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CHAPTER 4 ADDENDUM I

Invited Discussion

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ADDENDUM 1, CHAPTER 4

DISCUSSION

In the final analysis, there has never been a more closely scrutinized medical device than the breast implant. Moving forward from the original design introduced in the mid-1960s, tremendous improvements in engineering and clinical performance have been realized thanks to the expert input of experienced clinicians and talented engineers. The science of silicone has been elucidated thoroughly, and the currently available line of both silicone and saline breast implants are the best and safest implants yet devised. This is not to say that the journey has been easy. The silicone gel implant controversy of the early 1990s significantly hampered further design improvements in breast implants, and even at this late date, improved devices are still held up in the U.S. Food and Drug Administration review process, largely as a result of the stringent evaluation criteria that were developed to ensure the safety of these devices. How- ever, as difficult and frustrating as this process has been, one positive aspect that has emerged from this experience is that the design and manufacture of breast implants in the United States serves as a model of medical device manufacturing that is geared to the highest standards of performance and patient safety. It is with this in mind that the unfortunate Poly Implant Prothèse experience must be viewed.

To summarize, one individual, who is now under indictment, opened a breast implant manufacturing facility, Poly Implant Prothèse, or PIP, in France that eventually led to the manufacture of devices with several different types of industrial grade silicone as opposed to medical grade silicone. Also, the manufacturing processes used to make these devices were found to be substandard. In addition, over the past decade, an inordinately high rate of rupture of Poly Implant Prothèse implants was noted. This elevated rate of rupture is now confirmed in this article by Maijers and Niessen. As noted in the article, at 10 years, the per-implant-used rate of implant rupture is 24 percent and the per-patient rate is 33 percent. All of these devices were round, textured implants with a mildly cohesive gel. Taken at face value, this rupture rate is high; however, as noted by the authors in Table 4, other series have likewise demonstrated similar rates of shell failure with other types of devices. In one such study, an anatomically shaped, mildly cohesive silicone gel implant design from the early 1990s was associated with a per-implant rupture rate of 19 percent at 6 years.[1]

However, it is not necessarily the rate of shell failure that is the disturbing aspect of these findings, as other devices rupture at an equal or greater rate. Rather, it is the callous disregard for proper manufacturing practices that is the hallmark of this sad episode. The gel inside the implant is basically of unknown composition, as the formula used to create the gel was used in a hap- hazard and nonuniform manner, with the com- position of the gel changing according to the whims of the manufacturer.[2] Also, adherence to standard norms of responsible manufacturing was either insufficient at best, or nonexistent or even fraudulent at worst. It must be realized that cur- rent manufacturing processes of breast implants for companies based in

the United States use rigid controls and testing at every step of the process. Issues related to device standardization, toxicity testing, sterility, handling, packaging, and processing are monitored not only by the companies but also by frequent audits by the U.S. Food and Drug Administration. It is possible to actually visit a manufacturing facility for breast implants, and after witnessing first-hand the exacting and precise controls that are in place for the manufacture of these devices, one cannot help but be reassured about using these devices in our own patients. It is this level of ethical business conduct and device manufacturing that was sorely lacking with the Poly Implant Prothèse implant.

Given the fact that it is the composition of the gel—and not necessarily the fact that the shell fails at a high rate—that is the problem, it is then easy to understand why some would advocate removal of any known Poly Implant Prothèse implant. As noted by the authors, the rate of shell failure is essentially the same for the two groups studied, one with what is presumably an accepted form of silicone gel (year 2000 patients) and one with the industrial grade gel (year 2001 patients). How- ever, given the uncertain manufacturing processes applied to both groups of implants regardless of when they were made, coupled with the advancing age of these devices from the year 2000 and earlier, the recommendation to remove any and all Poly Implant Prothèse implants regardless of age can easily be supported. It has been suggested that devices manufactured after the year 2001 were subject to even more inconsistency and question- able manufacturing techniques, a fact that would seem to mandate removal of any device implanted in a patient regardless of when it was made. The basic fact is that the composition of the gel cannot be ascertained with any degree of certainty, and leaving an implant in situ creates unknown risk for the patient. As shown by this well-researched and well-documented article, it was only a minority of patients who presented with symptoms referable to their ruptured devices. Most of the ruptures were silent and were evident only on magnetic resonance imaging evaluation. Also, 13.5 percent of the patients presented with extracapsular leak- age of gel, an ominous finding, as removal of the gel can necessitate partial or even complete mastectomy in cases of significant parenchymal infiltration with silicone oils and gel. Considered together, it is clear from the data presented in this article that physical examination is an imperfect method of detecting rupture, the risk of silent rupture is significant, and leakage of gel of uncertain composition into the surrounding tissues is a described phenomenon. One could easily make the argument that not only should the implants be removed but also that a capsulectomy should be performed in an attempt to remove as much of the untested gel as possible that may have migrated into the surrounding capsule. It must be recognized, however, that a capsulectomy represents another magnitude of complexity related to implant surgery, and it remains to the best judgment of the operating surgeon as to the indications for such an approach in each individual patient.

The Poly Implant Prothèse implant controversy has enormous implications for health care in countries where the implant was commonly used. In France, the recommendation has been that each woman should have the implants removed, and public funds in a time of financial instability have been allocated to allow this to occur. Also, the impact of this recommendation on the individual practices of the physicians involved is significant. It is also likely that issues such as

this will recur in other developing countries where low-cost breast implants are being manufactured and sold. Given the Poly Implant Prothèse experience, it seems prudent to remember the old adage that you get what you pay for. Taking into account the facts presented in this article and the points of argument raised in this Discussion, it is the responsibility of the individual surgeon to evaluate each patient and determine whether implant removal is indicated after assessing the risk of a repeated breast procedure. As always, decisions must be individualized and made with the best welfare of the patient always in mind. Maijers and Niessen are to be congratulated for providing compelling, timely, and useful data that will allow informed decisions to be made to guide principled and sound patient care.

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