I think the single most salient reason why that rate is low is because everybody has instituted this concept of a logical decision-making process.

**Bengston:** I think I have an editorial that, hopefully, I will send to the publisher. I am going to send it in, and that's a little bit of pressure there, but I've been talking about this concept that actually a pastor friend of mine gave me. He, in a message, was talking about absolutes, beliefs, and preferences. It has absolutely transformed my life, not only from a spiritual standpoint but it is just so applicable to life, to practice, to just almost everything, and it's particularly applicable to this subject. I think that what has really changed for me is that I very specifically look at what the absolutes are for doing a breast augmentation the first time correctly. As long as I don't kind of blast through any of those absolutes and maintain those, then I expect a very good result with no or very few reoperations. When I have violated one of those principles, either by ignorance or by choice, then I've seen a higher complication rate. So, the key thing for me is, just as Bill said, in all aspects, the educational aspect, the evaluation of the patient, those sorts of things. And the follow-up. We each need to individually determine what the main absolutes are. For instance, coverage is the main absolute when it comes to breast augmentation. A precise, absolutely bloodless pocket is an absolute for me. So, determine those things, and then we can expect great outcomes.

**Jewell:** For me, it's maintaining congruence with a thought process, a process of action, and a process of management for these patients. By staying within these parameters that we've talked about, you can achieve consistently excellent outcomes. It's the factors that Bill talked about earlier, and the facts that you presented on today in the breast panels. It's the mindset that you can achieve this, it's doable, and you stick with patients who you can succeed with versus creating false expectations.

**Tebbetts:** Addressing reoperation rates, I believe, begins with a very basic concept, and that is, prioritize the patient, not just with lip service but in all decisions and actions. That means prioritizing what's good for the patient above what is economically good for the surgeon or surgeon organizations or implant manufacturers. The first logical step to me in addressing any problem is recognizing and acknowledging the processes and



policies that have not worked, that is, the causes of the unenviable track record. The single most important factor to address is simply to not repeat the same processes and policies that fostered the problem. To me, seven specific requirements are necessary to optimally reduce reoperation rates.

The first one is education. Curriculum content for surgeon education must be based on proved processes that are peer reviewed and published. Content must be depoliticized. Curriculum must be established by an unbiased, expert review body, such as a clinical research organization or CRO, not by professional surgeon organizations and not by implant manufacturers, both of whom have distinct potential conflicts of interest. Surgeon decision-makers cannot continue to define educational content and curriculum based on surgeon evaluations from previous educational venues. If those who need the education knew the answers, one might logically suggest that the problem wouldn't exist in the first place and certainly would not have persisted for more than two decades.

Second, the curriculum for surgeon education must include options-approved processes. Not a single option, but options. In addition, it must specify details of how to deliver these processes, not simply list or discuss the options.

Third, surgeon educators should be separated from the curriculum. Curriculum content defined by an unbiased review body can be disseminated more effectively to a much larger number of surgeons by instructors who first teach the defined curriculum, then express their own personal opinions. Personal opinions should be reserved for panels or case-study sessions that are in addition to, not substitutions for, an established curriculum.

Fourth, the format of educational venues for surgeons must change. The traditional programs of 15-minute lectures by non-content-matter experts expressing opinions that are not based on peer-reviewed and published processes should be replaced by educational models that have proved successful in business and other fields of medicine.

Fifth, effective transfer of curriculum content must be verified by surgeon testing. Every corporate entity in the United States, when it educates its people, tests them to be sure the information was transferred effectively, or it changes the way it delivers information.

Sixth, surgeons must be "incentivised" to imple-

ment proved processes. Outcomes data and reoperation rates should be recorded in a database that is managed by an unbiased third party, a database that is transparent and accessible to surgeons, patients, and the FDA.

Finally, seventh, patients must be educated in a staged, repetitive process. Patients must make their own choices based on education, and patients must be accountable for their role in their decisions.

In my opinion, absent any of these seven requirements, patients are likely to continue to experience excessively high reoperation rates.

**Spear:** *In my opinion, the single most important factor to be addressed is educating the surgeon, or getting the surgeon to adopt a philosophy. The philosophy should be to perform the most rational, logical, and safest surgery possible. I pretty much agree with my fellow panelists on this matter. I think surgeon education, patient education, and developing a systematic and rational approach to surgery, both in terms of planning and performing surgery, are all part of the package. I preach to my residents over and over again that the most important part of surgery is the preoperative planning and decision making. In most operations, the technical exercise is the easiest part. Along with preoperative planning and execution are patient education and appropriate postoperative care, but certainly preoperative planning and meticulous surgical technique are key factors. I often find it surprising that these basic simple concepts have not been adopted by more surgeons.*

**Teitelbaum:** Thank you. Picking up on something that Dr. Bengtson said, his absolute. Dr. Bengtson, why don't you tell us what, to you, are absolutes in reducing reoperations? I'd like to go around and have everybody tell me their absolutes.

**Bengtson:** I believe that to decrease reoperations, there are a number of different factors, but it really starts with patient education. I guess how I would answer that question is, I would look at what my reasons are, my specific reasons, for reoperations. I have a reoperation rate of about 2 percent for patients who require an elective or choose an elective implant change. That, to me, is a failure of my education and involving them with the decision-making process, because there is obviously some disappointment with the postoperative result. The second is a technical issue with using a textured device in a patient desiring a mastopexy. I've had to come back and revise some mastopexy patients or remove excessive skin, so that's a technical or a planning thing that I've changed. The third is a more implant-related is-

sue, such as capsular contracture and/or malposition or rotation. Those really are less than 1 percent of things. I think we need to look specifically at things such as irrigation techniques, which Bill talks about, and some other things technically to try and decrease those. So basically, the absolutes for me, from a technical standpoint, are coverage—that's the number one thing, that we don't exceed the coverage of the breast; number two, that the pocket is designed to fit the specific implant (particularly with the formed, stable, cohesive device, it's absolutely critical) and that the pocket is absolutely bloodless; and number three, that the patient is adequately educated as to what the implant and what the surgeon can produce. I think those are three of the top absolutes for me.

**Teitelbaum:** Dr. Jewell, Dr. Bengtson said that his absolutes are that the patients are educated, that there is adequate tissue coverage, and that the pocket is accurate and bloodless. Do you agree with those? Disagree? Would you add any others to that list?

**Jewell:** I agree. I think that the mindset of precision and finesse in the surgery that we do, with thoughtful planning, is key. I can only reemphasize the importance of education. I have heard you and Terry Tebbetts in your office, John, spend a great amount of time making sure that good decisions are made on the front end and the expectations are managed well. This is not a commodity operation that patients enter into ill-informed, with poor surgical technique and no way to manage problems afterward. I think that by defining this whole process and sticking to it, the reoperation rate can be very low. My reoperation rate is 2 percent, and my formed stable device? One was for surgical bleeding, one was for a scar revision, and the other was for a seroma that happened 6 months after an operation. So I have not had any size change or capsule reoperations. Maybe I'm lucky; time will tell.

**Tebbetts:** I agree with patient education. I'd take that a little bit further and say that the critical part of that process is not to say that you educated the patient but to have a patient educated to a point where that patient is capable of making any decision that you would make to about a 90 percent level. I know a lot of surgeons who think that's categorically impossible. I would submit that for those patients, there are better ways to educate those patients.

Second, I highly prioritize. My number one priority when it comes to surgical planning and tissue assessment is soft-tissue coverage. I have said it many times: There is no substitute for that. It's

not simply soft-tissue coverage; it's quantifiable soft-tissue coverage. If you want to say that a submammary approach provides adequate cover—or a subfascial, or retropectoral, or dual plane—if you do not have data going in that quantitate the soft-tissue coverage, we have no way to assess whether you know what you are talking about or not. So, quantitation of soft-tissue coverage is important.

I would also agree with Dr. Bengtson's comment about hemostasis. I use the term prospective hemostasis, because there is a difference. With typical hemostasis, I was taught as a surgeon that you cut what you need to cut and you stop the bleeding. The next level of that is, you never open 4 × 4 sponges for the operation. You simply do not open them, because bleeding simply does not occur. For those who have seen this operation done, they know it's possible. In fact, I know everyone sitting at this table knows that that's possible. I would add to that absolutely simple things, such as "Do not touch ribs with instruments." Surgical trauma is a major thing. I would also add that all choices should ultimately be made by the patient, unless the patient specifically relinquishes those choices to the surgeon in informed consent documents. Finally, the best way to measure all this stuff is by how the patient recovers. We can all stand up in meetings and talk about how we do surgery and atraumatic technique and no bleeding, but what we need to do is have a surgical Olympics, where surgeons operate side by side and we put a television camera with that patient beginning the minute she walks out of that surgery center, actually while she is recovering, and follow her for 24 hours. That would eliminate a lot of the subjective opinions and whatever that we hear at meetings. I think that needs to be done, and it has been done. People do not know, but it has.

**Teitelbaum:** Dr. Adams, any other absolutes that you can agree with, disagree with, or add to what we have already discussed?

**Adams:** I agree with everything that's been said. I would just again reemphasize that I think it's very easy to disregard the patient education aspect in this whole process that we've discussed, when in reality that's probably the single most important thing to do. If that's not done correctly, requests for size change and dissatisfaction, will be elevated.

I also think it's very important to, in your clinical preoperative process, make logical decisions and make as many of those as you can before you go into the operating room. The operating room then is just a template, systematic procedure, which has been alluded to by the other panelists.



I think doing that allows the operation to be carried out in a very systematic fashion and will allow you to have some of the benefits of 24-hour recovery and all the other things that we've talked about.

**Jewell:** Two things. One is the value of data keeping and collection, whether it's using the Tebbetts system or Bill Adams' approach or whatever. But collect data, get measurements in the beginning and collect them serially with regard to the outcome of your patient. If the patient is bottoming out, you will at least be able to spot that. Follow your numbers to see what is going on and use that as a way to improve your quality.

I think the other aspect is the issue of artistry in the operating room, the gestalt, and all the other things that people claim as great surgeons. I come into the operating room with a predetermined size of implant. I am able to get it right and size them, and it works very well, versus having two sizes above and two sizes below, with a backup in each category. So, improved techniques, and also the mindset that this is a manufacturing process. It's not artistry, and we're not Michelangelo with a block of granite here, but we are working on tissue. We need a process and a way to manage factors.

**Teitelbaum:** Everyone of you has said that education is important to reduce reoperations, but most surgeons think of education only as giving informed consent. Will one of you explain clearly why education reduces reoperations? Dr. Tebbetts?

**Tebbetts:** The better the decisions are that a patient makes first, and the surgeon makes second, the lower the reoperation rates will be. Any decision that's not based on education, or, stated another way, the more thorough any level of education, the higher the level of education, you at least have content on which to base decisions. Then education is not simply presenting content, whether it's to surgeons or to patients. Education assumes several things. One, it assumes that you have a body of content that's valid, and we certainly have that. Two, you have to have a method of delivery of that content that effectively delivers the message. Then you have to have some way of verifiability that I mentioned with respect to surgeon education. Only when those things are in place do you really have an educational process that is valid according to published educational models. Now, what does that all mean when it translates to the patient? It means that, and this has been stated time and again in medicolegal seminars and discussions, you present content to

a patient, and then that patient, by law, by informed consent law, has to make decisions. Informed consent law says that the patient has to make the decision. So you present content to the patient but not at a single setting, because they cannot digest all of it. You present it to the patient in multiple stages at different times, with intervals in between for the patient to digest it. Then you aid them in the decision-making process using templated systems, so that you make the patient make her own choices and you hold the patient accountable for the choices she makes. All of that is published. At least one system was published in this *Journal* in, I believe, October of 2002/2004. All the documents associated with that publication that we use are downloadable from the *Journal's* Web site, and certainly we are happy to provide input or additional documents to anyone who e-mails.

**Bengtson:** I think that kind of a big picture thing, what John is talking about, that covers the specifics, is really important to emphasize. One, we have to take a patient from what's possible to what's best. Where I am right now is that I present patients with a couple of paths. They come in and I'm still trying to figure out exactly what factors the patients used to get to the point where they think they want a certain breast implant size or cup size. We need to go from basically path no. 1, which is "I have in my mind," from the patient's standpoint, "where I want to be," to a path that says, "based on my specific breasts, my measurements, and my soft-tissue characteristics, what implant is best for me?" So that afterward, instead of patients being unhappy and always wanting something different, you can get them to say, "You know what? It may not be exactly what I thought I was going to get when I came in, but I have the best implant that's best for me and my body." I think that ultimately is my goal when I educate a patient.

**Tebbetts:** I would just ask Brad. . . . I think I know what you are talking about here, but to me one problem that we have is that we talk about a best implant. I think what you mean is, or I would ask you if what you mean is, what are the best options available to me, because there is no, in my mind, certain implant that's necessarily best in the hands of a skilled surgeon. A skilled surgeon can deliver acceptable to excellent results with virtually any implant. Now, the trade-offs are different, but is that what you mean?

**Bengtson:** Exactly. That's much better said. As always, you can say things much better than I can. I think the key, really, is as you talked about, and the patient does need to decide. Here are the

options, here are the trade-offs, which I love, and here are the good things and the bad things. There is not one best procedure or one best approach in all situations. Just to clarify what you talked about earlier, I think the patient. . . . Ultimately, the question comes to my mind, and I ask a lot of different surgeons this, who ultimately decides on the breast implant? Is it the patient or the surgeon? I think it is the patient, but it's based on what she presents with, with her breasts. When you say that the patient determines the breast implant and it's the patient's choice, I totally agree with that, and I think you would agree too, but it's up to the limit of what's best for her body. If she's asking me to go beyond that, then I do not do that operation.

**Jewell:** I also would like to commend John Tebbetts in this situation for writing his article with regard to outpoints, which is in a way saying to a patient, "Time out. You've been through three capsulectomies, and you've had new implants each time. You have recurrent capsular contraction; either live with it or take them out." And end the whole process, versus the expectations of trying to get it right when it hasn't gone right so far.

**Tebbetts:** I'd like to briefly add to what Dr. Bengtson said about the educational process. Another concept that's very helpful, or at least it's been helpful to me, is, in the educational process, as we present options to patients, to the extent that we can remove all the grays, we do that. In other words, you either want this, this, or this. There are no in-betweens here. When you allow patients to manipulate you into an in-between, regardless of what that is, you cannot deliver, because it's undefined. So to the extent that we can define exactly what we can do and what we cannot do, and we tell the patient what we can do and what we cannot do, those are the only viable choices.

**Teitelbaum:** Dr. Bengtson, what is the role of the manufacturers in this process to improve patient outcomes?

**Bengtson:** I really struggled with this whole concept. John would be upset with me, I think, but I was watching "The Price Is Right" between surgeries, in our surgery lounge. Yeah, little Tebbetts pops up on my shoulder and says, "You are not being efficient with your time. What are you doing there?" But watching these commercials, 100 percent of the commercials were manufacturer-based commercials direct-marketing to the patient pharmaceuticals, or knee replacement, or hip replacement, those sorts of things. I may come down pretty strong on this, but I think that the role. . . . My dad told me one thing. He was an educator for

a long, long time, both my parents were, and we were going through this discussion at the hospital. The hospital was basically trying to take over the practice of medicine, and I had this discussion with my dad, who had just retired from education, and he said, "Brad, we have the same problems in education. The role of the school or the university is to facilitate the education that occurs between a teacher, a professor, and a student." And I told the hospital administrators that, that they were trying to do this hospital merger in town and that doctors were not really for it. So this whole discussion ensued, and I said, "I think the hospital's role is to be a facilitator of the practice of medicine that occurs between a physician or a surgeon and a patient." I think the same is true for manufacturers. They can be a tremendous support. They can sponsor things, they can have very thorough Web sites with the information and everything like that, but I think their primary role should be to facilitate the best outcome possible with whatever device or drug that they have, to facilitate that surgeon-patient interaction and not get into the direct education of patients and that sort of thing.

**Teitelbaum:** Dr. Jewell, as you answer for us what you believe the role of the manufacturers could be, would you also discuss the role that the societies have, and how the two of them should be working or not working together?

**Jewell:** With regard to the role of the manufacturers, one is to keep a focus on improvements in these devices to minimize problems that still exist, with regard to an underfilled device, trickling, and things of this nature. Granted that most devices are made in ISO 9000-certified facilities, yet at the same time I think technologic advances can improve the quality of the devices. I think the aspect of a registry with transparent data in terms of how these devices perform is imperative, and it provides a benchmark of quality that surgeons and patients can understand and use to make decisions with regard to which devices are used.

Concerning the role of the professional societies, at [The American Society for Aesthetic Plastic Surgery], we are an educational society, and it is hoped that we can meet Dr. Tebbetts' standards with regard to surgeon education and verification of knowledge. But I would say there needs to be sort of a separation between church and state. Too often issues regarding manufacturers relate to competition, and that, in many cases, interferes with education.

**Tebbetts:** This happens to be an area that I've had a lot of experience with over the years. I plan to be entirely candid, regardless of who may dis-

agree or be offended by the following comments. First, from a very simple standpoint, breast implant manufacturers, like surgeons, should prioritize the patient in decision processes and actions, not just in their verbiage and marketing hype. Manufacturers have a responsibility to provide information that optimizes the use of their products. They, further, in my opinion, have an ethical responsibility to support surgeon education. The most effective way for manufacturers to positively impact reoperation rates is to support surgeon and patient education programs that focus on those seven priorities I listed earlier, and not purport to educate surgeons only in venues that are designed to primarily promote a company's products. While manufacturers have a responsibility to their stockholders to sell products, and they all have a right to hold venues to sell products to surgeons, I believe they also have a responsibility to patients to not only provide the best products possible but to contribute to and facilitate surgeon education using the approved processes that I discussed earlier.

Manufacturers also have a responsibility to provide surgeons and patients with complete and honest information about their products, about outcomes data, and about explanted device retrieval data. Currently, manufacturers do not share some basic information about implant products that could possibly impact patient outcomes, claiming that that information is proprietary. Manufacturers reintroduce products as "new" when in reality products are simply recycled versions of previous products from the past two decades. Manufacturers copy each other's products and "design" products without input from experienced clinical surgeons who best understand how those implants interact with patients' tissues over time. Manufacturers often select surgeons to "teach" who they feel will most effectively promote their products and who are least likely to challenge colleagues in an educational venue. Management at high levels in breast manufacturers sometimes lacks the most basic knowledge of clinical information that directly impacts outcomes in breast augmentation. Some high-level managers and decision makers have not reviewed even the most basic scientific literature that documents processes that have positively impacted patient outcomes. The result is a large number of decisions that impact patient outcomes being based primarily on marketing concerns instead of basic clinical knowledge about augmentation. Most recently, manufacturers have virtually excluded expert surgeons and their own appointed medical directors

from involvement in PMA study decisions that could directly impact patient outcomes.

So, to summarize, manufacturers have a responsibility to their stockholders; they should educate about their products; they should support surgeon education that is not product-related; they should deliver information and make that information transparent when it affects patient outcomes; and finally, they should rely in their decision-making processes on the help of expert surgeons in this area.

**Teitelbaum:** Dr. Adams, the reason often given by societies for not changing the way they teach about breast augmentation is that it would set a new standard of care. How would you respond to that?

**Adams:** I think that we ultimately are there for the patient, and I think that, as with other areas of medicine over time, better patient care has been delivered because the standard was revised and critically analyzed and changed over time. So, to that end, it is clear that things have evolved in breast augmentation and that there is a higher standard that we all can live by. Ultimately, the beneficiary of that is going to be the patient.

**Bengtson:** I agree. I think the focus should be on the patient. I tell the residents who are in our training program and our new associates that, ultimately, your heart and focus need to be on the patient, and that all the other things will kind of come into play and will work out fine, if you keep that focus. If you lose that focus because of either money, ambition, personal gain, or whatever it is, you are going to lose the ultimate goal and oftentimes end up with the exact opposite effect that you want.

**Teitelbaum:** Dr. Tebbetts, raising the standard of care seems to be a goal that should be axiomatic for any medical specialty. What is your perception as to the reason for resistance to doing that within our own specialty for augmentation mammoplasty?

**Tebbetts:** Insecurity.

**Teitelbaum:** Meaning what exactly?

**Tebbetts:** If I had to. . . First of all, I do not know. I think there are many possible reasons for people not wanting to change the standard of care. One of those is fear or insecurity that if somehow that standard of care is elevated, that I, as a surgeon, might have to change my lifestyle. I might have to make decisions differently. I might have to learn something different. I might have to adjust what I do, and I really do not want to do that, for whatever reason. But at the end of the day, the issue of standard of care should be very simple. Again, I would love to hear any surgeon explain to



any patient in a public forum, or explain to any patient advocate group in a public forum, their position that they do not want to elevate standard of care. I would love to hear that explanation.

**Bengtson:** Just a general comment. There is a really interesting article that came out about 5 years ago that showed that once a physician does a certain approach for more than 5 years, it's very, very difficult to get him or her to change that. I do not know all the different reasons for that, but I think that is really something that we will really have to address, because it is very difficult to teach something that everybody has done as a new procedure. For instance, just as an example, when the formed stable cohesive gel implants come out, if surgeons do not approach this as a brand new procedure, similar to going from an open brow lift to an endoscopic brow lift, or a skin-only face lift to a SMAS, there are really going to be problems and issues with it. That's a big fear that I have.

### QUESTION 5

**Teitelbaum:** Last question for Dr. Jewell: There is resistance about dramatically changing curricula, because there is concern that it would change the standard of care. *Why would the societies not want to do everything they could to constantly be raising the standard of care and always be challenging their membership to be doing new and better things for the patient, even if it were frustrating and demanded more learning from the doctor?*

**Jewell:** I agree. I think we should do everything through an educational process that eliminates this ambiguity in what we do and this sort of workaround culture. To say to our insecure colleagues, "It's okay. Take a leap of faith. Be an experimentalist. You will surprise yourself with regard to what you are capable of changing."

**Teitelbaum:** Dr. Jewell, you are president of the largest aesthetic plastic surgery organization in the world, and education has not changed dramatically in recent time, and I still heard, as recently as yesterday, that people do not want it to be a changed standard of care. So it's still not happening. Explain to me how you believe what you are saying today, but yet.... Where is the obstruction to what you believe, that you just told us, being implemented?

**Jewell:** I do not know if it's necessarily obstruction to implementation as much as a problem with adaptation. There are individuals who can adapt quickly to change. The vast majority, 75 percent of people, are either slow to late adapters, are cautious and reticent to change. We made changes,

for instance, in the S8 breast course curriculum here in New Orleans. We had longer presentations. We had in-depth discussions with regard to technique and technical factors.

**Tebbetts:** It strikes me as obvious that there is nothing wrong with a surgeon being insecure about doing something that the surgeon doesn't know how to do. It seems to me that that is in the best interest of the patient. So inherent to this entire discussion we are having is the premise that a surgeon shouldn't do what a surgeon doesn't know how to do, and that we must provide content that is verifiable, that is peer-reviewed, and that defines these processes, and we must do it really effectively. So, to make that really simple, we've got to give people not just a set of options; we have to tell people how to do this. The better the information we can provide, the more effectively we can deliver it. And to me, the answer is fairly clear: We simply haven't done that. We haven't done it effectively.

### CONCLUSION

**Teitelbaum:** As we are getting ready to conclude, I want to see if you can agree with the conclusion I want to draw from what I've heard. The conclusion I would make is that we've all agreed that the standard of care has changed. Peer-reviewed published data and the results that all of you have described you are getting yourselves, since you've looked at your own results, which have made you face reality and make necessary changes, have proven that a new level of augmentation with lower reoperations is already possible. Does everybody agree with that?

**All:** Yes.

**Adams:** That's it, then. Thank you very much. I say we make that a consensus statement of this roundtable. I would like to, again, thank each of you for participating, and I think this will make a great addition to the upcoming supplement.

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### DISCLOSURES

*Dr. Adams serves as medical director of the Mentor Corporation cohesive gel implant trial; an investigator for Inamed and Mentor cohesive gel IDE trials; an Inamed Academy faculty; and an Ethicon Innovation Council member. Dr. Teitelbaum receives travel expenses and a stipend for teaching from Inamed; he also receives office expense reimbursement for conducting clinical trials of cohesive gel implants from Inamed, Mentor, and*

*Silimed. Dr. Bengtson is an active participant in both Mentor and Inamed's adjunct silicone implant studies, is one of the lead investigators for Inamed's Style 410 cohesive gel implant study, and receives nominal fees to help administrate and offset the Style 410 implant study; he has participated in Inamed Academy teaching courses and received a stipend for his time and travel. He is not a consultant and has no patents, financial interest, or stock or equity interest in any implant company. Dr. Jewell is an approved clinical investigator for Inamed*

*and Mentor gel studies (Inamed Core and Style 410; Mentor CPG); he has received a small stipend from both companies to compensate administrative staff time regarding clinical follow-up and medical records administrative activities. A member of Dr. Tebbetts' family is an employee of a business entity that receives consulting fees and product royalty payments for products designed by the author from Inamed Corporation and Cardinal Snowden Pencer Corporation. Dr. Spear is a consultant to Lifecell, Ethicon, and Inamed corporations.*