Information for Women about the Safety of Silicone Breast Implants

Martha Grigg, Stuart Bondurant, Virginia L. Ernster, and Roger Herdman, Editors

ISBN: 0-309-52021-5, 32 pages, 7 x 10, (2000)

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INSTITUTE OF MEDICINE

NATIONAL ACADEMY PRESS
Washington, D.C.

The project from which this publication was derived, *Safety of Silicone Breast Implants*, was carried out by a committee of the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

Support for the project was provided by the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health under Task Order No. 36, Contract No. N01-OD-4-2139.

Library of Congress Cataloging-in-Publication Data

Information for women about safety of silicone breast implants / Martha Grigg ... [et al.], editors ; Institute of Medicine.
p. ; cm.
Derived from Safety of silicone breast implants.
Includes bibliographical references and index.
ISBN 0-309-06593-3
1. Breast Implants—Complications. 2. Silicones—Toxicology. 3. Mammaplasty. I. Grigg, Martha. II Institute of Medicine (U.S.)
[DNLM: 1. Breast Implants—adverse effects—Popular Works. 2. Silicone Gels—adverse effects—Popular Works. WP 910 I43 2000]
RD539.8 .I54 2000
618.1'90592—dc21

99-058759

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ABOUT THIS PUBLICATION

The Institute of Medicine report *Safety of Silicone Breast Implants* evaluates the evidence for associations of these devices with human health conditions, provides a comprehensive list of references, and makes recommendations for further research.

This publication, which is derived exclusively from that report, is a step toward meeting one of its recommendations—that is, making the information contained in the original report available to women who have or who are considering breast implants. In this publication, the Institute seeks to provide a short, easily understood version of that information to women.

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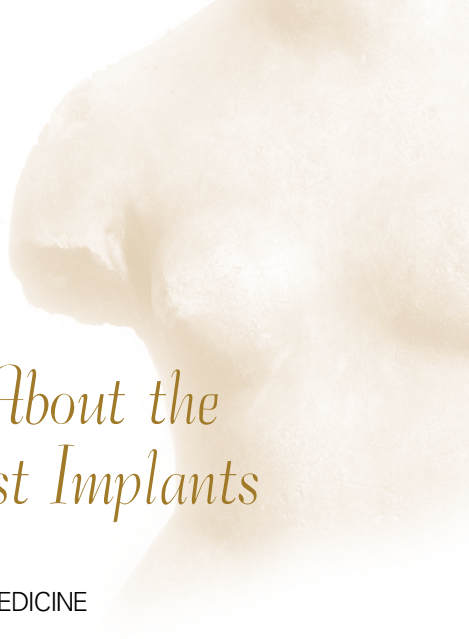


Information for Women About the Safety of Silicone Breast Implants

A REPORT OF A STUDY BY THE INSTITUTE OF MEDICINE

More than 1.5 million American women currently have silicone breast implants.

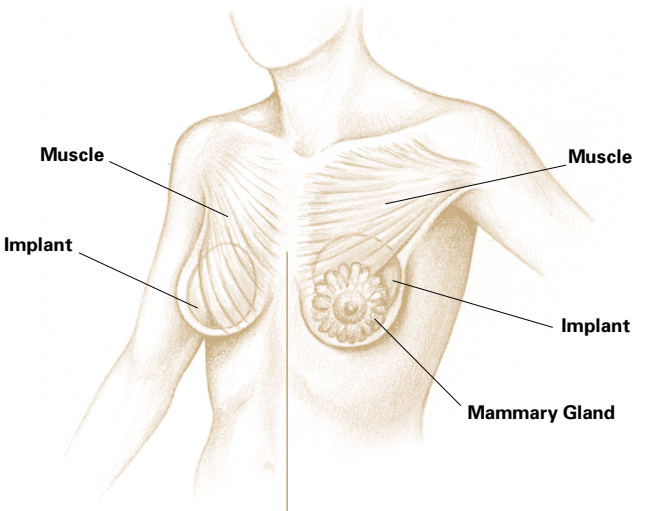
More than two-thirds of these women received implants because they wanted to improve their appearance by changing the size or shape of their breasts, a process called "augmentation." This number is not surprising, since a 1998 study showed 34% of American women were dissatisfied with their breasts. Most of the remaining women in the implant group had a very different reason for considering implants: They had lost one or sometimes both breasts to mastectomy, an operation for breast cancer that removes the breast. The breast is then "reconstructed" by the insertion of an implant.

Some women who are, or feel they are, at high risk for breast cancer have had prophylactic mastectomies to remove their breasts, followed by reconstruction with implants. Other women opted for reconstruction after noncancerous but troublesome breast problems.

Implants today are soft sacs, usually inflated with a saline, or saltwater, solution. The implant has a shell made of silicone, a rubber-like substance that the body tolerates comparatively well.

Until the 1990s, most implants contained a synthetic silicone gel that often had a more pleasing feel and look than today's saline-filled implants. But this same silicone gel has caused controversy because of fears that it produces ill effects in women receiving breast implants.

As many as two-thirds of women say they are very satisfied with their implants, even those who experienced postoperative problems. For some women with breast implants, the psychological benefits of the procedure may outweigh such problems.



RECONSTRUCTION AUGMENTATION

But other women have experienced upsetting complications that require surgery or even removal of the implant, such as:

- implant rupture, which can cause the silicone gel to leak out into neighboring tissue and even into other parts of the body;
- capsular contracture, an often painful distortion and shrinkage of fibrous tissue surrounding the implant;
- saline-filled implants that deflate, spilling the harmless solution into the body; or
- pain, from many causes, including postoperative muscular spasms and severe capsular contracture.

Some women have claimed even more potentially serious problems, alleging that the silicone in implants, particularly the silicone gel inside the implant sac, can cause connective tissue or other autoimmune diseases such as rheumatoid arthritis and lupus, neurological disorders, cancer, and even new silicone-related diseases. As a result of this belief, many lawsuits were filed against implant manufacturers by women claiming they were harmed by silicone breast implants.

Silicone: What Is It?

Silicone is derived from silicon, a semimetallic or metal-like element that in nature combines with oxygen to form silicon dioxide, or silica. Beach sand, crystals, and quartz are silica. In fact, silica is the most common substance on earth.

Silicon can be produced by heating silica with carbon at a high temperature. Further processing can convert the silicon into a long chemical chain, or polymer, called silicone—which can be a liquid, a gel, or a rubbery substance.

Various silicones are used in lubricants and oils, as well as in silicone rubber. Silicone can be found in many common household items, such as polishes, suntan and hand lotion, antiperspirants, soaps, processed foods, waterproof coatings, and chewing gum. Because silicone is relatively compatible with human tissue, it has been used in many types of implants, including those for the breast.

Several processes have been used in treating and making ready silicone for implants. The most common product of these processes is platinum-cured gel or liquid rubber, which was used in early implants. Other processes prepare the silicone for use in implants; however, all of these procedures require a final oven bake to ensure their purity and stability.

Noncrystalline silica is amorphous (shapeless) and is less toxic than the crystalline form. Amorphous silica powder is used in most silicone shells (elastomers). Although concerns have been raised that the silica in these shells can travel to breast tissue, experimental studies have not found amorphous silica in tissues near implants. Another worry voiced is that the amorphous silica could convert to sand (crystalline silica) within the body, but this is a chemical impossibility. No crystalline silica has been found in women with implants.

How This Study Came About

Until 1976, when the "Medical Devices" law was passed, there was no federal regulation of implants. Although the 1976 law gave the Food and Drug Administration (FDA) jurisdiction over such devices, breast implants were "grandfathered," meaning that manufacturers were not required to provide the FDA with scientific evidence of product safety unless questions arose about the safety and effectiveness of these already marketed devices.

Questions did arise about implants. In 1988, the FDA categorized silicone breast implants as requiring stringent safety and effectiveness standards and later required premarket approval applications from manufacturers. On April 10, 1991, the FDA issued a regulation requiring manufacturers of silicone-gel-filled implants to submit information on their safety and effectiveness in order for the devices to continue to be marketed. In 1992, the FDA banned most uses of silicone-filled implants because the manufacturers had not proved their safety. In 1993, the agency notified saline implant manufacturers that they, too, must submit safety and effectiveness data, although these implants were allowed to stay on the market.

For many years, women had complained about the lack of information they received before implant surgery. Many said they had received no data on possible complications, pain, and the chance that the implant would not last forever. This lack of information was due, in part, to the fact that silicone breast implants were widely used before there was any requirement for research and documentation of the safety and effectiveness of medical devices.

In 1997, the U.S. House of Representatives asked the federal Department of Health and Human Services to sponsor an extensive study of silicone breast implants. This comprehensive evaluation would include

- a scientific look at the components of implants, including an analysis of silicone chemistry, toxicology, and immunology;
- a history of breast implants and a description of their modern "generations," or the many forms they have taken over time;
- a review of complications occurring during or after breast implant surgery;

- an analysis of studies examining whether breast implants are related to connective tissue, rheumatic, and neurological diseases and cancer;
- an assessment of whether there are any effects of silicone implants on pregnancy, breast-feeding, and children; and
- an evaluation of how mammography and other breast imaging techniques are affected by silicone implants.

The Institute of Medicine (IOM), part of the National Academy of Sciences, was selected to perform this important work.

To accomplish its task, the IOM set up a 13-member committee—6 of them women—made up of distinguished members of the medical, scientific, and educational communities, with experience in radiology, women's health, neurology, oncology, silicone chemistry, rheumatology, immunology, epidemiology, internal medicine, and plastic surgery (see list on inside back cover). This was a group of volunteers, without conflicts of interest, and with no prior or current relationship with any implant lawsuits.

An important task of the committee was to study and review thousands of published scientific reports. The committee also studied selected industry research reports on silicone breast implants and heard presentations from the public, including representatives of consumer groups, researchers, and women with silicone breast implants.

The committee's goals were to produce recommendations regarding the need for further research on the safety of silicone breast implants and to provide information to women with breast implants or who were considering breast implant surgery.

WHAT THE IOM COMMITTEE FOUND

The committee's work resulted in a 440-page report covering all aspects of silicone breast implants. An important goal of the committee was to provide to women all the known information about silicone breast implants. What follows are highlights from the committee's report, which it hopes will be of help not only to women considering breast implants but also to those who already have them.

Positive Findings

The committee focused on several issues of major concern to women regarding the safety of silicone breast implants, including their

- potential for causing major disease,
- effect on breast-feeding,
- effect on unborn children,
- implications for radiation therapy,
- impact on the use of mammography to detect cancer,
- health effects given recent improvements in design and implantation procedures, and
- effect on the body's immune system.

In addition, the committee reviewed available data about the safety of silicone when implanted in the body. Some of the committee's major findings are summarized below.

Silicone Implants Do Not Cause Major Disease

Evidence clearly shows that silicone breast implants do *not* cause breast cancer or the recurrence of breast cancer. In fact, some studies suggest that women with breast implants have fewer new or recurring cancers. For example, a large, 14-year study of 3,182 women with cosmetic implants (augmentation) actually showed fewer cases of cancer (31) than would be expected (43) in a group of that size. The explanation for this lower-than-expected number of cancers is not clear. More studies should be conducted to determine whether or not the observation is valid and, if so, what might be contributing to the phenomenon.

Originally, concerns about cancer arose from studies that linked implant-formulated silicone with the development of cancerous tumors in rats. Such tumors can be induced if the implants are of a certain size, shape, and surface type and are made of a wide variety of substances, including glass and metal—not just silicone. No studies have demonstrated that such tumors ever develop in humans.

In addition, there is no evidence that silicone breast implants contribute to an increase in autoimmune (connective tissue) diseases. These diseases cause the immune system, which fights any invasion into the

body, to produce antibodies that attack the body's own tissues. Examples of autoimmune diseases are lupus, Raynaud's phenomenon (a painful response of the hands and feet to cold), rheumatoid arthritis, and scleroderma, a disease that involves thickening of the skin.

A report from the long-term Nurses' Health Study involving 87,505 women showed no link between implants and connective tissue disease or rheumatic conditions.

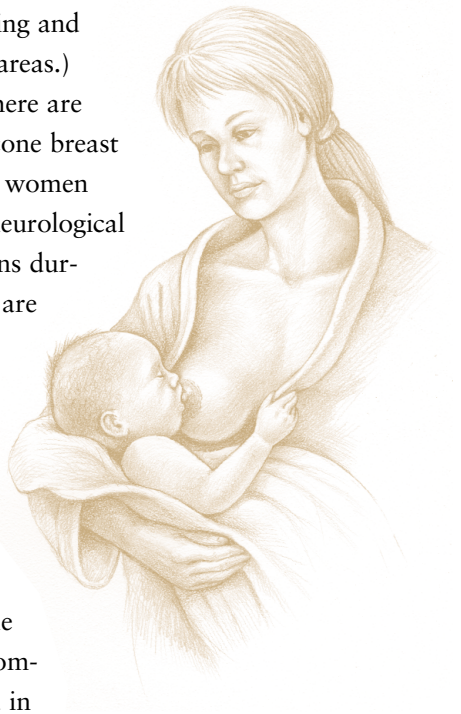
A review of 17 separate studies of the occurrence of connective tissue disease in the population was remarkable for the consistent finding of no elevated risk or no indication of an association of implants with disease.

Moreover, the committee found no proof or significant evidence of the existence of a "novel" systemic disease, as some researchers have claimed, caused by the presence of silicone implants.

Although symptoms found in neurological diseases such as multiple sclerosis, neuritis, Lou Gehrig's disease, or Ménière's disease (a disorder of the inner ear) have been reported by some to be associated with breast implants, two large studies failed to find an increased incidence of these, or any other neurological diseases, in women with implants.

Nor do animal studies support the idea of silicone-gel deposits as a cause of neurological disease. (The committee did find that if an implant ruptures, localized problems such as scarring and nerve compression can occur in the breast or arm areas.)

The committee also concluded that because there are more than 1.5 million American women with silicone breast implants, it would be expected that some of these women would develop connective tissue diseases, cancer, neurological diseases, or other systemic complaints or conditions during their life. Evidence suggests that such diseases are no more common in women with breast implants than in women without them.



Breast-Feeding Is Okay

A major concern about implants has been the possible adverse effects of silicone on breast-fed infants. It is important to note that much higher levels of silicon—from which silicone is derived—have been found in cows' milk and commercially available infant formula than are found in

the breast milk of women with implants. In fact, there is no evidence of elevated silicone levels in breast milk or any other substance that would be harmful to infants, nor are there any differences in silicone levels in the milk and blood of nursing mothers with implants and those without them.

Although some mothers with implants may find it difficult to produce an adequate milk supply, the committee urges that all mothers try breast-feeding, because it is beneficial to babies and is not harmful to mothers.

Silicone Implants Do Not Harm the Developing Fetus

Concerns have been raised about the possible harmful effects of silicone crossing the placenta to the developing fetus. The committee found no evidence of increased levels of disease or birth defects in children born to women with implants.

Radiation Does Not Hurt Implants, and Vice Versa

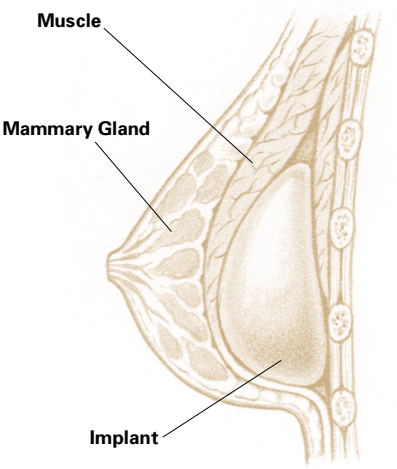
Contrary to some published reports, the committee found no significant evidence that implants interfere with radiation therapy. The implants showed good stability in reaction to any necessary radiation doses, and they did not interfere with radiation beams. Evidence is limited that radiation therapy can cause capsular contracture (shrinkage and distortion of the implant area) and somewhat less pleasing cosmetic results, but there is the potential for concern.

Breast Implants Have Improved Over Time, Reducing Some Health Risks

There have been many changes—and improvements—in silicone implants since they were first introduced in 1963.

Although the time frame involved is relatively short, early results have caused many to believe that the implants of today offer greater protection from rupture or painful capsular contracture. The majority of implants are now inserted behind instead of on top of the chest wall muscles that cover the breast area. Putting the implants behind the muscles lessens the chance of severe contracture, that is, shrinking and hardening of the tissue around the implant, and allows a better view of breast tissue when a woman has a mammogram.

The outside of the implant shell (the elastomer) is usually textured, also offering greater protection against contracture. The shell itself today is stronger, often with an additional inner barrier layer that helps guard against seepage.



Saline implants were not very popular when they were first introduced. Not only did they often "deflate," but also the cosmetic result was generally not as good as with the silicone-gel models. Patients complained about the "slosh effect," a fluid wave from within the implant that sometimes they could actually hear. Another negative factor was the implant's thin consistency, with wrinkling visible through the skin.

But today's saline implants are much improved. The high rate of deflation has been corrected, and better cosmetic effects have been achieved by slightly overfilling the implant and placing it behind, or deep into, the chest muscles.

Some saline implants used in reconstruction have valves, designed to be inflated gradually after surgery as new tissue forms around the pocket created. Early valves often leaked, resulting in deflation or possible bacterial contamination of the saline. These problems, too, have been corrected.

Recent studies indicate that a majority of women are satisfied with their implants. Complaints to the FDA dropped sharply in 1995, after peaking in the period from 1992 to 1994, a time frame marked by numerous lawsuits and much negative publicity.

Implants Do Not Weaken the Immune System

A foreign protein in the body is called an antigen, and many antigens are found in bacteria and viruses. The body reacts to the presence of an antigen by producing an antibody. T cells, a type of white blood cell, play an important part in defending the body against disease. When these defenders malfunction, the result is an autoimmune disorder—such as rheumatoid arthritis—in which the body's own cells and tissues are attacked.

These disorders can be brought about by toxins that provoke the body into producing antibodies against itself. There is no evidence, however, that silicone implants cause such a reaction.

Antibodies are the body's normal way of dealing with foreign substances, and their presence doesn't necessarily indicate disease.

The Independent Review Group, organized in the United Kingdom in response to women's concerns about silicone breast implants, concluded that, overall, silicones found in breast implants were bland substances with little toxicity and no adverse effect on the body's immune system.

In General, Silicone Is "Safe"

The committee studied and evaluated multiple documents on the history, chemistry, and toxicology of silicone implants. It noted that the wide use of silicone—in foods, cosmetics, lubricants, and a variety of consumer products—has resulted in extensive exposure to it by individuals in all developed countries.

Almost all studies agree that there are baseline levels of silicon, an indicator for silicone, in normal breast and other tissue. Silicon is found in moderately higher than baseline levels around saline implants and in the capsules around silicone-gel implants. Silicon levels are particularly high around ruptured implants. This silicon apparently does not travel to other parts of the body. The committee found that exposure of women to silicone from the breast implant is limited almost entirely to the implant, its capsule, and the tissue and lymph nodes immediately surrounding the area. The IOM committee concluded that the silicon found in distant tissues most likely reflects human exposure to the widespread presence of silicon and silicone in the environment. At the end of its investigation, the IOM committee concluded that the silicones found in breast implants do not provide a basis for concern at doses reasonably to be expected.

Negative Findings

The committee also reported on its findings regarding the health problems that can occur in women with implants. These included

- the need to replace implants,
- local complications, and
- the need for additional surgery or other medical interventions.

The most serious of these problems are "local" complications, meaning those that occur in or near the implant. Although generally not life threatening, such complications can cause discomfort and, in some cases, pose considerable risk. The IOM committee believes these local complications—

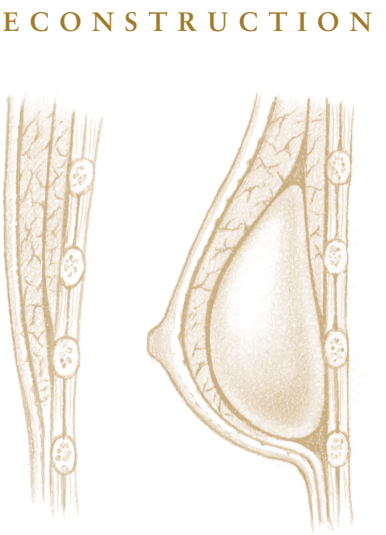
which occur often and may themselves prompt additional medical procedures, including operations—are the primary safety issue with silicone breast implants. The committee also recognizes that many of the reports reviewed in conducting this study were based on silicone-gel implants that were largely replaced by saline-filled implants in the early 1990s, and the risk of local complications is likely even lower with saline-filled implants.

Finally, although breast surgery has a low risk of death, many complications can occur when implants are removed, revised, or replaced.

Some of the problems the committee found follow.

Breast Implants Do Not Last Forever

The chances are great that most women will outlive their implants. The odds of having at least one replacement implant are high, and some women have had many more. A study of women receiving reconstruction over an average of 6 years showed that 16% of those with saline implants required replacements. Another study reported an 18% implant loss in women reconstructed with gel implants or submuscular expanders. A smaller study of women with implant troubles showed that, on average, over 12 years there were about three implants performed per woman.

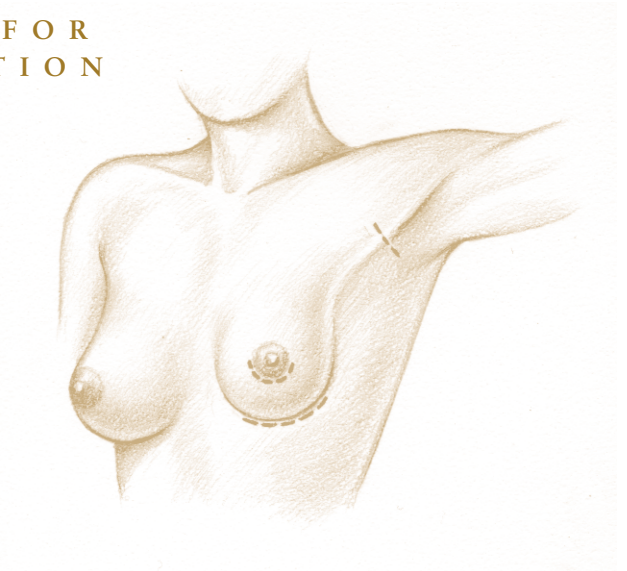


The risks of having a local complication—such as a replacement operation—continue to accumulate over time.

Local Complications Are Frequent with Gel-Filled Silicone Implants

Women with gel-filled silicone implants and those undergoing reconstructive surgery appear to have a greater chance of complications than do women who have saline implants or implants for augmentation. The operation for immediate reconstruction is more serious because it involves a significant surgical procedure (mastectomy or removal of the breast) followed by the implant procedure. Some studies have suggested that from 30 to 40% of these patients could expect complications.

INCISIONS FOR AUGMENTATION



This percentage may rise when an expander is used to help generate tissue growth in the breast area, and complications are probably more frequent when the woman has previously undergone radiation therapy. The possibility of more frequent and serious side effects following immediate reconstruction must be weighed against the psychological benefits of such a procedure.

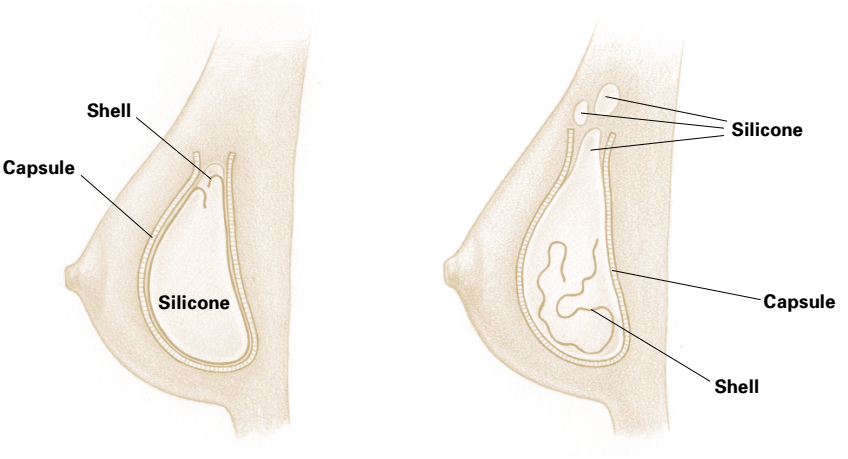
Women undergoing augmentation have fewer complications, especially if they have had modern "RTV" (room temperature vulcanized, or strengthened) saline implants. Still, the frequencies are high. A study of 2,855 women with modern saline implants showed 18% of augmented women and 36% of those with reconstruction had complications—within a year of receiving their implants—in one of four categories: infection, severe contracture, deflation, and implant removal.

The IOM committee found that a large number of women with implants could expect to have an additional procedure within the first 5 years after the original implant.

In addition, several studies indicate that removal of implants because of health fears is of little psychological value in relieving distress, depression, or anxiety.

Frequent Complications Mean Frequent Procedures

Frequent local complications include the rupture of silicone-gel-filled implants, the deflation of saline-filled implants, severe contracture of fibrous tissue around the implant, infections, hematoma (a pooling of clotted blood), pain, and implant displacement. The end result of these problems may be more surgery or other medical interventions.



RUPTURE Rupture occurs when silicone gel escapes the implant shell. Such a rupture may be caused by tiny flaws in the shell or by inadvertent needle pricks while the incision is being stitched up. Ruptures can also happen after a needle insertion (a biopsy, for example) or when the breast is severely squeezed or compressed either during procedures to break up fibrous tissue (capsular contracture) around the implant, or because of trauma caused by an automobile accident or even, some say, a too-tight hug. The implant shell may also weaken with time; in fact, this can be *expected* with older models.

With the rupture of a silicone-gel implant, the gel and fluid can sometimes escape into other tissues and even form an unwanted lump somewhere else on the body, such as the arm, armpit, or chest area. Often, however, the space between the fibrous capsule (which forms around all implant shells) and the implant can actually contain the gel, keeping it from spreading into surrounding tissue, so that the rupture goes unnoticed. This type of rupture is called "intracapsular."

One of the questions the IOM committee hopes will be explored is whether screening measures should be undertaken to find these "hidden" ruptures or whether diagnosis is necessary in women who have no symptoms (e.g., pain or leakage).

When both the implant shell and the capsule of a gel implant rupture or leak, the result is an "extracapsular" rupture that allows silicone to spill out or leak into body tissues. Most surgeons believe this condition should be corrected.

Surgery for extracapsular rupture consists of removal of the implant (explantation) as well as the capsule surrounding the implant (capsulectomy). These operations will require anesthesia, incisions, and stitches. And, of course, the surgical procedure may include a new implant as well.

The frequency of implant rupture is unknown. The IOM committee found studies reporting that the frequency of gel-filled implant ruptures varied from 0.3 to 77% of implanted women. The extreme variability of these percentages is due to the type and model of the implants, their length of implantation, the types of groups of women studied, and many other factors. Other investigators found no ruptures in late-model ("third-generation") gel implants, but more time is needed to observe these implants. Some reasons for the confusing statistics about ruptures are (1) ruptures are not always detected, (2) the composition of implants has undergone many changes over the years, and (3) the time interval varies and is not long enough to pick up late ruptures. Because of such conflicting information, the committee recommends further studies.

Further, the IOM committee concluded that it is unclear whether implants in current use will need replacement in 10 or 15 years, as some older models did, or will last longer.

DEFLATION It is usually very easy to spot a saline implant that has ruptured—within 2 or 3 days the harmless saltwater solution spills out into the surrounding tissue and the implant collapses, or deflates. Only occasionally does a "slow leak" (partial deflation) take from 1 to 2 years to become noticeable.

Although early saline implant models had frequent deflations, later models are less likely to do so—a 5 to 10% frequency after 10 years, according to one study. Ruptures, leaks, and deflations may be more common in gel-filled implants than in current saline-filled models, although one team of investigators showed that only 67% of saline implants were still in place at the end of 10 years, causing the researchers to comment that their study "confirms the obvious: Inflatable breast implants deflate with time."

The IOM committee concluded that deflation of modern first-year saline implants might run from 1 to 3% and that this percentage would rise steadily with time. The report strongly recommends that more studies be conducted to answer questions about today's implant rupture and deflation rates.

CAPSULAR CONTRACTURE The human body considers a breast implant—or any implant—to be a foreign agent and forms a protective capsule of fibrous tissue around the intruder, resembling the immature scar formed after a severe burn. This buildup of tissue is called a capsular contracture. If severe, it can cause painful and disfiguring squeezing as well as distortion of both the implant and the overlying tissue. The ensuing complications can be serious, including additional medical procedures to break down the overgrowth of protective tissue, or to remove it, or even to replace the implant itself. Additional surgery comes with its own risks, including infection, possible ruptures, and the hazards of anesthesia.

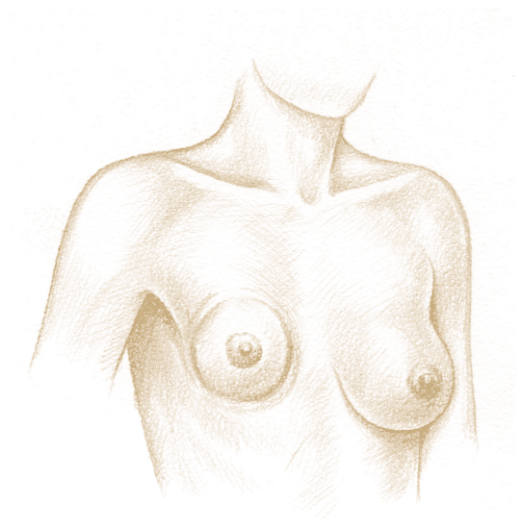
Some of these medical procedures—particularly "closed capsulotomy," where strong pressure is applied to the outside of the breast to help break up the fibrous capsule—are performed repeatedly on the same women. Problems with capsular contracture made up 28% of secondary procedures done on women with breast augmentation and 14% of those with reconstruction. A recent study showed that contracture was the reason for 73% of implant removals.

The severity of contracture is often measured using the Baker Classification, which has four categories:

Class I	The augmented breast is as soft as a nonaugmented one.
Class II	The breast is less soft and the implant can be palpated (felt) but is not visible.
Class III	The breast is firmer and the implant can be palpated easily and can be seen (or a distortion can be seen).
Class IV	The breast is firm, hard, tender, painful, and cold. Distortion is marked.

Most surgeons consider the first two classes satisfactory but not the last two. Women, however, have often tolerated Class III and IV contractures either by not seeking any medical help or by indicating, when asked, that they are satisfied with their implants. A 1990 study reported that 85% of women appeared satisfied with their implants even though 35% had experienced severe contracture.

A 1997 report on 186 implants showed Class III and IV contractures continuing to occur, "reaching 100% around silicone-gel-filled implants at 25 years."



Treatments for contracture other than closed capsulotomy include "open capsulotomy," in which an incision is made into the body to break up the capsule, and a "capsulectomy" or surgical removal of the capsule itself. This operation may also involve removal and replacement of the implant as well as loss of breast tissue. Replacement and capsulectomy also involve as much as an hour or more of operating time. The IOM committee reports an excess use of some procedures, particularly the closed capsulotomy, in treating contracture. Repeated capsulotomy, open or closed, has progressively less chance of success. Contracture with its treatment is an important and incompletely resolved issue in breast surgery. It is likely that contracture is a progressive phenomenon, slowly increasing with time.

Scientists and doctors do not know for sure *why* severe contracture happens. Some have suggested that trauma to the breast during the implant surgery itself or at another time may bring about thickening and constriction of the capsule. The silicone used in implants has also been named as a culprit in contracture capsules formed around gel implants. The IOM committee noted that most studies agree that baseline levels of silicon are found in all normal breast and other tissue. Definite proof of a relationship between the presence of silicone in the tissue and contracture is lacking, but silicone fluid injected directly into the breasts (an early and improper practice) does cause fibrosis, or hardening of tissue.

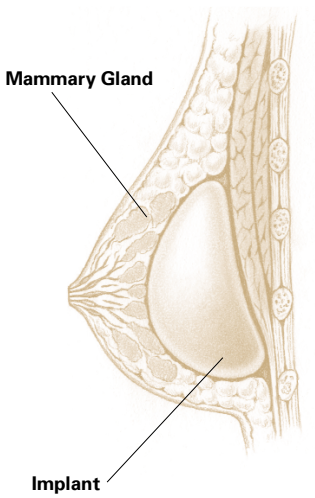
Although definitive studies are limited, evidence suggests that saline-filled implants have a reduced rate of contracture compared to

implants filled with silicone. Fewer cases of severe contracture are also reported in studies of textured-surface implants compared to those with smooth surfaces. Both patients and doctors in a 1997 study preferred the textured surface.

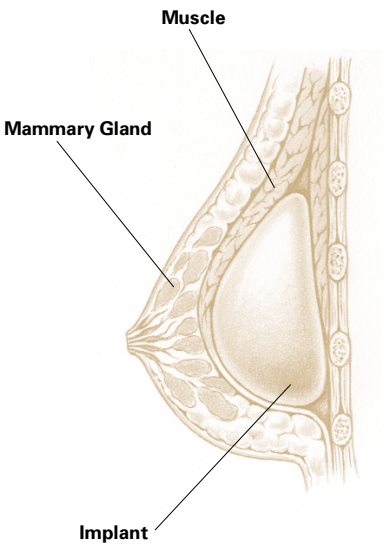
In one clinical study, women undergoing immediate reconstruction after mastectomy also showed fewer cases of contracture than did women having later reconstruction. And, after 5 years, contracture among reconstructed women in the study was less frequent than that among augmented women. However, the women with reconstruction had a much higher proportion of textured-surface implants and implants placed behind the chest muscles than did the women with augmentation. This probably explains this unexpected result and suggests how effective texturing and placement can be in reducing contracture.

Placement of the implant behind the chest muscles seems to lower the chance of contracture. One study demonstrated that the rate of contracture is 30% with submammary implants versus 10% with submuscular implants. The lower incidence of severe contracture with submuscular implant placement is important. The IOM committee

SUBMAMMARY



SUBMUSCULAR



believes patients and surgeons should consider this factor when discussing implant surgery options.

Despite the possibility of contracture, some plastic surgeons still put the implant just beneath the skin or breast or glands in 32% of augmentation implants, probably because the procedure can have a better cosmetic effect and cause less long-term pain than the submuscular procedure.

The use of steroids to reduce capsular contracture is not recommended. Steroids placed inside saline implants may carry other health risks and are not approved for use by the FDA. In addition, steroids may weaken the implant shell. The IOM committee recommends that any use of steroids should be postponed until carefully designed studies can be conducted to determine the risks and benefits of such use.

INFECTION Infection can cause serious complications. Sometimes an infection can develop in the area where the surgery was performed, requiring medical treatment, additional surgery, and possibly removal or replacement of the implant.

Most local infections—those due to bacteria such as staph, for example—may be treated with antibiotics. These infections are reported most often in women who have had reconstruction, particularly immediate reconstruction after mastectomy. Sometimes infection can lodge in the expander used in some reconstructions. The ducts of breasts also collect some normal bacterial inhabitants of the skin area, and occasionally these may cause infection.

Infection may even contribute to the development of severe capsular contracture. The very medical procedures used to correct the condition may expose the area to more bacteria. One of the problems is that slightly abnormal and not easily detected infectious conditions can exist in a "slime" layer around the implant where the infectious agents are protected from the effects of antibiotics. According to some studies, these "subclinical" infections may also contribute to such symptoms as fatigue, muscle or joint pain, and diarrhea.

In one study of various implant devices, 93% of the women who reported pain also had an infection. When patients were given antibiotics (usually for staph) and implant devices were replaced by sterile models, 90% of the new implants were reported to be pain free.

The evidence that the presence of bacteria around an implant might contribute to contracture is not conclusive, but certainly suggestive.

HEMATOMA Sometimes blood or tissue fluid collects around an implant, causing pain, infection, or other complications. In a small number of cases, repeat operations have been necessary to correct the problem. Plastic surgeons often use drains after implant surgery to manage bleeding and the collection of blood (hematoma) or fluid around implants, and some surgeons claim such drains help prevent contracture.

Hematomas may occur, rarely, many years after the implant operation in association with contracture, perhaps because a stiff capsule has developed tiny fractures. The committee concluded that there is insufficient evidence pointing to more frequent contractures and subsequent complications around hematomas.

PAIN Pain is one of the significant reasons for implant removal and replacement, although few studies dealing with local implant problems have involved information about pain.

Some studies have reported that a majority of women do experience pain after implant surgery, and this pain may be long lasting.

Patients also reported more pain with implants after mastectomies compared with mastectomies alone and with implants placed under the chest muscles instead of under the skin and breast glands.

A questionnaire returned to one study group reported substantial local pain after reconstruction (up to 50%) and up to 38% after augmentation. As with other studies, pain was also more common after submuscular (50%) implants compared to submammary implants (21%), and with saline implants (33%) compared to gel-filled ones (22%).

About 20 to 29% of patients with pain required pain-control medication. Formation of the implant capsule, especially when the implant is under the chest muscles, may cause nerve compression resulting in considerable pain that may require additional treatment.

The committee recognized that pain following surgery is not surprising given the damage that occurs to the nerves to the breast during implantation and reconstructive surgery, which in some cases occurs after injury to the nerves following mastectomy and, in some cases, lymph node surgery.

Pain may also be an indicator of trouble ahead. Sometimes the implant has to be removed, or a capsule forming under the chest muscles may result in more compression and pain and lead to more surgical procedures. Much of the pain with a late onset is caused by capsular contracture, but it can also be indicative of bacterial infections or rupture.

Conclusions

The IOM committee's review of research and medical studies shows a local, but not general, reaction to silicone breast implants.

- **There is no evidence that silicone implants are responsible for any major diseases of the whole body. Women are exposed to silicone constantly in their daily lives.**
- **There is no plausible evidence of a novel autoimmune disease caused by implants.**
- **The committee found no increase in either primary or recurrent breast cancer in women with breast implants. Some studies even suggest lower rates of breast cancer in implanted women.**
- **There is no danger in breast-feeding; cows' milk and infant formulas have a far higher level of silicon, a silicone component, than mothers' milk. Breast milk is the best food for babies.**
- **The major problems with implants are local, but not life-threatening, complications. These include implant removal, ruptures, deflations, capsular contracture, infection, and pain.**
- **Many women will have secondary problems such as severe contracture, rupture, and implant removal.**
- **Implants do not last forever; risks accumulate over time, and many women should expect to have more than one implant.**
- **Some women with breast implants are indeed very ill. However, the committee can find no evidence that these women are sick *because* of their implants.**

MAMMOGRAMS AND OTHER BREAST IMAGING IN WOMEN WITH IMPLANTS

Some women have expressed concern that the presence of an implant will make it difficult or impossible to use mammography for the early detection of breast cancer. The committee reviewed available literature on the use of mammography in women with implants and also examined the usefulness of other imaging techniques for the detection of implant rupture.

Mammograms—x-rays of the breast—have proved their value in finding breast cancer in its early stages. Randomized, controlled trials have confirmed that mammography significantly decreases breast cancer death rates.

Women with cosmetic breast implants undergo mammography and other imaging techniques just as do women without implants. In general, however, mammography is not necessary for reconstructed breasts because the breast tissue has been removed.

Questions have come up about the possibility that the implant itself might obscure some breast tissue in augmented breasts, making an early diagnosis of breast cancer by mammography more difficult. No studies of women with breast implants have shown increases in cancer deaths because of mammographic diagnostic delay. A large study of women with implants for augmentation actually showed fewer new cases of cancer than would be expected and also found the severity (stage) of these cancers at diagnosis to be about the same among women with and without implants. But the committee believes this question deserves further study.

The mammogram is an extremely important screening technique for finding breast cancer. All women in the age and risk categories appropriate for regular mammograms should continue to have them. The IOM committee realizes, however, that breasts augmented with implants can pose unique imaging problems, and that the success of the mammography depends in part on the experience and expertise of the technician.

Many women (about 40,000 in 1994, according to one report) had implants removed when questions about their safety arose and attracted adverse publicity. When an implant is removed (explanted), there is a chance that scar tissue will form in the breast area and show up on the mammogram as a suspicious mass.

Another possible problem for the radiologist concerns the textured shells used in many implants today, the surface of which may fill with tissue and mimic a rupture on the film. The capsule around the implant can

also calcify and resemble the small calcifications often associated with cancer cells. Or, worse, calcifications that *are* associated with cancer may look harmless. Capsular contracture can make it harder to obtain a good x-ray of breast tissue. The folds that can develop around the shell may also make diagnosis of implant rupture difficult.

To make mammograms more readable, some researchers have been investigating implant fillers that may be more x-ray friendly. Materials studied include peanut and soy bean oils. So far, there is insufficient evidence about their effectiveness and safety.

Many of the concerns about implants and mammograms arose in the 1960s and 1970s when both mammograms and silicone breast implants were in their infancy. Since then, both mammograms and implants have improved. Mammography now achieves more sophisticated imaging, and in 1988, a more advanced technique was introduced for manipulating the implant without compressing it. Although mammography may present some problems, the IOM committee recommends its use and notes that the procedure is quick and inexpensive. The committee suggests that women and their doctors consider submuscular implant placement, which makes diagnosis by mammography much easier and puts it more on a par with that available to women without implants. Updated techniques include avoiding unnecessary compression, with only enough pressure to keep the breast and implant from moving.

The committee finds mammography of limited value in detecting ruptures, particularly those contained inside the implant capsule. Even with extracapsular rupture, mammography can only diagnose the presence of silicone outside the capsule.

On a positive note, the report finds little evidence that procedures involving mammography cause ruptures.

Use of Ultrasound to Detect Implant Ruptures

Ultrasound uses a scanning device that converts an electrical current into high-frequency sound waves as it passes over the skin. The echoes of these waves form a pattern on a TV-like monitor. Ultrasound works particularly well in viewing soft tissue and fluids and is often used as a follow-up to suspicious findings on mammograms. A “snowstorm” effect on the monitor screen may indicate silicone gel outside the implant, a sign of rupture. When there is a capsular contracture, however, ultrasound may

not reliably determine whether a rupture is present, nor can it "see" the back of the implant.

Although ultrasound is inexpensive and can detect many ruptures, its reliability is highly dependent on the operator's skills.

Use of Magnetic Resonance Imaging to Detect Implant Ruptures

Magnetic resonance imaging (MRI) provides high-quality cross-sectional images of the inside of the body without the use of x-rays. This imaging device can be used to detect the presence of silicone gel and is the diagnostic tool of choice when mammography or sonograms suggest an implant rupture. MRI is the most accurate imaging technique for determining whether an implant is intact. The procedure is most effective when the magnetic resonance coils are specifically designed for the breast. Such modern MRI screening is a highly sensitive and specific test for ruptures.

MRI screening, however, is expensive and time consuming. The committee recommends more investigation into whether routine screening for ruptures should be done for women without any symptoms. Such a study should answer the question of whether all ruptures should necessitate having the implant and capsule removed, a procedure requiring an operation and possible tissue loss.

The committee made recommendations in three general areas:

1. health matters of importance to women and their physicians;
2. the need for standard procedures in informing women about breast implants, conducting studies on their safety, and approving changes in design; and
3. topics in need of more research.

Health Matters

- All women in the age and risk groups for which mammograms are recommended should continue to have them. Women who have increased risk factors should follow a schedule based on their doctors' recommendation. Regular mammograms are especially important as women grow older because most breast cancer occurs in women over 50.
- Mothers with breast implants for augmentation should try to breast-feed their babies. Breast-feeding is good for the baby and cannot harm the mother.
- Strong evidence indicates that placement of implants behind the chest muscles improves mammography performance and lessens the chance for local complications and repeat operations.
- The committee does not recommend closed capsulotomy as a treatment for capsular contracture.

The Need for Standards

Women often cannot identify the type of implants they have and frequently have received insufficient information before making a choice about them. In the case of some older implants, there may be no surviving information about the model in question. In the early days of silicone implants, some models were custom-made for individual plastic surgeons (who patented their devices). Such implants were sometimes used without any testing. In addition, some companies produced small quantities of unusual implants.

Competition was keen in the implant business and, without any regulation, sometimes both testing and medical and/or company records fell by the wayside. Because of the lack of historical data available, some case reports describing local and systemic complications do not have information on the implant make and models involved.

U.S. implant manufacturers have changed names, been bought out, merged, become part of national and international conglomerates, or gone into bankruptcy. Many foreign implants were also introduced in the United States. Today, however, there are only two companies—Mentor and McGhan Medical—making and selling implants in the United States.

Little wonder that many women—and the committee—believe it is time for the physical and chemical characteristics of implants to be spelled out, with clear-cut information made available on existing implants and standards imposed to ensure that future changes are made only when a thorough investigation shows no possible complications or other harmful effects on safety and health. Specifically,

- A standard consent procedure should be developed in which women would get information they need, including the possibility of local complications, before making an informed decision to have breast implant surgery.
- Accepted standards should be determined for concentrations of silicone within the body, whether an implant is present or not.
- An agreed-upon scientific approach is needed to approve any changes in the composition of silicone implants.

Areas Needing Additional Research

The IOM committee also assessed areas in which more research is needed before the safety of silicone breast implants can be fully understood. These include the following:

- ongoing studies of women with silicone-based breast implants to define and standardize their physical and chemical characteristics; such studies should include tracking the outcome in women with specific types of implants, such as silicone gel and saline, and the results of these studies should be communicated to women and their doctors;
- studies of local complications, including frequency of rupture, deflation, and severe contracture;
- research and evaluation of the use of diagnostic tests for ruptures in women without any symptoms and whether these asymptomatic ruptures need to be removed;
- evaluation of silicone and silicon amounts in saline implants;
- the accumulation of more data on saline implants;
- controlled studies on the use of steroids to reduce some local complications if that is to be considered (steroids are not approved by the FDA for use in breast implants, and their uncontrolled use may damage breast tissue and weaken the implant); and
- a comparison of stage of cancer detected by mammography in women with and without breast implants.

A History of Implants

Attempts to improve the look of the breast by augmenting its size and shape date back to the late 1880s. Among the materials inserted in breasts early on were ivory, glass balls, ground rubber, ox cartilage, and sponges, sacs, and tapes made from various synthetic substances. Later came rubber, Teflon, and silicone.

Some breasts were augmented by injection. In the 1940s, an array of liquid substances were injected into the breast, such as paraffin and petroleum jellies. Later, industrial silicone fluid and medical-grade silicones were injected into the breast by unlicensed practitioners, sometimes in staggering amounts. These methods of breast injection caused pain, skin discoloration, ulceration, infection, disfigurement, breast loss, liver problems, respiratory distress and pulmonary embolism, and even coma and death. The frequency of capsular contracture with presilicone implants may have reached 100%. Between 12,000 and 40,000 women received breast injections in Las Vegas before the procedure was declared a felony under Nevada state law in 1976.

MODERN GENERATIONS OF IMPLANTS

In 1963, Dow Corning Corporation introduced the first silicone-gel-filled implant. The earliest Dow shells had a high-molecular-weight "gum" filled with amorphous silica, and the gel in the implant was platinum cured. By the early 1970s, the Dow Corning Dacron-patched implant had achieved stunning popularity, accounting by one estimate for 88% of all implants sold.

These early implants had thick shells and gels. The silicone rubber elastomer shell usually had seams and a smooth surface. The inside contained a firm silicone gel and fluids. Rupture rates were low because of the tough shell, but complications from capsular contracture were common and gel-fluid seepage was probably considerable.

Some implants had internal dividers to keep the gel from sagging into the central part of the implant. Seal patches were used to close up any holes or slits left by manufacturers or the valve entrance to an expander, and are still used for manufacturing today's seamless implants.

By the late 1960s, Dow's shells had become less thick and were seamless. And in 1968, Heyer Schulte Corporation became the first domestic manufacturer of saline-filled implants. Early saline implants were fragile and heavy, with audible "sloshing," and there was a very high deflation rate of up to 76%, probably because of the high-temperature vulcanizing process used to "cure" or strengthen the contents.

The original thick-shell models were replaced in the 1970s and early 1980s by implants with thin shells. But these had a greater tendency to rupture and deflate. These "second-generation" implants were generally smooth surfaced and had high contracture and gel-fluid seepage rates. More flexible gels were introduced by various companies from 1972 to 1975, and thinner elastomer shells were introduced starting in 1972.

Another development in the 1970s was a polyurethane foam coating on the implant shell. This coating appeared to reduce contracture and was popular; an estimated 110,000 women or more received this type of implant before it was discontinued in 1991. The polyurethane coating appeared to diminish capsular contracture by causing an inflammatory reaction. This reaction discouraged formation of fibrous tissue around the capsule. But the polyurethane coating started disintegrating almost immediately, so that what eventually remained was a mostly smooth implant surrounded by a capsule containing foam fragments. Pain, fluid accumulation, and infection were reported. The foam fragments were one reason a polyurethane-coated implant was difficult to

remove. There is no hard evidence to support the idea that the polyurethane foam could lead to cancer. Beginning in the mid-1980s, most implant models were sold with a textured shell surface. The theory of texturing was similar to that of a polyurethane coating; that is, the growth of tissue into the irregular spaces of the shell would prevent collagen and other fibrous tissue from forming excess growth around the implant capsule.

Textured implants might also encourage the development of synovium, a thin membrane that secretes synovial fluid, a clear, sticky substance. Synovium may be a natural result of friction from the movement common in all breast implants.

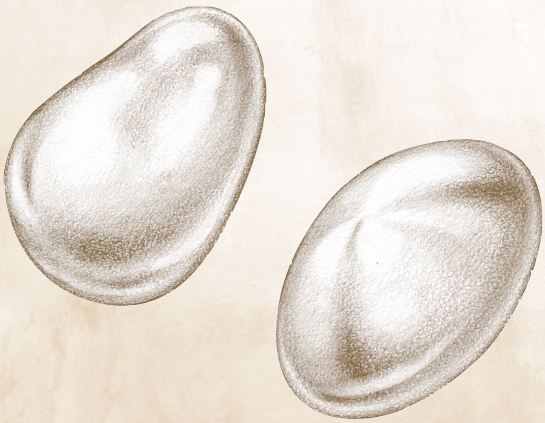
Another innovation in the second-generation implants was the "double lumen." These implants had two cavities and two shells, which were either "patched" together or had one shell floating freely inside the other. The double lumen was an attempt to provide the cosmetic benefits of gel in the inside cavity, while the outside lumen contained saline and could be used for an expander or even for injections of antibiotics or steroids. The saline lumen was also thought to control contracture and gel and fluid seepage or rupture, but studies over the years have largely disproved such theories.

Various types of expanders evolved over the years, some of them with permanent valves. A barrier coating on the inside of the shell was developed in the 1980s to help prevent silicone-gel "bleeding" or seepage. Rupture frequencies for silicone-gel implants were as follows:

- first generation (from 1963 to 1972)—very low,
- second generation (from 1972 to mid-1980s)—50 to 95% after 12 or more years, and
- third generation (from mid-1980s to present)—still uncertain, but possibly about 10% in 5 years.

This modern third generation of implants, which dates from the mid-1980s, also saw improved silicone-gel implants, saline implants with much better deflation rates, and stronger shells with barrier layers and texturing. Although these data are incomplete, this generation of implants may offer lower rates of deflation and rupture, fewer contractures, and less gel diffusion or "bleeding."

There was no standard breast implant in America. Since 1962, there have been some 240 different types, made by at least 10 manufacturers. Given variations in sizes, shapes, types of valves and patches, gels, and shells, one estimate puts at 8,300 the number of different types of implants available with slight variations over the years.



A majority of implants in place today are "single-lumen" (one-cavity) models filled with silicone gel. The shell ("elastomer") is made of silicone rubber and has an inside barrier coating of fluorosilicone or a modified layer of elastomer to help prevent silicone fluid from escaping. The outside of the shell often has a textured surface; tissue grows into this surface, stimulating an inflammatory reaction. This inflammation can delay the development of the fibrous tissue that causes capsular contracture.

In the 1990s, saline-filled, single-lumen implants almost completely replaced the formerly popular gel-filled models because of the 1992 FDA moratorium on the use of silicone gel. In addition, the popularity of immediate implant reconstruction after mastectomy has grown, from 3% of implants in 1983 to more than 25% in 1992. Reconstruction with implants reached its zenith of 40% of all implants in 1990; since then, more women have chosen to have a breast constructed out of tissue from other parts of the body (the "flap" form of reconstruction). But this is a more difficult operation and not suitable for all women.

It remains to be seen whether implants of this third generation will continue to be used or if forthcoming study results (and FDA decisions) will bring about still another generation of implants. Furthermore, there is less information available about saline implants than silicone-gel implants—silicone gel was the "fill of choice" until the 1990s. Saline implants contain a harmless saltwater solution, cannot have silicone leakage (because they don't contain silicone), and appear to have lower rates of capsular contracture. Still, the jury will be out until more studies are forthcoming.