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Health Characteristics of Postmenopausal Women with Breast Implants

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Abstract

Background—Implant breast augmentation has long been a subject of controversy in both the plastic surgery and mainstream media.

Methods—We evaluated characteristics of women who had breast implant surgery in the Women's Health Initiative observational study (WHI OS) between 1993 and 1998. Most women in this study cohort had breast implant surgery 20 or more years prior to recruitment into the WHI OS. The women who were in the WHI OS who had not undergone breast implant surgery served as the comparison group. There were 86,686 women in the WHI OS who did not have breast implant surgery and an absent history of breast cancer, and 1,257 women who had breast implant surgery and no prior breast cancer.

Results—Total mortality rates were substantially lower among women with breast implant as was incidence of coronary heart disease. Women with breast implants in this study had a lower BMI throughout adult life and were more physically active than control subjects. After adjustment for these variables, differences in total mortality were no longer statistically significant. Women who had breast implants reported overall poorer quality of life and emotional well-being. Among women with breast implant surgery, 7% of deaths were due to suicide (n=3) versus 0.4% (n=20) in controls.

Conclusion—Significant differences in health characteristics and quality of life measures are seen in a cohort of women with breast implants decades following implant surgery. Further longitudinal studies need to focus on both physical and psychological health among women undergoing breast implant surgery.

Introduction

Implant breast augmentation has long been a subject of controversy. (1-7) The Food and Drug Administration (FDA) has lifted their restrictions on the use of silicone gel-filled breast implants. (8) This decision occurred, in part, after epidemiologic studies demonstrated that the link between connective tissue disorders and silicone breast implants were largely unsubstantiated. (9-13) There has been limited data available on long term health status of breast implant patients.

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We evaluated the characteristics of women who had breast implants surgery and entered the Women's Health Initiative observational study (WHI OS) between 1993 and 1998. Most women in the study cohort had breast implant surgery 20 or more years prior to recruitment into the WHI OS. The women who were in the WHI OS who had not undergone breast implant surgery served as the comparison group. We focused on several important questions. First, what are the health characteristics and health behaviors of the postmenopausal women who previously had breast implant surgery 20-25 years ago. Second, what were the subsequent morbidity and mortality outcomes between 1998 and September 2005 in these women? Third, what were the differences in self-reported psychological behaviors and characteristics between the two cohorts? The long term effects of surgery are very important since women generally have surgery at younger ages and incubation period for possible adverse outcomes could be very long.

Methods

The WHI has been described in detail. (14,15) The WHI was initiated in 1992. Postmenopausal women ranging in age from 50 to 79 were enrolled at one of 40 WHI clinical centers nationwide into either a clinical trial (WHI CT) which included about 64,500 women or an observational study (WHI OS) that included about 100,000 women. Between October 1, 1993 and December 31, 1998, 93,676 postmenopausal participants age 50-79 were enrolled in 40 centers throughout the United States in the OS. Of the 93,676 women, 83% were white, 8.2% black, 3.9% Hispanic, 2.9% Asian-Pacific Islanders, 0.5% American Indian and 1.4% of unknown ethnicity. At the initial clinic visit, baseline data were collected via self-administered questionnaires and standardized interviews, as well as objective physical measurements.

After completion of the initial survey, the OS participants were contacted on an annual basis. Specific details of illness and hospitalizations were obtained. Medical record including discharge summaries and results of relevant diagnostic and laboratory tests were collected. The diagnoses of interest included cardiovascular disease, certain cancers including breast, colon, rectum, ovary and endometrium, hip fractures, and total mortality through September, 2005.

The initial health surveys of WHI OS asked the following: "Did you ever have an operation to increase your breast size, breast augmentation or have breast reconstruction using a breast implant?" If known, the type of breast implant was also documented. We excluded all women who had prior history of breast cancer. The questionnaire also asked the age at which the women underwent breast implant surgery. The information was collected in 5-year groups so the exact implant-years could not be calculated in our cohort.

Daily activity level, health-related behaviors, and aspects of psychological attitudes and emotions were assessed at baseline. Established, well-validated surveys included the RAND SF-36. (16)

Overall quality of life and satisfaction with quality of life were each assessed by single-item questions. (14) Occurrence and perceived stressfulness of eleven stressful life events (such as the death of a spouse) were assessed using a validated construct. (17,18,19) Negative emotional expressiveness (the degree to which a woman expressed her negative emotions) was measured using a subscale of the original King and Emmons instrument (20) that has been validated for use among all race/ethnicities in the WHI. (21)

Psychological attitudes included cynical hostility (hostile cognitions/general mistrust of others) and optimism (the expectation that good things will happen in the future). Cynical hostility was assessed by the cynicism subscale of the Cook-Medley Questionnaire. (22) Optimism was assessed by the Life Orientation Test-Revised (LOT-R). (23) Sleep disturbance was assessed by the 5-item WHI-Insomnia Rating Scale (IRS). (24) Social strain, measuring negative aspects

of social relationships, was assessed using a 4-item scale. (25) Social support was assessed using the subscale of the Medical Outcomes Study. (26) General health symptoms were assessed using a 34 item-scale (used in prior studies of postmenopausal women) measuring the occurrence and severity of symptoms. (27)

Finally, depressive symptoms were assessed using the screening algorithm developed by Burnam and colleagues (28) which produces a logistic regression equation (range of 0 - 1, with scores ≥ 0.06 indicating depressive symptoms).

Baseline refers to time of recruitment to the WHI and not time of surgery.

Categorical variables were presented as n (%) and continuous variables as mean (SD). All continuous variables were examined for normality prior to the analyses. Between group comparisons were assessed by Chi square tests, analyses of variance or analyses of covariance when appropriate. All analyses were conducted using SAS 9.1.3 and $p < 0.05$ was considered as statistically significant. When indicated, multivariate analyses were performed to adjust for age, BMI, waist circumference, METs per week, or education.

Because of the very large sample size, many small differences between implant surgery patients and controls are “statistically significant” but of little or no clinical or biological significance. We have therefore focused statistical testing to preplanned hypotheses related to survivorship, CHD, breast cancer, and measures related to body composition, exercise and diet and psychological variables as BMI was a major determinant of likelihood of breast augmentation surgery due to smaller breast size.

Results

There were 86,686 women in the WHI OS who did not have breast implant surgery and an absent history of breast cancer, and 1,257 women who had breast implant surgery and no prior breast cancer. Among the 1,257 who had breast implant surgery, 67% ($n=836$) had reported silicone gel implants, 17% ($n=217$) reported saline implants, 5% ($n=60$) reported “other” implants, and 12% ($n=148$) did not know the type of implant they had received.

The relationship of age at surgery to age at screening for the WHI OS is shown in Tables 1 and 2. As previously noted, implant-years could not be calculated because data were collected in age groups, rather than by exact age. However, for most of the women, there appeared to be a 20-30 year lapse between the time of the breast implant surgery and entry into the WHI OS. The prevalence of breast implant surgery was noticeably greater in the younger age group in the WHI OS; 2.3% of women 50-59 at entry to the WHI had breast implant surgery, 1.3% of women 60-69, and 0.6% of women 70-79. The frequency of breast implant surgery was lower among blacks than the other ethnic groups (Table 2).

Rates of breast implant surgery were similar by level of education (Table 2). Breast implant surgery was directly related to income levels at time of recruitment to the WHI, 1% of those with an annual income less than \$10,000 reporting history of breast implant surgery compared to 2.7% of those reporting an annual income greater than \$150,000 (Table 2). Regional differences in breast implants were also found, with higher prevalence of breast implants in the South and the West, compared to the Northeast or Midwest: 2.0% for the South, 2.1% in the West, 0.9% in the Midwest and 0.6% in the Northeast. The breast implant cohort reported both an increased frequency of cigarette smoking, 1.3% among never smokers versus 2.1% among current smokers ($p=0.001$), and higher alcohol consumption, 1.1% <1 drink per week versus 2.1% 5-6 drinks per week ($p=0.001$).

A similar percentage of women who had breast implant surgery were currently married (60.4% versus 60.6%). A slightly higher percentage of women who had breast implant surgery, however, were divorced (22.3% versus 15.7% for those without surgery). Women with and without breast implants had similar menstrual and reproductive histories.

Women with breast implant surgery reported a higher frequency of mothers who had breast cancer (11 versus 8.6%, $p=0.005$), but not sisters or daughters who had breast cancer. They also reported a higher frequency of prior breast biopsy (33 versus 22%, $p=0.001$). Women who had breast implant surgery reported a lower frequency of hypertension, diabetes, coronary artery disease and cataracts but no differences in reported history of asthma and hyper- or hypothyroidism (Table 3). There was a significant increase in reported prevalence of lupus, 1.2% (15/1220) among women with breast implants versus 0.5% (462/85,127) in controls ($p=0.001$). The data did not indicate whether the diagnosis of lupus chronologically preceded or followed breast implant surgery. The history of lupus and rheumatoid arthritis was not confirmed in many cases by review of medical records. (29)

Mean BMI was 24.4 kg/m^2 (SD 4.3) and median of 23.6 kg/m^2 for the women who had breast implant surgery as opposed to 27.3 kg/m^2 (SD 5.9) and median of 26.1 kg/m^2 for those who did not have breast implant surgery. The likelihood of having breast implant surgery ranged from 3.1% for women with BMI less than 18.5 kg/m^2 , to 0.4% for those who were obese (BMI $>30.0 \text{ kg/m}^2$). Waist circumference (WC) was significantly smaller among women who had breast implants. (Table 2)

The documented weight histories of the cohorts with and without breast implants were used to determine the differences in weight at specific age periods. At age 18, there was a statistically significant, but relatively small, difference between women who eventually did or did not undergo breast implant surgery (Table 4). This weight differential increased as the women aged. In women who underwent breast implant surgery, the mean gap between weight at age 18 and maximum adult weight was 31 lbs, as compared to about a mean 42 lb difference between weight at age 18 to maximum adult weight for those who did not undergo breast implant surgery. The women who had breast implant surgery gained less weight between ages 18-50, or age 18 to maximum adult weight. We then excluded women with BMI $>30 \text{ kg/m}^2$ from our analyses, since this group of women were unlikely to have undergone breast implant surgery. Even when obese participants were excluded, BMI was still significantly lower for those who had breast implant surgery (23.5 kg/m^2) versus no implant surgery (24.5 kg/m^2) ($p=0.01$). This difference held true when the analysis was then restricted further to women with BMI of less than 25 kg/m^2 .

Baseline dietary data were collected using the Food Frequency Questionnaire. (Table 5) The breast implant cohort, who were in general thinner, reported a daily caloric intake of 1,497 k/cal (SD 597 k/cal) as compared to 1,564 kcal (SD 598 k/cal) as reported by the control population ($p=0.0001$). As previously noted, the implant group had a higher alcohol intake, reporting 7.1 g/day compared to the 5.6 g/day consumed by the control group ($p=0.0001$).

Women who had breast implant surgery consistently reported a higher level of daily physical activity and exercise. (Table 6) This disparity held true even when restricted the analysis to women with BMI of less than 25 kg/m^2 . The differences in physical activity, while statistically significant, were relatively small.

Quality of life, psychological well-being, and social functioning of the women were assessed. Women who had breast implants reported better scores on physical functioning and reported less role limitations related to physical health. However, women who had breast implants reported overall poorer quality of life and emotional well-being (Table 7). Note that because of the large sample size, many of the reported differences are small but statistically significant.

The overall trend, however, is for a more negative response for women who had breast implant surgery. See the Appendix Table for more detailed description of the measures in Table 7.

The breast implant group also reported poorer social functioning, and greater limitation of activities due to emotional health. Women with breast implant surgery reported a higher score on the depression screening algorithm, 0.6 versus 0.4 for the controls, $p=0.000$. A higher percentage of women also reported a score >0.06 , 15.6% versus 11% for the controls, $p=0.001$.

There were 43 deaths among women (Table 8) who had breast implant surgery and 5,525 among controls. Among women with breast implant surgery, 7% of the deaths were due to suicide ($n=3$) versus 0.4% ($n=20$) in the controls. One of 3 women with breast implant surgery and 5 of 20 women without breast implant surgery who committed suicide had a modified CES-D score >0.06 , indicative of possible depression.

Total mortality rates were substantially lower among women with breast implants (Table 9) as was the incidence of CHD. After adjustment for age, BMI, physical activity and education, these differences in total mortality were no longer statistically significant. Breast cancer incidence was lower and remained so even after adjustment for other risk factors. Incidence of diabetes mellitus was lower in women with breast implants even after adjustment for BMI, but the difference was not significant after including waist circumference into the adjusted analysis.

Discussion

The women who have undergone breast implant surgery in the WHI OS have provided a rare and perhaps unique opportunity to evaluate health, lifestyles, risk factors, and psychosocial outcomes many years after their breast implant surgery. These women are not a random sample of older women with prior breast implant surgery. They self selected for the participation in the WHI OS. Women who had breast implant surgery also self selected for the surgery and, in the case of this study, survived long enough to be eligible for enrollment in the WHI. However, the representation across the United States and long follow up provided a unique sample. Women with breast implants remained at a lower BMI throughout their adult life than the cohort without implants. Women with breast implants appeared to possess better physical health and decreased incidences of cardiovascular diseases and cancer, much of the difference owing to disparities in weight and physical activity.

The discrepancies in BMI and truncal obesity, and the ensuing physical health benefits, may or may not be entirely attributable to differences in dietary and exercise habits. It is possible that genetic attributes contribute to ability to store fat and lower BMI and a smaller amount of fat in the breast tissue that would lead to request for breast implant surgery.

Breast implant patients do not demonstrate universally healthier behaviors. They smoke and drink alcohol at a higher prevalence in our study, which is consistent with the literature. (15) The higher rate of tobacco use is likely contributory to the higher rate of lung cancer and pulmonary disease among women who have had breast implants.(30)

The psychological aspects of the WHI OS data are less auspicious in women with breast implants. Although the women with breast implants were physically healthier, they reported a higher incidence of psychosocial and emotional stressors and depression. They also reported a greater degree of limitation of activity secondary to physical health, despite reporting superior physical function compared to the cohort without implants. We have no data on emotional status prior to surgery and the women may have improved psychological profiles after surgery.

Other studies report that cosmetic surgery leads improvements in at least three areas of psychosocial functioning: body image, quality of life and depressive symptoms. (31,32) Relative

psychological frailty found in women with breast implants may have existed at the time of, and was not a result of, the breast implant surgery. A Danish study also reported a higher than expected incidence of depression and psychiatric hospitalizations in women prior to the breast implant surgery. (33) The increased risk of suicide, although slight, is consistent across several investigations. (34,35)

Women who have breast implants may be at increased risk for suicide prior to the surgery, and the performance of breast implant surgery did not eliminate this risk. We recently reported that morbidly obese women who had bariatric surgery also have a substantial increased risk of suicide many years after the bariatric surgery. (36) A Swedish study found that women with breast implants were significantly more likely to report a variety of health and mood related complaints than the breast reduction cohort. (37) The breast implant group in their study also reported more depressive symptoms. The breast implant cohort in our investigation was less optimistic and less satisfied with quality of life than women without implants, suggesting that psychological differences may impact symptoms-reporting.

A Danish study noted an increase in mortality among women who had cosmetic breast implant surgery as compared to the general population, notably for nonmalignant lung disease and suicide. (38,39)

In the WHI, there was a significant decrease in breast cancer incidence for breast implants versus control women, even after the comparison was adjusted for age, BMI, education, and METs per week. The small differences in reproductive history also cannot account for the lower risk of breast cancer. Other studies have also reported lower risk of breast cancer after implant surgery. (40-43) Two studies, one from the United States and the other from Denmark, noted that there was no difference in breast cancer risk. (44,45)

A higher percentage of women with breast implants reported a diagnosis of lupus (n=15). It would be imprudent to delineate a conclusion from such a small number of cases. Inaccuracy of self-reported diagnosis of lupus is very likely. (16)

Conclusions

The women with breast implants were overall healthier, more physically fit, and less likely to be obese. They reported more social and psychological disability.

This study has limitations that may effect the results. The women self-reported breast implant surgery. It is likely that some women with breast implant surgery did not report it. However, given the large sample of non-breast implant women, 86,000, the inclusion of a small number of women misclassified as not having breast implant surgery would have a small effect on the results. We have little data on characteristics of women at the time of surgery.

A prospective study could better delineate the long-term physical, behavioral and psychosocial health outcomes. Monitoring of social and psychological well being may be very important in view of the apparent increased risk of suicide after breast implant surgery.

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Table 1

Scale & Characteristics
1. Rate Quality of Life
Question: <i>Overall, how would you rate your quality of life?(0 = worse, 10 = best)</i>
Location: WHI: Psychosocial/Behavioral (F38-Daily Life)
Origin: ?
2.Satisfied with Quality of Life
Question: <i>How satisfied are you with your current quality of life? (1 = dissatisfied, 10 = satisfied)</i>

Scale & Characteristics

WHI: Psychosocial/Behavioral (F38-Daily Life)

Origin: ?

3. Role Limitations due to Emotional Problems

Question(s): subscale from SF-36, 1-100, with higher scores indicating higher level of emotional health.

WHI: Psychosocial/Behavioral (F38-Daily Life) - EMOLIMIT

Origin: SF-36

4. Emotional Well-Being

Question(s): subscale from SF-36, 1-100, with higher scores indicating higher level of emotional health.

WHI: Psychosocial/Behavioral (F38-Daily Life) – Var 196, EMOWELL

Origin: SF-36

5. Energy/Fatigue

Question(s): subscale of SF-36, 1-100, with higher scores indicating a more favorable health state.

WHI: Psychosocial/Behavioral (F38-Daily Life) – Var #197, ENERFAT

Origin: SF-36

6. Hostility Construct

Question(s): 13 Qs, with higher scores indicating higher levels of mistrust toward other people. Sum of 13 T/F items resulting in a possible range from 0-13 where a higher score indicates greater hostility.

WHI: Psychosocial/Behavioral (F38-Daily Life) Var # 198, HOSTIL

Origin: Cook Medley Scale, Cynicism Subscale

7. General Health Construct

Question(s): from SF-36, 0-100, with higher scores indicating a more favorable health state.

WHI: Psychosocial/Behavioral (F38-Daily Life) – Var #199, GENHLTH

Origin: SF-36

8. Life Event Construct #1 (0,1 scoring)

Question(s): construct of Y/N to 11 possible major life events (such as losing a spouse), range 0-11, higher score indicating greater number of life events.

WHI: Psychosocial/Behavioral (F38-Daily Life) – Var #200, LFEVENT1

Origin: WHI BAC: Alameda County Study and BHAT.

9. Life Event Construct #2 (0,3 scoring)

Question(s): same as above but 0-3 scoring incorporates how much the event affected the individual. Range 0-33, with a higher score indicating a greater number of life events. (takes into account perceived stressfulness of each event).

WHI: Psychosocial/Behavioral (F38-Daily Life) – Var # 201, LFEVENT2

Origin: WHI BAC: Alameda County Study and BHAT.

10. Negative Emotional Expressiveness (NEE)

Question(s): 4 questions on expression of negative emotions: summary score 1-5, where a higher score indicates greater expressiveness of negative emotions.

WHI: Psychosocial/Behavioral (F38-Daily Life) Var #203-NEGEMOT

Origin: King L & Emmons R, 1990

11. Optimism construct

Scale & Characteristics

Question(s): LOT-R. 6 components coded 1= strongly disagree to 5= strongly agree. Range 6-30, higher score = greater optimism, and lower score = greater pessimism.

WHI: Psychosocial/Behavioral (F38-Daily Life) = Var #204, OPTIMISM

Origin: LOT-R. Scheier & Carver, 1994.

12. Pain Construct

Question(s): 2 Questions from quality of life, pain subscale from SF-36, Range 0-100, with higher scores indicating favorable health state (less pain).

WHI: Psychosocial/Behavioral (F38-Daily Life) - #205, PAIN

Origin: SF-36

13. Role Limitations Due to Physical Health

Question(s): 2 Qs from SF-36 quality of life subscale. Range 0-100, with higher scores indicating favorable health state

WHI: Psychosocial/Behavioral (F38-Daily Life) – Var #206-PHYLIMIT

Origin: SF-36

14. Physical Functioning Construct

Question(s): Subscale on quality of life from SF-36. Range 0-100, with higher scores indicating favorable health state

WHI: Psychosocial/Behavioral (F38-Daily Life), Var PHYSFUN.

Origin: SF-36

15. Sleep Disturbance Construct

Question(s): Summary score 4-24 where a higher score indicates greater sleep disturbance.

WHI: Psychosocial/Behavioral (F38-Daily Life) 209, SLPDSTRB.

Origin: ?

16. Social Functioning

Question(s): 2 Q's, quality of life subscale on social functioning. Range 0-100, with higher scores indicating favorable health state

WHI: Psychosocial/Behavioral (F38-Daily Life) – SOCFUNC.

Origin: SF-36

17. Social Strain Construct

Question(s): Scale measuring negative aspects of social relations. Sum of 4 components coded from 1=non to 5=all. Summary score range 4-20 where a higher score indicates more social strain.

WHI: Psychosocial/Behavioral (F38-Daily Life) – Var #211, SOCSTRN

Origin: Antonucci TA, Kahn RC, Akiyama H (1989).

18. Social Support Construct

Question(s): Medical Outcomes Study (MOS), sum of components coded from 1= none of the time to 5=all of the time. Summary score range 9-45, where a higher score indicates more social support.

WHI: Psychosocial/Behavioral (F38-Daily Life)- Var #212, SOCSUPP

Origin: Medical Outcomes Study (MOS),

19. Symptom Construct

Question(s): Average of 34 items measuring occurrence and severity of symptoms. Summary score range 0-3, where a higher score indicates a more favorable health state.

WHI: Psychosocial/Behavioral (F38-Daily Life) = Var #213, SYMPTOM

Origin: "PEPI, national, and other surveys"

Depressive symptoms (Not in Table 7, but added into the text)

Shortened CES-D/IDS screening instrument.

PSHTDEP range 0-1, higher score indicating a greater likelihood of depression. Cutoffs of 0.06 and 0.009 have been used to indicate depression (we use 0.06 in the optimism/cynical hostility paper and in the current paper on breast reconstructive surgery).

References

1. Fock KM, Feng PH. Connective tissue diseases after augmentation mammoplasty. *Arthritis. Rheum* 1994;27:1440. [PubMed: 6508866]
2. Fock KM, Feng PH, Tey BH. Autoimmune disease developing after augmentation mammoplasty: report of 3 cases. *J. Rheumatol* 1984;11:98–100. [PubMed: 6699842]
3. Van Nunen SA, Gatenby PA, Basten A. A post-mammoplasty connective tissue disease. *Arthritis. Rheum* 1982;25:694–697. [PubMed: 7092967]
4. Weiner SR, Paulus HE. Chronic arthropathy occurring after augmentation mammoplasty. *Plast. Reconstr. Surg* 1986;77:185–192. [PubMed: 3945681]
5. Spiera H. Scleroderma after silicone augmentation mammoplasty. *JAMA* 1988;260:126–238.
6. Giltay EJ, Moens HJB, Riley AH, Tan RG. Silicone breast prostheses and rheumatic symptoms: a retrospective follow-up study. *Ann. Rheum. Dis* 1994;53:194–196. [PubMed: 8154939]
7. Jacobsen PH, Holmich LR, McLaughlin JK, et al. Mortality and suicide among Danish women with cosmetic breast implants. *Arch. Intern. Med* 2004;164:2450–2455. [PubMed: 15596635]
8. FDA News Nov 17;2006 :P06–189.
9. Silverman BG, Brown SL, Bright RA, Kaczmarek RG, Arrowsmith-Lowe JB, Kessler DA. Reported complications of silicone gel breast implants: an epidemiologic review. *Ann. Intern. Med* 1996;124:744–756. [PubMed: 8633836]
10. Gabriel SE, O'Fallen WM, Kurland LT, Beard CM, Woods JE, Melton LJ. Risk of connective-tissue diseases and other disorders after breast implantation. *N. Engl. J. Med* 1994;330:1697–1702. [PubMed: 8190133]
11. Bryant H, Brasher P. Breast implant and breast cancer: reanalysis of a linkage study. *N. Engl. J. Med* 1995;332:1535–1539. [PubMed: 7739707]
12. Sanche-Guerrero J, Colditz GA, Karlson EW, Hunter DJ, Speitzer FE, Liang MH. Silicone breast implants and the risk of connective tissue diseases and symptoms. *N. Engl. J. Med* 1995;332:1666–1670. [PubMed: 7760867]
13. Brinton LA, Malone KE, Coates RJ, et al. Breast enlargement and reduction: results from a breast cancer case-control study. *Plast. Reconstr. Surg* 1996;97:269–275. [PubMed: 8559808]
14. The Women's Health Initiative Study Group. Design of the Women's Health Initiative Clinical Trial and Observational Study. *Control. Clin. Trials* 1998;19:61–109. [PubMed: 9492970]
15. Nabel EG. The Women's Health Initiative. *Science* 2006;313:1703. [PubMed: 16990517]
16. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. conceptual framework and item selection. *Med. Care* 1992;30:473–483. [PubMed: 1593914]
17. Erkman LF, Syme SL. Social networks, host resistance, and mortality: a nine-year follow-up study of Alameda County residents. *Am. J. Epidemiol* 1979;109:186–204. [PubMed: 425958]
18. Ruberman W, Weinblatt E, Goldberg JD, Chaudhary BS. Psychosocial influences on mortality after myocardial infarction. *New. Engl. J. Med* 1984;311:552–559. [PubMed: 6749228]
19. Matthews KA, Shumaker SA, Bowen DJ, et al. Women's Health Initiative. Why now? What is it? What's new? *Am. Psychol* 1997;52:101–116. [PubMed: 9104085]
20. King LA, Emmons RA. Psychological, physical, and interpersonal correlates of emotional expressiveness, conflict, and control. *Eur. J. Personality* 1995;5:131–150.
21. Michael YL, Perrin N, Bowen D, et al. Expression and ambivalence over expression of negative emotion: psychometric analysis in the Women's Health Initiative. *J. Women. Aging* 2005;17:5–18. [PubMed: 15914416]
22. Cook W, Medley D. Proposed hostility and Pharisaic-virtue scales for the MMPI. *J. Appl. Psychol* 1954;38:414–418.

23. Scheier MF, Carver CS, Bridges MW. Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem): a reevaluation of the Life Orientation Test. *J. Pers. Soc. Psychol* 1994;67:1063–1078. [PubMed: 7815302]
24. Levine DW, Kaplan RM, Kripke DF, Bowen DJ, Naughton MJ, Shumaker SA. Factor structure and measurement invariance of the Women's Health Initiative Insomnia Rating Scale. *Psychol. Assess* 2003;15:123–136. [PubMed: 12847773]
25. Rook KS. The negative side of social interaction : impact on psychological well-being. *J. Pers. Soc. Psychol* 1984;46:1097–1108. [PubMed: 6737206]
26. Sherbourne CD, Stewart AL. The MOS social support survey. *Soc. Sci. Med* 1991;32:705–714. [PubMed: 2035047]
27. Effects of estrogen or estrogen/progestin regimens on heart disease risk factors in postmenopausal women. The Postmenopausal Estrogen/Progestin Interventions (PEPI) Trial. The Writing Group for the PEPI Trial. *JAMA* 1995;273:199–208. [No authors listed]. [PubMed: 7807658]
28. Burnam MA, Wells KB, Leake B, Landsverk J. Development of a brief screening instrument for detecting depressive disorders. *Med. Care* 1988;26:775–789. [PubMed: 3398606]
29. Walitt BT, Constantinescu F, Katz JD, et al. Validation of self-report of rheumatoid arthritis and systemic lupus erythematosus: The Women's Health Initiative. *J. Rheumatol* 2008;35:811–818. [PubMed: 18398940]
30. McLaughlin JK, Lipworth L, Fryzek JP, Ye W, Tarone RE, Nyren O. Long-term cancer risk among Swedish women with cosmetic breast implants: an update of a nationwide study. *J. Natl. Cancer. Inst* 2006;98:557–560. [PubMed: 16622125]
31. Sarwer DB, Wadden TA, Whitaker LA. An investigation of changes in body image following cosmetic surgery. *Plast. Reconstr. Surg* 2002;109:363–369. [PubMed: 11786842]
32. Rankin M, Borah GL, Perry AW, Way PD. Quality-of-life outcomes after cosmetic surgery. *Plast. Reconstr. Surg* 1998;102:2139–2145. [PubMed: 9811016]
33. Kjoller K, Friism S, Mellenkjaer L, et al. Connective tissue disease and other rheumatic conditions following cosmetic breast implantation in Denmark. *Arch. Intern. Med* 2001;161:973–979. [PubMed: 11295960]
34. Sarwer DB, Nordmann JE, Herbert JD. Cosmetic breast augmentation surgery: a critical overview. *J. Womens. Health. Gend. Based. Med* 2000;9:843–856. [PubMed: 11074950]
35. McLaughlin JK, Wise TN, Lipworth L. Increased risk of suicide among patients with breast implants: do the epidemiologic data support psychiatric consultation? *Psychosomatics* 2004;45:277–280. [PubMed: 15232039]
36. Omalu BI, Cho P, Shakir AM, et al. Suicides following bariatric surgery for the treatment of obesity. *Surg. Obes. Relat. Dis* 2005;1:447–449. [PubMed: 16925267]
37. Fryzek JP, Signorello LB, Hakelius L, et al. Self-reported symptoms among cosmetic breast implant and breast reduction surgery. *Plast. Reconstr. Surg* 2001;107:206–213. [PubMed: 11176625]
38. Kjoller K, Holmich LR, Jacobsen PH, et al. Epidemiological investigation of local complications after cosmetic breast implant surgery in Denmark. *Ann. Plast. Surg* 2002;48:229–237. [PubMed: 11862025]
39. Henriksen TF, Homlich LR, Fryzek JP, et al. Incidence and severity of short-term complications after breast augmentation: results from a nationwide breast implant registry. *Ann. Plast. Surg* 2003;51:531–539. [PubMed: 14646643]
40. Deapen DM, Pike MC, Casagrande JT, Brody GS. The relationship between breast cancer and augmentation mammoplasty: an epidemiologic study. *Plast. Reconstr. Surg* 1986;77:361–368. [PubMed: 3952193]
41. Deapen DM, Bernstein L, Brody GS. Are breast implants anticarcinogenic? A 14 year follow-up of the Los Angeles Study. *Plast. Reconstr. Surg* 1997;99:1346–1353. [PubMed: 9105362]
42. Brisson J, Holowaty EJ, Villeneuve PJ, et al. Cancer incidence in a cohort of Ontario and Quebec women having bilateral breast augmentation. *Int. J. Cancer* 2006;118:2854–2862. [PubMed: 16381020]
43. Berkel H, Birdsall DC, Jenkins H. Breast augmentation: a risk factor for breast cancer? *N. Engl. J. Med* 1992;326:1649–1653. [PubMed: 1588977]

44. Brinton LA, Lubin JH, Burich MC, Colton T, Brown SL, Hoover RN. Breast cancer following augmentation mammoplasty (United States). *Cancer. Causes. Control* 2000;11:819–927. [PubMed: 11075871]
45. Friis S, McLaughlin JK, Møller H, et al. Breast implants and cancer risk in Denmark. *Int. J. Cancer* 1997;71:956–958. [PubMed: 9185696]

Table 1Breast Implant Surgery Among WHI OS^a Participants Without Breast Cancer at Baseline

	Age at Screening			Total (%)
	50-59	60-69	70-79	
Age at breast implant surgery	Number (%)	Number (%)	Number (%)	
<30	61 (84.7%)	11 (15.3%)	0 (0.0%)	72 (100%)
30-34	134 (75.3%)	39 (21.9%)	5 (2.8%)	178 (100%)
35-39	186 (70.7%)	67 (25.5%)	10 (3.8%)	263 (100%)
40-44	137 (46.3%)	139 (47.0%)	20 (6.8%)	296 (100%)
45-49	84 (38.9%)	113 (52.3%)	19 (8.8%)	216 (100%)
50-54	38 (27.7%)	72 (52.6%)	27 (19.7%)	137 (100%)
≥55	3 (3.5%)	48 (56.5%)	34 (40.0%)	85 (100%)

^aWomen's Health Initiative Observational Study

Table 2

Breast Implant Surgery and Baseline Characteristics at Time of Recruitment Among WHI OS^a Participants Without Breast Cancer at Baseline

	Number	Percent
<i>Body mass index</i>		
< 18.5	33	3.1
18.5-24.9	776	2.2
25-29.9	327	1.1
30-34.9	74	0.5
35-39.9	19	0.4
≥ 40	12	0.4
<i>Waist</i>		
> 88 cm	162	0.5
≤ 88 cm	1090	1.9
<i>Ethnicity</i>		
Native American	6	1.5
Asian	42	1.7
Black	36	0.5
Hispanic	59	1.7
White	1090	1.5
Other	20	2.0
<i>Age at Screening for WHI</i>		
50-59	646	2.3
60-69	495	1.3
70-79	116	0.6
Total	1257	1.4
<i>Region</i>		
Northeast	120	0.6
South	443	2.0
Midwest	163	0.9
West	531	2.1
<i>Education</i>		
≤High School	200	1.1
<College	533	1.7
College	152	1.5
>College	365	1.4
<i>Income</i>		
≤10K	37	1.0
10K to <20K	92	1.0

	Number	Percent
20K to <35K	210	1.1
35K to <50K	225	1.4
50K to <75K	243	1.5
75K to <100K	141	1.8
100K to <150K	142	2.5
≥150K	86	2.7
<i>Hormone Use</i>		
Never used	242	0.7
Past user	164	1.3
Current user	843	2.1
<i>Smoking Status</i>		
Never smoked	560	1.3
Past smoker	564	1.5
Current smoker	115	2.1

^aWomen's Health Initiative Observational Study

Table 3

Baseline Disease History in Percent

Breast Implant Surgery				
	No	Yes	p-value	Age adjusted p-value
Hypertension				
No	57211 (66.5%)	971 (77.9%)		
Yes	28875 (33.5%)	275 (22.1%)	<.0001	<.0001
Diabetes				
No	81725 (94.4%)	1228 (97.8%)		
Yes	4877 (5.6%)	27 (2.2%)	<.0001	<.0001
CHD ^a				
No	79780 (92.1%)	1188 (94.5%)		
Yes	6844 (7.9%)	69 (5.5%)	0.002	0.252
Arthritis				
No	44569 (51.7%)	691 (55.5%)		
Yes	41591 (48.3%)	555 (44.5%)	0.009	0.379
Rheumatoid arthritis ever				
No	80805 (94.7%)	1174 (94.6%)		
Yes	4545 (5.3%)	67 (5.4%)	0.909	0.364

^a coronary heart disease

Table 4

Breast Implant Surgery and Weight at Different Ages (Among WHI OS^a Subjects without Breast Cancer at Baseline)

	Breast Implant Surgery		p-value
	No	Yes	
	Mean (SD)	Mean (SD)	
Weight at about age 18	122 (17.7)	118 (15.3)	< .0001
Weight at about age 35	132 (20.5)	124 (14.8)	< .0001
Weight at about age 50	145 (27.5)	133 (20.8)	< .0001
Maximum adult weight	164 (35.5)	148 (25.9)	< .0001
Minimum adult weight	118 (16.9)	112 (14.3)	< .0001

^aWomen's Health Initiative Observational Study

Table 5

Breast Implant Surgery and Dietary Data (Forms 60a/60b) (Among WHI OS^a Subjects without Breast Cancer at Baseline)

	Breast Implant Surgery		p-value	Age adjusted p-value
	No	Yes		
	Mean (SD, median)	Mean (SD, median)		
Dietary Energy (kcal)	1564 (598, 1469)	1497 (597, 1392)	<.0001	<.0001
Dietary Alcohol (g)	5.6 (11.2, 1.0)	7.1 (11.1, 1.8)	<.0001	<.0001
Dietary total fat (g)	55.8 (30.5, 48.9)	52.3 (30.3, 45.4)	<.0001	<.0001
Dietary Fiber (g)	17.2 (7.2, 16.3)	16.8 (7.1, 15.9)	0.041	0.061
Daily Fruit Consumption (med portion)	2.1 (1.3, 2.0)	1.9 (1.3, 2.0)	0.0003	0.058
Daily Vegetable Consumption (med portion)	2.3 (1.3, 2.0)	2.3 (1.3, 2.0)	0.531	0.690
Dietary Calcium (mg)	779 (435.3, 684.1)	748 (425.3, 658.2)	0.002	0.001

^a Women's Health Initiative Observational Study

Table 6

Breast Implant Surgery and Baseline Exercise Data in Percent in Participants with Body Mass Index <25 at Baseline (Among WHI OS^a Subjects without Breast Cancer at Baseline)

	Breast Implant Surgery		p-value *	Age-adjusted p-value
	No	Yes		
	Mean (SD, median)	Mean (SD, median)		
Recreational physical activity (# episodes/week)	6.2 (4.19, 5.0)	6.7 (4.49, 6.0)	0.008	0.013
Recreational physical activity of ≥ 20 min (#episodes/week)	5.0 (4.08, 5.0)	5.7 (4.45, 5.0)	0.001	0.002
Moderate to strenuous physical activity (# episodes/week)	3.8 (3.68, 3.0)	4.5 (4.10, 4.0)	<.0001	0.001
Moderate to strenuous physical activity of ≥20 min (# episodes/week)	3.2 (3.53, 2.5)	3.9 (4.04, 3.0)	<.0001	0.0002
Minutes of recreational physical activity per week	233 (196, 195)	270 (244, 225)	0.012	0.020
Minutes of mod-strenuous physical activity per week	145 (168, 90)	186 (203, 125)	<.0001	0.003
Minutes of strenuous physical activity per week	42.6 (81.8, 0.0)	57.9 (93.7, 0.0)	<.0001	<.0001
Total METs per week	16.5 (15.4, 12.8)	20.1 (18.2, 15.8)	<.0001	0.001
METs from walking per week	6.2 (6.8, 3.8)	6.9 (7.9, 3.8)	0.329	0.422

Note: log transformed values are used in the comparison

* Wilcoxon test was used for the comparison.

^aWomen's Health Initiative Observational Study

Table 7

Quality of Life and Breast Implant Surgery (Among WHI OS^a Subjects without Breast Cancer at Baseline)

	No Breast Implant Surgery				Breast Implant Surgery				Age-adjusted p-value
	N	Mean	SD	N	Mean	SD	p-value		
SF 36 Measures									
General Health Construct	85481	73.9	18.3	1237	75.7	19.2	0.001	0.030	
Role Limitations Due to Physical Health	85744	72.9	36.3	1247	75.7	35.7	0.008	0.667	
Role Limitations Due to Emotional Problem	85842	83.7	30.0	1244	81.2	32.8	0.003	0.002	
Physical Functioning Construct	85057	81.1	20.4	1239	85.4	19.1	<.0001	0.0003	
Social Functioning	85850	89.3	18.4	1246	87.9	19.7	0.007	0.019	
Emotional Well-being	85402	78.6	14.7	1239	77.2	15.7	0.001	0.041	
Pain Construct	86044	74.3	23.7	1249	74.5	24.1	0.796	0.606	
Energy/Fatigue	85516	63.7	19.4	1245	64.5	20.5	0.148	0.089	
Rate Quality of Life	86076	8.3	1.5	1250	8.1	1.6	<.0001	0.005	
Satisfied with Quality of Life	86090	8.1	1.9	1249	7.8	2.2	<.0001	0.002	
Life Event Construct #1 (0,1 scoring)	84852	1.7	1.4	1221	1.8	1.5	<.0001	0.019	
Life Event Construct #2 (0-3 scoring)	84852	3.3	3.2	1221	3.7	3.5	<.0001	0.001	
Negative Emotional Expressiveness (NEE)	85804	2.8	0.6	1241	2.9	0.6	0.178	0.400	
Hostility Construct	83171	3.7	2.8	1202	3.5	2.7	0.003	0.008	
Optimism Construct	84379	23.3	3.5	1223	23.5	3.7	0.007	0.018	
Sleep Disturbance Construct	84869	12.6	3.3	1242	12.7	3.3	0.607	0.487	
Social Strain Construct	84692	6.5	2.5	1228	6.9	2.6	<.0001	0.007	
Social Support Construct	84354	35.9	7.9	1232	35.3	8.3	0.007	0.0002	
20 Symptom Construct	79083	0.4	0.3	1171	0.5	0.3	0.001	0.003	

^aWomen's Health Initiative Observational Study

Table 8Cause of Death By Breast Implant Surgery (Among WHI OS^a Subjects without Breast Cancer at Baseline)

Breast Augmentation				
No			Yes	
Cause of Death		Col %		Col %
Cancer	2227	40.3	15	34.9
CHD ^b related	1181	21.4	6	14.0
Cerebrovascular	426	7.7	2	4.7
Accident, etc.	149	2.7	6	14.0
Pulmonary embolism	47	0.9	0	0.0
Other causes	1121	20.3	9	20.9
Unknown	347	6.8	5	11.6
Total	5498	100	43	100

^aWomen's Health Initiative Observational Study;^bcoronary heart disease

Table 9Outcome and Breast Implant Surgery (Among WHI OS^a Subjects without Breast Cancer at Baseline)

Breast Implant Surgery	N	Number of Deaths	Mortality Rate (Per 10,000)	Adjusted Mortality Rate (per 10,000)
All-Cause Mortality				
No	86686	5525	6.4	83.7
Yes	1257	43	3.42	44.3
				81.7, 89.2
				34, 101.7
				p=0.471 ^b
				p=0.637 ^c
CHD ^b Mortality				
No	86686	1181	1.4	17.9
Yes	1257	6	0.5	6.2
				16.7, 20.1
				1.9, 36.6
				p=0.401 ^a
				p=0.464 ^b
Breast Cancer Incidence				
No	86208	3524	4.1	54.5
Yes	1250	30	2.4	31.3
				52.7, 56.3
				21.9, 44.8
				54.7
				17.8, 71.8
				p=0.015 ^b
				p=0.014 ^c
CHD ^b Incidence (among those without diabetes at baseline)				
No	79364	4126	5.2	69.1
Yes	1181	26	2.2	28.6
				66.9, 71.2
				19.5, 41.9
				71.9
				46.8
				68.3, 75.7
				24.8, 90.6
				p=0.055 ^b
				p=0.074 ^c
Diabetes Incidence (among those without CHD ^b at baseline)				
No	81190	4066	5.0	66.3
Yes	1220	30	2.5	31.9
				64.3, 68.3
				22.2, 45.5
				66.4
				33.2
				62.9, 69.9
				p=0.045 ^b

Breast Implant Surgery	N	Number of Deaths	Mortality Rate (Per 10,000)	Adjusted Mortality Rate (per 10,000)
p=0.093 ^c				

^aWomen's Health Initiative Observational Study;

^bComparison adjusted for age, body mass index, education and total METs per week;

^cComparison adjusted for age, waist, education and total METs per week