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Augmentation Mammoplasty: Cohesive Silicone Gel or Saline-Filled Implants?

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ABSTRACT

The author presents his experience of the last 4 years, using saline-filled or cohesive silicone gel breast implants for augmentation. The prospective study included 62 patients seeking operation for underdevelopment or cosmetic reasons. Mean age was about 29.5 years. Fifty six patients had bilateral and 6 patients had unilateral breast augmentation. One hundred eighteen implants were inserted subglandular through a submammary incision. Size of implants ranged from 180cc to 500cc. Twenty implants were saline-filled and ninety eight were cohesive silicone gel. All implants were textured. Follow-up was for 1.5-4 years. Five patients were re-operated upon during the period of follow-up. Because of the high spontaneous deflation rate of saline-filled implants, the author confined to cohesive silicone gel implants, in cosmetic augmentation, which produced higher satisfaction among the patients; with lower incidence of complications.

INTRODUCTION

Breast augmentation is one of the most frequent interventions practiced in plastic surgery. The female breast represents femininity and gives the feminine body image.

In 1895, Czerny achieved the first breast augmentation by transplanting some lipomas under the breast. In 1899, Gersuny used paraffin injections to augment the breast **[1]**.

Cronin and Gerow introduced a new prosthesis, at the Third International Congress of Plastic Surgery in 1963, which consisted of a solid shell with a gel-filled interior. Later modifications included substituting saline for the original silicone gel and the addition of an exterior polyurethane coating. The breakdown products of the polyurethane coating were linked to sarcoma formation in rats. The Food and Drug Administration in the United States banned all polyurethane-coated implants **[2]**. There has been no scientific evidence of any cause-effect relation between silicone implants and autoimmune disease or malignant tumours **[1]**.

The main concerns raised about breast implants included carcinogenicity, autoimmune diseases, product failure and impaired mammographic evaluation.

Implants vary according to their filling of silicone, saline or others. Their lumen may be single or double. Their surface may be smooth or textured. Their profile may be high or low, round or anatomical. Their size may be fixed or expandable.

Incisions described for breast augmentation included infra-mammary, peri-areolar, axillary or peri-umbilical. The implant may be inserted subglandular or sub-muscular.

Baker's classification of capsular contracture after augmentation mammoplasty:

Class I : Breast absolutely natural; no one could tell breast was augmented.

Class II : Minimal contracture. I can tell surgery was performed, but patient has no complaint.

Class III : Moderate contracture; patient feels some firmness.

Class IV: Severe contracture; obvious just from observation.

The aim of this study was to look into the advantages and disadvantages of saline-filled implants and cohesive silicone gel implants in trying to achieve the best results for the best interest of the patients, especially after noticing the high deflation rate of saline-filled implants.

MATERIAL AND METHODS

Sixty two patients were studied: fifty six patients had bilateral breast augmentation and six patients had unilateral augmentation. One hundred eighteen implants were inserted: twenty saline-filled and

98 cohesive silicone gel. Size of breast implants inserted ranged from 180cc to 500cc. All implants were textured and inserted, through a sub-mammary incision, sub-glandular with suction drains.

Age of the patients ranged from 22 years to 45 years. Mean age was about 29.5 years. Indications for breast augmentation included underdevelopment of the breasts and involutional small breasts.

Patients for breast reconstruction after mastectomy and those who had Becker's expanders inserted for expansion were excluded from the study. Follow-up was done for 1.5-4 years. The prospective study took place during the period of time from the year 2000 to 2004.

RESULTS

About 94% of the patients (58 patients) were very satisfied with the results after one year from their operation. Two saline-filled implants out of the twenty used (10%) deflated. Two patients (3%) expected their breasts to be larger than the augmented size.

Three patients (30%) with saline-filled implants and thirteen patients (25%) with cohesive silicone gel implants showed Baker's class II capsular contracture after 2 years from the operation. Four patients showed moderate rippling in breast during the 3rd year after implantation (Baker's class III capsular contracture).

Five patients were re-operated upon during the period of follow-up:

- 2 patients for deflation.
- 1 patient for larger size of implants.
- 1 patient for capsular contracture.
- 1 patient with persistent pain after violent physical assault.

Fig. (1):
(A): Pre-operative, front view.
(B): Pre-operative, side view.
(C): Post-operative, front view.
(D): Post-operative, side view.

Fig. (1-A)

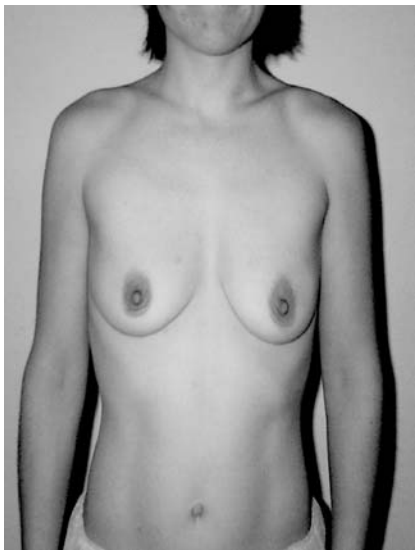

Fig. (1-B)

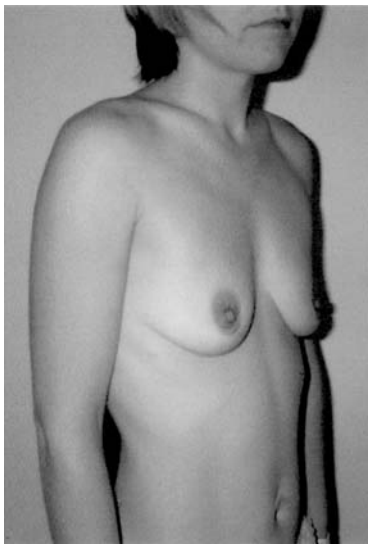

Fig. (1-C)

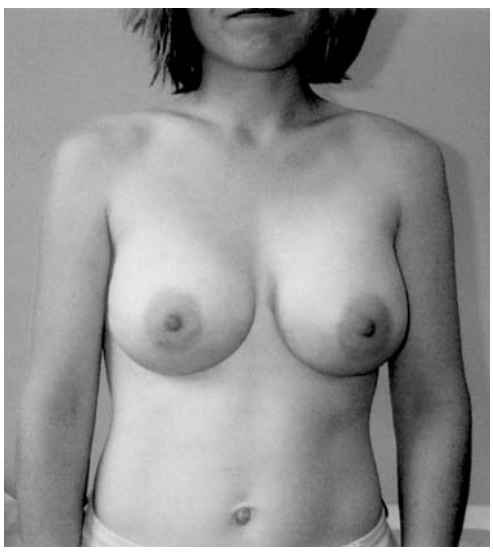

Fig. (1-D)

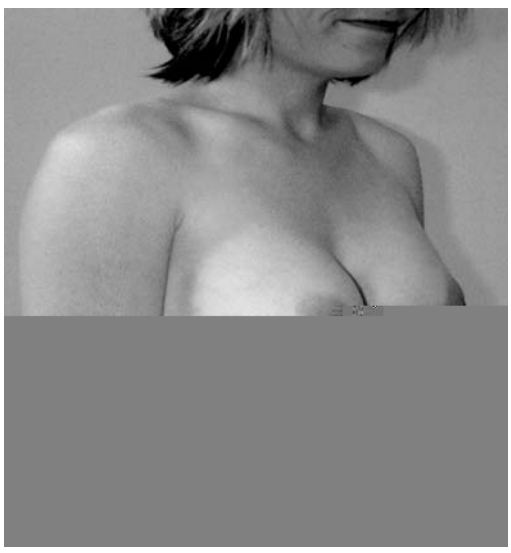

Fig. (2-A): Pre-operative, front view.

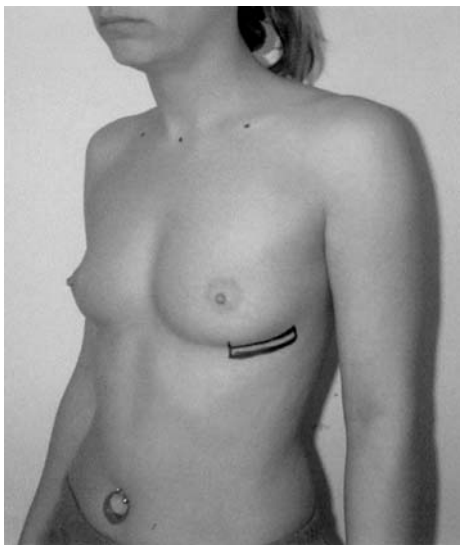

Fig. (2-B): Pre-operative, side view.

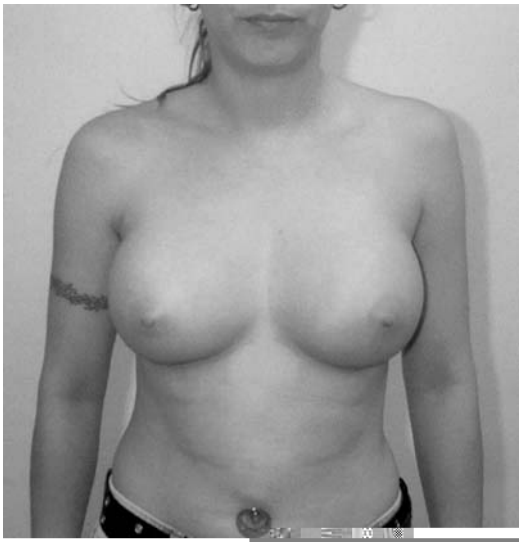

Fig. (2-C): Post-operative, front view.

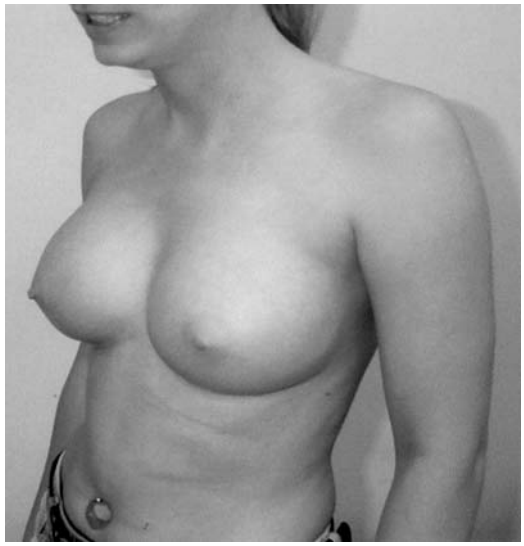

Fig. (2-D): Post-operative, side view.

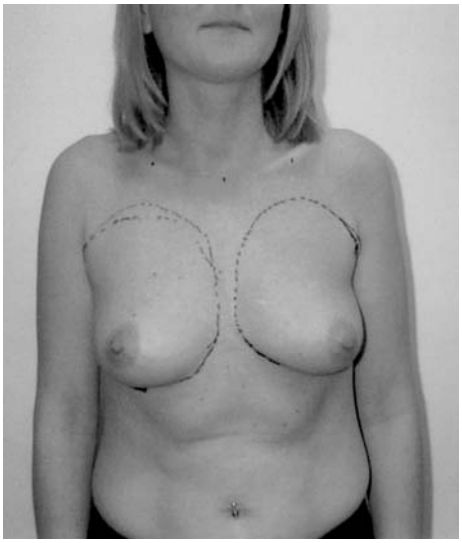

Fig. (3-A): Pre-operative, front view.

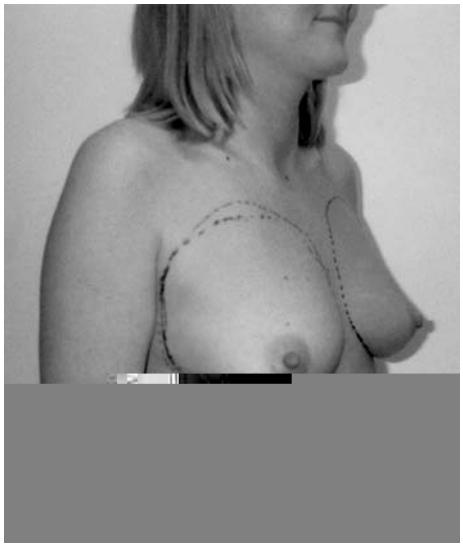

Fig. (3-B): Pre-operative, side view.

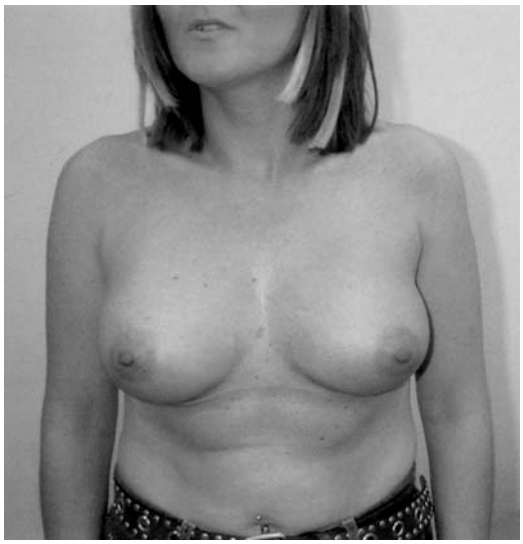

Fig. (3-C): Post-operative, front view.

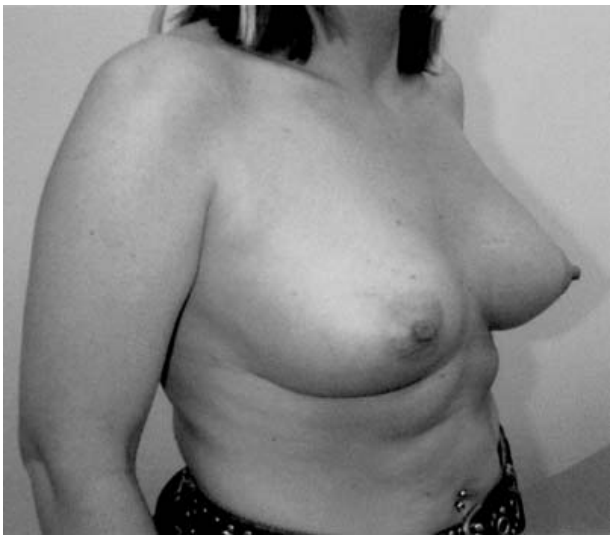

Fig. (3-D): Post-operative, side view.

DISCUSSION

Deflation rates reported for saline-filled breast implants in literature have varied widely, ranging from 2% to 76% **[3,4]**. Gutowski et al. **[5]** ran a study which represented a single manufacturing era and multiple clinical practices, and demonstrated an overall deflation rate of 5.5% with an average follow-up of 6 years.

Cunningham et al. **[6]** found in their study a deflation rate of 5.8% with a follow up of 13 years and a 10-year actuarial implant survival rate of 96.9%. They confirmed that sub-mammary or subpectoral implant position bears no impact on spontaneous implant failure. Re-operation rate was 27.8% and patient satisfaction was 93%.They observed, among 41 patients having 74 implants, an alarmingly high implant deflation rate of 35.1% of the Surgitek saline-filled implant in a single clinical practice.

It was found that the implant type was the most significant factor for predicting deflation: Surgitek implants had 17-fold greater risk of spontaneous implant deflation compared with other implant models **[7]**, Heyer-schulte and Mentor model 1800 had 3-fold higher risk of deflation; also implant size greater than 450 cc was a modest risk factor for deflation **[6]**.

Copeland et al. **[8]** performed microscopic examination of the peri-capsular tissue of 54 patients with textured-surface saline-filled implants and compared these with 51 patients with smooth-walled implants over a 2-year period. The capsules that had formed around virtually all textured-surface implants had silicone fragments present either in extracellular spaces, in vacuolated histiocytes, or in the form of foreign body granulomas in surrounding fibroadipose tissue but not in capsules associated with smooth-walled implants. In 87% of samples of peri-capsular tissue from textured saline implants, the contact surface displayed reactive synovial metaplasia.

Textured-surface implants are reputed to produce better cosmetic results and fewer complications related to capsular contracture than smooth-walled prostheses **[9-13]**. Malata et al. **[14]** reported an incidence of adverse capsular contracture, after 3 years, of 59% for smooth implants and 11% for textured ones in a randomised double blind study.

Numerous case reports have suggested a linkage between silicone gel implants and connective tissue diseases. No statistically significant elevation of risk was found **[15-17]**. The principal connective tissue disorders concerned included scleroderma, scleroderma-like disorders, rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome, dermato-myositis, polymyositis and polymyalgia rheumatica. The relative rarity of these diseases has made analysis difficult because of the small numbers of patients involved **[2]**.

Reports of the carcinogenic potential of the breakdown products of polyurethane and sarcoma formation in implanted rats have raised concerns about the incidence of carcinoma in the augmented population **[19]**. Two large epidemiological studies have examined the subsequent risk of breast cancer

following augmentation, one with 13-year and the other with 15.5-year follow-up **[20,21]**. These studies concluded that a lower incidence of breast carcinoma was found in augmented patients than in non-implanted control subjects. A possible explanation for these unexpected findings is that smaller-breasted women may be less predisposed to get breast cancer.

Slavin **[2]** reported the incidence of the common complications following augmentation mammoplasty which included: capsular contracture (8-38%), hematoma (1-6%), seroma (2.6%), infection (1-4%), hypertrophic scarring (2-5%), deflation (1-6%) and numbness (0.2%).

Conclusion:

- The controversies continue.
- Saline-filled implants had a high rate of spontaneous deflation in the author's experience.
- Cohesive silicon gel implants were found satisfactory and with less rate of complications.

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