

National Institutes of Health  
October 2, 2000  
NCI Press Office  
(301) 496-6641

## **Questions and Answers for Silicone Breast Implant Study and Breast Cancer Risk**

### **1. What is the purpose of the breast implant study?**

The National Cancer Institute (NCI) is conducting a study to determine the long-term health effects associated with silicone breast implants, including any changes in breast cancer risk. Although implants have been linked to various short-term complications, less is known about their long-range effects. The current study, evaluating breast cancer risk and breast implants, appears in the November issue of *Cancer Causes and Control*.

Future analyses will evaluate the occurrence of other cancers and connective tissue disorders, as well as the causes of death. The characteristics of the 13,500 participants and 4,000 comparison patients in the study are described in a paper published in March 2000 (see question 7).

### **2. Why was the study initiated?**

Breast implants were first marketed in the early 1960s, before the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act required that medical devices be shown to be safe and effective. Silicone was initially assumed by manufacturers to be biologically inactive and, therefore, to have no harmful effects. However, cases of connective tissue disorders and cancers were reported in several short-term studies.

Because there were few reports on the long-term safety of implants, in 1992, the Food and Drug Administration (FDA) restricted the use of silicone gel breast implants to controlled clinical trials of women seeking breast reconstruction. To address many of the unanswered questions, Congress directed the National Institutes of Health in the same year to undertake a large follow-up study to assess the long-term health effects of exposure to silicone breast implants.

It is estimated that between 1.5 and two million women in this country have had breast implants since they first appeared on the market. Before the 1992 FDA ban, implants

(more)

were typically made of a silicone shell filled with silicone gel, with saline-filled implants being less popular. Currently, it is not known how many women have silicone vs. saline implants, but women with both types of implants are included in the NCI study.

### **3. What are the principal findings of the study?**

- The authors found no association between breast implants and the risk of subsequent breast cancer.
  - There was no association of breast cancer risk with years of follow-up.
  - Breast cancer risk was not associated with any particular type of implant.
  - Breast tumors tended to be detected at a somewhat later stage among breast implant patients than among the control group, but the difference was not statistically significant and could be due to chance.
- There was no significant difference in breast cancer mortality between the implant and comparison patients.

### **4. Who are the participants in the study?**

The participants include 13,500 women who had implant surgery for cosmetic reasons in both breasts before 1989. For comparison, about 4,000 women similar in age who had some other type of plastic surgery, such as removal of fat from the stomach or wrinkles from the face or neck, were identified. All participants were from 18 plastic surgery practices in six geographic areas (Atlanta, Ga.; Birmingham, Ala.; Charlotte, N.C.; Miami and Orlando, Fla.; and Washington, D.C.). The practices were chosen because the plastic surgeons had performed large numbers of cosmetic breast implant surgeries prior to 1989 and were willing to give the investigators access to their records.

### **5. What is the design of the study?**

The medical records from the plastic surgery practices were reviewed to identify patients who were eligible for the study. For eligible patients, trained medical records abstractors collected information about the surgical procedures, the type of implant, any complications, and factors which might affect health status, such as weight or medical history.

(more)

Patients were then traced through a variety of sources. Living subjects were asked to complete a mailed questionnaire to collect information about their health status, including whether they had subsequent plastic surgery as well as lifestyle factors that could affect their health (menstrual, pregnancy, and breast-feeding history, weight, hormone use, cigarette smoking, alcohol consumption, and medical history). Extensive data on the potential short-term (rupture) and longer-term complications (cancer, connective tissue diseases, symptoms of connective tissue disease) were also obtained through the questionnaire.

No clinical examinations were done on the living patients for this study. Attempts were made to verify patient reports of cancer and connective tissue diseases by retrieving medical records from physicians who had diagnosed or treated these diseases. Death certificates were collected for the patients who had died to verify the causes of death.

About 80 percent of the original 13,500 implant patients and 4,000 controls were successfully traced. About 70 percent of those traced as alive completed the questionnaires. These percentages are similar to other comparably designed epidemiologic studies.

**6. How do the characteristics of women with breast implants compare to women in the general population?**

Previous studies have shown that breast implant patients are different from the general population in a number of ways. Some studies have reported that implant patients tend to have different reproductive and medical histories and different lifestyle characteristics.

**7. How do the characteristics of the women in this study compare to other plastic surgery patients?**

The authors of the current study published a paper in the March 2000 issue of *Plastic and Reconstructive Surgery* characterizing a subset of the participants. Data collected from 7,447 breast implant patients and 2,203 patients with other types of plastic surgery showed that implant patients were significantly more likely than other plastic surgery patients to be white, to have less education, to have early ages at first birth, to be thin, and to be screened frequently for breast disease. However, there were no differences between the two groups with respect to family income, number of pregnancies, alcohol consumption, cigarette smoking, histories of previous gynecologic operations, or operations for benign breast disease. Therefore, the authors believe that other plastic surgery patients may be a more appropriate comparison group than women in the general population for studies of the health effects of breast implants.

(more)

## 8. What is unique about this study?

This is one of the longest and largest studies to date on the health effects of breast implants. Most previous investigations have looked at the effects of implants over a shorter time period, typically less than 10 years. Besides the short follow-up periods, previous studies have been too small to evaluate rare diseases.

In addition, previous reports have not included information about types of devices implanted or risk factors affecting health, such as medical history, screening practices, and lifestyle behaviors (see question 5). All of these factors are included in the current NCI study.

Another unique feature of this study is that the investigators compared the breast cancer risks of the implant patients to both the general population and other plastic surgery patients. Previous studies have generally used only the general population for a comparison group, except for a recent Swedish study that compared women with implants to those with breast reduction procedures.

## 9. How do these results compare to other breast implant studies?

### *Breast cancer risk:*

A number of previous studies have evaluated the relationship between breast implants and subsequent breast cancer risk. Most have shown that the risk of developing breast cancer is less among women with implants compared to women without implants. In several of the studies, the size of the reduced risk was as much as 50 percent to 60 percent. However, these studies generally did not have detailed information on patient characteristics that could affect the development of breast cancer (see question 5), and had follow-up times of less than 10 years.

NCI researchers found a slight decrease in breast cancer risk during the initial 10-year period. However, this decrease was not seen with increasing follow-up time. The reduced risk immediately after implantation may have reflected the effect of pre-implantation screening; i.e., women at high risk for breast cancer were unlikely to have received implants. The average length of follow-up in the NCI study was 12.9 years among the implant patients vs. 11.6 years among the comparison patients.

### *Type of implant:*

Previous studies have not included detailed information about types of implants. The women in this study had cosmetic surgery between 1962 and 1988, during a time when a great number of changes were taking place in the manufacturing of breast implants such as the shell thickness, the type of shell coating, and the gel composition. This is the first study to look across such a long time-frame and show that the type of implant had no effect on breast cancer risk.

(more)

*Stage at diagnosis and breast cancer mortality:*

Some clinical studies have suggested that women with breast implants have more advanced breast cancer when diagnosed than women without breast implants. However, in two larger epidemiologic studies, there did not appear to be differences in stage at diagnosis or survival rates among the two groups.

In the current study, NCI researchers found a shift toward somewhat later detection of breast cancers among the implant patients compared to the controls. Even though the differences were not statistically significant, there were consistently smaller percentages of *in situ* (early-stage) cancers among the implant patients. However, there was no significant difference in breast cancer mortality between the implant and comparison patients. This finding consistent with the one other study that looked at this issue. The authors recommended further surveillance of breast cancer death rates among implant patients.

**10. What's the difference between silicone implants and saline implants?**

Implants are soft silicone sacs, inflated with either saline solution (salt water) or a synthetic silicone gel. Until 1992, when the FDA banned silicone-filled implants (except for use in controlled clinical trials among women seeking breast reconstruction), 90 percent to 95 percent of the implants contained the silicone gel because it had a more pleasing look and feel than the saline-filled implants. Since the 1992 ban, 90 percent to 95 percent of the implants have been saline-filled.

**11. Does the study distinguish between the effects of saline and silicone implants?**

Yes, the study includes women with saline and silicone implants, but no altered breast cancer risk was associated with either type of implant. Of all the implant patients in the study, 49.7 percent received silicone gel implants, 34.1 percent double lumen implants, 12.2 percent saline-filled implants, 0.1 percent other types of implants, and 3.8 percent unspecified types of implants. Double lumen implants have two shells; the inner sac is filled with silicone gel and the outer with saline.

**12. Does the study address the health effects of breast cancer patients who receive implants for breast reconstructive surgery?**

No, not directly. The participants in the study were limited to women who received breast implants for cosmetic reasons and did not include breast cancer patients.

About 80 percent of breast implants in the United States are for cosmetic surgery and 20 percent for breast reconstruction. The majority of previous studies have focused on women who received implants for cosmetic reasons.

(more)

**13. What have other studies shown about the risk of breast cancer in women undergoing breast reconstruction after breast cancer surgery?**

Less is known about the risk of breast cancer following reconstructive surgery compared to cosmetic surgery. One small study reported no increase in the development of second primary breast cancer in women with silicone implants following mastectomy compared to women who received mastectomies without implants. The small size of the study, however, limits the conclusions.

Any study of the risks of breast cancer or other cancers with women who receive reconstructive implants is more complicated than one involving women with cosmetic implants because it needs to take into account the effects of different breast cancer treatments. A study with breast cancer patients would best be done in the context of a clinical trial where comparisons can be made between women who choose to have reconstruction and those who do not, but who otherwise have received identical treatments.

**14. What measures were taken to ensure the objectivity of the study?**

- The study was funded entirely by the government, not by plastic surgeons, implant manufacturers, or other special interest groups.
- Government scientists, not manufacturers of implants or plastic surgeons, designed and provided scientific oversight for the study.
- To participate in the study, plastic surgeons had to agree to allow investigators to see all of their records, not just records for selected patients.
- Information gathered through the participant questionnaire about diseases such as cancer or connective tissue disorders was confirmed by the medical records of oncologists, rheumatologists, and other physicians who had seen the study respondents for these illnesses.
- The investigators obtained detailed information on other factors which could affect health status.
- Death certificates were collected for the patients identified as deceased to verify the causes of death.
- Scientific oversight for the study is provided by NCI's Board of Scientific Counselors and its Breast Implant Study Advisory Panel, a multidisciplinary panel of national experts and consumer representatives.

**15. What is the role of the Breast Implant Study Advisory Panel?**

(more)

The role of the advisory panel has been to provide continuing scientific review of the study. The panel is made up of academic scientists, including oncologists, plastic surgeons, rheumatologists, epidemiologists, and patient advocates. The panel meets regularly with the researchers to address issues involving data analysis and interpretation, and reports to NCI's Board of Scientific Counselors.

**16. Does NCI have a role in the legal actions against manufacturers?**

No, NCI does not have a role. Contrary to some reports, the attorneys representing women who were taking legal action against the manufacturers of the implants were not consulted by NCI investigators as to which plastic surgery practices to include in the study. A number of professional plastic surgery organizations, including the American Society of Plastic and Reconstructive Surgeons and the American Aesthetic Society, were consulted to help identify long-standing practices in which at least 500 cosmetic operations were done prior to 1989 and in which the surgeons retained complete records and were willing to give the researchers complete access to them. The NCI investigators performed their own review of the patient records.

Louise A. Brinton, Ph.D., principal investigator for the study, interacted with plaintiff attorneys on two occasions in 1995 in order to encourage the attorneys not to dissuade their clients from participating in the NCI study. The researchers had similar discussions with a number of advocacy groups. A fact sheet was developed to address several misconceptions about the research and was widely disseminated to various breast implant advocacy groups, plastic surgeons and their professional organizations, and lawyers.

**17. Who are the investigators in this study?**

Brinton is chief of the Environmental Epidemiology Branch in NCI's Division of Cancer Epidemiology and Genetics (DCEG). Additional NCI investigators are Jay H. Lubin, Ph.D., and Robert N. Hoover, M.D., also from DCEG, and S. Lori Brown, Ph.D., research scientist from the FDA's Center for Devices and Radiological Health in Rockville, Md. Theodore Colton, Sc.D., from the Department of Epidemiology and Biostatistics at the Boston University School of Public Health in Massachusetts, was under contract with the study team as was Mary Cay Burich from Abt Associates Inc., in Chicago, who assisted with specific data collection tasks.

**18. What are the publications so far from the NCI breast implant study?**

Brinton L.A., Brown S.L., Colton T., Burich M.C., Lubin J. Characteristics of a Population of Women with Breast Implants Compared with Women Seeking Other Types of Plastic Surgery. *Plastic and Reconstructive Surgery* 2000;105(3):919-27.

(more)

(more)

Brinton L.A., Lubin J.H., Burich M.C., Colton T., Brown S.L., Hoover R.N. Breast Cancer Following Augumentation Mammoplasty (United States). *Cancer Causes and Control* 2000;11(9): 819-827.

**19. What additional studies with this cohort are underway?**

Analyses of the causes of mortality and the occurrence of cancers other than breast cancer are in process and similar analyses of connective tissue disorders will follow.

###

For more information about cancer, visit NCI's Web site at <http://www.cancer.gov>.

(more)