

Silicone Breast Implants and Connective Tissue Disease

An Updated Review of the Epidemiologic Evidence

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Abstract: Numerous meta-analyses, weight-of-the-evidence, and critical reviews have summarized data from case-control and cohort studies, published through 1999, which have been conducted to evaluate the potential association between cosmetic silicone breast implants and the occurrence of well-defined connective tissue diseases, as well as a hypothesized new atypical disease, which does not fulfill established diagnostic criteria for any known connective tissue disease. These reviews have unanimously concluded that there is no evidence of an association between breast implants and any of the traditional connective tissue diseases evaluated individually or combined or atypical connective tissue disease. We have performed an updated review of the results of epidemiologic studies published since 1999. Two long-term follow-up studies of women with breast implants in Denmark and a retrospective cohort study in Australia found no excess of definite connective tissue disease, including rheumatoid arthritis, systemic sclerosis, systemic lupus erythematosus and Sjogren's syndrome, among women with cosmetic breast implants compared with breast reduction or other plastic surgery controls or women in the general population. No consistent evidence was observed of increased risk of definite connective tissue disease in women with extracapsular ruptures in 2 studies which evaluated risk by rupture status among women with cosmetic breast implants. The results of several studies provide no evidence of a higher frequency of undefined connective tissue disease among women with cosmetic breast implants or of a rheumatic symptom profile unique to these women and/or indicative of a specific atypical connective tissue disease. In conclusion, the most recent epidemiologic investigations have been remarkably consistent with earlier epidemiologic studies in finding no evidence of an excess of any individual connective tissue disease or all connective tissue diseases combined, including both established and atypical or undefined connective tissue disease, among women with cosmetic silicone

breast implants. Thus, the conclusions reached in earlier independent reviews have not changed based on data published during the subsequent years.

Key Words: breast implants, connective tissue disease

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Concern about a link between connective tissue disease (CTD) and silicone breast implants was initially raised in the 1980s and early 1990s by anecdotal case reports of symptoms and diagnoses of autoimmune disorders occurring among women with breast implants. Around the same time, the US Food and Drug Administration received a growing number of adverse event reports of problems with breast implants, including complaints of “bleeding” implants, connective tissue disorders that could produce arthritis-like pain and swelling in the joints, fibrous tissue spreading around the implants, and swelling of skin and limbs.

During the past decade, more than 20 case-control and cohort studies have been conducted in North America and Europe to evaluate the potential association between cosmetic silicone breast implants and the occurrence of CTDs. Initially, the primary concern was the occurrence of systemic sclerosis, although these epidemiologic studies have examined the occurrence of numerous CTDs, including fibromyalgia, Grave's disease, Hashimoto's thyroiditis, lupus (including discoid or localized lupus and systemic lupus erythematosus [SLE]), morphea, polymyositis or dermatomyositis, Raynaud's syndrome, rheumatoid arthritis, and Sjogren's syndrome. In addition to well-defined CTDs, an association has also been hypothesized between silicone breast implants and a new atypical disease, which does not fulfill established diagnostic criteria for any known CTD. It has been suggested that breast implant patients experience symptoms of apparent connective tissue, rheumatic, or autoimmune origin that do not fit the profile for a defined CTD, including cognitive dysfunction, severe joint and muscle pain, incapacitating fatigue, and skin abnormalities. Attempts have been made to define these syndromes, which may be referred to as “undifferentiated,” “atypical,” or “mixed”

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