Observations and conclusions from 20 years' experience with the single-lumen inflatable breast implant with 3500 patients

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PG Whidden. Observations and conclusions from 20 years' experience with the single-lumen inflatable breast implant with 3500 patients. Can J Plast Surg 1993;1(1):39-43. Thirty-five hundred patients underwent breast augmentation between April 1972 and April 1992; 68% were followed for a minimum of one year. The capsular contracture rate (Baker II or greater) was 8% and the product failure rate was 1%, using the Mentor/Heyer-Schulte RTV diaphragm-valve, centre-fill device. The replacement of an occasional deflated implant appears far preferable to the correction of the higher than 8% incidence of capsular contracture widely reported with the use of silicone gel-filled implants.

Key Words: Capsular contracture, Deflation, Perseverance, Placement

Observations et conclusions tirées de 20 ans d'expérience avec un implant mammaire gonflable à lumière unique chez 3 500 patients.

RÉSUMÉ: Trois mille cinq cents patientes ont subi un ajout mammaire entre avril 1972 et avril 1992. Soixante-huit pour cent ont été suivies durant au moins un an. Le taux de contractures capsulaires (Baker II ou plus) a été de 8% et le taux d'échec du produit a été de 1% avec les dispositifs à remplissage central munis de diaphragmes-valves RTV de Mentor/Heyer/Schulte. Le remplacement occasionnel d'un implant dégonflé semble de loin préférable à la correction des contractures capsulaires fréquemment rapportées (8%) lors de l'usage d'implants au silicone.

The most important objectives of aesthetic breast augmentation are to achieve:
- Enhanced breast volume (size)
- Natural breast contour (shape)
- Soft breast tissue-like texture (softness)
- Breast symmetry (symmetry)
- The least conspicuous skin scar (skin scar)

In 1967, Heyer-Schulte of California incorporated their own patented valve into the low-profile round prosthesis which became popularized by Jenny (1) who proposed an areolar margin incision. I have found that this device best achieves the above objectives.

This article presents personal observations and conclusions derived from experience based upon over 3500 patients who have undergone breast augmentation from 1972 to 1992.

The major advantages of the single-lumen inflatable prosthesis are:
- It can be placed in the submammary space with a long term risk of capsular contracture of less than 10%.
- Submuscular placement is not mandatory, especially in

The patient presenting with adequate breast mass and/or moderate ptosis, where submuscular placement is contraindicated (Figure 1).
- The devices are available pending favourable premarketing application approval by the US Food and Drug Administration and the Health Protection Branch in 1993.
- Tiny areolar or axillary incisions will accept any size of implant.
- Subtle volume adjustments can correct subtle asymmetry.
- The smooth-shelled or textured inflatable devices can be placed submammary in conjunction with a Benelli 'pursestring' mastopexy (2) for correction of moderate ptosis with sufficient breast tissue coverage.

The major disadvantages associated with this implant are:
- The 'waterbed' or 'ripple' effect which is evident in the augmented hypoplastic breast and which dictates submuscular placement wherever possible in this group.
- Breast tissue atrophy is seen in some submammary augmentations. This is possibly related to the compressive effect of the highly mobile saline, again favouring the submuscular placement where glandular cover is not generous.

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Large periprosthetic spaces may develop, submuscular or submammary, possibly relating to the pummelling effect of the nonviscous saline within the envelope over time.

Capsular contracture cannot be ignored (even Baker II), since the life expectancy of the shell of the inflatable prosthesis is severely compromised by capsular contracture and the crease-fatigue phenomenon, and will deflate (3). This fact mandates postoperative follow-up examinations for at least one year.

Implant deflation. Between 1981 and 1991, I performed 2307 breast augmentations using the Mentor/Heyer-Schulte inflatables with a minimum follow-up of one year. This group showed a capsular contracture rate of 8% and a product failure rate of 1%. More than two-thirds were submammary placements.

The incision: Access to the surgical plane of dissection and placement is gained by the areolar incision, which has the advantages of providing an inconspicuous skin scar usually, allowing better visualization of the pocket from the ‘centre’ of the breast mound in all directions, and allowing submusculofascial or submammary placement.

The axillary approach may be warranted if the areola is very pale or tiny, particularly if a submuscular placement is indicated.

METHODS

Although my current techniques have evolved from a large personal series over the past 20 years, I credit other investigators for much of the experimental work upon which my present methods are based (see acknowledgements).

Primary breast augmentation is performed under local or general anesthesia depending upon the plane of dissection and the patient’s suitability. After areolar (or axillary) incision, subcutaneous dissection is carried toward the inframammary fold and a vertical transglandular incision exposes the prepectoral fascia. A generous submammary or submuscular pocket is then developed beginning with blunt dissection and completing dissection with the coagulation current. Next 5000 U of bacitracin and 20 mL of 0.25% bupivacaine with adrenaline, 1/200,000 dilution, are instilled into each space, and the Mentor smooth-shell, Model 1600 saline implant is put in position. I do not add methylprednisolone (Solu-Medrol; Upjohn) or an antibiotic solution to the lumen of the implant. Closure is accomplished with 4-0 Dexon or Vicryl for the transglandular incision and the deep dermis and the skin edges are coapted with Proxistrips. A 100 mg indomethacin rectal suppository (Indocid; Merck Sharpe & Dohme) is then inserted (potent prostaglandin inhibitor). The patient is then fitted with a fully elasticized brassiere (Warner style number 1046) and the procedure concluded. I have found the use of drains postoperatively to be unnecessary.

Follow-up is at two days, seven days, 14 days, and then at intervals of six weeks, three months and seven months, for a total of one year (Figure 2), and then yearly thereafter. Sixty-eight per cent of patients were faithful in returning for follow-up at one year.

All patients receiving the smooth-shell prosthesis performed expansion exercises beginning on the second postoperative day (and these were carried out for 30 seconds four times a day for the first three months and then twice a day ‘forever’).
Beyond one year, patients are instructed to return for examination during pregnancy, during lactation, or if a breast mass is detected. Virtually all of the patients requiring surgical revision have elected to retain breast augmentation and to submit themselves for further maintenance care.

**RESULTS**

**Complications:** From a review of 3500 patients over 20 years, the following complications have been identified.
- Hematoma 0.5% (immediate surgical evacuation is required);
encapsulation was detected. Thirty-six per cent of bilateral submammary capsular contractures reformed unilaterally and these were treated by capsulectomy and replacement – 12% of these recurred and were treated by capsulotomy and bilateral submuscular placement. Thirteen per cent of bilateral submammary capsular contractures reformed bilaterally and these were treated after a healing interval by capsulectomy and bilateral submuscular textured inflammables.

- Unilateral capsular contracture – 6%, treated by capsulectomy and reinserction of the prosthesis at a six- to 12-month interval after detection. Fourteen per cent of unilateral submammary capsular contractures reformed and these were treated after a healing interval by capsulectomy and bilateral submuscular placement or capsulectomy and bilateral submammary replacement with textured inflatables. Three per cent of submuscular smooth-shell placements encapsulated unilaterally and 2% of submammary textured inflatables encapsulated unilaterally; both groups were treated after an additional healing interval by capsulectomy and bilateral submuscular placement of textured inflatables.

Submuscular group (less than one-third of this series):
- Bilateral capsular contractures – 1%, treated by capsulectomy and placement of submuscular textured inflatables with no recurrence of capsular contracture.
- Unilateral capsular contracture – 2%, treated by capsulectomy and submuscular replacement with a less than 1% recurrence of capsular contracture. These were treated after an additional healing interval by capsulectomy and bilateral submuscular textured inflatables.

**DISCUSSION**

In order to achieve maximal results with saline implants the following measures should be adhered to closely.

- The prosthesis must be placed in the space (submammary or submuscular) which is correct for the patient’s breast volume and degree of ptosis (Figure 4).
- Do not underfill the prosthesis; fill it to at least the product designated volume, or as much as 30 mL above.

- Do not accept capsular contracture (even Baker II), since the life expectancy of the shell of the inflatable prosthesis will be compromised.
- Do provide patients with updates regarding the breast implant controversy (7), and the American Society of Plastic and Reconstructive Surgeons position statement and recommended Patient Information Update for Informed Consent (8).
- I suggest that every surgeon who performs breast implant surgery should contact the Health Protection Branch, requesting the regulatory agency to review the premarking application submissions made in 1989 and approve the textured inflatable prosthesis for unrestricted use in Canada.

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