Incidence of Silicone Breast Implant Rupture

Lisbet R. Hølmich, MD; Søren Friis, MD; Jon P. Fryzek, PhD; Ilse M. Vejborg, MD; Carsten Conrad, MD; Susanne Sletting, MD; Kim Kjøller, MD; Joseph K. McLaughlin, PhD; Jørgen H. Olsen, MD, DSc

Hypothesis: The incidence of silicone breast implant rupture varies with implantation time and type of implant.

Objective: To measure the incidence of implant rupture by repeated magnetic resonance imaging (MRI) among women with silicone breast implants.

Design, Setting, and Participants: In 1999, 271 women who had received breast implants at least 3 years before, and who were randomly chosen from a larger cohort of women with cosmetic breast implants, underwent a baseline MRI. A second MRI was performed in 2001; 317 silicone implants (in 186 women) that were intact at the baseline MRI (n=280) or were intact at baseline but removed before the second MRI (n=37) were included in the rupture incidence analyses.

Main Outcome Measures: Implants were diagnosed with definite or possible rupture. Crude and implant age-adjusted incidence rates were calculated, and implant survival was estimated based on the observed rupture rates.

Results: We found 33 definite ruptures (10%) and 23 possible ruptures (7%) during the 2-year period. The overall rupture incidence rate for definite ruptures was 5.3 ruptures/100 implants per year (95% confidence interval, 4.0-7.0). The rupture rate increased significantly with increasing implant age. Double-lumen implants were associated with substantially lower rupture risk than single-lumen implants. For modern implants intact 3 years after implantation, we estimated rupture-free survival of 98% at 5 years and 83% to 85% at 10 years.

Conclusions: The risk of implant rupture increases with implant age. A minimum of 15% of modern implants can be expected to rupture between the third and tenth year after implantation.

Arch Surg. 2003;138:801-806

Although breast implant rupture is a well-known complication of breast implant surgery, little is known about the timing and frequency of ruptures. In Europe, silicone breast implants are still the preferred implants for cosmetic and reconstructive breast surgery, whereas in the United States saline implants have been standard since 1992, when the use of silicone gel implants was restricted to patients enrolled in clinical trials. Rupture of saline implants becomes apparent shortly after its occurrence due to absorption of the leaking saline. By contrast, silicone gel implant rupture often remains unnoticed by both patient and physician because the leaking silicone is kept in place by the surrounding fibrous scar membrane and no visible reabsorption occurs.

Several clinical studies have estimated the prevalence of implant rupture based on findings at explantation, and attempts to estimate implant survival based on pooling of explantation data have been made. However, because these studies are mainly based on symptomatic women seeking surgery, they constitute a biased selection of women with breast implants, presumably resulting in overestimation of rupture frequency. Recently, 2 studies using magnetic resonance imaging (MRI) in women with cosmetic silicone breast implants, randomly selected from larger cohorts of women with implants, reported rupture prevalences of 26% for implants with a median time in situ of 12 years and 55% for implants with a median time in situ of 16.4 years. However, rupture prevalence can only be used, at best, as a surrogate measure for incidence, and to our knowledge no study has directly examined the incidence rate of implant rupture.

In the present study, we measured the incidence of silicone breast implant rupture by means of repeated MRI among Danish women with cosmetic silicone breast implants.
In 1999, we performed a baseline MRI examination of 271 women with cosmetic silicone breast implants to establish the prevalence of implant rupture. In short, the women were randomly chosen from a larger cohort of all women (N=1308) who had received cosmetic breast implants at 3 private plastic surgery clinics and 1 public hospital from 1973 through 1998 and who subsequently participated in a clinical follow-up study during 1998 (N=692). For the first MRI, women who received implants in 1997 or later were excluded. Thus, all calculations presented in this report are for implants that were intact for at least 3 years.

All women who underwent the first MRI were considered eligible for the second MRI examination, regardless of the diagnosis at the first MRI (Figure 1), with the exception of 44 women whose implants had been removed or exchanged as a consequence of findings at the first MRI or on the basis of clinical indication before the second MRI (eg, capsular contracture, desire for larger implants). Thus, these 44 women did not undergo the second MRI, with the exception of 1 woman who was operated on unilaterally and whose contralateral breast was eligible for the second MRI. Three women had emigrated and could not be reached, and 19 declined to participate. This left 206 women with cosmetic silicone breast implants for the second MRI, which was carried out during 2001. Of these 206, those with at least 1 intact implant at the first MRI in 1999 contributed data to the analyses of rupture incidence. Similarly, among the 44 women who underwent surgery, implants that were intact at the time of the first MRI and were removed prior to the second MRI were also included in the incidence analyses.

**EXAMINATION BY MRI**

At the baseline MRI, all patients were examined at 1 of 3 MRI medical centers (center 1, 2, or 3) depending on their place of residence. Imaging for the second MRI followed the same protocol as in the first MRI; however, for the present study, only centers 1 and 2 participated. The MRI machine at center 3 was not used for the second MRI study because it could not generate silicone-excited sequences, which in some cases improve the sensitivity. The study subjects from centers 1 and 2 were examined using the same machine for both MRI examinations: center 1, Siemens Vision 1.5 Tesla (Siemens AG, Erlangen, Germany); center 2, Philips NT5 (Philips Medical Systems BV, Best, the Netherlands). Both scanners were equipped with a dedicated breast coil. The 80 women examined at center 3 in 1999 were examined at center 1 for the second MRI.

**MRI EVALUATION**

Images were evaluated independently by 4 readers using a standardized form, which was developed in a previous pilot study. Three possible outcomes were diagnosed: definite implant rupture, possible implant rupture, and intact implant. In case of rupture, it was determined whether the silicone was contained within the fibrous capsule surrounding the implant (intracapsular rupture) or had escaped outside the boundaries of the normal fibrous capsule (extracapsular rupture). Details about image evaluation and the criteria for rupture diagnosis have been described in detail previously.

**RECLASSIFICATIONS OF BASELINE MRI DIAGNOSES**

Images from the baseline and second MRIs were compared for all study subjects and implants, regardless of the diagnosis at baseline MRI. In some cases, this cast doubt on the initial assessment of the implant, which led to post hoc reclassification of the first MRI diagnosis for 14 implants in 13 women. Reclassifications occurred because the second set of pictures added extra information, which in retrospect could have been seen in the baseline images, and took place after discussion and agreement among the 4 readers. The changes in diagnosis were as follows: 7 implants originally diagnosed as intact were reclassified as being possibly ruptured; 4 implants originally diagnosed as intact were reclassified as being ruptured; 1 implant originally diagnosed as possibly ruptured was reclassified as being ruptured; 1 implant originally diagnosed as ruptured was reclassified as intact; and 1 implant originally diagnosed as possibly ruptured was reclassified as intact.

In 1 woman who underwent surgery before the second MRI, an implant was described as intact at the operation but had been diagnosed as ruptured at the first MRI. This implant was reclassified as intact at baseline (Figure 1).

A total of 317 implants, intact at baseline, in 186 women thus contributed to the rupture incidence analyses (Figure 1). For 280 implants the status of the implant was determined by the second MRI examination, and for 37 implants the status was determined at surgery.

**IMPLANT CHARACTERISTICS**

The study implants were divided into 3 implant generations, which is a crude classification system reflecting product development over time. First-generation implants with rather thick silicone shells were used in Denmark from 1974 through 1978, the softer, thin-shelled second-generation implants were available from 1979 through 1987, and the barrier-coated, low-bleed implants, which are currently in use, have been available since 1988. Thus, the implants were categorized based on either the calendar period of implantation or on the presumably more accurate information about shell characteristics, which, however, was only available for 66% of the study implants.
Implants were also characterized as single-lumen implants or the less common double-lumen implants with 2 membranes, the larger inner chamber containing silicone and the outer, smaller chamber containing saline. A rupture diagnosis for a double-lumen implant entailed rupture of both membranes.

ANALYSES AND STATISTICAL METHODS

A 2-year cumulative incidence was calculated as the number of ruptured implants divided by the number of implants. Implant age was calculated as the difference in years between the year of the first MRI and the year of implantation. Implant time at risk (implant follow-up time) was calculated as the number of implants included in the rupture analysis multiplied by the exact time from first to second MRI or from first MRI to explantation. Rupture incidence rates were calculated as the number of ruptured implants divided by the implant time at risk. The rupture incidence rates were stratified according to implant age (by the 8 categories defined in the Table), generation, and other implant variables. In addition, direct implant age-standardized rupture rates and 95% confidence intervals (CIs) were calculated by weighting the crude rupture incidence rates in the predefined implant age strata with the implant age distribution in the total study material. Cox regression analysis was performed to evaluate relative risks when adjusting for implant age, implant type and placement, and the center where the first MRI was conducted. Finally, cumulative rupture-free implant survival was calculated using a piecewise exponential distribution, where over each of the 8 defined age intervals (Table) the rupture rate was assumed to be constant and equal to the estimated age-specific rupture incidence rate (per implant per year). All analyses were done with SAS statistical software, version 6.12 for Windows (SAS Institute Inc, Cary, NC). The Central Scientific-Ethical Committee of Denmark approved the study.

RESULTS

During the mean observation period of 24.0 months (range, 1.2-31.1 months), 33 definite ruptures occurred, of which 26 were diagnosed at MRI and 7 at operation, yielding a cumulative incidence of 10% (Table). Six (23%) of 26 ruptures diagnosed at MRI were extracapsular ruptures. A total of 23 implants were possibly ruptured, 22 diagnosed at MRI and 1 during surgery, where it was described as “sticky,” but intact. Overall, the rate of definite ruptures was 5.3 ruptures/100 implants per year (95% CI, 3.5-7.1), and the rate of possible and definite ruptures combined was 8.9 ruptures/100 implants per year (95% CI, 6.6-11.3). When restricting the analysis to MRI-diagnosed ruptures, the rate of definite rupture decreased slightly (4.4 ruptures/100 implants per year; 95% CI, 2.7-6.1). A slightly higher proportion of possible ruptures was found among implants that were examined at center 3 at the first MRI, suggesting that some possible ruptures prevalent at the first MRI may have been missed, but the frequency of definite ruptures was similar regardless of the center used for the first MRI. The rupture rates did not change materially when the implants diagnosed at center 3 at the first MRI were excluded.

The risk of rupture, expressed as the proportion of ruptured implants, and the crude rupture incidence rates increased with implant age regardless of the definition used (Table). The implant age–adjusted rupture rates were low and of similar magnitude for first- and third-generation implants, regardless of definition, whereas second-generation implants had a significantly higher rate if definite and possible ruptures were combined, but not if only definite ruptures were considered. The large disparity in the results was due to the substantial number of possible ruptures among second-generation implants. A similar pattern was apparent if the shell characteristics definition for implant generation was applied.

Only 1 definite and 1 possible rupture were diagnosed among the 90 double-lumen implants, which were almost entirely third-generation implants. Accordingly, both the crude and the implant age–adjusted rupture incidence rates were significantly lower for double-lumen implants than for single-lumen implants. The rupture rate differed significantly according to implant placement, but this difference disappeared after adjusting for implant age because in the early years of implantation nearly all implants were placed subglandularly, whereas later the submuscular position was favored. There was little variation in rupture rates according to the age of the women at the time of implantation (data not shown).

Cox regression analysis confirmed the above findings; when adjusting for implant age, type, position, and center were the first MRI was performed, the only independent explanatory variable for implant rupture was increasing implant age (data not shown).

Figure 2 shows the estimated rupture-free survival curves based either on definite ruptures or definite and possible ruptures combined for all implants in the study, which had been implanted at least 3 years before the baseline MRI. The first part of the curve is based on the available data for third-generation implants, the middle part corresponds primarily to second-generation implants, and the last part to first-generation implants. Based on this analysis, 98% of third-generation implants can be estimated to be intact after 5 years in situ, whereas 83% to 85% can be estimated to be intact 10 years after implantation, depending on the definition of rupture. The second-generation implants had considerably higher rupture rates, and only 48% to 63% can be estimated to be intact 15 years after implantation. Likewise, based on the data for first-generation implants, only 6% to 21% of the oldest implants will be intact after 25 years in situ.

COMMENT

Through repeated MRI examination, we examined the incidence of breast implant rupture in a group of women with cosmetic silicone breast implants, randomly selected from a larger cohort as described. Overall, the incidence rate for definite rupture was 5.3 ruptures/100 implants per year. In accordance with the findings of our previous prevalence study, we found that the rupture rate varied with implant age and generation. The newer low-bleed, third-generation implants were found to be rather durable for the first 6 to 8 years, after which the rupture incidence rate increased. The earlier implant generations had higher rupture rates, primarily due to longer time in situ, which was found to be the single most im-
important risk factor for rupture. Adjustment for implant age revealed that the risk of rupture was highest among second-generation implants and that double-lumen implants were associated with considerably lower rupture risk.

Several clinical studies have tried to estimate the prevalence and incidence of rupture on the basis of findings at explantation. Several clinical studies have tried to estimate the prevalence and incidence of rupture on the basis of findings at explantation. Because these studies primarily included symptomatic and self-selected groups of patients, selection bias is likely to be present, and the study populations are not representative of all women with breast implants. Furthermore, the use of prevalence data to estimate rupture incidence is problematic. Our study is the first to examine the incidence of implant rupture and also the first to estimate rupture-free implant survival based on incidence data.
In our prevalence study,\textsuperscript{7} we chose to focus on definite ruptures. Based on subsequent findings at explantation, we found that in most cases of an MRI diagnosis of possible rupture, a definite rupture was actually present. We therefore believe the true rupture rates to be closest to the rates for the combined group of definite and possible ruptured implants. In the prevalence study, we found that 3\% of the 3- to 5-year-old third-generation implants and 16\% of the group of 6- to 10-year-old implants were ruptured. This is in close accordance with the present incidence study, in which we estimated that approximately 2\% and 15\% of third-generation implants that are intact after 3 years can be expected to develop definite ruptures by 5 and 10 years, respectively.

The primary strength of this study is the ability to obtain true incidence data, which have not been available in any previous study. Furthermore, the investigation of women who were randomly selected from a larger cohort yielded results applicable to the general population of women with cosmetic silicone implants. The major limitation of this study is the small sample size, which makes the estimates somewhat imprecise, and which made it difficult to perform multiple stratifications by variables other than implant age and generation. It seems reasonable to assume that implant manufacturer could also be a determinant, as well as conditions related to surgery, implant size, and other factors. We were unable to include implants younger than 3 years in the incidence study, and our findings do not provide information about the natural history of rupture in these early years after implantation. A survivor bias may have influenced our estimates, yielding rupture rates that were too low, because the included implants had to remain intact for 3 years, and because we could not take into consideration implants that had been explanted before the first MRI. This type of bias would primarily affect results concerning the oldest implants. The incidence rates were based on occurrence of ruptures between 2 time points, and the time window in which events were sampled was small in order to gather incident rather than prevalent ruptures. Although MRI is the imaging modality with the highest sensitivity and specificity for diagnosing breast implant rupture,\textsuperscript{20} some implant ruptures may be overlooked, and false-positive results are possible. A small pilot study prior to the first MRI revealed a sensitivity of 86\% and a specificity of 100\% for rupture diagnosis,\textsuperscript{4} which is in good accordance with other studies in this area.\textsuperscript{20,23-26} Because we deliberately decided to have a high specificity rather than a high sensitivity in this study, some ruptures may have been overlooked. We know from surgical reports on explantations among study participants that there were virtually no false-positive results (1 false-positive rupture in 60 women who underwent surgery either after the first or second MRI). Some authors claim that the criterion standard for investigation of implant status is explantation.\textsuperscript{1,16} However, our study reveals that many ruptures do not lead to surgery, so these would not be identified by this method. In addition, it is well recognized that some ruptures occur during explantation surgery.\textsuperscript{27,28}

It is a common experience among radiologists that the sensitivity of MRI, as well as mammography, increases when new pictures are compared with older pictures of the same case, and reclassifications, as in the present study, can be expected.\textsuperscript{29,30} In an earlier study, we compared self-reported health outcome and the presence of autoimmune antibodies in women with ruptured implants vs women with intact implants at the first MRI.\textsuperscript{31} Because of the reclassifications described in the present study, we felt obliged to redo the analyses for the health-outcome study. We found no differences in our results or conclusion; ie, we found no differences in self-reported health status or presence of autoimmune antibodies according to breast implant status.\textsuperscript{31}

In conclusion, we find that implant rupture incidence increases with implant time in situ. The third-generation implants currently in use are relatively durable for the first 6 to 8 years in situ, after which the rupture rate increases. The 10-year rupture-free implant survival for implants intact at 3 years is estimated to be 83\% to 85\%, and poorer survival should be expected for older implants. Routine exchange of implants exceeding 10 years of age, as suggested by some plastic surgeons, may give a false sense of security, because a minimum of 15\% of modern implants can be estimated to be ruptured at that age. On the other hand, treatment of asymptomatic implant rupture, and in particular the recommendation of explantation, remains controversial, and sound scientific studies in this area are scarce. Investigations of untreated ruptures, including the changes over time in ruptured implants, are needed.

Accepted for publication February 22, 2003.

This study was supported by the International Epidemiology Institute, Rockville, Md, which in turn received funding from the Dow Corning Corporation, Midland, Mich, and by the Danish Cancer Society, Copenhagen, Denmark. The external funding source (Dow Corning Corporation) had no role in or access to the study design, data collection, data analysis, data interpretation, writing of the report, or the decision to submit it for publication.

We thank the plastic surgeons Vibeke Breiting, MD, Anna Jørgensen, MD, and Poul Harboe Jacobsen, MD, as well as Bodil Brandt, MD, and Mette Wolthers, MD, for their invaluable help in data collection for the clinical follow-up part.
of this study. We thank Christen Krag, MD, DSc, for professional advice and helpful discussions during the study and statistician Robert E. Tarone, PhD, for constructive contributions to the analyses as well as critical reading of drafts for this report. We also thank the several plastic surgeons who supplied us with information about implant status at examination. Finally, we express our gratitude to the women who volunteered for this study.

Corresponding author and reprints: Lisbet Hølmich, MD, Danish Cancer Society, Institute of Cancer Epidemiology, Strandboulevarden 49, DK-2100 East, Copenhagen, Denmark (e-mail: lisbet@cancer.dk).

REFERENCES