Breast Implants in a Cohort of Breast Cancer Patients 10-Year Retrospective Reconstruction Study ("SEER Study")

Breast Implants in a Cohort of Breast Cancer Patients

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Abstract

To evaluate the frequency and characteristics of breast implant use in women treated for breast cancer, we conducted a large population-based cohort (N=6563) study of women <65 years of age at diagnosis of primary breast cancer in 1983, 1985, 1987, or 1989, and who were residents of three geographic areas covered by the SEER program (Iowa, San Francisco-Oakland, and Seattle-Puget Sound). All of the women had early stage breast cancer treated with mastectomy. Survey data on the use of breast implants for reconstructive surgery were collected on this cohort in 1993 and linked with the 1995 SEER follow-up data containing information on the demographic and clinical characteristics of the breast cancer patients.

Overall, eighteen percent of the women in the cohort had received breast implants (n=1159), and details regarding the implants were available for 1012 women who had received a total of 1375 breast implants. The majority of these implants were silicone gel filled (41%) or a combination of silicone gel and saline (37%), while 16% were saline. During the following period 32% (n=445) of the implants were removed. Reasons for removal included capsular contracture in 29% (n=130) and rupture, leak or deflation in 13% (n=58). Within the first five years after insertion, 24% of all implants had been removed, while 38% had been removed by ten years.

These data indicate that the integrity of implants is affected by the duration of use. However, in this cohort of breast cancer patients who had reconstructive surgery, 60% of the breast implants were still in place ten years after insertion.

Introduction

Breast implants have been used for more than thirty years by an estimated one to two million women in the United States.[1,2] In recent years, approximately 20-40% of the more than 150,000 implants inserted annually have been for purposes of breast reconstruction following mastectomy.[3,4] Subsequent to the controversy surrounding the FDA's 1992 moratorium on the use of silicone-gel filled implants, women who received reconstructive surgery with implants as part of their breast cancer treatment constitute one of the largest groups to receive implants. It is, therefore, important that research continues to investigate the use and safety of these devices.

In this report, we examine the frequency of breast implant use in a population-based cohort of women with breast cancer as well as the characteristics of these implants including the duration of use, frequency of removals and reasons for removals.

Methods

The study population for this analysis was a cohort of women identified in 1993 for the Surveillance of Breast Cancer Patients with Breast Implants Study conducted to describe the prevalence and types of breast implants used for reconstruction following mastectomy. These patients were identified through the population-based cancer registries of the Seattle-Puget Sound area of northwestern Washington State, Northern California, and the State of Iowa. These registries are participants in the Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute (NCI). All women diagnosed with *in situ* or invasive (stage I, stage IIa, or unstaged) primary breast cancer, who were less than 65 years of age when diagnosed in 1983, 1985, 1987, or 1989, who were treated with mastectomy as part of their initial course of therapy, and who were residents of one of the three SEER catchment areas at the time of diagnosis were selected.

A total of 6597 eligible patients were identified, 1918 from the Seattle-Puget Sound area, 2616 from Northern California, and 2063 from Iowa. Each patient's physician was contacted by mail requesting information on whether the woman had received a breast implant following treatment for breast cancer and permission to contact the patient. After physician consent was received, the patient was sent an introductory letter and a response form asking whether she had received an implant and, if so, for willingness to complete a questionnaire about the procedure. All women from northwestern Washington State and from Iowa who responded that they had undergone breast reconstructive surgery and were willing to receive the study questionnaire, were sent the self-administered questionnaire and a consent form for release of medical records regarding this procedure. Women who failed to respond to the mailed questionnaire were contacted by telephone and asked to complete a telephone interview and to provide consent for medical record review. All women from Northern California had the questionnaire administered over the telephone. In the event

that the woman was deceased, the next-of-kin was asked to provide information on the patient's implant status and consent for medical record review. Levels of participation from the three study sites are summarized in Table 1.

Medical records were then reviewed for additional details of the implant surgery if the woman or her next-of-kin provided consent. For the State of Iowa, a physician record abstraction including the same information was substituted for the medical record review if the latter was not available. Medical record review was completed for 83.6% of the eligible women with implants from the Seattle-Puget Sound study site and medical record or physician review for 85.2% of the eligible women from Iowa. Exact information on record reviews were not available from Northern California.

A computerized datatape containing the information from the response forms and questionnaire data from the Surveillance of Breast Cancer Patients with Breast Implants Study was provided by the SEER Program. This tape was then linked with the February 1995 SEER follow-up datatape containing information on the demographic and clinical characteristics of the breast cancer patients in the cohort.

We identified a total of 1169 women who had received breast implants from physician, patient, or next-of-kin reports, medical record review, or combinations thereof. Ten of these women were later excluded from the analysis either because they didn't have an implant in the breast with cancer which made them eligible for the study despite an earlier implant in the contralateral breast (n=5) or because the breast implant was received prior to the breast cancer diagnosis (n=5). Additionally, there were eleven women who had received an implant following the breast cancer diagnosis that met the study eligibility requirements although they had also previously received an implant in the contralateral breast. For these women, only information about the implant placed in the breast which had a tumor making them study eligible was included in the analysis.

Women with breast implants (n=1159) were compared with women without breast implants (n=5404) on the following characteristics: residence, age at diagnosis, year of diagnosis, race, marital status, and stage of disease at the time of diagnosis: Chi-square tests were performed to assess differences between the two groups of women. The types of implant(s) received, whether or not they had been removed and, if so, reasons for removal, and the duration of implant use were then described as well as removal status, reasons for removals and duration of use by type of implant. The open-ended responses to the reason for implant removal provided by the physician, patient or medical record were reviewed and categorized into sub groups. Components of these categories of reasons for removal are presented in Table 2.

For implants that had been removed, both the date of implant insertion and date of removal were obtained from the patient or physician questionnaires and these dates were used to estimate duration of exposure. For implants that had not been removed, duration was calculated using the date of insertion from the questionnaires to date of last follow-up that was either the date the questionnaire was returned or the date of the medical record abstraction, whichever was later. Kaplan-Meier curves were used to estimate duration of implant exposure according to whether or not the implants were removed.

Results

Overall, 39% of the breast cancer patients in this study were from Northern California, 31% from Iowa and 29% from the Seattle-Puget Sound area (Table 3.). A greater percentage of the Seattle women (23%) received breast implants following mastectomy than women from Northern California (18%) or Iowa (12%). Fifty-five percent (n=638) of the women received implants in one breast only, while 32% (n=374) received bilateral implants. An additional 13% (n=147) had received at least one implant, but all other information about the implant(s) was missing, including laterality.

Women who were white were more likely to receive implants following mastectomy than women of other racial groups (Table 3). Although white women constituted 90% of the study population, they constituted 96% of the women with implants and received 97% of the total number of implants. Women who had received implants were also slightly more likely to be married than women who had not received implants (76% and 72%, respectively).

The ages of the women when diagnosed with primary breast cancer ranged from 21 to 64 years, and younger women (<50 years) were more likely than older women to have received implants for breast reconstruction (Table 3). The median age at diagnosis of women with implants was 46 (mean: 46.8 years) while that for women without implants was 55 (mean: 53.0 years). Women with implants were more likely to have had their breast cancer diagnosed in the later two years of the study, 1987 and 1989, rather than in the earlier years of 1983 or 1985. In addition, women who received implants in general had lower stages of disease at the time of diagnosis than women who did not receive implants. Twenty-two percent of women with implants were diagnosed with *in situ* carcinoma of the breast as compared with less than 10% of women without implants, while 31% of women with implants were diagnosed with stage IIa disease compared with 41% of women without implants.

Excluding the 147 patients with implants but with all related details unknown, there were 1375 breast implants among the 1012 breast cancer patients for whom detailed information regarding implant use was available (Table 4). Of these implants, 41% (n=559) were silicone gel-filled and 37% (n=505) were a combination of silicone gel and saline as in double, triple or quadruple lumen implants. Saline implants comprised 16% of the total number of implants. Sixteen (1.2%) of the implants were stated to be expanders and assumed to contain saline, although the type of permanent implant received was unknown.

Thirty-two percent (n=445) of the implants were removed and the reasons for removal are enumerated in Table 4, with a more specific description of the categories of reasons listed in Table 2. Sixty-seven implants (4.9% of the total number of implants) were removed due to rupture, leakage, deflation or other mechanical reasons, either for these reasons alone or in combination with capsular contracture, problems with healing, aesthetic concerns, media related reasons, staged reconstruction, malignancy or other reasons. Twenty-four of these implants (1.7% of the total) ruptured and 34 (2.5%) developed leaks. Almost one third of the implants removed

(n=130, 9.5% of the total) were removed because of capsular contracture, which is the tissue's response to a foreign object. Aesthetic concerns accounted for 16% of removals (5.2% of total implants) and staged reconstruction for 19% of removals (6% of total). Concerns raised by negative publicity contributed to the removal of 7% of the total number of implants and recurrent malignancy of some type to 4%.

The duration of implant use for implants that were not removed, and for which we had estimates of the length of time they had been in place, ranged from less than one month to 136 months, with a median duration of 70 months (mean: 70 months). The median duration of use of implants that were removed, on the other hand, was 12 months (mean: 26 months), with a range from less than one month to 122 months. While 7% of the implants removed were removed during the first month (2% of the total number of implants), 14% were removed after having been in place for at least four years (4.6% of total). Of implants with estimated duration of use (n=1160), over 60% had been in place for more than four years, including those that were subsequently removed.

Table 5 presents a description of implant removals, reasons for removals, and duration of use by the type of implant. While a larger percentage (43%) of saline implants were removed than silicone gel or silicone gel/saline implants (29% and 30%, respectively), this may be due to misclassification of saline implants, whereby saline expanders may be incorrectly included in this category. Implant rupture was reported in 2% (n=11) of the silicone gel implants, in 2.6% (n=13) of the combined silicone gel/saline implants, and in none of the saline implants. Leaking or deflation of implants occurred with slightly greater frequency for saline implants (4.5%) compared with silicone gel filled implants (1%) or silicone gel/saline implants (2.6%).

Overall, silicone gel filled implants and silicone gel/saline implants had longer durations of use than saline implants. This was true for implants that had been removed as well as for those that had not been removed. For implants that remained in place, the median duration of use for silicone gel implants was 71 months (mean: 71 months), for silicone gel/saline implants the median duration was 70 months (mean: 70 months), while for saline implants the median duration was 59 months (mean: 60 months). Similarly, for implants that were removed, silicone gel implants were left in place for a median duration of 15 months (mean: 30 months) and for silicone gel/saline implants 12.5 months (mean: 26 months) compared with the median duration for saline implants of 7.4 months (mean: 16 months).

Results of the Kaplan-Meier analysis (Table 6) show that five years after insertion, 23.7% of all implants had been removed, while 39.8% had been removed by ten years (Table 6 A). For silicone implants, 21% had been removed by five years and 50.5% by ten years of use. All silicone/saline implants that were removed were removed after approximately 9 years of use and all removed saline implants were removed by 7 years. Of all removed implants, 22.8% of those removed for reasons of rupture, leak or deflation were taken out by five years after insertion and over 98% by ten years (Table 6 B). Fifteen percent of silicone implants removed for rupture, leak or deflation were removed within 5 years, whereas, in that same time period 53.5% of ruptured, leaking or deflated saline implants were removed (Table 6 B).

Although there was some indication that the use of saline implants increased and the use of silicone gel implants decreased during the study period, there was no clear trend evident to account for the shorter durations of use of saline implants compared with the other two major types. However, as noted earlier, some of the implants classified as saline may, in fact, have been shorter-term saline expanders.

Discussion

The overall prevalence of breast implants in this population-based cohort of 6563 patients treated with mastectomy for primary breast cancer was 17.7%. While this is higher than other estimates of the prevalence of breast implants in the general population of women (0.8%[4] to 1.2%[5]), our estimate is based on women who received implants for purposes of breast reconstruction following surgical removal of the breast and does not include implants received for cosmetic augmentation of the breast. In addition, approximately 90% of the women in our cohort were white, and white women are more likely to receive breast implants than women of other racial groups.[4]

One of the limitations of this study is the level of non-response, which ranged from 16.6% to 22.9% for the individual study sites and was 20.5% overall. If non-respondents differed from the women who participated in the study on implant status, characteristics of implant use, and demographic characteristics, our findings may overestimate or underestimate the true prevalence and characteristics of implants in women with breast cancer. Furthermore, because our sample included women with *in situ*, stage I, stage IIa, or unstaged invasive breast cancer, our findings are generalizeable only to women who meet these criteria.

A major strength of this study is that it is the first large-scale investigation of implants used for breast reconstruction after mastectomy in a cohort of women with breast cancer. Prior studies have included few women with breast cancer who received implants and primarily provided information on implants used for augmentation. A further strength is that the cohort is population-based and thus avoids potential selection bias, which may result if participants are chosen from particular institutional or community practices. Thus the findings should be generalizeable to similar women with breast cancer. In addition, since this is a defined group of women, direct estimates of the prevalence of different types of implants, implant removals, reasons for removals and duration of implant use can be calculated. An additional strength of this research is the detailed nature of the medical record abstraction, which was used to validate the type of implant exposures and reduce the amount of missing information for different types of implants.

Our finding that capsular contracture, either alone or in combination with other problems, was the largest single reason for implant removal is in keeping with other studies of complications of implants.[6-7] Similarly, our findings that capsular contracture occurs more frequently in silicone or double or triple-lumen implants than in saline filled implants has been shown in other studies.[7-10] Our overall estimate of 29.2% for this complication is lower than some previously reported estimates, which range as high as over 90%.[7-11] The contractures noted in our study, however, were

reported as reasons for removal whereas in the other reports, the estimates were based on physical examination or observation of the women, including those who did not have their implants removed. Furthermore, since capsular contracture can contribute to visible disfigurement, some of the implants removed for reported aesthetic reasons by the women in our study may actually include some for whom contracture contributed to the aesthetic problem. If this is the case, our estimates of capsular contracture as the reason for implant removal may be too low.

In our study, removal of an implant for deflation from rupture or leaking occurred in 4.2% of the total implants inserted. This is similar to the 5% failure rate reported by Destouet et al.,[12] and a bit lower than the 6.5% reported by Harris et al.[13] In both of these studies, however, detection of the leak or rupture was accomplished by mammography or ultrasound and the percentages indicated the number of women affected, rather than the number of implants. Studies that have evaluated explanted implants report rates of ruptures and bleeds as high as 40%,[14] 66%,[15] and even 71%.[16] Of the total number of removed implants in our study, however, 13% were reported removed for reasons of rupture or leaks.

Additionally, our research confirms the findings of other studies that the age of the implant is an important factor in its integrity.[14-17] Over 98% of all implants in our study that were reported to have ruptured or leaked were removed within ten years of implantation. Overall, however, for implants of any type and considering removal for any reason, over 60% of the implants in our study cohort were still in place ten years after insertion.

Because breast cancer is the most frequent cancer diagnosed in American women,[18] and mastectomy remains a common treatment for this disease, reconstructive surgery with breast implants is an important concern for women with breast cancer. Information about available implants, their use and their safety is important for these women and their physicians, as well as for women considering implant use for cosmetic augmentation. Our study evaluated the characteristics of breast implants and the prevalence of removals and complications of implants by type of implant over an eleven year span. Due to increased removals with time since implantation, particularly for reasons of rupture or leak, the longevity of the implant needs to be considered. However, according to our results, the majority of implants remain intact for ten years or more. This information may be reassuring to physicians and their patients undergoing mastectomy.

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Table 1. Description of participation by study site.

	Total		Northern California		Iowa		Seattle/Puget Sound	
	n	%	n	%	n	%	n	%
Eligible for implant study	2,482	100	2,059	100	1,916	100	6,457	100
physician refusal	41	1.7	5	0.2	87	4.5	133	2.1
patient/next-of-kin refusal	116	4.7	51	2.5	13	0.7	180	2.8
unable to locate	412	16.6	285	13.8	267	13.9	964	14.9
language problem	46	1.8	—	—	2	0.1	48	0.7
Implant status								
no known implant	1,512	60.9	1,489	72.3	1,140	59.4	4,141	63.3
implant, refused questionnaire or lost to follow-up	—	—	—	—	44	2.3	44	0.7
implant, completed questionnaire	401	16.2	229	11.1	365	19.1	995	15.4
Total number of participants	1,983*	77.1	1,718	83.4	1,505	78.6	5,206	79.5

* Includes 70 women whose implant status was determined by Kaiser medical records.

Table 2. Reported reasons for removal of breast implants by type of problem

I. Mechanical
   a. rupture
   b. leaking
   c. deflation
   d. injury, accident or puncture

II. Capsular contracture
   a. contracture
   b. pain
   c. migration of pocket
   d. re-positioning
   e. scar tissue
   f. itching or burning

III. Healing related
   a. infection
   b. improper healing
   c. necrosis
   d. bleeding
   e. rejection of implant

IV. Aesthetic
   a. migration/repositioning
   b. dimpling
   c. asymmetry, contour, size problems

V. Media-related concerns
   a. autoimmune disease or symptoms
   b. concern or fear/media reports
   c. allergic reaction

VI. Staged reconstruction
   a. parts replacement
   b. permanent implant

VII. Malignancy
   a. recurrent disease

VIII. Unknown or other
   a. personal preference
   b. non-implant related infection
   c. muscle structure
   d. chest wall or mastectomy defect or deformity

Table 3. Distributions of selected demographic and clinical characteristics of patients with and without breast implants following mastectomy for breast cancer.

	Women with breast implants n=1159		Women without breast implants n=5404		X^2	p-value
	n	%	n	%		
Registry						
Northern California	469	40.5	2122	39.3		
Iowa	257	22.2	1801	33.3	70.63	p<0.001
Seattle-Puget Sound	433	37.4	1481	27.4		
Race						
white	1112	95.9	4799	88.8		
black	16	1.4	245	4.5	55.52	p<0.001
other	26	2.2	327	6.1		
unknown	5	0.4	33	0.6		
Marital status						
single	93	8.0	475	8.8		
married	879	75.8	3868	71.6	12.28	p=0.006
separated/divorced/widowed	175	15.1	945	17.5		
unknown	12	1.0	116	2.2		
Age at diagnosis						
21-29	21	1.8	34	0.6		
30-39	226	19.5	433	8.0		
40-49	474	40.9	1295	24.0	435.07	p<0.001
50-59	345	29.8	2018	37.3		
60-64	93	8.0	1624	30.1		
Year of diagnosis						
1983	209	18.0	1280	23.7		
1985	284	24.5	1273	23.6	18.03	p<0.001
1987	359	31.0	1505	27.9		
1989	307	26.5	1346	24.9		
Stage of disease						
in situ	259	22.4	531	9.8		
I	378	32.6	1983	36.7	155.08	p<0.001
IIa	356	30.7	2201	40.7		
unstaged	166	14.3	689	12.8		

Table 4. Characteristics of breast implants in a cohort of women with breast cancer who underwent mastectomy.[a]

	Right Implant[b] n=679		Left Implant[c] n=696		Total Implants n=1375	
	n	%	n	%	n	%
Type of implant(s)						
silicone gel[d]	275	40.5	284	40.8	559	40.7
silicone gel and saline[e]	262	38.6	243	34.9	505	36.7
saline[f]	104	15.3	118	17.0	222	16.1
expanders[g]	8	1.2	8	1.2	16	1.2
unknown	30	4.4	43	6.2	73	5.3
Implant removal status						
no known removal	451	66.4	479	68.8	930	67.6
removed	228	33.6	217	31.2	445	32.4
Reasons for removal	n=228		n=217		n=445	
mechanical alone	12	5.3	23	10.6	35	7.9
mechanical + other	13	5.7	19	8.8	32	7.2
capsular contracture alone	56	24.6	40	18.4	96	21.6
capsular contracture + other	18	7.9	16	7.4	34	7.6
healing alone	13	5.7	19	8.8	32	7.2
healing + other	4	1.8	4	1.8	8	1.8
aesthetic alone	32	14.0	35	16.1	67	15.1
aesthetic + other	5	2.2	0	–	5	1.1
media related	6	2.6	4	1.8	10	2.2
staged reconstruction	43	18.9	41	18.9	84	18.9
malignancy	4	1.8	2	0.9	6	1.3
other + unknown	22	9.6	14	6.5	36	8.1
Implant ruptured[h]	9	3.9	15	6.9	24	5.4
Implant leaked/deflated[h]	12	5.3	22	10.1	34	7.6
Duration of implant use (months)						
implants not removed	n=451		n=479		n=930	
<48	109	24.2	111	23.2	220	23.7
48-71	117	25.9	113	23.6	230	24.7
72-95	105	23.3	134	28.0	239	25.7
96+	80	17.7	86	18.0	166	17.8
unknown	40	8.9	35	7.3	75	8.1
implants removed	n=228		n=217		n=445	
<1	12	5.3	19	8.8	31	7.0
1-2	13	5.7	12	5.5	25	5.6
3-5	26	11.4	17	7.8	43	9.7
6-11	24	10.5	28	12.9	52	11.7
12-23	23	10.1	21	9.7	44	9.9
24-47	23	10.1	24	11.1	47	10.6
48+	38	16.7	25	11.5	63	14.2
unknown	69	30.3	71	32.7	140	31.5

[a] Excludes 147 women with implants but all related details unknown
[b] Excludes 6 implants in right breast prior to the diagnosis of the study tumor in the left breast
[c] Excludes 5 implants in left breast prior to the diagnosis of the study tumor in the right breast
[d] Includes silicone gel plus expander or unknown type
[e] Includes silicone gel plus saline implants or double or triple or quadruple lumen implants
[f] Includes saline plus expander or unknown type
[g] Assumed to be saline but type of permanent implant unknown
[h] Represents the number of specific ruptures or leaks included in mechanical category above

Table 5. Implant removals, reasons for removals, and duration of implant use by implant type in a cohort of women with breast cancer who underwent mastectomy*

	Silicone gel n=559		Silicone gel and saline n=505		Saline n=222		Expanders n=16		Unknown n=73	
	n	%	n	%	n	%	n	%	n	%
Implant removal status										
no known removal	397	71.0	355	70.3	126	56.8	2	12.5	50	68.5
removed	162	29.0	150	29.7	96	43.2	14	87.5	23	31.5
Reasons for removals	n=162		n=150		n=96		n=14		n=23	
mechanical alone	9	5.6	17	11.3	5	5.2	0	--	4	17.4
mechanical + other	10	6.2	12	8.0	8	8.3	0	--	2	8.7
capsular contracture alone	43	26.5	30	20.0	16	16.7	0	--	7	30.4
capsular contracture + other	8	4.9	17	11.3	8	8.3	1	7.1	0	--
healing alone	19	11.7	8	5.3	4	4.2	0	--	1	4.3
healing + other	3	1.9	5	3.3	0	--	0	--	0	--
aesthetic alone	30	18.5	24	16.0	11	11.5	0	--	2	8.7
aesthetic + other	2	1.2	1	0.01	1	1.0	1	0.1	0	--
media related	8	4.9	2	1.3	0	--	0	--	0	--
staged reconstruction	19	11.7	22	14.7	28	29.2	12	85.7	3	13.0
malignancy	3	1.9	1	0.01	2	2.1	0	--	0	--
other + unknown	8	4.9	11	7.3	13	13.5	0	--	4	17.4
Implant ruptured†	11	6.8	13	8.7	0	--	0	--	0	--
Implant leaked/deflated†	6	3.7	13	8.7	10	10.4	0	--	5	21.7
Duration of implant use (months)										
implants not removed	n=397		n=355		n=126		n=2		n=50	
<48	80	20.2	90	25.4	45	35.7	1	50.0	4	8.0
48-71	106	26.7	89	25.1	29	23.0	0	--	6	12.0
72-95	111	28.0	91	25.6	24	19.0	0	--	13	26.0
96+	66	16.6	69	19.4	17	13.5	1	50.0	13	26.0
unknown	34	8.6	16	4.5	11	8.7	0	--	14	28.0
implants removed	n=162		n=150		n=96		n=14		n=23	
<1	12	7.4	10	6.7	7	7.3	0	--	2	8.7
1-2	6	3.7	11	7.3	5	5.2	3	21.4	0	--
3-5	14	8.6	15	10.0	12	12.5	2	14.3	0	--
6-11	15	9.3	14	9.3	15	15.6	4	28.6	4	17.4
12-23	23	14.2	13	8.7	8	8.3	0	--	0	--
24-47	20	12.3	19	5.4	3	3.1	1	7.1	4	17.4
48+	32	19.8	21	14.0	9	9.4	0	--	1	4.3
unknown	40	24.7	47	31.1	37	38.5	4	28.6	12	52.2

* Excludes 147 women with implants but all related details unknown
† Represents the number of specific ruptures or leaks included in mechanical category above

Attachment 17

Table 6. Kaplan-Meier analysis of duration of implant use by reason for removal and type of implants

A. Removal of implants for any reason - (Total implants: n=1160; total implants removed: n=305)*

	5 years		7 years		10 years	
	n	%	n	%	n	%
All types combined	261	23.7%	290	28.2%	305	39.8%
Silicone gel	98	21.0%	112	27.4%	122	50.5%
Silicone/saline	88	20.9%	97	25.1%	103	34.2%†
Saline	57	36.5%	59	40.7%	59	40.7%‡

* Excludes 215 implants with unknown duration of use (140 removed, 75 not removed)

† All silicone/saline implants that were removed were removed after a little more than 9 years use. Follow-up on the remaining implants continued for approximately 11 years.

‡ All saline implants that were removed were removed by 7 years of use. Follow-up on the remaining implants continued for approximately 11 years.

B. Removal of implants due to rupture/leak/deflation - (Total implants removed: n=284; total removed due to rupture/leak/deflation: n=46)*

	5 years		7 years		10 years	
	n	%	n	%	n	%
All types combined	28	22.8%	38	48.5%	46	98.3%
Silicone gel	7	15.0%	11	38.7%	16	98.3%
Silicone/saline	14	31.1%	17	49.9%	20	76.8%†
Saline	9	53.5%	10	100%‡	--	NA

* Excludes all expanders and all implants of unknown type as well as implants removed after unknown duration of use.

† Silicone/saline implants that were removed for reasons of rupture/leak/deflation after approximately 9 years use.

‡ All saline implants that were removed for reasons of rupture/leak/deflation were removed by 7 years of use.