I S S U E B R I E F

What Does the Institute of Medicine Report Say About the Safety of Silicone Breast Implants?

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The Institute of Medicine (IOM) completed a report in 1999 on the safety of silicone breast implants.[1] The report did not involve any new research – it was a review of the literature that existed at that time.

The IOM report concluded that breast implants frequently result in local complications, some of them serious or debilitating, such as pain, capsular contracture, and rupture. Little attention has been focused on these findings.

Instead, the major focus has been on the report's chapter reviewing 17 epidemiological studies of classic connective tissue diseases such as lupus and scleroderma. These were the only epidemiological studies available in 1999, but most did not evaluate the atypical connective tissue disease symptoms or fibromyalgia symptoms that many patients report. Almost all of these studies were funded by implant manufacturers at a time when they were preparing their defense against escalating legal challenges from women reporting serious health problems. These same 17 studies, as well as three additional studies, were also included in a meta-analysis published in 2000.[2] The IOM report and the meta-analysis have been cited as proof that breast implants do not cause disease, but both were limited by the quality of the same 17-20 epidemiological studies on connective tissue disease, only 15 of which were published in peer-reviewed journals. The IOM report also included a chapter on implants and cancer, focused almost exclusively on breast cancer. The few studies that evaluated other types of cancer included large numbers of women who had implants for less than 10 years or even less than 5 years – too short a period of time to measure an increased risk of cancer.

Since the IOM report was based on the limited research available in 1999, it was never meant to be the "final word" on the topic. The authors concluded that the weight of existing evidence at that time did not prove that breast implants cause diseases.

Research Evidence After the IOM Study Raises Concerns

Several well-designed epidemiological studies published more recently have reported statistically significant increases in the risk of serious diseases among women with breast implants. An epidemiological study by scientists at the National Cancer Institute (NCI) analyzed mortality among women who had breast implants for **at least seven years**. They found that breast implant patients were

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twice as likely to die from brain cancer, three times as likely to die from lung cancer, and four times as likely to commit suicide, compared to other plastic surgery patients.[3] Two studies conducted in Scandinavia found an increase in lung cancer and suicide among women with breast implants.[4, 5]

A subsequent study of the same data set by many of the same scientists from NCI found that women with breast implants were significantly more likely to report several autoimmune diseases, such as rheumatoid arthritis.[6] However, many of the women made errors in their self-reported diagnoses; for example, many women who reported having rheumatoid arthritis had osteoarthritis instead, according to their medical records. This suggests that there are increased symptoms among these women, but the exact diagnoses are unclear. As a result, the researchers concluded that the association between breast implants and arthritis, scleroderma, Sjogren's syndrome, and other connective tissue diseases need further study.

A study of women who had silicone breast implants for at least six years, conducted by scientists at the Food and Drug Administration (FDA), found that women with implants leaking outside the scar capsule were more likely to report fibromyalgia and several other autoimmune diseases. The comparison group was women with silicone implants that were not leaking outside the capsule.[7]

Why are the research findings from the last few years so different from the earlier studies included in the IOM report? First, the IOM review of epidemiological research was focused almost entirely on classic connective tissue diseases. Second, several of the studies found increases in connective tissue diseases that would have been statistically significant if maintained in a larger sample. Overall, the IOM report was limited by the serious shortcomings of the research that had been conducted at the time the report was written. One expert, the chair of the FDA's General and Plastic Surgery Devices Advisory Panel, pointed out that "what was considered by them [the IOM] reflected low-quality data in the age of evidence-based medicine."[8]

The shortcomings of the epidemiological studies that the reports summarized include:

♦ **The studies had too few women with breast implants.**

- The case-control studies included very few women with implants, either as cases or controls. For example, the study by Strom *et al.* (see discussion, page 11) compared women with rheumatologic diseases with women without diseases, and **only one woman with implants was in the study**.

- The cohort studies included more women with implants than the case-control studies, but not enough to study women with rare diseases. For example, Gabriel *et al*. (see discussion, page 5) compared only 749 women with breast implants to a comparison sample to evaluate the prevalence of several connective tissue diseases. The authors acknowledged that the sample was too small to evaluate a doubling of the risks of rare diseases such as scle roderma.

♦ **The women in the studies didn't have implants long enough to develop most diseases**. For example, the study by Schusterman *et al.* (see discussion, page 8) did not include any women who had breast implants for more than 2.5 years. Most autoimmune diseases take much longer than that to develop and be diagnosed. Research is needed on women with implants for a longer period of time to deter-

mine if exposure to breast implants increases health risks.

♦ **Control group or comparison sample was inappropriate.** In one study, the comparison sample was comprised of women with other rheumatologic diseases (Goldman *et al.*, see discussion, page 10). In several studies, the comparison sample was comprised of breast reduction patients, a group that differs significantly from augmentation patients on several measures, and is apparently at higher risk of autoimmune diseases than the general population.

♦ **Studies did not include medical exams.** All but one of the case-control studies asked women if they had breast implants (usually over the telephone) and did not verify if the information was correct. In the cohort studies, most of the data about illness relied on medical records, some on hospitalization records, and a few on self-reported illnesses. Medical exams and diagnoses by physicians unaware of which women have breast implants would be the most reliable measure of any link between implants and illness. Only one study included medical exams – the Schusterman study, which included women with implants for less than 2.5 years.

♦ **Studies did not evaluate the symptoms that are most widely reported by women with implants, such as pain, memory loss, and fatigue**. The studies only evaluated a few, classically diagnosed autoimmune diseases.

Information about the sample sizes, outcome measures, and other methodological information about the 20 studies reviewed are attached.

References:

1 Bondurant S, Ernster V, Herdman, R, eds. Safety of silicone breast implants. Washington, DC: Institute of Medicine; 1999.

2 Janowsky EC, Kupper LL, Hulka BS. Meta-analyses of the relation between silicone breast implants and the risk of connective-tissue diseases. *New England Journal of Medicine*. 2000;342:781-90.

3 Brinton LA, Lubin, JH, Burich MC, et al. Mortality among augmentation mammoplasty patients. *Epidemiology*. 2001; 12: 321-326.

4 Koot VCM, Peeters PHM, Granath F, et al. Total and cause specific mortality among Swedish women with cosmetic breast implants: prospective study. *British Medical Journal*. 2003; 326: 527-528.

5 Jacobsen PH, Holmich LR, McLaughlin JK Mortality and suicide among Danish women with cosmetic breast implants. *Archives of Internal Medicine*. 2004, 164: 2450.

6 Brinton, LA, Buckley, LM, Dvorkina, O et al. Risks of connective tissue disorders among breast implant patients. *American Journal of Epidemiology*. 2004, 180: 619-27.

7 Brown SL, Pennello G, Berg WA, et al. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. *Journal of Rheumatology*. 2001; 28:996-1003.

8 Letter from Dr. Whalen available: www.breastimplantinfo.org/news/whalenlet.htm.

Cohort Studies

Cohort studies compare women with breast implants to a group of women who are similar in terms of age, race, and health who did not have breast implants.

Edworthy, S.M., Martin, L., Barr, S.G., et al. A Clinical Study of the Relationship Between Silicone Breast Implants and Connective Tissue Disease. *Journal of Rheumatology* 1998; 25: 254-260.

Number of implant recipients: 1,576 **Number of controls:** 727

Does the study include mastectomy patients receiving implants? NO

Diseases studied: Any classic connective tissue disease including rheumatoid arthritis, lupus, scleroderma, and Sjogren's syndrome.

Minimum length of time with implants included in study: Unclear

Average length of time with implants: 13.5 years

Additional notes: Women with breast implants were 44% more likely to have a diagnosis of rheumatoid arthritis (relative risk: 1.44). That difference was not statistically significant. When interviewed about their health, women with implants were significantly more likely to have difficulty solving thought problems, have numbness in their extremities, muscle pain, headache, and hand pain. However, those symptoms were not included in the meta-analysis. This study relied on medical records. The authors did not question or examine patients directly.

Friis, S., Mellemkjaer, L., McLaughlin, J.K., et al. Connective Tissue Disease and other Rheumatic Conditions Following Breast Implants in Denmark. *Annals of Plastic Surgery* 1997; 39: 1-8.

Number of implant recipients: 2,570 **Number of controls:** 11,023

Does the study include mastectomy patients receiving implants? YES, 1,435 of 2,570

Diseases studied: Any classic connective tissue disease, including lupus, Sjogren's syndrome, rheumatoid arthritis, and scleroderma. Also looked at "other and ill-defined" rheumatic conditions.

Minimum length of time with implants included in study: To be in this study a woman could have had implants for less than one year.

Average length of time with implants: 7.2 years for reconstruction group, 8.4 years for augmentation group.

Additional notes: Only women who were hospitalized for connective tissue disease were categorized as ill, not outpatients. According to the authors, the study had only limited power to detect an increased risk of any specific connective tissue disease. The control group consisted of women who had breast reduction surgery or mastectomy without receiving implants. Although the difference was not significant, the rate of scleroderma, lupus, and Sjogren's syndrome in mastectomy patients receiving implants was 30% higher than expected. The authors found an increase in rheumatic complaints in all of the groups and therefore concluded that breast surgery increases the risk of connective tissue disease, and that the implants themselves do not cause connective tissue disease. The authors did not question or examine patients directly.

Gabriel, S.E., O'Fallon, W.M., Kurland, L.T., et al. Risks of Connective tissue Diseases and Other Disorders after Breast Implantation. *New England Journal of Medicine* 1994; 330: 1697-1702.

Number of implant recipients: 749 **Number of controls:** 1,498

Does the study include mastectomy patients receiving implants? YES, 125 of 749

Diseases studied: Any classic connective tissue disease, including lupus, Sjogren's syndrome, rheumatoid arthritis, and scleroderma. Also looked at other disorders such as Hashimoto's thyroiditis, cirrhosis, sarcoidosis, and cancer.

Minimum length of time with implants included in study: Women in this study could have had implants for less than one year.

Average length of time with implants: 7.8 years

Additional notes: Women with breast implants had a 35% higher rate of arthritis, which was not statistically significant (relative risk: 1.35). Morning stiffness was 81% higher for implant patients, which was significantly higher than for women without implants (relative risk: 1.81). The authors estimated that they would need to have studied 62,000 women with implants for an average of 10 years to detect a 100% increase (or less) in rare diseases such as scleroderma. This study relied on medical records. The authors did not question or examine patients directly.

Giltay, E.J., Bernelot Moens, H.J., Riley, A.H., et al. Silicone Breast Prostheses and Rheumatic Symptoms: a Retrospective Follow Up Study. *Annals of Rheumatic Diseases* 1994; 53: 194-196.

Number of implant recipients: 235 **Number of controls:** 210

Does the study include mastectomy patients receiving implants? YES, approximately 56 of 235, but they were not analyzed separately

Diseases studied: Rheumatic complaints, use of anti-rheumatic drugs, and medical consultations regarding rheumatic symptoms. For those reporting rheumatic symptoms, a rheumatologist made an assessment of the likelihood of a rheumatic disease.

Minimum length of time with implants included in study: Two years

Average length of time with implants: 6.5 years with a range of two to 14 years

Additional notes: Women with silicone breast implants reported significantly more rheumatic complaints than controls, but there was no evidence of increased prevalence of common rheumatic diseases, such as fibromyalgia, rheumatoid arthritis, or Sjogren's disease. The results may not accurately describe the health risks for mastectomy patients, since they were a small minority of the women in the study. The control group consisted of women who had an unspecified cosmetic procedure that did not include silicone products. The study relied on questionnaires completed by the patients. The authors did not question or examine patients directly.

Hennekens, C.H., Lee, I.M., Cook, N.R., et al. Self-Reported Breast Implants and Connective tissue Diseases in Female Health Professionals. *Journal of the American Medical Association* 1996; 275: 616-621.

Number of implant recipients: 10,830 **Number of controls:** 384,713

Does the study include mastectomy patients receiving implants? YES, 18% of 10,830

Diseases studied: Any classic connective tissue disease including lupus, Sjogren's syndrome, rheumatoid arthritis, and scleroderma. Also included mixed connective tissue disease.

Minimum length of time with implants included in study: To be in this study, a woman could have had implants for one year.

Average length of time with implants: Not stated, but the authors analyzed the women in three groups: up to four years, five to nine years, and 10 or more years after receiving implants and showed no increased risk with increased duration of exposure.

Additional notes: Implant patients had a 25% higher rate of connective tissue disease, whether they were reconstruction or augmentation patients (relative risk: 1.25). This was statistically significant, and the researchers concluded that there is a small increased risk of connective tissue disease among women with implants. Although it is a cohort study, this study was analyzed with case-control and cross-sectional studies in the meta-analysis because information about the disease and the patient's exposure to silicone breast implants was gathered at the same time. The study relied on questionnaires completed by the subjects, who were health professionals. The authors did not question or examine the women directly.

Nyren, O., Yin, L., Josefsson, S., et al. Risk of Connective Tissue Disease and Related Disorders Among Women with Breast Implants: A Nation-Wide Retrospective Cohort Study in Sweden. *British Medical Journal* 1998; 316: 417-422.

Number of implant recipients: 7,442 **Number of controls:** 3,353

Does the study include mastectomy patients receiving implants? YES, 3,942 of 7,442

Diseases studied: Hospitalizations for classic connective tissue disease including lupus, Sjogren's syndrome, rheumatoid arthritis, and scleroderma. Also studied hospitalizations for related diseases.

Minimum length of time with implants included in study: One month

Average length of time with implants: Six years for reconstruction patients, 10.3 years for augmentation patients.

Additional notes: Only women who were hospitalized for connective tissue disease were categorized as ill, not outpatients. The authors acknowledge that the sample size was too small to draw conclusions about links between breast implants and rare diseases they studied, such as scleroderma. The control group consisted of women who had breast reduction surgery. Both groups who had breast surgery had slightly higher than expected rates of connective tissue disease. This study relied on hospital records. The authors did not question or examine patients directly.

Park A.J., Black, R.J., Sarhadi, N.S., et al. Silicone Gel-Filled Breast Implants and Connective Tissue Diseases. *Plastic and Reconstructive Surgery* 1998; 101: 261-268.

Number of implant recipients: 317 **Number of controls:** 419

Does the study include mastectomy patients receiving implants? YES, 207 of 317

Diseases studied: Signs and symptoms of connective tissue and autoimmune disease, such as antinuclear antibodies, rheumatoid factor, joint pain, fatigue, Raynaud's syndrome, etc.

Minimum length of time with implants included in study: Not specified

Average length of time with implants: Six years for reconstruction patients, five years for augmentation patients.

Additional notes: Because the sample size was so small, the authors acknowledge that a health risk would have to exceed 320% for reconstruction patients and 1600% for augmentation patients in order to be statistically significant. In addition, approximately half of the women had implants for less than six years. Because of these shortcomings, this study does not provide useful information. The study included two controls for each implantation patient. Half of the controls were maternity patients and half were outpatients from the plastic surgery department. The authors did not specify what types of procedures the plastic surgery controls received. The study subjects were interviewed and received a medical examination.

Sanchez-Guerrero, J., Colditz, G.A., Karlson E.W., et al. Silicone Breast Implants and the Risk of Connective tissue Diseases and Symptoms. *New England Journal of Medicine* 1995; 332: 1666-1670.

Number of implant recipients: 1,183 **Number of controls:** 86,318

Does the study include mastectomy patients receiving implants? YES, 525 of 1,183 for cancer or prophylaxis, but they were not analyzed separately from augmentation patients

Diseases studied: Any classic connective tissue disease, including lupus, Sjogren's syndrome, rheumatoid arthritis, and scleroderma. Excluded women with milder or atypical cases of connective tissue disease.

Minimum length of time with implants included in study: One month

Average length of time with implants: 9.9 years

Additional notes: According to the authors, the study does not exclude small health risks of implants that would be of public health importance. The study was designed to minimize "reporting bias" of health problems by implant patients by excluding any health problems diagnosed after May 1990, which was six months before the major media coverage of implant problems. They did not minimize bias in the opposite direction; for example, they included women who only had implants for one month. Also, they should have excluded women who reported receiving breast implants from 1952 to 1961, since breast implants had not yet been invented. Including these women and their inaccurate statements increased the average years of implantation. The study relied on questionnaires completed by the subjects, who were health professionals. The authors did not question or examine the women directly, although, for a random sample of 100 women, they verified whether the women had breast implants by reviewing their medical records.

Schusterman, M.A., Kroll, S.S., Reece, G.P., et al. Incidence of Autoimmune Disease in Patients after Breast Reconstruction with Silicone Gel Implants Versus Autogenous Tissue: A Preliminary Report. *Annals of Plastic Surgery* 1993; 31: 1-6.

Number of implant recipients: 250 **Number of controls:** 353

Does the study include mastectomy patients receiving implants? YES, all were mastectomy patients.

Diseases studied: Patients were considered to have rheumatic disease if they had been seen by a physician who made the diagnosis on clinical grounds with corroborating laboratory evidence and had prescribed therapy.

Minimum length of time with implants included in study: 10 months

Average length of time with implants: Does not specify, but maximum period for any patient is 2.5 years

Additional notes: Length of follow-up was too short to be meaningful. The authors state that the report must be considered preliminary because the onset of autoimmune disorders could occur two to 21 years after implantation.

Wells, K.E., Cruse, C.W., Baker, J.L. Jr., et al. The Health Status of Women Following Cosmetic Surgery. *Plastic and Reconstructive Surgery* 1994; 93: 907-912.

Number of implant recipients: 222 **Number of controls:** 80

Does the study include mastectomy patients receiving implants? NO

Diseases studied: Study looked at the incidence of 23 symptoms and the diagnosis of connective tissue disease such as rheumatoid arthritis, lupus, scleroderma, and Raynaud's disease.

Minimum length of time with implants included in study: Not specified

Average length of time with implants: 4-5 years

Additional notes: The authors compared women who had breast implants to those who had liposuction, rhinoplasty, or eyelid lifts. The average age of women getting breast implants was almost 10 years younger than those getting the other cosmetic procedures. Tender and swollen glands under the arm were more likely in implanted women. Symptoms that were more frequent in implanted women but did not achieve statistical significance were: easily tired, muscle pain, swollen and tender glands in the neck, change in hand color with cold, weight gain, swollen and painful joints, and general stiffness. The authors acknowledged that the small sample size could explain why the differences did not achieve statistical significance. The authors reported no cases of scleroderma or lupus. Arthritis was present in 5% of implanted women and 3% of controls. One implanted woman reported Raynaud's disease. The study relied on questionnaires completed by the subjects. The authors did not question or examine the women directly.

Case-control or cross-sectional studies

These studies compare women suffering from a particular disease (cases) to those who are healthy (controls) and determine whether breast implants are more common in the ill women.

Burns, C.J., Laing, T.J., Gillespie, B.W., et al. The Epidemiology of Scleroderma Among Women: Assessment of Risk from Exposure to Silicone and Silica. *Journal of Rheumatology* 1996; 23: 1904-1911.

Number of cases: 274 **Number of controls:** 1,184

Diseases studied: Scleroderma

Additional notes: This study revealed no increased likelihood that women with scleroderma reported having silicone breast implants. However, women with scleroderma were significantly more likely to report other exposures to silicone. Women with scleroderma were identified by contacting rheumatologists, hospitals, and a scleroderma support group. They were then interviewed by telephone to determine past exposure to silicone or silica.

Dugowson, C.E., Daling, J., Koepsell, T.D., et al. Silicone Breast Implants and Risk for Rheumatoid Arthritis. *Arthritis and Rheumatism* 1992; 35: Suppl: S66.

Number of cases: 300 **Number of controls:** 1,456

Disease studied: Rheumatoid arthritis

Additional notes: This study was a non-peer-reviewed abstract from a scientific meeting. One case and 12 controls had breast implants before diagnosis. There was no increase in the likelihood that rheumatoid arthritis patients reported having breast implants. The study was based on a questionnaire sent to women with rheumatoid arthritis and age-matched controls asking if they had breast implants.

Englert, H.J., Brooks, P., et al. Scleroderma and Augmentation Mammoplasty - A Casual Relationship? *Australia and New Zealand Journal of Medicine* 1994; 24: 74-80.

Number of cases: 286 **Number of controls:** 253

Disease studied: Scleroderma.

Additional notes: This study found no increased likelihood that women with scleroderma reported having breast implants, although the authors acknowledged that the study lacked the power to detect an increased risk of lower than 150-200%. The study was based on a telephone questionnaire. The information on whether the women had implants was self-reported to the interviewer on the telephone and unverified.

Goldman, J.A., Greenblatt, J., Joines, R., et al. Breast Implants, Rheumatoid Arthritis, and Connective Tissue Diseases in a Clinical Practice. *Journal of Clinical Epidemiology* 1995; 48: 571-82.

Number of cases: 721 **Number of controls:** 3,508

Disease studied: Rheumatoid arthritis and other connective tissue disease.

Additional notes: Instead of comparing sick women to healthy women, all of the women in this study were patients in a rheumatology practice. The authors found no increased likelihood that women with rheumatoid arthritis and other connective tissue disease reported having breast implants. The women who had breast implants were significantly younger than those who did not have implants. The authors acknowledged that since the study took place in the practice of a single clinician, there is the potential for referral or selection bias. Also, many patients were seen for only a single assessment. Fewer than half were seen in that practice for more than one year. Additionally, the author acknowledged that losing women to follow up could have resulted in a selection bias. The authors relied on medical records to determine who had breast implants.

Hochberg, M.C., Perlmutter, D.L., Medsger, T.A. Jr., et al. Lack of Association Between Augmentation Mammoplasty and Systemic Sclerosis (Scleroderma). *Arthritis and Rheumatism* 1996; 39: 1125-1131.

Number of cases: 837 **Number of controls:** 2,507

Disease studied: Scleroderma.

Additional notes: The study revealed no difference in the likelihood that women with scleroderma reported having breast implants, although the authors noted that 1,000 cases and 3,000 controls would be needed in order to detect a two-fold increase in scleroderma. For women with scleroderma, information about whether they had breast implants was gathered from a self-administered questionnaire. Controls were given the identical questionnaire over the telephone. For both groups, the information was unverified.

Lacey, J.V. Jr., Laing, T.J., Gillespie, B.W., et al. Reply to Letter: Epidemiology of Scleroderma Among Women: Assessment of Risk from Exposure to Silicone and Silica. *Journal of Rheumatology* 1997; 24: 1854-1855.

Number of cases: 189 **Number of controls:** 1,043

Disease studied: Scleroderma

Additional notes: This study was briefly described in a letter in the *Journal of Rheumatology*. It was not peer-reviewed. In a telephone interview, researchers asked women diagnosed with scleroderma about their exposure to silicone (including silicone gel breast implants) and compared the likelihood with similarly aged controls. One case and 10 controls reported having silicone breast implants. There was no increased likelihood that women with scleroderma reported having breast implants.

Laing, T.J., Gillespie B.W., Lacey, J.V. Jr., et al. The Association Between Silicone Exposure and Undifferentiated Connective Tissue Disease Among Women in Michigan and Ohio. *Arthritis and Rheumatism* 1996; 39: Suppl:S150.

Number of cases: 206 **Number of controls:** 2,239

Disease studied: Undifferentiated connective tissue disease

Additional notes: This study was a non-peer-reviewed abstract from a meeting. In telephone interviews, researchers asked women with undifferentiated connective tissue disease about their silicone exposure and compared the exposure with similarly aged controls. Although there were no raw data in the abstract, the authors state that women with undifferentiated connective tissue disease were significantly more likely to report having all types of implanted devices, including breast implants. For silicone breast implants, the adjusted odds ratio was elevated, but did not achieve statistical significance (women with undifferentiated connective tissue disease were 127% more likely to report having silicone breast implants than controls). Women with undifferentiated connective tissue disease were significantly more likely to report having other types of devices containing silicone, such as, internal fixation devices, artificial joints, pacemakers, non-CNS shunts or catheters.

Strom, B.L., Reidenberg, M.M., Freundlich, B., et al. Breast Silicone Implants and Risk of Systemic Lupus Erythematosus. *Journal of Chemical Epidemiology* 1994; 47: 1211-1214.

Number of cases: 133 **Number of controls:** 100

Disease studied: Lupus

Additional notes: Only one woman in the study reported that she had breast implants. Information was gathered by telephone interview. The study did not detect an increased likelihood that women with lupus had breast implants, although the small number of cases and controls severely limited the statistical power of this study.

Teel, W.B., A Population-Based Case-Control Study of Risk Factors for Connective Tissue Diseases. (Ph.D. dissertation. Seattle: University of Washington, 1997.

Number of cases: 427 **Number of controls:** 1,577

Disease studied: All connective tissue diseases

Additional notes: Non-peer-reviewed doctoral dissertation. No information available.

Wolfe, F., Silicone Breast Implants and the Risk of Fibromyalgia and Rheumatoid Arthritis. *Arthritis and Rheumatism* 1995; 38: Suppl:S265.

Number of cases: 1,270 **Number of controls:** 1,134

Disease studied: Compared women with rheumatoid arthritis and fibromyalgia (though fibromyalgia data not included in meta-analysis) to women with osteoarthritis and healthy women.

Additional notes: Only fourteen women reported having breast implants in the study. The information on whether the women had implants was self-reported and unverified. This study was a non-peer-reviewed abstract from a meeting. It compared 533 patients with fibromyalgia and 637 with rheumatoid arthritis to a control group that included 479 women with osteoarthritis. Women with fibromyalgia or rheumatoid arthritis were no more likely to report having silicone breast implants than controls. Patients were asked to fill out questionnaires and controls (healthy women) were questioned on the telephone.