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Maijers, M.C.

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CHAPTER 4

Prevalence of rupture
in Poly Implant Prothèse Silicone Breast Implants
Recalled from the European market in 2010



M.C. Majers
F.B. Niessen

ABSTRACT

BACKGROUND: Known complications of silicone breast implants are rupture and silicone leakage, complications that are related not only to generation and implant age but also to the manufacturer. Implants from the French manufacturer Poly Implant Prothèse showed more rupture than expected and were banned from the European market in 2010. Clinics in Europe recalled their patients, but prevalence of rupture in these implants has not been previously reported.

METHODS: All women who underwent breast augmentation in 2000 and 2001 in the Jan van Goyen Clinic, Amsterdam, The Netherlands, were informed about concerns regarding the quality of their implants. Medical records were used to trace manufacturer and implantation specifics. One hundred twelve women with proven Poly Implant Prothèse implants were enrolled in this study. All women underwent physical examination and magnetic resonance imaging and were interviewed for complaints to determine the prevalence of symptomatic and asymptomatic rupture.

RESULTS: Two hundred twenty-four Poly Implant Prothèse implants were evaluated with a mean implant age of 122 months. Of these 224 implants, 54 had ruptured. Magnetic resonance imaging showed that 33 percent of women had at least one ruptured implant. There was no significant difference in rupture rate of implants manufactured in 2000 and 2001.

CONCLUSIONS: One third of the women who had undergone breast augmentation with Poly Implant Prothèse implants were shown to have at least one ruptured implant after 10 years; 45.9 percent had bilateral rupture and 13.5 percent had extracapsular leakage. These were mostly asymptomatic ruptures. The rupture prevalence rate for Poly Implant Prothèse implants after 10 years is 24 percent.

BACKGROUND

Silicone breast implants have been used for breast augmentation for over five decades. There have been five generations of silicone breast implants, and they come in different shapes, sizes, shell layers and levels of projection. In the United States, these implants were a subject of debate and introduced again onto the market after their abolishment ended in 2006. In Europe, they have been safely used throughout.

Rupture and silicone leakage are well known complications¹⁻³ of breast implants. The prevalence rate of rupture is related not only to generation and implant age but also to the manufacturer.⁴ Case reports from 2006 have shown an unexpected high prevalence of rupture and silicone leakage in women with implants from the French manufacturer Poly Implant Prothèse.^{5,6} Because of these reports, the manufacturer was inspected by the French health watchdog Agence Française de Sécurité sanitaire des Produits de Santé) in 2009. It was found that the silicone gel used in these implants from the manufacture year 2001 onwards was unauthorized for medical use and approved instead for use in mattresses and cushions.⁷ In March of 2010 Poly Implant Prothèse implants were therefore banned from the European market. Plastic surgeons were advised to recall women with Poly Implant Prothèse implants from the year 2001 onward to come for physical examination and in case of a suspected rupture to undergo magnetic resonance imaging or ultrasound. If one of the implants was found ruptured, the advice was to remove both implants.

At our institution the brand Poly Implant Prothèse was the most frequently used breast implant for cosmetic augmentation in the years 2000 and 2001. It was decided to contact all women, who underwent augmentation during those years, although the advice was to recall women from 2001 only. The prevalence of rupture was determined using magnetic resonance imaging screening and the results are compared with the literature.

PATIENTS AND METHODS

All women (475) who underwent augmentation at the Jan van Goyen Clinic, Amsterdam, the Netherlands, in the years 2000 and 2001 with breast implants from the manufacturer Poly Implant Prothèse were informed by letter about the concerns of the quality of their implants. They were requested to come for follow-up. All of these women's medical records were used to trace manufacturer and implantation specifics. A cross-sectional study was designed without a control population to determine the point prevalence of implant rupture after 10 years. Not all the women could be reached, because their contact information was found to be out of date. Of the 474 letters sent, 165 resulted in a follow up visit.

During first enrollment, some women were found ineligible for the study for reasons such as there was a different implant manufacturer [13 had Monobloc hydrogel (Laboratoires Arion, Mougins Sophia-Antipolis, France), 18 had McGhan (McGhan Medical, Santa Barbara, Calif.), and five were

unknown], no medical record could be found, the implantation date was outside of the range, or there was a contraindication for magnetic resonance imaging ($n = 13$; reasons included pregnancy, breastfeeding, claustrophobia, breast cancer, clear rupture on ultrasound, cancellation, and change of implants before the follow-up date). An additional four women had previous revisions and change of implants, excluding these and the above-noted women, 112 unselected women with 224 proven Poly Implant Prothèse implants were enrolled in the study (Fig. 1).

All women were interviewed and underwent a standardized clinical examination by a plastic surgeon, which included inspection and palpation. The following abnormal findings were documented: asymmetry, changed form, consistency and/or size and palpable masses in breasts or axilla. Capsular contracture was documented according to the Baker classification.⁸

All women were referred to a single magnetic resonance imaging facility to undergo (silent) rupture screening according to an established protocol. All subjects completed magnetic resonance imaging screening within 6 weeks of the physical examination and 85 (76 percent) did so within 2 weeks. We obtained magnetic resonance images using a 1.5-T unit (Siemens Magnetom Symphony, Siemens Medical Solutions, Erlangen, Germany.) Open CP Breast array coils were used for imaging both breasts of each patient. Short T1 inversion recovery T2-weighted axial images were obtained in all cases with image parameters as follows: echo times, 70 msec. Short T1 inversion recovery T2-weighted axial and sagittal images with spectral suppression of silicone were obtained with an echo time of 84 msec. Short T1 inversion recovery T2-weighted axial and sagittal images were obtained with spectral suppression of water with echo time of 84 msec. All had repetition times of 2120 msec, inversion recovery of 140 msec, slice thickness of 4mm, a 256 x 128 matrix, and field of view of 320 x 320 mm. The images were evaluated by an experienced radiologist using signs defined by protocol as either evidence for rupture or not and evidence for extra-capsular leakage or not.

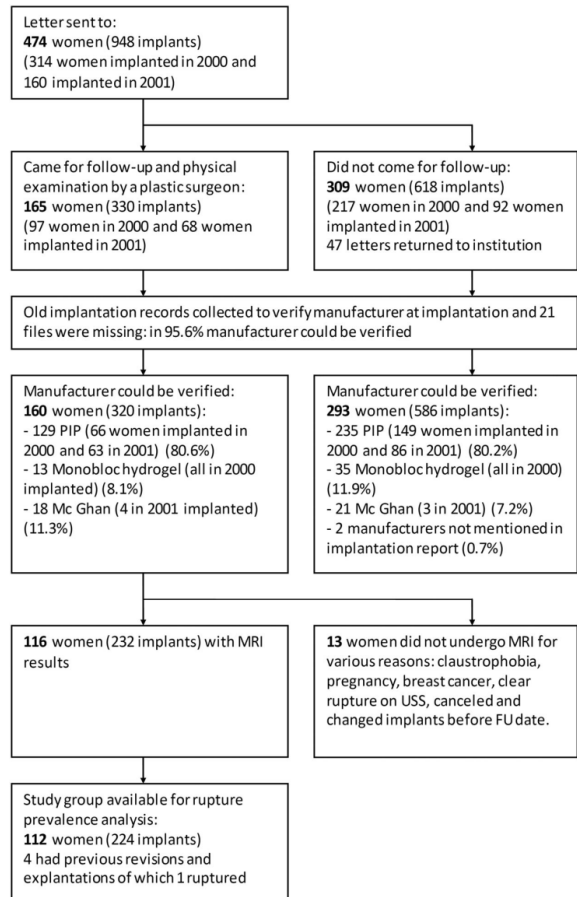


Figure 1. Study flowchart. PIP= Poly Implant Prothèse; MRI= magnetic resonance imaging; USS= ultrasound scanning; FU= follow-up.

In all analyses, the unit of observation was the woman, not the implant. The data were analyzed using SPSS 17.0 (SPSS, Inc., Chicago, Ill). Quantitative standard statistical significance was used in Pearson chi-square tests of the data tables. The critical level of statistical significance chosen was $p < 0.05$.

RESULTS

Table 1. Characteristics and frequency and prevalence of ruptured implants in 112 women with implants from the manufacturer Poly Implant Prothèse

Characteristics	All women (n=112)		Ruptured (n = 37)	
	No	%	No	%
Age at implantation				
< 20 years	6	5,4	1	16.7
20-24 years	13	11,6	7	53.8
25-29 years	17	15,2	6	35.3
30-34 years	28	25	5	17.9
35-39 years	22	19,6	7	31.8
> 40 years	26	23,2	11	42.3
Volume of implant				
< 200 ml	2	1.8	0	0.0
200-250 ml	13	11.6	3	23.1
250-300 ml	33	29.5	11	33.3
300-350 ml	40	35.7	17	42.5
350-400 ml	20	17.9	6	30.0
400-450 ml	4	3.6	0	0.0
Year of implantation				
2000	55	49.1	17	30.9
2001	57	50.9	20	35.1
Position of implant				
subglandular	93	83.0	32	34.4
subpectoral	19	17.0	5	26.3
Symptomatic				
asymptomatic	78	69.6	25	32.1
symptomatic	34	30.4	12	35.3
Physical examination				
suspicion of rupture	12	10.7	6	50.0
no findings	100	89.3	31	31.0
Baker classification				
Baker I	77	68.8	21	27.3
Baker II	20	17.9	8	40.0
Baker III	14	12.5	7	50.0
Baker IV	1	0.9	1	100.0

*Ruptured according to magnetic resonance imaging (33.0 percent).

At magnetic resonance imaging screening of 224 Poly Implant Prothèse implants, 54 implants (24 percent) showed rupture. In 112 women, magnetic resonance imaging showed rupture of at least one of their implants in 37 women (33 percent), of which 17 (45.9 percent) were ruptured bilateral and five (13.5 percent) presented with evidence of extracapsular leakage. Of the 37 women with at least one ruptured implant only 12 (32.4 percent) had any preexisting complaints (so-called symptomatic ruptures), and the majority (68.6 percent) were asymptomatic or “silent” ruptures.

The mean age of the 112 enrolled women at the time of their implantation was 33.5 years (range, 17 to 52 years). Of these women, 55 underwent augmentation with PIP implants in 2000 and 57 underwent augmentation in 2001. The 224 proven Poly Implant Prothèse implants had a mean implant age of 122 months (range 111 to 133 months) at time of their physical examination. All implants were round, textured Poly Implant Prothèse silicone breast implants. The size implanted most frequently was 330ml and varied from 185 to 430ml. Of the 112 women, 19 had their implants placed in a subpectoral position and 93 had their implants

placed in a subglandular position. Table 1 summarizes all characteristics of our study group and the results of the magnetic resonance imaging screening. We found no significant correlation between prevalence of at least one ruptured implant and the following factors: volume and location of the implants, age of the women at implantation, and the implantation year. Most of the implants were positioned subglandular in our study group. Of the 93 women with subglandular implants 32 (34.4 percent) had at least one ruptured implant compared with five out of 19 women (26.3 percent) with subpectorally placed implants, the difference however was not significant.

Of the 112 women assessed by physical examination, 12 showed physical signs of rupture, six of which (50 percent) were confirmed by magnetic resonance imaging results. Table 2 lists the physical signs found and the frequency. Of the other 100 women (89.3 percent) not suspected of having ruptured implants by physical examination, 31 women had at least one ruptured implant on magnetic resonance imaging. There were 14 women with Baker grade III capsular contracture, of which seven had at least one of their implants ruptured, and only one woman with Baker grade IV contracture, which was ruptured.

Table 2. Findings at physical examination and frequency		
Findings at examination	All women	
	No	%
No findings	100	89.3
Asymmetry	4	3.6
Palpable lymph node in axilla	3	2.7
Changed size, form or consistence	5	4.5

Only 34 of the 112 women (22 percent) mentioned any pre-existing complaints when interviewed. Table 3 lists the complaints raised by women, the symptoms were not a reason for them to come to the clinic independently for follow-up. In the 78 women who reported no complaints magnetic resonance imaging still found rupture of at least one of their implants in 25 of these patients (32.5 percent).

Of the 55 women implanted in 2000, 17 (30.9 percent) had at least one ruptured implant, compared with 35.1 percent in women who received implants in 2001. In 2001, we saw more bilateral ruptured implants, 50 percent versus 41.2 percent in 2000 and more extracapsular leakage.

Table 3. Self-referred complaints and frequency		
Self-referred complaints	All women	
	No	%
No symptoms	78	69.6
Pain or burning sensation	20	17.9
Changed size, form or consistence	9	8
Mass in mamma or axilla	4	3.6
Loss of sensation	1	0.9

DISCUSSION

This study was initiated to study the prevalence of rupture from the manufacturer Poly Implant Prothèse, which have been banned from the European market since 2010, to investigate whether the case reports and suggested higher incidence of rupture in this brand could be objectified. A point prevalence of 24 percent rupture of implants after 10 years was found. To judge whether or not this is unacceptably high compared to other manufacturers, results were compared with the literature.

Silicone breast implants come in many generations. The second generation was found to have a higher prevalence of rupture, than the first and third generations. The third generation was made in an attempt to create a more cohesive silicone gel but felt less natural. In Europe, the most recent generation of “form stable” single-lumen enhanced cohesive silicone gel implants became available in the mid-1990s.⁹⁻¹¹ The highly cohesive silicone gel fillers have been replaced by moderately less cohesive gel and less cross-linking, in an attempt to prevent capsular contraction and to maintain a softer and more natural feel⁹. The Poly Implant Prothèse silicone implant is one of these newer implants and the cohesive silicone gel implant was advertised to have a strong elastomer shell containing the Poly Implant Prothèse silicone gel, which was soft, able to retain memory, and would not leech away from the shell, even when cut in half.



Figure 2. Three last-generation silicone breast implants, with a Poly Implant Prothèse implant between two McGhan implants.

Our study was a direct consequence of the recall of these Poly Implant Prothèse implants with unauthorized content, ordered by European authorities in 2010. Until now, the exact content of this silicone gel has been unclear. This makes it difficult to compare the prevalence of rupture in these implants with other implants introduced by other manufacturers around the same time. Macroscopically, these implants do not differ much from other implants of the same fabrication year from other

manufacturers. Figure 2 shows modern moderate cohesive silicone gel breast implants that have been sliced open. The two outer implants shown are from the last generations of the manufacturer McGhan. The example in the middle is a Poly Implant Prothèse implant. The authors do have the opinion that the physical properties of the unauthorized gel used in 2001 has a less cohesive feel, than the gel of the other implant brands.

Although a control group was not used in this study, 18 women were first enrolled in the study and had magnetic resonance imaging screening, although medical records later revealed they underwent implantation with McGhan implants instead of Poly Implant Prothèse implants. Of

these, only one woman (5.6 percent) showed a rupture of one of their implants. A point prevalence of 24 percent of implant rupture after 10 years is high when compared to modern generation implants,¹²⁻¹⁶ but comparable to that of older generation implants.^{3,17-19} Table 4 shows an overview of magnetic resonance imaging studies and the point prevalence of rupture reported in asymptomatic patients implanted with silicone implants of different manufacturers with a follow-up of 10 years or longer. Recent studies on augmentation with modern high cohesive silicone gel implants reported implant rupture prevalence as low as 1.1 percent in Mentor implants¹³ and 3.8 percent in Inamed implants¹⁶ but after a follow-up period of only 6 years. The 10-year results of these studies are yet to be published. Older studies with a follow up period of 10 years or more, in contrast, also found relatively high rates of asymptomatic implant rupture of 26 and 55 percent in patients with cosmetic implants.^{3,19} These studies, however, include a variety of implants from different generations and manufacturers, which complicates comparison with our results.

The product recalled was from the year 2001 onward as, since March 2001, the unauthorized silicone gel was used, according to the French authorities. However, we found a comparable prevalence rate of at least one of their implants that ruptured in women who received implants in 2000. In 2001, more bilaterally ruptured implants were seen, there were more signs of extracapsular leakage. Our study was not intended to investigate whether the cause of the high rupture rate was the unauthorized gel or not, but if the unauthorized gel was used only from March of 2001 onward, we can conclude that this unauthorized gel did not significantly contribute to the rupture rate. The fact that women with implants made by Poly Implant Prothèse before 2001 have a comparable high prevalence of rupture of their breast implants therefore suggests that the poor quality shell rather than the unauthorized silicone gel is in fact the cause of the higher prevalence of rupture in this specific brand. This theory is supported by previous reports on poor quality of the shell of implants with saline and hydrogel content of the same manufacturer.^{20,21} Hydrogel breast implants from this manufacturer raised concerns and were withdrawn voluntarily from the European and U.S. markets in December of 2000.^{22,23}

French authorities recently advised explantation of all Poly Implant Prothèse silicone breast implants from 2001 onward. Other European authorities continue to follow the initial advice to explant Poly Implant Prothèse implants only for proven leakage of at least one or both implants, but this has been under debate. Our results show that the international advice to recall silicone implants manufactured by Poly Implant Prothèse only from the year 2001 onward is unjust to women who underwent implantation in 2000 and in whom the rupture rate is comparable high. We can only draw conclusions regarding implants from the year 2000, the year before the unauthorized gel was used; however, more research is needed to draw conclusions regarding previous years.

The results of our study provide a reliable estimate of long-term prevalence of silicone breast implant rupture of devices from the French manufacturer Poly Implant Prothèse; however there are limitations. The exact timing of rupture in our study is unknown. The incidence of rupture of

these implants could only be reported if our cohort would be followed prospectively. Not all patients who underwent breast augmentation in 2000 and 2001 with Poly Implant Prothèse implants at our institution answered to the recall. Every study on implant rupture is subject to selection bias, and only a minority of our patients reported existing complaints. We therefore believe we managed to include randomly unselected women who happen to have received these banned Poly Implant Prothèse implants 10 years ago.

CONCLUSIONS

More than one in three patients who underwent breast augmentation with Poly Implant Prothèse implants were shown to have at least one of their implants ruptured after 10 years. The rupture prevalence rate in our study for Poly Implant Prothèse breast implants after 10 years is 24 percent, which is higher than rates for most modern implants reported in literature but comparable to that of previous generations. The majority of affected women have asymptomatic intracapsular rupture of at least one of their implants. Poly Implant Prothèse breast implants from the year 2000 show no significant difference in prevalence of rupture compared with breast implants with the unauthorized silicone gel from 2001. We suggest that a shell of poor quality, rather than unauthorized silicone gel, is the cause of the higher likelihood of rupture in this brand. The advice of European authorities to recall implants in women with Poly Implant Prothèse implants from 2001 onward seems to be unjustified. The content of the gel does not contribute to the high rupture rate in Poly Implant Prothèse implants. Instead, the fact that the rupture prevalence is unacceptably high should, according to the authors, be the reason to explant all Poly Implant Prothèse implants regardless of fabrication year. We suggest that further information is needed regarding the prevalence rate of other brands of modern implant rupturing after 10 years for comparison with our results of Poly Implant Prothèse silicone implant rupture prevalence.

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