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## COMPLICATIONS LEADING TO SURGERY AFTER BREAST IMPLANTATION

SHERINE E. GABRIEL, M.D., M.Sc., JOHN E. WOODS, M.D., W. MICHAEL O'FALLON, PH.D., C. MARY BEARD, R.N., M.P.H.,  
LEONARD T. KURLAND, M.D., DR.P.H., AND L. JOSEPH MELTON III, M.D.

### ABSTRACT

**Background** Local complications that require additional surgical procedures are an important problem for women with breast implants.

**Methods** We studied 749 women who lived in Olmsted County, Minnesota, and received a first breast implant at the Mayo Clinic between 1964 and 1991. We identified complications that occurred after the initial procedure and after any subsequent implantation. A complication was defined as a surgical procedure performed for any of the following reasons: capsular contracture; rupture of the implant; hematoma or bleeding; infection or seroma of the wound; chronic pain; extrusion, leakage, or sweating of the implant; necrosis of the nipple, areola, or flap; malfunction of the filler port of a tissue expander; and wound dehiscence.

**Results** During follow-up (mean, 7.8 years; range, 0 to 25.8), 208 (27.8 percent) of the women underwent 450 additional implant-related surgical procedures. Ninety-one (20.2 percent) were anticipated, staged procedures or were done because the patient requested a size change or aesthetic improvement, and 359 procedures (79.8 percent) had at least one clinical indication (thus constituting a complication). Complications occurred in 178 (23.8 percent) of the 749 women and involved 274 (18.8 percent) of the 1454 breasts with implants and 321 (18.8 percent) of the 1703 implants. The most frequent problem was capsular contraction (131 women), followed by implant rupture (43 [5.7 percent]), hematoma (43), and wound infection (19). The rate of complications was significantly lower ( $P < 0.001$ ) among women with cosmetic implants (6.5 percent at one year, 12 percent at five years) than among those who received implants after mastectomy for breast cancer (21.8 percent at one year, 34 percent at five years) or prophylactic mastectomy (17.3 percent at one year, 30.4 percent at five years).

**Conclusions** Women who have had breast implantation frequently experience local complications during the subsequent five years. Complications were significantly less frequent among patients who received implants for cosmetic reasons than among those who received implants after mastectomy for cancer or for cancer prophylaxis. (N Engl J Med 1997;336:677-82.)

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IN the United States, 1 million to 2 million women have undergone breast implantation.<sup>1,2</sup> We previously reported the results of a retrospective cohort study that showed no increased risk of connective-tissue or autoimmune disorders among women with breast implants as compared with women without implants.<sup>3</sup> Even among investigators who are unimpressed with the risk of systemic side effects associated with breast implants, there is concern that local complications may be an important problem.<sup>4-7</sup> However, no population-based data on this subject are available. Consequently, we undertook this analysis to describe the occurrence of surgically treated local complications in the population-based cohort of women residing in Olmsted County, Minnesota, who received their first breast implant at the Mayo Clinic between January 1, 1964, and December 31, 1991.

### METHODS

#### Collection of Data

The methods of case ascertainment and the procedures for follow-up have been described in detail elsewhere.<sup>8</sup> The study was approved by the institutional review board of the Mayo Clinic and Foundation. In this study, as in most Rochester Epidemiology Project studies,<sup>9</sup> a large number of potential cases were screened through a review of medical records in order to ensure that information about each case was complete, eliminate duplicates, and certify that all the included cases fulfilled explicit residency, temporal, diagnostic, and surgical criteria.

We obtained a list of 971 identifying numbers of purported Olmsted County residents who had undergone breast implantation, breast augmentation, or breast reconstruction. A review of the complete (inpatient and outpatient) community medical records of all of these cases showed that there were 19 duplicates

From the Division of Rheumatology and Internal Medicine (S.E.G.), the Department of Health Sciences Research (S.E.G., W.M.O., C.M.B., L.T.K., L.J.M.), and the Division of Plastic Surgery (J.E.W.), Mayo Clinic and Mayo Foundation, Rochester, Minn. Address reprint requests to Dr. Gabriel at the Department of Health Sciences Research, Mayo Clinic, 200 First Street SW, Rochester, MN 55905.

(cases in which two identifying numbers had been assigned to the same person). Of the remaining 952 cases, 127 were excluded for the following reasons: 55 patients had had breast operations that did not involve implants (such as breast reduction), 50 had been incorrectly classified as residents of Olmsted County, 11 were residents of Olmsted County who had undergone their first breast implantation elsewhere, 6 cases represented transcription errors, 3 cases involved lost or unavailable medical records, and 2 patients were men who had received implants (for example, for congenital absence of the pectoralis muscle).

Data collection was completed for the remaining 825 women. Of these women, 76 were residents of one of the six counties adjacent to Olmsted County. These patients were excluded from the final cohort in order to maintain the integrity of the population-based study design, even though other analyses including them (which were presented in a preliminary report<sup>10</sup>) led to conclusions similar in every respect to those of the analyses of the Olmsted County case cohort. The final sample size was, therefore, 749. This cohort was subdivided according to the reason for implantation: cosmetic, cancer (reconstruction after mastectomy for breast cancer), or prophylactic (reconstruction after subcutaneous mastectomy for cancer prophylaxis among women at high risk for breast cancer).

One of four trained nurse-abstractors reviewed each woman's entire medical record (including all inpatient and outpatient reports from the local providers of medical care), and information was obtained on the occurrence of and the indications for any of various implant-related surgical procedures. These procedures were removal of the implant, replacement of the implant, open capsulotomy (incision of the fibrous capsule surrounding the implant), capsulectomy (removal of the fibrous capsule), incision and drainage of a wound abscess, evacuation of a hematoma, wound repair, excision or grafting of the skin because of necrosis, and adjustment of the filler port of a tissue expander. A tissue expander is a balloon-type prosthesis that is typically placed under the pectoral muscle and expanded gradually (usually over the course of several weeks) by means of a tube that leads to a filler port through which saline is injected transcutaneously. The prosthesis is commonly expanded to a size considerably larger than that ultimately desired. It is allowed to remain overexpanded for several months, after which saline is withdrawn through the port to reduce the prosthesis to the desired size, thus yielding a soft, naturally contoured breast. After sizing is complete, a small incision is made and the subcutaneously positioned filler port is withdrawn through a self-sealing valve with the patient under local anesthesia.

Implant removal was categorized as temporary if the implanted device was removed to facilitate another procedure (such as drainage of a hematoma) and then reinserted (either during the second procedure or at a later time) and as permanent if the device was removed and not reinserted. The scheduled replacement of a temporary tissue expander with a permanent implant was considered a procedure but not an implant removal. All indications for each procedure were recorded. Clinical indications included capsular contracture or formation; rupture of the implant; hematoma or bleeding; infection or seroma of the wound; extrusion, leakage, or sweating of the implant; chronic pain; necrosis of the nipple, areola, or flap; filler-port malfunction; and wound dehiscence. Other indications included the request of the patient, replacement of a temporary device, replacement of the implant with a more modern device, and replacement of the implant due to the age of the device. A complication was considered to have occurred if there was at least one clinical indication for a surgical procedure.

Follow-up for each of the women continued from the time of the first implantation procedure until migration from Olmsted County, death, or the end of study follow-up (1993). Vital status at the time of the last follow-up contact was also recorded for each patient.

Data were recorded on a pretested data-collection form, entered into a computer, and edited with various on-line checks for

range and consistency. To ensure that the data regarding implant-related surgical procedures were of high quality, 50 sets of medical records were reviewed a second time by one of us. In consultation with surgical colleagues and the other co-investigators, we developed explicit definitions for surgical procedures and their indications. A data-collection instrument that incorporated these definitions was designed and pretested. Using this instrument, we re-abstracted the medical records of all patients originally identified as having had an implant-related surgical procedure.<sup>3</sup>

### Statistical Analysis

The Kaplan-Meier product-limit method was used to estimate the probabilities of overall survival and of survival free of complications as functions of the length of time since implantation for subgroups defined according to the reason for implantation and other factors. A generalization of the Cox proportional-hazards model, developed to analyze correlated survival data,<sup>11-13</sup> was used to examine the effects of several variables (age, the date of implantation, the number of previous implants, the number of previous complications, and the reason for the implant) on the time until the first complication after each implantation. The end points were correlated, because most women had bilateral implants and some had multiple implants in the same breast. In these analyses, follow-up of each breast implant continued until a complication occurred, the implant was removed, or the date of the last follow-up contact was reached.

## RESULTS

Among the 749 Olmsted County women who received their first breast implants at the Mayo Clinic and fulfilled all the criteria for inclusion in this study, the reason for implantation was cosmetic for 532, related to cancer for 125, and related to prophylactic mastectomy for 92. The average age at the time of the initial implantation was 31, 49, and 40 years for the cosmetic, cancer, and prophylactic groups, respectively. These 749 women were followed for 5847 person-years (mean, 7.8 years; range, 0 to 25.8).

### Surgical Procedures after Initial Implantation

After the initial implantations, 450 implant-related surgical procedures (including 23 two-stage operations, each of which was counted only once) were performed during follow-up. These procedures were performed in 208 women (27.8 percent) and involved 334 breasts (23 percent of the 1454 breasts with implants) and 394 implants (23.1 percent of the 1703 implants). Altogether, 818 indications were recorded for these 450 procedures, and many of the procedures were performed because of multiple indications. Among the 818 indications, 495 were classified as clinical and 323 as "other."

### Complications after Initial Implantation

Of the 450 procedures performed after initial implantation, 91 were performed as anticipated, staged procedures or because of the patient's request for a size change or aesthetic improvement. Of the remaining 359 procedures, 164 were performed solely for clinical reasons, and 195 involved both clinical and other indications. By definition, a clinical indication for a surgical procedure was considered a

complication. Altogether, these complications occurred in 178 (23.8 percent) of the 749 women and involved 274 (18.8 percent) of the 1454 breasts with implants and 321 (18.8 percent) of the 1703 implants (Table 1). Complications occurred in association with 19 percent of the 1465 implants containing silicone and 17 percent of the 238 other implants ( $P=0.42$ ). The most frequent complication was capsular contracture, followed by implant rupture, hematoma, and wound infection. Forty-three women (5.7 percent) had implant ruptures.

Of the 178 women with complications, 70 (39.3 percent) had one complication, 74 (41.6 percent) had two, and 34 (19.1 percent) had three or more. Of the 274 breasts in which complications occurred,

212 (77.4 percent) each had one complication, 46 (16.8 percent) had two, and 16 (5.8 percent) had three or more. At least one complication developed in 321 of the 1703 implants. One complication occurred in 291 (90.7 percent), two in 24 (7.5 percent), and three or more in 6 (1.9 percent). In the implants with multiple complications, the earlier complications (such as hematoma drainage) were of the type that did not require permanent removal of the implant.

**Complication Rate over Time**

Data on the 321 first complications (of the total of 359) were used to assess the likelihood of a complication. Figure 1 shows the Kaplan–Meier estimates of the cumulative risk of first complications among

**TABLE 1.** INDICATIONS FOR 450 SURGICAL PROCEDURES IN 208 WOMEN (INVOLVING 334 BREASTS AND 394 IMPLANTS) AFTER INITIAL BREAST IMPLANTATION.\*

INDICATION	NO. OF PROCEDURES†	BREASTS OPERATED ON		WOMEN OPERATED ON	
		NO.‡	% OF TOTAL (1454)	NO.§	% OF TOTAL (749)
<b>Clinical</b>					
Capsular contracture	272	212	14.6	131	17.5
Rupture	60	56	3.9	43	5.7
Hematoma	55	51	3.5	43	5.7
Wound infection	23	21	1.4	19	2.5
Wound seroma	17	16	1.1	16	2.1
Extrusion of implant	15	14	1.0	14	1.9
Leakage, sweating of implant	14	14	1.0	9	1.2
Chronic pain	13	13	0.9	8	1.1
Necrosis of nipple, areola, or flap	12	12	0.8	11	1.5
Filler-port malfunction	5	5	0.3	5	0.7
Wound dehiscence	5	5	0.3	4	0.5
Other¶	4	4	0.3	4	0.5
<b>Total</b>	<b>359</b>	<b>274</b>	<b>18.8</b>	<b>178</b>	<b>23.8</b>
<b>Other</b>					
Patient's request	61	55	3.8	36	4.8
Replacement of temporary device	30	30	2.1	20	2.7
Replacement with modern device	5	5	0.3	4	0.5
Replacement due to age of device	3	3	0.2	2	0.3
Other**	6	6	0.4		
<b>Total</b>	<b>91</b>	<b>84</b>	<b>5.8</b>	<b>57</b>	<b>7.6</b>
<b>Overall total</b>	<b>450</b>	<b>334††</b>	<b>23.0</b>	<b>208‡‡</b>	<b>27.8</b>

\*The total cohort was 749 women with breast implants (involving 1454 breasts with implants and 1703 implants).

†The total number of indications exceeds that of procedures because some patients had more than one indication for a procedure. In particular, there were also nonclinical indications (e.g., the patient's request) for 195 of the 359 procedures performed for a clinical indication.

‡The total number of indications exceeds the number of breasts because there was more than one indication for the procedure in some cases.

§The total number of indications exceeds the number of women because some women had more than one indication for a procedure.

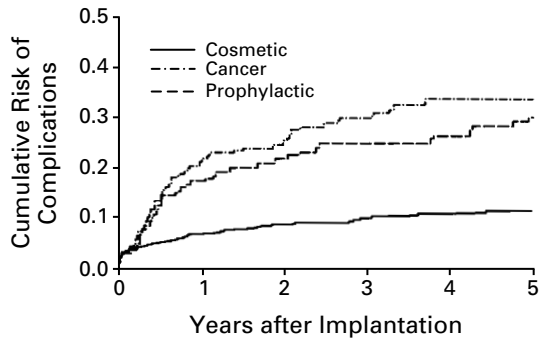
¶Other clinical indications included nipple drainage (1 case), separation of skin from the sternum (1), retained drain (1), and adhesion (1).

||Patients requested the procedure for cosmetic reasons.

\*\*Other nonclinical indications included cancer (1 case), completion of tattoo excision (1), mastectomy (2), and replacement of silicone with an expander (2).

††The overall total number of breasts is less than the sum of the corresponding totals because in 24 breasts, there were both clinical and nonclinical indications for different procedures.

‡‡The overall total number of women is less than the sum of the corresponding totals because 27 women had both clinical and nonclinical indications for different procedures.



NO. OF IMPLANTS						
Cosmetic	1163	879	747	620	541	455
Cancer	274	202	170	134	106	83
Prophylactic	266	195	171	154	144	119

**Figure 1.** Cumulative Risk of Complications in 1703 Implants (Kaplan–Meier Estimate), According to the Reason for the Implantation.

**TABLE 2.** COMPLICATION RATES ACCORDING TO THE REASON FOR INITIAL IMPLANTATION.\*

REASON	TIME AFTER INITIAL IMPLANTATION					
	<60 DAYS		60 TO 270 DAYS		>270 DAYS	
	rate†	P value‡	rate†	P value‡	rate†	P value‡
Cosmetic	24.0		3.6		1.8	
Cancer	25.3	0.81	29.0	<0.001	5.7	<0.001
Prophylactic	21.8	0.86	24.9	<0.001	4.5	<0.001

\*The total cohort was 749 women with 1703 implants.  
 †Values are the complication rates per 100 person-years of follow-up.  
 ‡P values are for the hypothesis that the rate ratio of the cancer group as compared with the cosmetic group, or of the prophylactic group as compared with the cosmetic group, equals 1.0.

**TABLE 3.** ESTIMATED CUMULATIVE INCIDENCE OF COMPLICATIONS, ACCORDING TO THE TIME AFTER AND REASON FOR IMPLANTATION.\*

REASON	TIME AFTER INITIAL IMPLANTATION					
	60 DAYS		270 DAYS		5 YEARS	
	%	95% CI	%	95% CI	%	95% CI
Cosmetic	3.7	2.5–5.1	5.7	4.0–7.6	12.0	9.1–15.2
Cancer	4.0	2.1–6.6	19.1	13.9–24.0	34.0	27.2–41.3
Prophylactic	3.4	1.1–6.9	16.0	10.4–22.6	30.4	23.1–38.4

\*Cumulative incidence was estimated by the Kaplan–Meier method. CI denotes confidence interval.

the 1703 implants according to the reason for the initial implantation (cosmetic, cancer-related, or prophylactic). For each group, the risk of complications was highest during the first few months after the insertion of the implant. Of all first complications, more than 50 percent occurred within the first year of follow-up, 75 percent by the third year, and 83 percent by the fifth year. Few individual implants were still being followed up after five years, and only a few new complications occurred each year thereafter. The maximal follow-up possible for the most recent implants was three or four years. Therefore, we analyzed the occurrence of complications within the first five years after the insertion of each implant.

**Predictors of the Complication Rate**

The risks of a complication for the three implant groups differed over the follow-up period (Fig. 1). Because the assumptions of the proportional-hazards model were not satisfied during the entire period of follow-up, we subdivided the follow-up into three periods after implantation and fit models assuming proportionality of hazards within these intervals. For the first 60 days after implantation, the rate of occurrence of a first complication ranged from 21.8 per 100 person-years (prophylactic group) to 25.3 per 100 person-years (cancer group) and did not differ significantly between the groups (Table 2). Consequently, the cumulative percentage of implants in which a first complication developed within 60 days was nearly identical for the three groups (Table 3). During the period from 61 to 270 days after implantation, the rate of complications in the cosmetic group decreased to 3.6 per 100 person-years, and to 1.8 per 100 person-years thereafter. In contrast, the rates in the cancer and prophylactic groups continued at high levels from 61 to 270 days (29.0 and 24.9 per 100 person-years, respectively) after implantation, after which they decreased (to 5.7 and 4.5 per 100 person-years, respectively). Thus, the complication rates were significantly higher in the cancer and prophylactic groups than in the cosmetic group after 60 days ( $P < 0.005$ ). By five years after implantation, the percentage of implants with complications was nearly three times as high in the cancer and prophylactic groups as in the cosmetic group (Fig. 1 and Table 3).

Proportional-hazards models were fitted to assess the effects of five factors on the risk of a first complication after implantation. The reason for the initial implantation ( $P < 0.001$ ) and the age at implantation ( $P < 0.001$ ) were significant factors, whereas the date of implantation ( $P = 0.66$ ), the number of previous implants ( $P = 0.30$ ), and the number of previous complications ( $P = 0.20$ ) were not. After adjustment for the reason for the initial implantation, age was no longer significant ( $P = 0.35$ ), whereas the date of implantation ( $P = 0.09$ ) was of marginal sig-

nificance, with a trend toward lower complication rates in more recent years in the cosmetic group (Fig. 2). After adjustment for the reason for implantation, the number of previous implants ( $P=0.35$ ) and the number of previous complications ( $P=0.46$ ) were still not significant predictors of the risk of a first complication.

**Mortality**

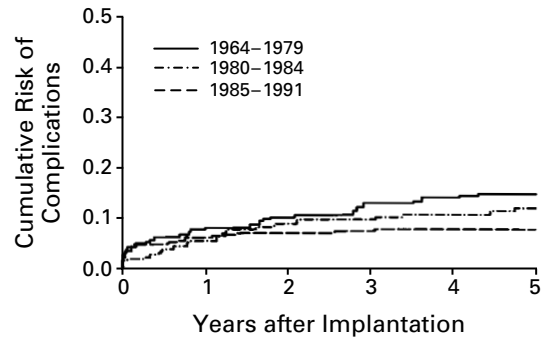
Survival among the three cohorts is shown in Figure 3. Patients in the cancer group had a much lower overall rate of survival than those in the other groups, even after adjustment for differences in age.

**DISCUSSION**

We previously compared the risks of connective-tissue and other autoimmune disorders among women living in Olmsted County who had breast implants with the risks in a control group of women who did not have implants. We found no significant differences in risk between the groups.<sup>3</sup> Other studies have reported similar findings.<sup>14-18</sup> The frequency of local complications in women with breast implants is also a source of concern.<sup>4-7</sup> In the current study of the 749 Olmsted County women with implants, 23.8 percent had at least one local complication each after implantation, and additional surgical procedures, involving 18.8 percent of the 1454 implanted breasts, were necessary. The roughly 24 percent complication rate is essentially the same as that reported for autologous breast reconstruction.<sup>19</sup> Complications were significantly less frequent after cosmetic implantation than after implantation following mastectomy for cancer or for cancer prophylaxis.

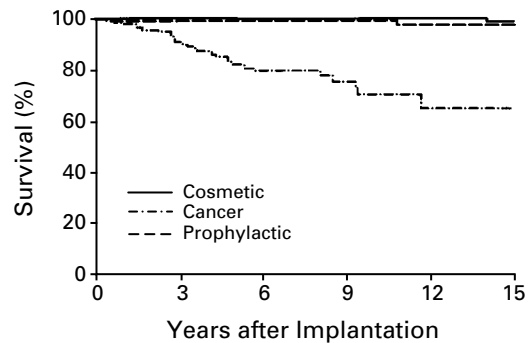
Most previous estimates of complication rates after breast implantation have been derived from referral-based case series that typically had relatively short periods of follow-up.<sup>20-27</sup> In this study, we evaluated complications and surgical interventions in a population-based cohort of women with breast implants. Because of differences in the study groups (ours included patients with cancer, whereas previous studies did not; ours included the outcomes of operations done by several different surgeons, whereas others typically described the experience of one surgeon), in the definition of a complication (ours referred only to events that required surgical intervention, whereas other studies' definitions varied), and in the duration of follow-up, our results are not directly comparable with those of previous studies.<sup>20-27</sup>

Despite these differences, the complication rates we found were similar to or lower than those previously reported. For example, the estimated risks of a complication in the first 60 days were 3.7 percent, 4.0 percent, and 3.4 percent for the cosmetic, cancer, and prophylactic groups, respectively, which are similar to those in other reports.<sup>5,23</sup> By five years, however, the overall risk increased to 12.0 percent,



NO. OF IMPLANTS						
1964-1979	420	290	250	213	200	183
1980-1984	343	264	243	234	215	204
1985-1991	400	331	257	177	130	74

**Figure 2.** Cumulative Risk of Complications (Kaplan-Meier Estimate) among Women Who Underwent Breast Implantation for Cosmetic Reasons, According to the Date of Implantation.



NO. OF IMPLANTS						
Cosmetic	532	379	279	200	95	59
Cancer	125	94	51	33	7	5
Prophylactic	92	87	77	60	33	27

**Figure 3.** Survival (Kaplan-Meier Estimate) among Women Who Received Breast Implants, According to the Reason for the Implantation.

34.0 percent, and 30.4 percent, respectively. The rates of leakage (occurring in 1.0 percent of the breasts with implants) and rupture (3.9 percent) in our study are much lower than previously reported rates.<sup>4,5,7</sup> Similarly, only 17.5 percent of the women in our study underwent operations for capsular contracture, as compared with a rate of 37.6 percent for severe contracture in another recent study.<sup>6</sup> The reported rates of postoperative complications in patients who had breast reconstruction with autologous tissue are similar to ours.<sup>19,28-30</sup> Thus, breast reconstruction by any method is associated with a substantial risk of complications.

Our findings must be interpreted with several limitations in mind. Our data were based on a review of medical records and are susceptible to the limitations inherent in medical-records documentation. Howev-

er, we defined complications as only the events that resulted in surgical intervention, and we could provide virtually complete ascertainment of such procedures, whether they were performed on an inpatient or an outpatient basis. Our ability to review the entire medical record (including all outpatient and inpatient reports by the local providers of medical care) and our detailed procedures helped ensure the completeness of the data on these events. However, the same cannot be said of other complications, which may be of less consequence. For example, we did not report all capsular contractures or hematomas, because many mild hematomas and contractures (which require no treatment) were probably considered unimportant by either the patient or her physician and therefore were not documented in the medical record. In fact, many of these do not even come to physicians' attention. We did not examine the effect of these events on the patients' overall health status and quality of life. We also did not evaluate the patients' overall satisfaction with their implants. Such data would add an important perspective to discussions about the proper role of breast implantation.

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