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STUDY OF RUPTURE OF SILICONE GEL-FILLED BREAST IMPLANTS (MRI COMPONENT)

An FDA study on rupture of silicone gel-filled breast implants 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 the 907 women in this study had silicone gel-filled breast implants. Some women who had silicone gel-filled breast implants were invited to undergo a magnetic resonance imaging (MRI) examination of their breasts to determine whether their implants had ruptured. MRI allows the radiologist to see the breast implant while it is still inside the breast.

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. This cohort included only women who were patients at two plastic surgery practices. 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 rupture study had two parts. In the first part, 907 women were interviewed about surgeries in which implant(s) were surgically removed (interview component of the study).

- One third of the 907 women in the first part of the study reported that they had at least one surgery in which their implant was removed and replaced. 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.

- In the second part of the study, 344 women with silicone gel breast implants received MRI examinations to detect possible implant rupture. The women, selected randomly from the first part of the study, were invited to have MRI exams when they were called to be in the study until all the MRI appointments planned for the study had been filled. The study had funding for up to 400 MRI exams to be accomplished at a particular MRI facility under contract for a certain period of time. Of the 445 women invited to have an MRI, 80% (359) accepted and had the examination. Women were invited for the MRI exam without regard to whether they had symptoms of breast implant rupture. Those who accepted the appointments and came were no more likely to think their breast implant was ruptured than women who declined the examination or did not come to their appointments.

- The 344 women who received MRI examinations had a total of 687 implants. The average age of the women in the MRI cohort was 51 ± 8 years. Most women in this cohort had a single lumen gel breast implant (82%) and the remainder had a double-lumen gel breast implant (silicone and saline). For the 677 implants for which this information was available, the average implant age was 17 ± 3 years.

- Three independent radiologists reviewed the results of all of the women's MRIs and for each implant, determined whether it was intact, indeterminate (suspicious for rupture), or ruptured. The agreement between the radiologists was very high.

Results

- At least two of the three study radiologists agreed that 378 of the 687 implants were ruptured (55%). This means that 69% of the 344 women had at least one ruptured breast implant.

- Radiologists observed that silicone gel had leaked outside the fibrous scar capsule that forms around the implant in 85 of the 687 implants (12%). Of the 344 women, 73 (21%) had silicone gel outside the capsule in one or both breasts.

- Factors that were associated with rupture: the age of the implant, the implant manufacturer, and whether the device was implanted above or beneath the chest muscles.

Limitations of the Study

- This cohort included only women who were at two plastic surgery practices. It is unknown whether the results of the study might have been different if patients from other parts of the U.S. had been included.

- Only 80% of those invited to have an MRI examination agreed.

- Many types of silicone gel-filled breast implants were included in this study.

- While MR imaging is considered the best method for imaging breast implants for rupture, it is not perfect.

Conclusion

- MRI examination in this cohort of patients demonstrated that the majority of women had at least one ruptured implant.

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