

Study of Silicone Gel Breast Implant Rupture, Extracapsular Silicone, and Health Status in a Population of Women

The FDA has recently completed a study on the health effects of ruptured silicone gel breast implants. The study was published in the May 2001 Journal of Rheumatology.

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.
- Implant rupture is a device failure – the implant is no longer performing as intended.

Protocol

- Three hundred and forty-four women with silicone gel breast implants responded to an FDA questionnaire in which they were asked whether they had persistent symptoms including joint pain, swelling, or stiffness; rash on the breast or chest; or fatigue.
- Women were also asked whether a doctor diagnosed them with any of a list of illnesses such as scleroderma, systemic lupus erythematosus (SLE), Sjogren's syndrome, Raynaud's syndrome, fibromyalgia, chronic fatigue syndrome, or other connective tissue disease not already listed.
- After the questionnaire was completed, women underwent a magnetic resonance imaging (MRI) examination of their breasts to detect whether their current implants were intact or ruptured. The MRI examination can also tell whether silicone gel has leaked outside of the fibrous scar capsule that forms around the breast implant.

Results

- Women with MRI diagnosed breast implant rupture were no more likely than women with intact implants to report that they had either persistent symptoms or doctor-diagnosed illnesses that were listed.
- Women with MRI-diagnosed extracapsular silicone gel (that is silicone that had migrated outside the fibrous scar around the implant) were 2.8 times more likely to report that they had the soft tissue syndrome, fibromyalgia. This association remained statistically significant after taking into account other factors including whether women thought their implants were ruptured, implant age, and implant manufacturer. Fibromyalgia is a syndrome characterized by widespread pain, fatigue, and sleep disturbance.
- Women with MRI-diagnosed extracapsular silicone gel were 2.7 times more likely to report that they had "other connective tissue disease," a category that included a diverse group of illnesses such as dermatomyositis, polymyositis, and mixed connective tissue disease. This association did not remain statistically significant after taking into account other factors including whether women thought their implants were ruptured, implant age, and implant manufacturer.

Limitations of the Study

- Women who developed fibromyalgia before they had a breast implant could not be distinguished from women who developed fibromyalgia after breast implant surgery. This study does not show cause and effect, but a statistical association between extracapsular silicone and fibromyalgia.
- Women in this study did not receive a medical examination to confirm their self-reported diagnosis. When diseases are self-reported, some women may have a disease and not report it, and others may not have the disease but incorrectly report that they do have it.

Strengths of this Study

This is the first study in which the status of all women's breast implants, with respect to rupture, has been known.

Conclusions

The data suggest an association between extracapsular silicone gel and fibromyalgia. If other studies are consistent with these findings, women should be informed of the potential risk of developing fibromyalgia if their breast implants rupture and silicone gel escapes the fibrous scar capsule.

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