
High Visibility Studies in Environmental Cancer: Breast Implants and Cancer

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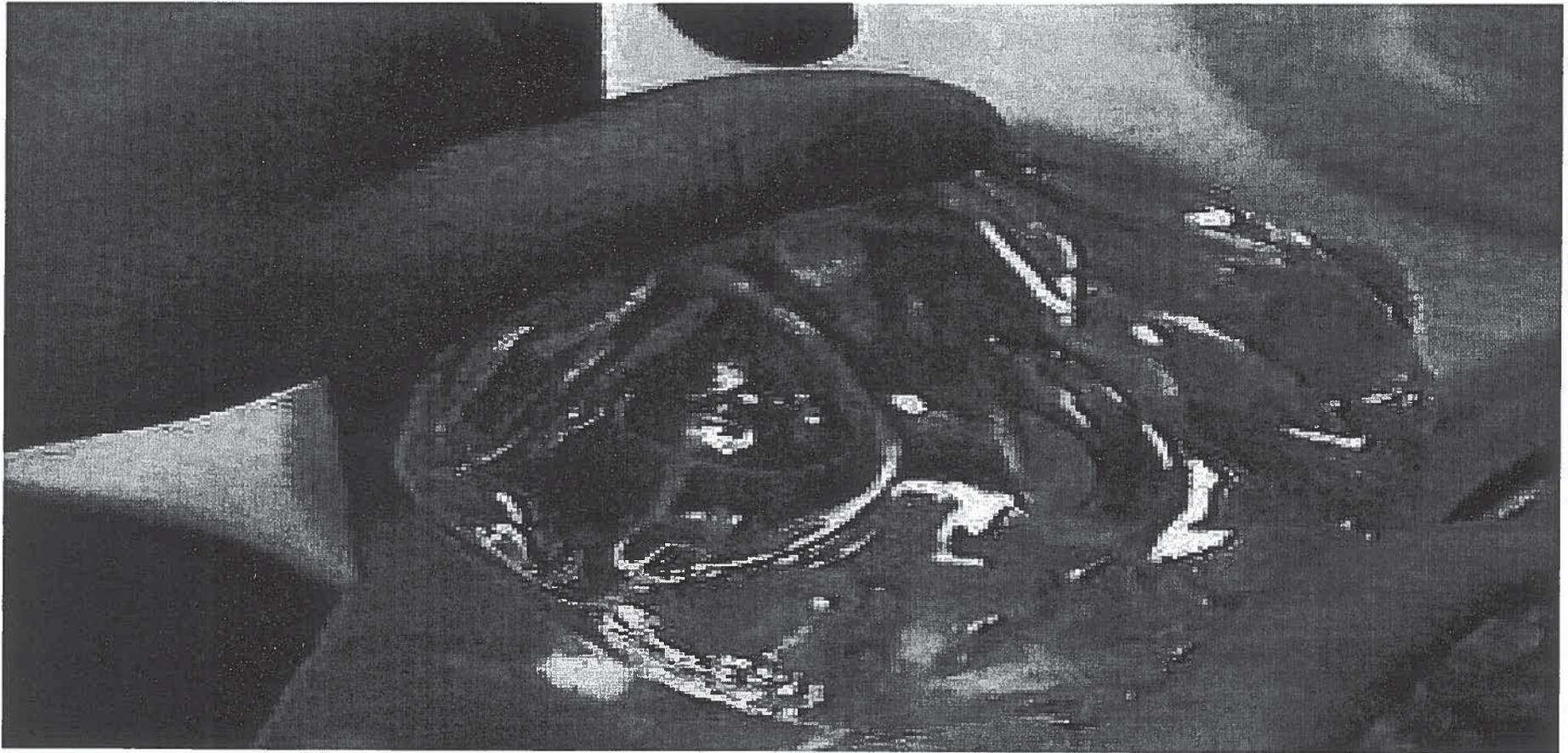
Division of Cancer Epidemiology and Genetics

National Cancer Institute

Long-Term Health Effects of Breast Implants: Rationale for Study

- **Approximately 1-2 million women have obtained breast implants**
- **Many anecdotal reports of possible disease associations**
- **Epidemiological investigations difficult to interpret given small sample sizes, limited follow-up, absence of detailed information, controversial funding sources**

Silicone Breast Implants: First Marketed in 1962



Concerns Regarding Long-Term Effects of Silicone Breast Implants

- **Breast implant leakage or rupture which could lead to immunologic or infectious consequences**
- **Toxic effects of silicone or other materials in the implants**
- **Foreign body response**
- **Interference with mammographic visualization of breast lesions**

Congressional Mandate for Study: 1992 Senate's Appropriations Committee

“The Committee is concerned with the uncertainty surrounding the potential adverse side effects associated with the use of silicone breast implants. Despite the estimated millions of women who have received implants, sufficient scientific information does not exist to allay the concerns which have been raised. The Committee encourages the Institute to develop a strategy for conducting longitudinal studies on women on the various types of silicone implants...”

Long-Term Follow-up of Breast Implant Patients: Methodology for Study

- **Retrospective cohort study**
- **Patients identified from 18 plastic surgery practices in Atlanta, Birmingham, Charlotte, Miami, Orlando, Washington DC**
- **13,488 women with bilateral augmentation mammoplasties prior to 1989 identified**
- **3,936 comparison subjects identified, comprising patients with other types of plastic surgery at same practices**

Methodology (cont.)

- **Medical records abstracted for identifiers, implant type, complications, risk factors**
- **Vital status and location information determined through multiple sources**
- **Successful tracing of 79.9% of implant and 81.7% of comparison patients**
- **Detailed questionnaires obtained from 70.7% of implant and 71.2% of comparison patients**
- **Death certificates and medical records retrieved to more precisely define endpoints**

Descriptive Information Regarding Breast Implant and Other Plastic Surgery Patients

| | Implant Patients | Comparison Patients |
|---------------------------------------|-------------------------|----------------------------|
| Mean age at study entry (yrs.) | 34.8 | 42.0 |
| Person years of follow-up | 96,675 | 26,151 |
| Mean year of study entry | 1982.9 | 1984.1 |
| Mean years of follow-up | 12.9 | 11.6 |

Breast Implant Research: Difficulties Encountered

- **Identifying plastic surgeons who would allow complete access to their records**
- **Location of a group of highly mobile patients, many of whom had multiple name and address changes**
- **Convincing study participants, advocacy groups and plaintiff lawyers of the unbiased nature of the research**
- **Confidentiality issues**
- **Freedom of Information requests**

NCI Breast Implant Study Advisory Panel

Chair: Mimi Yu, Ph.D. (Epidemiologist)

Panel Members

Bernard Chang, M.D. (Plastic surgeon)

Harold Harvey, M.D. (Oncologist)

Kim Calder, M.P.S. (Breast cancer advocate)

Lenore Everson, M.D. (Radiologist)

Jennifer Kelsey, Ph.D. (Epidemiologist)

Thomas Mustoe, M.D. (Plastic surgeon)

Paul Plotz, M.D. (Rheumatologist)

Paul Stolley, M.D. (Epidemiologist)

Diana Zuckerman, Ph.D. (Women's health advocate)

Breast Implants and Breast Cancer: Rationale for Concern

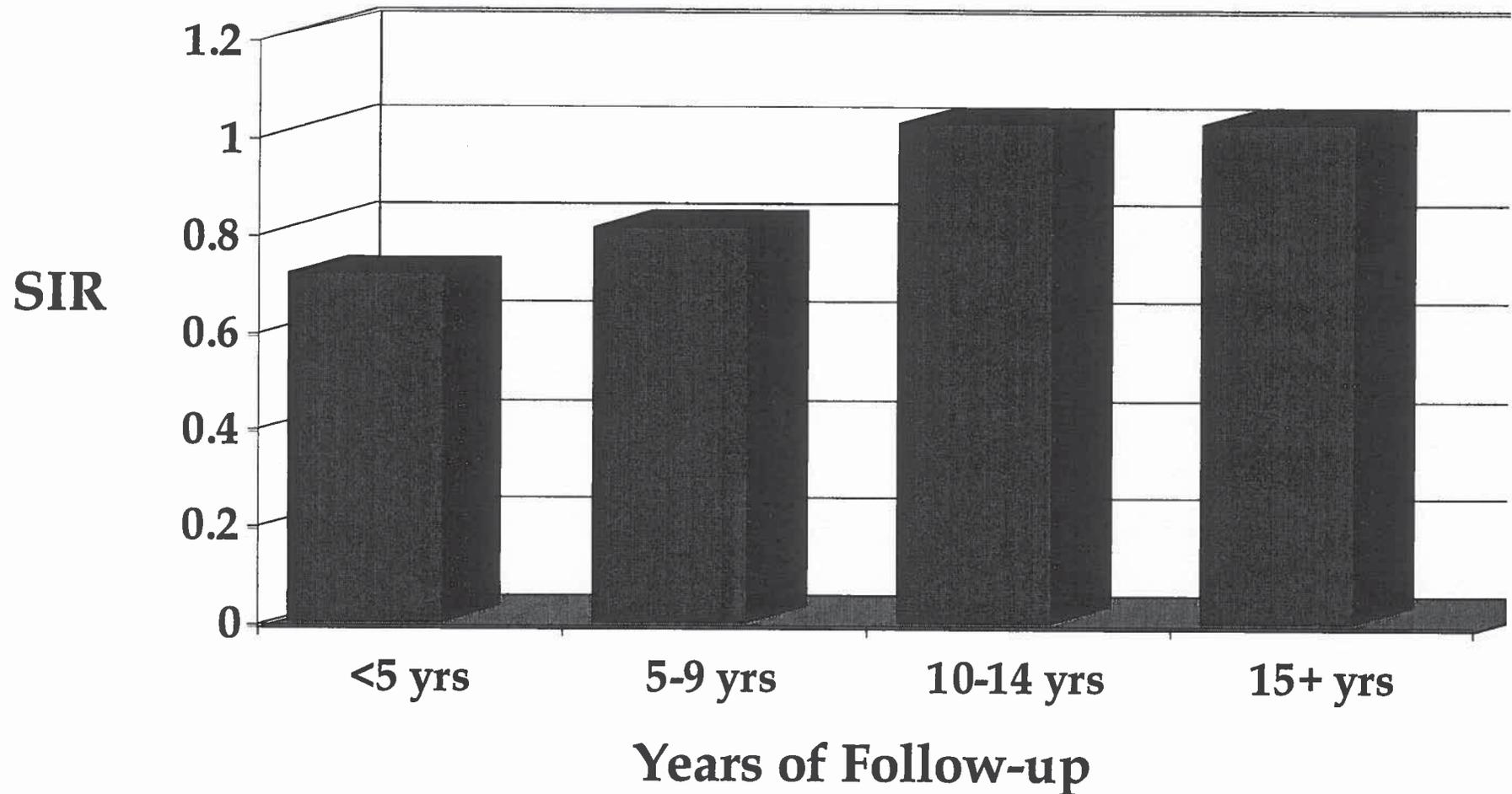
- **Interference with mammographic visualization of breast lesions**
- **Clinical reports of breast cancer among women receiving either injections of free silicone or silicone breast implants**
- **Cohort and case-control studies have generally found *reduced* breast cancer risk among women with implants, but limited information on patient characteristics**

***Brinton LA, Lubin JH, Burich MC,
Colton T, Brown SL, Hoover RN.
Breast cancer following augmentation
Mammoplasty (United States).
Cancer Causes and Control 2000;11:819.***

Invasive and *In Situ* Breast Cancers among Cohort Members

| | Implant Patients | Other Patients |
|-------------------------|-----------------------------|---------------------------|
| Observed cancers | 136 | 60 |
| Expected cancers | 152.2 | 62.7 |
| SIRs | 0.89 | 0.96 |
| 95% CI | 0.8-1.1 | 0.8-1.1 |

SIRs of Breast Cancer Risk Among Breast Implant Patients by Years of Follow-up



Additional Results

- **No substantial variation by type of implant received (49.7% of patients received silicone gel implants, SIR=0.95)**
- **Similar conclusions reached when implant patients compared to other patients and relative risks (RR) calculated**
- **RRs did not vary by levels of other risk factors (e.g., socioeconomic status, weight, breast size, reproductive behavior)**