Secondary Surgery and Silicone Implants: One Center's Experience Before and After the Food and Drug Administration Hearings of 1991 and 1992

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Learning Objectives:
The reader is presumed to have a broad understanding of plastic surgical procedures and concepts. After studying this article, the participant should be able to:

1. Define the changes in the practice of breast implant surgery that followed the FDA hearings on silicone gel-filled breast implants.

2. Characterize the expected life span of breast implant devices, which can be predicted from historical data.

Physicians may earn 1 hour of Category 1 CME credit by successfully completing the examination based on material covered in this article. The examination begins on page 175.

A retrospective study was performed to compare reoperative breast implantation surgery before and after the Food and Drug Administration (FDA) hearings in 1991 and 1992 on silicone breast implants. The two groups were compared regarding the motivation, findings, and procedures associated with the operations.

One hundred seventy-one patient records were reviewed covering the years 1989 to 1994, evenly straddling 1991; of those, 146 charts had sufficient data to be included in the study. Each implant and each implantation operation were counted as a separate event. Before November 1991, 64% of reoperations were performed on the senior author’s own original patients, whereas after 1991, only 33% were. Fifty-seven percent of the reoperations performed before November 1991 were performed on patients requiring augmentation in contrast to those patients requiring reconstruction; after 1991, 78% of the reoperations were augmentation mammoplasties.

In the early period, reoperation was primarily performed to correct asymmetry (47%) or...
capsular contracture (47%); it was rarely performed for rupture (3%) or infection (3%) and never for anxiety or pain. In the later period, contracture (44%) and asymmetry (18%) remained as common causes, but anxiety (11%) and pain (8%) appeared as new factors, and rupture was suspected more often (21%). One of the most dramatic, if not surprising, findings was the choice for replacement implant. In the earlier period, saline solution-filled implants were used 12% of the time, whereas in the later period, they were used 80% of the time. Finally, implants removed that were more than 15 years old had ruptured nearly 50% of the time.

Since 1991 much attention has been focused on women who have undergone silicone implantation surgery. This study is a review of one surgeon’s experience over a 6-year period with women requiring secondary breast implantation surgery. The goal was to collect epidemiologic and clinical outcome data and evaluate trends occurring in the aftermath of the implant controversy that erupted in 1991.1

Material and Methods

The 6-month period from the fall of 1991 to the spring of 1992 was a pivotal time in the history of silicone gel-filled breast implants. During that time, television newscaster Connie Chung aired her controversial investigative report on CBS, and then-Commissioner David Kessler of the Food and Drug Administration (FDA) announced a moratorium on the use of silicone gel-filled implants.2 In the news media alone, the number of magazine articles and television and radio programs increased over 1000% after November 1991, compared with the previous 3 years (unpublished data; http://www.ohiolink.edu). There was a simultaneous increase in the number of articles published in professional journals that dealt with all aspects of silicone gel-filled implants.3–19 Therefore for the purposes of this study, we defined the predebate period as the years 1989 to 1991 and the postdebate period as the years 1992 to 1994.

In this retrospective study of the senior author’s cases from 1989 to 1994, 171 consecutive patient records were evaluated. More than 50 different items were reviewed, including implant type, implant location, perioperative complications, systemic illnesses, type of reoperation, and number of device ruptures. Of the 171 charts reviewed, 146 charts had sufficient data to be included. The study group was composed of women who had their original silicone gel-filled implants removed or replaced and included patients who had undergone reconstructive or augmentation surgery. Each implantation surgery was counted as a separate surgical experience, and data were collected about each implant. These data were evaluated to determine trends in referral, motivation, and outcomes for patients who had secondary breast implantation surgery and were assessed in light of the two defined time periods.

Results

Of the 146 patient records that contained sufficient information, 91 breast reconstructions (40 patients) and 212 breast augmentations (106 patients) were performed. Some of the reconstructions were counted more than once because the patients had more than one reoperation during the study period. Each operation was counted as a unique event. Before 1992 a majority of the patients (64%) initially were patients of the senior author. After 1992, only one third of the patients had their initial operation performed by the senior author; approximately two thirds (67%) of the patients had their initial operation performed by other surgeons (Figure 1). Although augmentation remained the primary reason for the original operation throughout both periods, the percentage of patients undergoing reconstructive surgery in the postdebate study population decreased from 42% to 21% (Figure 2). The number of patients who underwent augmentation increased from 57% to 79%. Twenty-five percent of the original implantations were subglandular in the early period, whereas 43% were initially subglandular in the later period.

I reoperated on a total of 120 breasts (77 patients) in the 1989 to 1991 period, as compared with 183 breasts (100 patients) in the 1992 to 1994 period. Capsular contracture was found to be the primary and most common impetus for surgery in both periods; 47% in the early period and 44% in the later period (Figure 3). Before 1992 no patients mentioned anxiety as the motivating reason for their secondary surgery. During the next 3 years, though, 11% of the women identified silicone anxiety as the primary reason for undergoing secondary breast implantation surgery. In addition, before 1992 only about 3% of the patients sought reoperation because of suspected implant failure; this increased to 21% in the postdebate period. No patients mentioned systemic connective tissue complaints (e.g., scleroderma,
fibromyalgia, or lupus) as a primary concern in the early period, but 11% did in the later period.

There was an increase in the number of gel-filled implants removed during the post-FDA hearing period (1992 to 1994) as compared with the earlier period (Figure 4). This correlates to the increased number of patients whose initial surgery was performed by other surgeons who used more gel implants than the author. The average age of the implants removed in the posthearing period was 5 years older than in the earlier period. Similarly, the number of failed or ruptured implants identified at the time of reoperation in secondary surgery also increased in the posthearing period (Figure 5).

In the early period, 120 implants were removed or replaced; 17 of these (14%) had ruptured. Ninety-four of these implants were less than 5 years old, and of these, nine (9%) had ruptured. Of the six implants that were more than 10 years old, three (50%) had ruptured. In the later period, 183 implants were removed, and 58 (32%) had ruptured. Forty-nine of these 183 were less than 5 years old, and only 4 (8%) of those 49 had ruptured. Sixty-three of the 183 implants in the later period were more than 10 years old, and 35 (55%) of those 63 had ruptured. Of the 28 implants over 15 years old, 19 (68%) had ruptured.

A combination of factors, including patient preference, evolving surgical philosophy, and FDA regulations led to a shift of procedures and the type of implant used after 1991. In the early period, there were 55 capsulotomies. In the later period, there were only 12 capsulotomies and 112 capsulectomies. In the predebate period, saline solution-filled implants were used for replacement implants in only 12% of the cases, but in the later period from
1992 to 1994, saline solution-filled implants were used for 80% of the replacement implants (Figure 6).

**Discussion**

The peak of the silicone gel-filled implant controversy in the fall of 1991 and the winter of 1992 was a turning point in the use of those devices. This review examines a number of different issues that arose both before and after the FDA hearings of 1991 and 1992. One of the most significant findings was the change in patient populations. Increased media attention in 1991 and after affected the flow of patients both new and old. Before 1992, 64% of the patients on whom reoperations were performed had originally been operated on by the senior author; after 1992 that number fell to 33%. A great many patients came forward in response to the FDA hearings and media attention. These patients often sought surgeons other than their original surgeon, either because of a change in referral pattern, conflicts with the original surgeon, or loss of continuity with the original surgeon. With this change in patient traffic patterns, the number of patients with silicone gel-filled implants on whom I reoperated for breast reconstruction declined from 43% to 21% after 1991. This change in patient mix
accounts for some of the other differences found between these two groups.

In the early group, reoperation was related to local problems such as capsular contracture (47%), asymmetry (47%), infection (3%), and suspected rupture (3%). Asymmetry was common because so many of these patients had had reconstructive surgery. With the increase in media attention and the proportionate increase in augmentations, asymmetry (18%) was less an issue, but pain (6%), anxiety (11%), and suspected rupture (21%) had become more important problems to address.
Before 1992 many of the patients on whom we had reoperated had relatively new silicone gel-filled implants. After 1991, with the increase in the number of patients operated on by surgeons not in this practice came an increase in the age of the implants themselves. In the early period, 94 (78%) of the 120 implants were less than 5 years old. In contrast, in the later group, 123 (67%) of 183 implants were more than 5 years old. With the increasing age of the implants came an increasing frequency of rupture. Thus after 1991 32% of the implants had ruptured, whereas only 14% had ruptured in the earlier period. In addition to the increasing age of those implants comes the likelihood that many of these older devices were not made as well as the newer implants, which are made with more durable silicone elastomer shells. The older the implants, the higher the rupture rate. In the later group, 8% of implants less than 5 years old were found to have ruptured. For implants that were between 10 and 15 years old, 41% had ruptured. Figure 5 depicts the age at which 50% of the study implants were likely to rupture.

Although data on ruptured implants are significant, it is important to remember that these were earlier-generation implants and that the patients were not randomly selected but rather were operated on for symptoms including suspected rupture. Thus the rupture data from our experience are almost certain to be worse than one might expect from an asymptomatic group. Our patients, like patients in many other reported series, were preselected and thus our data are subject to some selection bias.

In the earlier period, capsulotomy was commonly performed; after 1991 capsulectomy was far more common. This correlated with a number of factors, including a greater number of ruptured implants and increased patient anxiety after 1991. In addition, during this period, capsulectomy became our preferred treatment for most patients with capsular contracture. It is our impression that most patients do better if the scar capsule is also removed at the time the silicone gel-filled implants are simply removed or are replaced with new silicone gel- or saline solution-filled implants. We are careful, however, not to remove the capsule if it will jeopardize the skin, muscle, or chest wall. When possible, during implant replacement surgery, we place the new implants in a subpectoral position, which we believe is a generally more favorable position than the subglandular position for accurate mammography.

With the media’s critical attention to silicone gel-filled implants, the FDA’s moratorium on their use in January 1992, and the subsequent restriction of their use in April 1992, it is not surprising that silicone gel-filled implants were used less often after 1991. In the early period 12 (12%) of 102 replacement implants were saline solution...
filled, whereas 81 (80%) were silicone gel filled, either double-lumen (56%), polyurethane (16%), or single-lumen gel (8%). After the peak of the silicone controversy, the use of saline solution-filled implants rose to 106 (80%) of 133. The use of silicone gel-filled implants fell to 16% (21 of 133). Only 4% of the patients in the early group chose to remove their implants without replacement; after 1991, this number increased to 24%.

In analyzing the trends that have occurred in one institution since the silicone debate ignited in late 1991, it has become obvious to us that there is at least a temporal relationship between the media presentation of implant data and the public’s response. This is not surprising, as evidenced by Larson et al., who found that most patients relied on the media as their primary source of information on many issues, including breast implants.

To further assess the attention that breast implants have gotten in the mass media over the study period 1989 to 1994, a computer-based reference guide, Periodical Abstracts, was used as a reference source. Periodical Abstracts is the mass media’s equivalent to Medline. It is a computer catalogue of more than two million articles and television and radio programs from more than 2000 sources since 1986. In the prehearing period, only 31 articles and one television program highlighted breast implants. From the time the Connie Chung report aired (November 8, 1991) to the end of 1994, 272 articles had been published, and 56 television programs and six radio programs had been broadcast, representing an increase of more than 1000% in coverage of the breast implant controversy (Figure 7). We believe that the combination of media attention with then-FDA Commissioner Kessler’s announced FDA restriction on silicone gel-filled implants (effective April 1992) were important factors in our experience with women requiring secondary breast implant surgery during the period 1992 to 1994.

Conclusion

Media and FDA scrutiny of silicone gel-filled implants has certainly affected our practice and that of all plastic surgeons who use these devices. As a result, there was a marked critical change during the fall of 1991 and winter of 1992 in how these devices are used and how they are regarded by surgeons and their patients. There is now a clear understanding that these devices, and perhaps all devices, have a limited life span. Their potential for failure is most likely a function of time: older implants are more likely to fail than newer ones. The realization that someday the fill material may very likely escape the containing shell affects the way plastic surgeons and their patients think about implant fill materials.

In spite of their shortcomings, saline solution–filled implants are exceptionally safe in the event of a device rupture. And although saline solution–filled implants have a reputation for more frequent rupture than silicone gel–filled implants, the data from this and other reports suggest that the failure rate of older gel implants may in fact be comparable.

Recent scientific studies cast doubt on the prospect that silicone gel–filled implants cause any systemic illness, either connective tissue or cancer. Nevertheless, the media’s attention to implants has brought forward a great many patients with older implants who have a variety of concerns, some valid and some proven invalid. Many of these patients ultimately had surgery and were helped. The knowledge and experience gained from this episode by the public and plastic surgeons have ultimately enabled us to become better equipped to deal with the future sequelae of these and other devices.

References