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**STUDY OF RE-OPERATIONS AND
SELF-REPORTED SILICONE-GEL BREAST IMPLANT RUPTURE
(INTERVIEW COMPONENT)**

FDA has recently completed a study on how often women who had breast implants had to go back to their surgeons for additional surgery on their breast(s). The study was presented at the Sixth World Biomaterials Congress on May 18, 2000.

The study, performed in Birmingham, Alabama, involved women who had their first breast implant before 1988. The majority of women in this study had silicone gel-filled breast implants. Women responded to a telephone questionnaire in which they described past surgeries and whether or not their implants were found to be ruptured after the surgeries. Women also responded to questions about the reason they had the surgery.

The Institute of Medicine recently released its report on the safety of silicone breast implants. It concluded that the primary problems with silicone implants were local complications, including implant removal, ruptures, deflations, capsular contracture, infection, and pain.

FDA conducted this study because of concerns about the frequency and results of rupture. Rupture is a concern because:

- Rupture of silicone gel-filled implants may allow silicone to migrate through the tissues. The relationship of free silicone to development or progression of disease is unknown.
- Rupture is a device failure – the implant is no longer performing as intended.

Protocol

- Women in this study were identified because they had been in a National Cancer Institute study on women with breast implants. Women who responded to a questionnaire in the NCI study were eligible for this study if they still lived in Alabama. Nine hundred seven (907) women were interviewed about surgeries in which implant(s) were removed.
- Women were also asked the main reason they had their implants removed, and if an implant rupture was suspected prior to the surgery.
- If women reported that their implant surgery was for a suspected implant rupture, they were asked about symptoms that they may have had and about whether they knew of a possible cause of the rupture.

- Some women also gave the FDA permission to obtain the medical records for the surgeries they described. These records were examined to determine how often breast implant rupture was reported in the surgical record.

Results

- One third of the 907 women in the study – 303 women -- reported that they had had at least one surgery in which their implant was removed or replaced.
- The most common reason for surgery was for problems with the implant that affected the breast (103 of 303). These include:
 - suspected implant rupture,
 - pain,
 - capsular contracture,
 - displaced implant,
 - seroma (a collection of serum below the skin),
 - hematoma (hemorrhage under the skin with blood clots forming),
 - infection,
 - extrusion (implant pushing through the skin), and
 - other reasons.
- The second most common reason for surgery to remove the breast implant was because of concern over the safety of silicone (92 of 303).
- Other reasons for surgery were disease or symptoms which women or their physicians thought were related to the implant, or because of planned or staged surgeries (e.g., replace tissue expander, or because women wanted a different size of implant, etc.).
- 73 of the 303 women reported that they went to surgery because of a suspected breast implant rupture. 70% of these women suspected that their implants were ruptured because of breast pain, chest pain or other upper body pain, and 58% of these women reported suspecting implant rupture because of changes in the shape of their breasts.
- Of the 303 women reporting additional surgeries, 171 reported that at least one of their implants was found to be ruptured or leaking.
- 215 of the women agreed to allow FDA to obtain their medical records for the surgery they described, and at least one surgical record was obtained for 165 of these women.
- Of the 165 women for whom a medical record had been collected, 85 reported that they had a ruptured implant. However, only 69 of the medical records indicated that there was a ruptured implant. There are several possibilities for the discrepancy: the researchers could have collected a medical record for a different surgery than the one reported, the

physician may not have recorded whether it was ruptured, or the woman may have mistakenly told us that her implants were ruptured when they weren't.

- For the 303 women who reported a second surgery, the average time to the surgery was 11.5 years after their first breast implants were implanted.

Limitations

- The 907 women in this study were a subset of 1247 women in the Birmingham, Ala., area who were part of an NCI study on breast implants. The authors were unable to obtain interviews with all of the 1247 women in NCI's cohort. It is not known if this subset is representative of women with silicone gel-filled breast implants.
- Researchers were unable to retrieve any medical records for nearly half of the women who reported a surgery related to their breast implants. (The most frequent reasons were no consent, doctors' refusal, or missing records.) It is unknown whether the women for whom records collected were representative.

Conclusions

- A third of the women in the study had to have at least one surgery in which their breast implants were removed or replaced.
- The most common reason for the first surgery was problems with the implant that affected the breast, i.e., local complications, with breast implant rupture, pain, and capsular contracture comprising the largest portions of this category in order of prevalence.

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