

Special Report

Initial Report From an Online Breast Augmentation Follow-Up Survey

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Background: *The first Online Breast Augmentation Survey (Aesthetic Surg J 2004;24:117-135) reported on women who had undergone or who were considering breast augmentation with regard to motivation for surgery, patient satisfaction with results, and other issues. The Food and Drug Administration and others have also raised questions concerning informed consent, follow-up, health insurance, and related issues dealing with breast augmentation.*

Objective: *An Online Breast Augmentation Follow-Up Survey was designed to collect data from women who had undergone breast augmentation with regard to informed consent, follow-up, complications and problems following breast augmentation, and health insurance.*

Methods: *The survey comprised 56 questions, many of which were presented in a multiple-part format. Women who visited the Web site www.implantinfo.com and who had undergone breast augmentation were invited to participate in the survey. An independent research firm, Industry Insights, Inc. (Columbus, OH), assisted with the final design and collected and analyzed the data.*

Results: *The survey was posted from April 8–June 30, 2003. Surveys were submitted by 1350 women. Ninety-two percent of respondents said that surgeons asked them to return for regular follow-up during the first postoperative year. Ninety percent said they would return to the original surgeon if a problem developed. Almost all respondents (94%) said that they had been informed by the surgeon, the surgeon's staff, or both of specific problems or complications that might be associated with breast implants and augmentation; 89% said that the information they received was adequate. Eighty percent said they complied with the surgeon's recommendations for follow-up visits, although compliance declined after the first postoperative year. The survey also showed that most women who undergo breast augmentation seek out information about the procedure before surgery from independent sources, in most cases from Web sites. Eighty-eight percent of respondents said they were involved in some way in deciding on implant size; 88% said they were satisfied with breast size after surgery. Fourteen percent of respondents reported additional implant-related surgery after the original augmentation.*

Conclusions: *Our data indicate that almost all patients are advised to return for follow-up visits, that most comply with their surgeons' recommendations for follow-up in the first postoperative year, and that the main reason for non-compliance is an absence of problems with implants. The survey also indicates that patients receive adequate informed consent from the surgeon or the surgeon's staff and that they also seek out information on their own. Finally, the data suggest that women who have undergone augmentation have a realistic appreciation of the problems involved and are willing to tolerate minor complications. (Aesthetic Surg J 2004;24:229-243)*

In a previous article (*Aesthetic Surg J 2004;24:117-135*), we reported results from our first online survey. The instrument — the Online Breast Augmentation Survey (OBAS) — was designed to collect data from a large, geographically diverse, and anonymous group of women with breast implants. Posting of the survey on an independent Web site (www.implantinfo.com) and subsequent data analysis

were funded by the Aesthetic Surgery Education and Research Foundation (ASERF).

The OBAS was so successful and produced so much data that we decided to design a second survey to address additional questions concerning breast augmentation that have been raised by officials of the Food and Drug Administration (FDA) and its Scientific Advisory Panel on Medical Devices, as well as by members of the

plastic surgery community. FDA officials and others have criticized plastic surgeons and breast implant manufacturers for the number of patients who are lost to follow-up in research studies and the current clinical trials of silicone gel and saline implants. Additional criticism has come from some opposed to the availability of breast implants (especially those filled with silicone gel) who have claimed that plastic surgeons do not provide sufficient or accurate information to prospective patients that would allow these women to make a truly informed decision about breast augmentation. These critics also maintain that women with breast implants cannot obtain health insurance. Such assertions require data to support or refute them.

One of our primary purposes in designing this Online Breast Augmentation Follow-Up Survey (OBAFUS) was to investigate why some women do not return to their surgeons for routine follow-up and what might motivate them to refrain from doing so. We also sought to learn what survey respondents remember about the information they received as part of the informed-consent process before breast augmentation. In addition, we included a series of questions to assess the availability of health insurance to women with implants. Finally, whereas the OBAS asked whether survey respondents had experienced complications or problems related to their implants, in the OBAFUS we explored this issue in greater depth. We asked women who had experienced complications to rate their severity as a means of learning how bothersome specific problems are to the women themselves.

The OBAFUS required a serious time commitment from the women who responded, and we are greatly indebted to them for their willingness to participate. Our gratitude again extends to the www.implantinfo.com Web site, which hosted the survey. The site staff's willingness to help with both online surveys made these studies possible.

Methods

The OBAFUS, which we designed in January 2003, consisted of 56 questions asking for a "yes", "no", or "don't remember" response; lists of choices for which respondents could check all items that applied; open-ended "blanks" available for specifying "other" options; and questions in which respondents were asked to rate items using a 5-point Likert scale. Sixteen questions included both a yes/no component and another component that asked for an additional response from those

who answered yes to part A. A question containing a list of options from which women could check all that applied might be long enough to fill a computer screen. Consequently, completing the survey was no small task.

Early in the survey design process, in which we were assisted by both the American Society for Aesthetic Plastic Surgery (ASAPS) and ASERF, we contracted with Industry Insights, an independent survey research firm, to handle the final survey design and the collection and analysis of data. All women who visited the www.implantinfo.com Web site and had previously undergone breast augmentation were offered the opportunity to participate in the survey. They were assured that their participation would be anonymous. Those who decided to participate were directed to click on a link that took them to the Industry Insights Web site, where the survey was completed and submitted online. All responses were stored and analyzed at Industry Insights; at no time did we, ASAPS, ASERF, or www.implantinfo.com personnel have access to the data. As the data were analyzed, Industry Insights sent us the results.

The survey was posted from April 8–June 30, 2003. Surveys were submitted by 1350 respondents during this posting period. Industry Insights used SPSS software (SPSS, Inc., Chicago, IL) to clean the data (eg, to check for reasonableness and remove duplicate responses) and tabulate the results. In this initial report on the OBAFUS, we present basic frequencies yielded by the SPSS Tables module.

Results

Demographics of survey respondents

Demographic variables for the 1350 survey respondents are shown in [Table 1](#). The demographic profile suggests that women who seek breast augmentation are generally at a stable point in their lives. The median age was 34 years (range 19–89 years), and 74% said they were in long-term relationships (65% married, 9% part of an unmarried couple). Only 9% were divorced; 14% were single. The group was also well educated, with 45% having at least a bachelor's degree and another 39% having some college. The average annual household income was greater than \$50,000 for 68% of the group. (This percentage may actually have been higher; 10% of the respondents said they preferred not to answer this question.) Respondents seemed to reflect a good geographic representation of the country, with 31% living in large

Table 1. Demographic variables of survey respondents

Variable	%
Type of area lived in	
Major urban area/large city	31
Medium-size city	32
Town	24
Rural area	14
Marital status	
Married	65
Member of unmarried couple	9
Single	14
Divorced	9
Separated	2
Widowed	1
Race	
White	88
Black	2
American Indian	1
Hispanic/Latino	5
East Asian/Pacific Islander	3
Southwest Asian	<0.5
Highest level of schooling	
Graduate/professional degree	13
Some graduate school	4
College graduate	28
Some college	39
High school	16
Junior high	<0.5
Average annual household income	
\$100,000 or more	23
\$75,000–\$99,999	19
\$50,000–\$74,999	26
\$25,000–\$49,999	18
Less than \$25,000	3
Prefer not to answer	10

cities, 32% in medium-sized cities, 24% in smaller towns, and 14% in rural areas. Respondents hailed from all 50 states, and the percentages from each state seem to generally reflect the country's population distribution. The most populous states had the most respondents, as would be expected. The states with the largest representation were California (15.2% of respondents), Florida (9%), and Texas (6.6%), followed by New York (4.5%). Seventy-seven respondents (5.7%) were from other countries, primarily Canada and Great Britain.

Table 2. Implant variables

Variable	%
Months with implants	
6 mo–1 yr	20
1–2 yr	24
2 yr	24
Type of implants	
Saline	85
Silicone gel	13
Double lumen	1
Other	1
Not sure	<0.5

The categories for the variable of race were taken from the 2000 US Census form. As is reflected in most US breast implant literature, 88% of respondents were white.

Table 2 gives information on the respondents' implants. The only questions related to type of implant involved filler material and time elapsed since augmentation. Only about a quarter of the respondents said they had had implants for more than 2 years. The median duration of implantation was 12.0 months (range 1 week–35 years).

All survey questions were compared with the demographic variables (Table 1) and implant variables (Table 2) in an attempt to find any major differences by question (eg, implant filler type, duration of implantation, level of education or income, etc). Few differences were found and will be noted where applicable.

Routine follow-up visits with surgeons

Approximately half the survey questions were designed to elicit information on whether respondents saw their surgeons for follow-up visits as recommended and, if not, why not. We also wanted to know what might motivate women to comply better with follow-up recommendations. The women were first asked whether their surgeons had told them to return for regular postoperative visits during the first year after breast augmentation. Ninety-two percent said yes, 6% said no, and 2% said they did not remember. They were then asked how many postoperative visits they were supposed to have during the first postoperative year. The median number was 4.

We next posed a question applicable to all respondents: "Did your surgeon recommend that you return for

Table 3. Reasons women did not schedule or keep follow-up appointments recommended by their surgeons*

Reason	%
No problems with implants and see no reason for follow-up	24
I would schedule an appointment if I thought I had a problem	21
Other	14
Getting time off work for a doctor's visit is difficult	8
I am unhappy with my breast implants	7
My primary physician checks my implants	6
Follow-up appointments are time-consuming and inconvenient	6
I have routine mammograms that show that my implants are intact	5
I moved to another town/city and have not found a new doctor	5
I do not like my plastic surgeon	3
Getting someone to watch my children is difficult	3
I can't afford a routine follow-up visit	3
I do not like my surgeon's office staff	2
I do not want anyone to know I have breast implants	2
I had my implants removed and not replaced	2
I do not like having my breasts photographed	1
Going to my surgeon's office makes me feel embarrassed/uncomfortable	1
I don't think routine follow-up visits are important	1
I see a different plastic surgeon regularly	1
Family/friend doesn't think follow-up visits are important	<0.5
Office visits make me feel like a patient, and I don't like that	<0.5

*Multiple responses allowed; percentage in descending order.

a routine checkup?" Fifty-six percent of respondents said yes, 35% answered no, and 9% said they did not remember. Those who answered yes to this question were asked their surgeons' recommendations for routine checkups. Sixty-four percent said once a year, 7% said twice a year, 3% said 3 times a year, 3% said 4 times a year, and 3% said more than 4 times a year; 20% said their surgeons told them to check in whenever they wanted. Among those who said a routine checkup was recommended, 17% said they did not schedule or keep such an appointment and 3% said they did not remember; therefore 80% followed their surgeons' recommendations. However, compliance seems to decline over time. Thirty-three percent of those who had had implants for longer than 2 years said they had missed a follow-up visit, compared with 17% of the group as a whole.

Women who did not schedule or keep routine follow-up appointments were asked why they had not done so. Multiple options were offered, and respondents were asked to check all that applied (Table 3). The respondents (24%) chose the option "No problems with implants and see no reason for follow-up." Twenty-one

percent checked "I would schedule an appointment if I thought I had a problem."

The responses in Table 4 indicate that 90% of respondents would see the original plastic surgeon if a problem developed. Even if they had moved away from their surgeons, 83% said they would inform the original surgeon if a problem developed.

Only 7% of respondents said they did not keep recommended follow-up appointments because they were unhappy with their implants; 5% cited having moved to another area, 3% said they did not like the plastic surgeon (or, in 2% of cases, his or her staff), 2% said they have had their implants removed but not replaced, and 1% said they see a different plastic surgeon. Because multiple responses were permitted, we do not know how many of these percentages reflect answers from the same respondents.

The cost of an office visit does not seem to be a serious deterrent to follow-up. Only 3% attributed missing follow-up exams to the cost. When asked whether their surgeons charge a fee for breast augmentation follow-up visits, 69% of respondents said no, 18% said they weren't

Table 4. What respondents would do if an implant problem developed

If you thought you had a problem with your implants, what would you do first?

See my original plastic surgeon	90%
See a different plastic surgeon	6%
See my primary physician	4%
Ignore the problem or just live with it	1%

If you moved to a new city/town away from your original surgeon and an implant problem developed, would you inform your original surgeon about the problem?

Yes	83%
No	6%
Not sure	11%

Table 5. Reasons women with breast implants see their plastic surgeons for routine follow-up examinations*

Reason	% of "5" ratings (very important)	Mean
To find out if there is any problem with an implant that is not obvious	68	4.52
To talk with the surgeon about any breast implant-related concerns	66	4.53
To follow a doctor's recommendations	64	4.47
To make sure implants are intact	61	4.37
To get reassurance from the surgeon that the implants are okay	59	4.32
To get a regular breast exam by someone familiar with implants	54	4.21
To make sure a mammogram does not show any problems	48	4.07
To keep informed about any new breast implant information	35	3.74
To relieve concern that implants may damage a woman's health	31	3.62
Other	51	3.60

* Survey used a 5-point rating scale on which 5 denoted "very important" and 1 "unimportant."

sure, 11% said they were charged after the first year, and 2% said they were charged for all visits.

Table 5 depicts responses to the question "Why do you think women with breast implants see their plastic surgeons for routine follow-up exams?" This question was intended to make respondents think beyond their own reasons and consider why all augmentation patients do or should see their surgeons on a regular basis. The survey asked women to rate the items on a 5-point scale, with 5 indicating "very important," 3 "neutral," and 1 "unimportant." The first 5 reasons in the table were judged important by more than 83% of respondents when 4 and 5 ratings are considered together.

Ways to improve follow-up

Breast augmentation patients who do not return for regular follow-up visits can pose a challenge for their sur-

geons. We therefore asked, "What factors or incentives would motivate you to see your surgeon for recommended follow-up appointments?" Eleven options were offered, and respondents were asked to rate each on a 5-point scale on which 5 represented "very important," 3 "neutral," and 1 "unimportant." The percentages of items that received a rating of 5 are shown in Table 6. Those options with a mean of 4 or greater were clearly the most important to the respondents. Options in which something would be given to the patient for free were obviously not important. In response to an earlier question, most respondents reported that they were not charged for routine follow-up visits, and a no-charge office visit was an important incentive for keeping appointments. To improve follow-up, surgeons should give these women a better explanation of why return visits are important. In addition, a reminder from the sur-

Table 6. Factors or incentives that received a 5 rating (very important) as ways to motivate respondents to keep follow-up appointments*

Factor or incentive	%	Mean
No charge for the office visit	67	4.36
Knowing that my implant warranty will be voided if I miss a recommended appointment	64	4.20
Other ideas (specified)	62	3.96
An explanation of why follow-up appointments are important	52	4.11
A reminder from my surgeon to come in for a routine follow-up visit	49	4.11
An opportunity to receive updated information on breast implants	44	4.04
More flexible office hours so I don't have to miss work	28	3.18
A free consultation about another cosmetic surgery procedure	22	2.85
A free massage, skin-care treatment, manicure, or pedicure	21	2.74
An opportunity to participate in an anonymous breast implant registry	19	2.97
A gift (e.g., free skin-care product)	15	2.48

* Survey used a 5-point rating scale with 5 representing "very important" and 1 "unimportant."

Table 7. Factors or incentives that received a 5 rating (very important) as ways to motivate respondents to return for follow-up in a clinical trial*

Factor or incentive	%	Mean
An agreement to pay for any needed implant-related surgery for the duration of the clinical trial (10 years) if all recommended follow-up appointments are kept	78	4.58
Free breast implant warranty against deflation or rupture	76	4.62
No charge for office visits	68	4.45
Voiding of my implant warranty if I miss a recommended appointment	61	4.23
A reminder from my surgeon to come in for routine follow-up visits	59	4.35
An explanation from my surgeon of why follow-up is important	53	4.25
Other ideas (specified)	48	3.70
A cash payment for each follow-up visit	36	3.34
More flexible office hours so I don't have to miss work	33	3.43
An opportunity to participate in an anonymous breast implant registry	25	3.28
A free consultation about another cosmetic surgery procedure	22	2.97
A free massage, manicure, or pedicure for each follow-up visit	22	2.87
A free skin-care product or treatment at each follow-up visit	17	2.67

* Survey used a 5-point rating scale with 5 representing "very important" and 1 "unimportant."

geon's office that a follow-up visit had been or needs to be scheduled was important to respondents, 75% of whom rated this item as either a 4 or 5. Although voiding of an implant warranty would be punitive and is not an option for surgeons, it would be a major motivator—this item was given a 4 or 5 rating by 77% of respondents.

Maintaining patient participation in manufacturer-sponsored clinical trials has typically been a problem for manufacturers and surgeons who monitor these women. We therefore asked what factors or incentives would

motivate the respondents to keep routine follow-up appointments specifically as part of a clinical trial. The results are presented in [Table 7](#). Two new options offered for this question received the highest ratings: payment for necessary implant-related surgery during the 10 years of a clinical trial and a free warranty against implant deflation or rupture. These items were rated as important or very important by 88% and 91% of respondents, respectively. Implant manufacturers might want to consider these options as a means of improving follow-up compliance in

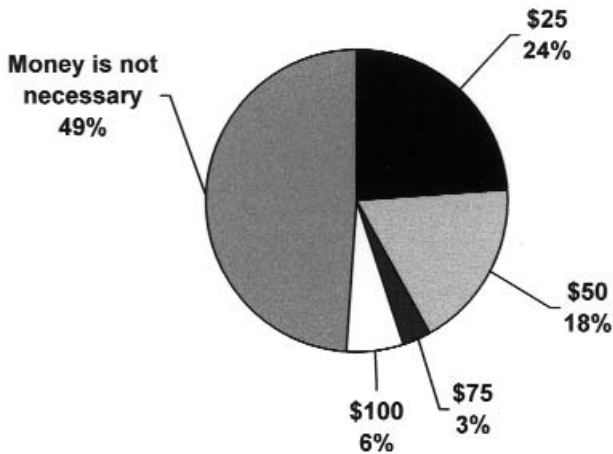


Figure 1. Minimum cash payment sufficient to motivate respondents to see their surgeons regularly during a clinical trial.

clinical trials, even though they would require action or payment on the part of the manufacturer.

Only 36% of respondents rated a cash payment for follow-up visits as very important. Respondents were asked what minimum amount of money would be sufficient to motivate them to keep follow-up visits in a clinical trial if a cash payment were offered. The answers are depicted in [Figure 1](#). We also wanted to know whether respondents would prefer a cash payment for each follow-up visit or a larger lump-sum payment at the end of the 10-year study. Payment for each visit was greatly preferred (81% vs 19% for a lump sum at the end of the trial).

Health insurance coverage of women with breast implants

We asked several questions about health insurance coverage. One set of questions dealt with current coverage; a second set was designed for women who applied for health insurance after receiving breast implants ([Table 8](#)). Of the 91% with insurance, 81% were in a group plan and 19% had an individual policy. As indicated in [Table 8](#), 13% of respondents applied for health insurance after undergoing augmentation. Of this group, 9% (14 women) were denied coverage, but there is no way of knowing whether the denial was related to their implants. For those women who reported an exclusion of breast augmentation from coverage (19%), the maximal duration of exclusion was 2 years. Five percent were charged a premium for breast coverage.

Table 8. Survey respondents with health insurance

Health insurance status	Yes	No
Do you currently have health insurance?	91%	9%
Did you have health insurance when you got your breast implants?	89%	11%
Have you applied for health insurance since getting your breast implants?	13%	87%
For the 13% who applied for coverage after getting breast implants:		
Were you denied coverage?	9%	91%
Were your breasts excluded from coverage?	19%	81%
Were you charged a premium for breast coverage?	5%	95%

Informed consent

A large section of the survey dealt with issues related to informed consent. Almost all respondents (95%) said that their surgeon, the surgeon’s staff, or both spoke with them or gave them printed material about breast implants and augmentation before the surgery. In addition, 84% reported that they were educated by their surgeon, the surgeon’s staff, or both on the various types of breast implants. Fourteen percent said that they were not informed, and 1% said that they did not remember ([Table 9](#)).

Slightly more respondents (89%) reported being informed by their surgeons about potential limitations and disadvantages of breast augmentation than about its potential benefits and advantages (80%). Of those who remembered being informed, the survey inquired about the specific benefits and limitations listed in [Table 10](#). Not all items listed would necessarily be mentioned during the informed-consent process. For example, we would be surprised if a surgeon claimed that an improved sex life and marriage are benefits of breast augmentation. Fortunately, very small percentages of respondents reported having been told such information.

In response to another question, 95% of respondents said their surgeons had informed them about specific problems or complications that might be associated with breast implants and augmentation. Those who answered “yes” were directed to check the items discussed, which are listed in [Table 11](#). Small variations in responses to similar items are evident when [Tables 10](#) and [11](#) are compared.

Other issues related to informed consent that were

Table 9. Percentage of respondents who remembered being informed about different augmentation-related options

Option	%
Various implant types (84%)	
Filled with saline solution	90
Filled with silicone gel	49
Smooth surface	87
Textured surface	75
Round shape	86
Teardrop shape	65
High profile	34
Moderate profile	23
Incision location (88%)	
In the breast crease	83
Around the areola	76
In the armpit	53
Through the navel	15
Implant position (above or below muscle)	94
Advantages and disadvantages of different options	
Various breast implant types	79
Both implant positions	88
Different incision locations	80

Table 11. Percentage of respondents informed by surgeons about specific potential problems associated with breast augmentation

Problem	%
Capsular contracture (breast hardening)	96
Change in breast or nipple sensation	92
Implant deflation or rupture	92
Infection in the breast or around implant	77
Need for another implant-related surgery	70
Breast size or shape not symmetrical	62
Bleeding that could require surgery	61
Breast pain or burning (not present before surgery)	61
Skin wrinkling caused by implant	53
Interference with mammography	53
Abnormal feel of the breast	50
Breasts may be smaller than expected	39
Breasts may be larger than expected	39
Unexpected migration of implant to another position	38
Implant not positioned properly	38
Potential problems of large implants	29
Trouble with breastfeeding (not present before surgery)	26

Table 10. Percentage of respondents informed by surgeons about potential benefits/advantages and limitations/disadvantages of breast augmentation

Benefits or advantages	%
Larger breasts	83
Looking better in clothes	76
Increased self-confidence	65
Increased self-esteem	64
Increased cleavage	45
Correction of sagging	42
Improved sex life	12
Improved marriage	4
Limitations or disadvantages	
Complications are possible after surgery	95
Breast implants don't last forever	90
Later implant surgery will probably be needed	78
Implants may interfere with nursing	28
Implants alone may not correct breast sagging	26
Implants do not fix stretch marks	21
Implants may affect health-insurance coverage	16
Implants cannot save a troubled marriage	9

addressed in the survey dealt with explanations by the surgeon of the risks of surgery, as well as what could be expected during the postoperative recovery period. Discussions of surgical risks were recalled by 90% of respondents. Specifically, the following topics were addressed by surgeons: anesthesia (91%), being too active too soon (72%), pain medications (66%), smoking history (58%), antibiotics (52%), history of aspirin use (44%), and use of muscle relaxants (35%). Almost all respondents (97%) remembered discussions of postoperative recovery expectations. The particular issues asked about in the survey are shown in [Table 12](#).

Only 21% of respondents said they had been informed by their surgeons about alternatives to breast augmentation. Of those who remembered discussions about alternatives, 80% said they were told that they could wear a padded bra or do nothing. Small numbers mentioned the following alternatives: exercise (14%), counseling to accept breast size (9%), using a vacuum bra (8%), and taking hormones (6%).

Delivery and adequacy of informed consent

We asked several questions about how respondents received information related to informed consent and inquired as to what method was most helpful in the deci-

Table 12. Percentage of respondents informed by surgeons about what to expect during the postoperative recovery period

Postoperative issue	%
Activity restrictions	97
When to return to see surgeon	96
Expected pain	96
Expected swelling	95
Medications available or required	94
Type of bra to wear	93
Problems to call surgeon about	92
When to shower	90
When to begin exercising	86
How long discomfort would last	84
Recommended follow-up visit frequency	83
Time off work	80
When stitches come out	79
When to resume sex	50
When and what to eat	47

Table 14. Helpfulness of information received before breast augmentation*

Source of information	%	Mean
Visiting an independent Web site	83	4.79
Discussion with surgeon	69	4.52
Discussion with surgeon's staff	55	4.29
Visiting the ASAPS Web site	40	4.00
Talking to friends	38	3.82
Patient education brochure	34	4.03
Surgeon's computer presentation	33	3.89
Surgeon's video presentation	27	3.76
Implant manufacturer's information	21	3.72
FDA booklet on breast implants	21	3.69

* Survey used a 5-point rating scale on which 5 denoted "most helpful" and 1 "least helpful." "Don't know" responses and unanswered questions were removed from data analysis.

sion-making process. As Table 13 indicates, only a small percentage of surgeons provide videos (23%) or computer presentations (10%) about augmentation. We also asked, "With respect to any information you received before breast augmentation, how helpful was each source of information?" For the options listed in Table 14, respondents who received information in a given form

Table 13. Methods by which informed consent information was received

Method	%
Received printed information about breast implants	92
Implant manufacturer's brochure	79
Surgeon's own printed information	74
Manufacturer's warranty brochure	63
Brochure from plastic surgery society	49
FDA booklet on breast implants	45
Saw an educational video about breast implants	23
Viewed a computer presentation about breast implants	10

were asked to rate its helpfulness on a 5-point scale (5 = "most helpful," 3 = "neutral," 1 = "least helpful"). All the items have a mean rating greater than 3.6, but only 3 were judged to be "most" helpful by more than half of the respondents: "visiting an independent Web site," "discussion with surgeon," and "discussion with surgeon's staff." The respondents seem to have correctly interpreted the meaning of "discussion" as a give-and-take between the surgeon and patient. We also posed this question: "In general, how do you learn or retain information best?" Respondents were again asked to rate 4 options on a 5-point scale, with 5 indicating "most helpful" and 1 representing "least helpful." As shown in Table 15, listening to an explanation was judged the least helpful. In light of the responses given in Table 14, we assume that "listening" was considered a passive act, whereas "discussion" was more of an active interchange.

At the end of the section on informed consent, we asked the following question: "In terms of helping you make an informed decision about choosing breast augmentation, do you feel the information provided by your surgeon was: adequate, inadequate, or no information was provided." Eighty-nine percent rated the information they received as adequate, 9% rated it inadequate, and 2% said they were given no information.

On the assumption that plastic surgeons understand the risks, benefits, and expectations of breast augmentation better than other types of surgeons do, we asked a question designed to show how much respondents knew about their surgeons. The results, shown in Table 16, are somewhat confusing. The survey permitted multiple responses, but more women said their surgeons were board-certified in plastic surgery (85%) than said their

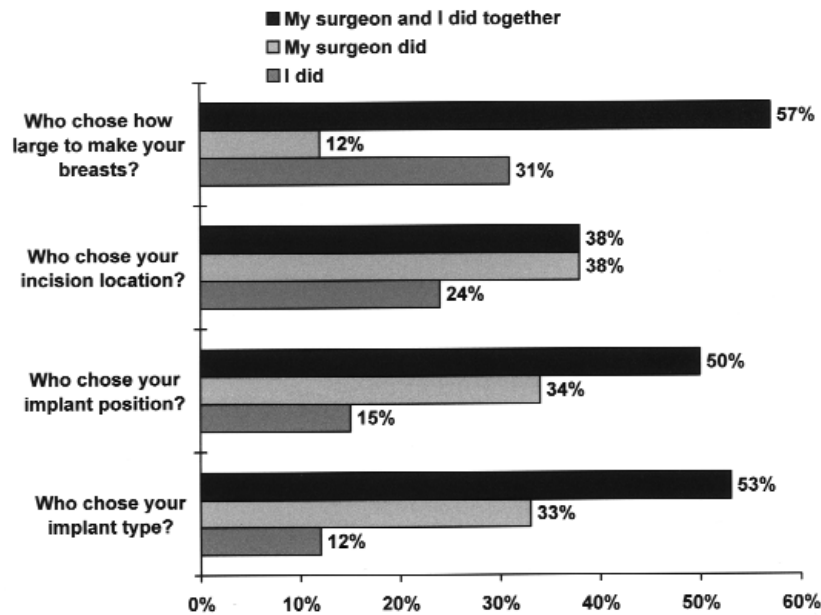


Figure 2. Patient and surgeon input into choice of augmentation-related options.

Table 15. How respondents best learn or retain information*

Method	%	Mean
Verbally (listening to an explanation)	38	4.07
Printed material I can read	54	4.36
Visually (photos, videos, computer)	64	4.53
Combination of the above	78	4.69

*Survey used a 5-point rating scale on which 5 denoted "most helpful" and 1 "least helpful." "Don't know" responses and unanswered question were removed from data analysis.

Table 16. Which, if any, of the following apply to your surgeon?

Status	%
Board-certified by the American Board of Plastic Surgery	85
Member of the American Society of Plastic Surgeons	62
A plastic (cosmetic) surgeon	60
Member of the American Society for Aesthetic Plastic Surgery	44
Don't know	8

surgeons were plastic surgeons (60%). Only 8% did not know whether any of the options applied to their surgeons. Despite some confusion, these data indicate that augmentation patients are familiar with their surgeons' credentials, especially whether they are board-certified in plastic surgery.

Patient involvement in decisions about their breast implants

Preoperative discussions with surgeons typically involve such topics as implant type, implant position, incision location, and implant size. We asked who made the choices about these variables. As illustrated in Figure 2, the women were most involved in deciding breast size, with only 12% saying their surgeons made the choice.

Eighty-eight percent said that, alone or with their surgeons, they made the decision about implant size. Sixty-five percent said they were involved in choosing implant position, 65% in choosing implant type, and 62% in choosing incision location.

The survey offered a list of options and asked which helped the women decide what postaugmentation breast size they wanted. Multiple responses were allowed. Seventy-one percent said they used photographs from magazines, Web sites, and other sources; 56% said they picked an ideal bra-cup size; 50% said they chose an implant size; 28% said they used their own breast measurements; 26% said they tried padded bras; and 20%

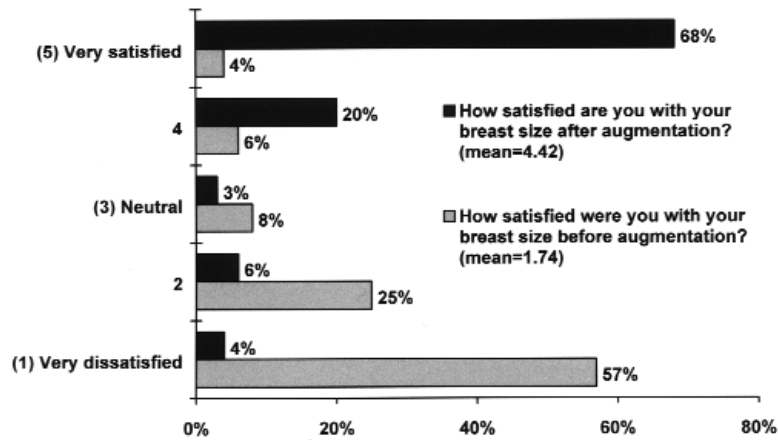


Figure 3. Satisfaction with breast size before and after augmentation.

Table 17. Problems or complications experienced by survey respondents and the severity rating assigned by those who had the problem

Problem or complication	Experienced problem (%)	Rated "severe problem" (%)*	Mean rating for problem
Temporary change in breast/nipple sensation	34	3	2.06
Breast pain/burning (not present before receiving implants)	28	6	2.31
Permanent change in breast/nipple sensation	20	13	2.77
Breast size or shape not symmetrical	18	18	2.91
Implants turned out to be too small	14	14	3.19
Skin overlying implant looked wrinkled or rippled	13	17	2.68
Other problems	12	44	3.83
Capsular contracture	10	32	3.33
Implant not positioned properly	7	43	3.81
Implant unexpectedly moved or migrated to a different position	6	49	4.04
Implants turned out to be too large	5	23	2.96
Implant rupture or deflation	3	78	4.59
Infection in breast or around implant	2	46	3.79
Breast cancer diagnosis after getting implants	1	100	5.00
Bleeding that required another surgery	1	67	4.33
Trouble with breastfeeding (not present before receiving implants)	1	33	3.00

* Survey used a 5-point rating scale in which 5 indicated a severe problem and 1 a minor problem.

cited other methods. The "other" methods written in most often were wearing an implant or sizer inside a bra and trying on clothes (cited by 8%) and/or wearing plastic bags or pantyhose filled with rice, oatmeal, or even birdseed or hair gel inside a bra (cited by 4%).

Satisfaction with implant size is related to postoperative satisfaction in general. In addition, dissatisfaction with implant size is a leading reason for revision surgery, cited by 37% of women who submitted our earlier

OBAS. Figure 3 indicates that 88% of respondents are satisfied or very satisfied with their breast size after augmentation, compared with 10% who are dissatisfied or very dissatisfied. The mean for breast size satisfaction was 4.42 after augmentation, a significant increase from the 1.74 mean before surgery.

Implant complications

The survey contained a list of possible breast implant

problems and complications and asked respondents to check any of these they had experienced (Table 17). The list was nearly identical to the one included in the question asking whether the women had been informed about specific potential problems (Table 11). Multiple responses were allowed. Those who reported a specific problem were then asked to rate the severity of the problem. A 5-point rating scale was used on which 5 signified a severe problem and 1 signified a minor problem. The percentage of problems given a 5 rating is also shown in Table 17, along with the mean severity rating for each item. For almost all items, the degree of severity correlated with the need for additional surgery. In just 1% of respondents was breast cancer diagnosed after augmentation, but this item was understandably rated as very severe (100% for those who had the problem). Complications with a low frequency but a high severity rating included implant rupture or deflation (3% frequency, 78% severity), bleeding necessitating additional surgery (1% frequency, 67% severity), implant migration (6% frequency, 49% severity), and infection (2% frequency, 46% severity). The severity of problems such as a change in breast or nipple sensation, breast pain or burning, and asymmetry was judged to be relatively minor.

Complications led to revision surgery for some women; 14% of the 1350 respondents said they underwent additional implant-related surgery after the original augmentation. Among those who reported undergoing revision, the mean of the total number of all surgeries was 2.4 (because the original augmentation counts as 1 surgery, the mean number of revisions is 1.4). The survey did not ask about reasons for revision, but many can be inferred from the reported problems shown in Table 17.

Discussion

Routine follow-up visits

Convincing breast augmentation patients to return for routine visits is a source of frustration for many surgeons because augmentation is one of the few aesthetic procedures that involves implantation of a device that must be checked regularly. A missed follow-up appointment is an especially serious problem when a breast augmentation patient has voluntarily enrolled in a clinical trial and then fails to return for scheduled follow-up.

Some critics of breast implants have claimed that women who do not return for routine follow-up are unhappy and have probably gone to another surgeon to

have the implants removed. However, plastic surgeons have generally assumed that women who cancel or do not schedule follow-up appointments are having no problems. Part of the purpose of our survey was to resolve this debate by asking a large group of women who had undergone augmentation whether they keep routine appointments and, if not, why not.

Ninety-two percent of respondents said their surgeons told them to return for follow-up visits during the first year after augmentation; the median number of requested visits was 4. However, only 41% of respondents said their surgeons had recommended regular follow-up visits after the first year. This percentage should be much higher; a woman with breast implants ideally should undergo an annual examination by her plastic surgeon. In our opinion, telling a patient to return whenever she wants—is as reported by 20%—is not adequate.

However, specifying yearly visits is no guarantee that patients will comply; 17% of respondents said they did not schedule or keep recommended follow-up appointments. The survey results clearly indicate that the main reason women do not return for recommended appointments after undergoing breast augmentation is that they have had no problems with their implants and see no reason for follow-up. Moreover, most respondents indicated that they would see the original surgeon if any problems developed. Clearly the idea that women do not return to their original surgeons for follow-up because they are unhappy with their breast implants is not supported by the 1350 survey respondents. On the contrary, the OBA-FUS indicates that breast augmentation patients who are not seen or heard from can be presumed to be free of implant problems until they tell their surgeons otherwise.

This is one of the major findings of this study. The question, however, can be answered definitively only through continuance of the National Breast Implant Registry, which tracks the implantation and removal of implants by lot number. The registry can succeed only if all surgeons routinely help register their patients.

Occasionally women do not return for follow-up visits because their surgeons do not recommend such visits. Including this as a possibility in the list of reasons for not keeping follow-up appointments did not occur to us when the survey was designed. However, in an open-ended comment space that accompanied this question, 18 respondents (2.6% of those answering the question) said that follow-up was not recommended.

When asked why women with breast implants do see

their plastic surgeons for routine follow-up exams, most of the reasons offered in the survey were judged important by respondents, and most of the options received a mean rating higher than 4 on a 5-point scale. In addition to following doctor's recommendations, the other highly rated reasons were related to making sure implants are intact and that no problems have developed. Many responses to the open-ended "other" option associated with this question echoed these choices but others involved sentiments such as these: Follow-up is good preventive medical care or routine maintenance; breast augmentation is an investment; follow-up provides peace of mind and makes you responsible for your own body/health. Some respondents said that follow-up appointments let patients know their surgeons care about them or noted that they enjoy saying hello, whereas a few others took this opportunity to say their surgeons don't spend enough time listening to their concerns or don't seem to care about them.

Informed consent

A major purpose of the OBAFUS was to evaluate the delivery and adequacy of informed consent by asking women whether they were informed about a wide range of topics before augmentation. There is no way to confirm what the respondents were actually told, but it seems doubtful they would say they were informed about something if they were not. Almost all the women (95%) remembered receiving printed materials about breast implants and augmentation before undergoing surgery. We did not specifically ask whether they had read those materials.

As [Table 9](#) shows, not all implant-related variables were discussed by surgeons, but the seriousness of this omission is unclear. For example, fewer than half of the respondents said they were informed about silicone gel-filled implants, but this likely reflects the fact that many (perhaps most) surgeons could not offer gel implants for augmentation. In addition, not all surgeons feel comfortable with the transaxillary and transumbilical approaches, which may explain why these incisions were discussed less frequently. Implant profiles (high and moderate) were the least-discussed variables, and we doubt most women know which profile they have. Approximately 80% of respondents said they were informed about the advantages and disadvantages of the different implant options. Ideally these figures should approach 100% for all variables.

Because informed consent is so important, one value of

the survey should be to let plastic surgeons know which subject areas need to be strengthened. A good starting point is the list of specific potential problems shown in [Table 11](#). Only 3 of the items were remembered by more than 91% of respondents (capsular contracture, altered sensation, and implant failure). Curiously, 92% said they were told about implant deflation or rupture, yet only 70% said they were informed about the possible need for another implant-related surgery. One would think that implant failure and the need for additional surgery would be closely associated, but some sort of disconnect appears to have occurred. (The same disconnect is evident on similarly worded items seen in [Table 10](#)). If surgeons are discussing these problems and complications before breast augmentation, their patients may not understand the implications. Although survey respondents may have been made aware of these possible problems through the printed materials they received or by way of other methods, we recommend that this information come directly from surgeons, their staff members who have been trained in the delivery of informed consent, or both.

On the other hand, examination of this series of informed consent questions as a whole indicates that most women are getting the basic, most important information about breast implants. On questions posed with yes, no, and "don't remember" answers, 94% said their surgeons had informed them about specific problems or complications that might occur, 90% said they had been informed of surgery risks, and 97% remembered having discussions about postoperative recovery expectations. In addition, when the survey asked whether respondents felt that the information they received from their surgeons was adequate for making an informed decision about choosing augmentation, 89% said it was adequate. This question appeared near the end of the survey, after women had worked their way through lists of possible and actual complications. These percentages are quite good; the weaknesses of informed consent appear when women are asked whether specific problems or risks were discussed.

The survey also indicated that brochures are not the most effective way of educating patients. In fact, all the printed materials received relatively low ratings when respondents were asked which sources of information were most helpful to them. At the same time, on another question that asked how respondents best learn or retain information, printed material was rated "most helpful" by 54%. Visual communication (photos, videos, computer) was given a "most helpful" rating by 64%, but a

combination of methods was rated “most helpful” by 78%. It may be that a multimedia approach is the most effective way of ensuring informed consent.

Yet even a well-designed slide presentation cannot replace the value of an old-fashioned discussion between patient and surgeon. As shown in [Table 14](#), discussion with the surgeon and his or her staff were the second and third most helpful sources of information respondents received. These discussions were more important than written materials or a computer/video presentation. Most surgeons have no doubt noticed that patients today seem to be quite well informed about breast augmentation before they ever make an appointment with a plastic surgeon. This can only be explained by the fact that the source of information rated most helpful to survey respondents was the Internet, which confirms that many of them conducted their own independent research into the procedure. The survey was filled out online, so those who responded obviously use the Web. However, personal experience confirms that breast augmentation patients generally are familiar with what is available through the Internet. The Internet offers an overwhelming amount of information from sources that encompass plastic surgery professional societies, the FDA, implant manufacturers, medical literature, articles in the popular press, legal documentation of the controversy surrounding silicone gel-filled implants in the early 1990s, independent Web sites such as www.implantinfo.com, and chat room comments—both positive and negative—from women who have experienced the surgery. Because a Web search will bring up all these sources, no one can claim that the information is biased in one direction or another. All points of view are available. Judging from our survey results, women looking for information about breast augmentation are likely to gravitate toward sites they perceive as independent sources.

Implant complications

The fact that most survey respondents had had their implants for less than 2 years requires that caution be used in the interpretation of some of the data. Most local complications develop within the first few years after surgery (capsular contracture, infection, hematoma, changes in sensation), and most revision surgeries conducted for reasons such as implant-size change or correction of asymmetry are performed during the same period. Therefore the survey likely reflects the actual frequency of early complications and revisions. Implant failure is prob-

ably the most common reason for revision after several years. Although the median implantation time for survey respondents was 12 months, 24% of respondents have had implants for more than 2 years, and the range extended to 35 years. To our knowledge, this study is the first to ask women to rate the severity of an experienced complication on a scale from a minor to a major problem.

For those who reported having a problem, the data suggest that women have a realistic assessment of how serious a problem really is and that they are willing to tolerate minor local complications.

This section of the survey included an “other” option that allowed women to write in other problems they had experienced. Twelve percent of respondents cited an “other” complication and also rated its severity. Many of these open-ended responses included items on the list, and further analysis is needed to sort out whether duplicates exist. For example, 15 women made reference to “rippling” in the open-ended “other” option, but we do not yet know whether these same women checked the option for “skin overlying implant looked wrinkled or rippled.” Several women commented on their particular asymmetries and may also have checked one of the asymmetry problems on the list. This type of possible overlap occurred with other options shown in [Table 17](#).

Several problems were not on the list but perhaps should have been, even though their frequencies would have been very low in a group this large (1350). Ten women reported too-visible scars, 9 cited Mondor’s cord, 8 said that their implants had bottomed out, 7 complained of implant palpability and 3 others said their husbands didn’t like the feel of their implants, 5 said they had experienced some delay in the healing of their incisions, 4 complained about the heaviness of saline implants, 2 lactated for a few weeks after surgery, 2 cited rotation of what we assume to be anatomically-shaped implants, and 1 reported the appearance of stretch marks after surgery that weren’t visible before. Several with implants placed in the subpectoral position made comments about muscle distortion when they exercise. Others remarked that their implants haven’t dropped evenly, although these women said they haven’t had implants very long. Eight women took the opportunity to say that a second surgery had corrected their problems.

Twelve responses to this open-ended “other” option dealt with severe illnesses attributed by these women to implants, including multiple sclerosis, malignant melanoma, viral meningitis, and “autoimmune deficiency,” as well as generalized statements about “silicone poi-

soning” and “toxic implants.” One woman said she needed bilateral mastectomy after gel implants ruptured years ago. Four of these 12 responses appear to have come from 2 women who submitted the survey twice (parts of the wording were too similar to be coincidence), and another 2 responses likely were submitted by 1 woman. Assuming that these open-ended responses represent 10 very angry and unhappy women, their responses represent 10 of 1350, or 0.7% of the total.

Conclusion

The OBAFUS was a 56-item questionnaire that was offered on the www.implantinfo.com Web site. To our knowledge, it is the first research investigating whether women with breast implants return to see their surgeons for routine follow-up appointments, the reasons they may not return, and factors that might motivate them to do so. The data collected from the 1350 survey respondents provide a wealth of information that plastic surgeons and those who organize clinical trials should find useful.

Eighty percent of women who responded to the survey said they follow their surgeons' recommendations for follow-up appointments. Surgeon recommendations for follow-up visits decline after the first year following breast augmentation, as does the rate of patient compliance. At the same time, only 17% of respondents said they did not schedule or keep recommended appointments. The most common reason for missing a follow-up visit was that the respondent was not experiencing any implant problems. These findings clearly contradict the assertion made by some that women who do not return for follow-up are unhappy with their breast implants and have probably had them removed by a different surgeon.

Patient compliance with recommended follow-up could be improved with a few simple actions. One is to provide patients with a clear explanation of why follow-up visits are important so that they will understand the advisability of regular checkups. Several respondents noted that they traveled several hours for breast augmentation surgery and that they are not inclined to travel such a distance for follow-up appointments. This is understandable, but surgeons should talk to these patients about the need for routine implant evaluation by another plastic surgeon or even the family physician or gynecologist. According to the survey, reminders to return for follow-up would also be effective in getting patients to return; where applicable, this reminder should mention that there is no charge for the office visit.

Another major function of the survey was to investigate the adequacy of informed consent. The survey indicates that most patients felt that their informed consent was adequate. It does seem, however, that survey respondents should have had better recollection of specific details related to risks and complications. There is, of course, no way to know what the women were told and how much they might have forgotten.

Questions about the types or forms of information patients received reveal that people do not process all methods of presentation equally. Some individuals learn best with visual media, others are auditory learners, and some need to read the information. Most seem to learn best through a combination of informed consent materials. More multimedia consent tools should be developed and shared within the plastic surgery community. However, brochures, video, and computer presentations cannot replace the primary role surgeons themselves play in the informed-consent process.

Another important finding of the OBAFUS is that breast augmentation seems to have very little impact on a woman's ability to obtain health insurance. Denial of insurance, a breast-exclusion clause, and a premium charge are all unfair, but they do not seem to be widespread.

Further analysis of data collected from the OBAFUS is being conducted, and additional reports will follow. ■

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