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

Peter G Whidden BA MD FRCSC FACS
Cosmetic Surgery Centre, Calgary, Alberta

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-shell 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.

Correspondence and reprints: Dr Peter G Whidden, 300 Scarboro Village, 1608 - 17th Avenue SW, Calgary, Alberta T2T OE3. Telephone (403) 228-2558, Fax (403) 229-3441

Figure 1) Left 21-year-old (1.7 m, 59.1 kg [5'7", 130 lb]) para 0, gravida 0, physical education student presented with bilateral tubular-breast deformity. **Right** 18 months after bilateral submammary placement of 325 (325) Mentor Style 1600 prostheses in combination with circumferential pursestring mastopexy

- 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 submusculo-fascial 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 coated 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').

Figure 2) Left 29-year-old (1.78 m, 63.7 kg [5'10", 140 lb]) para II, gravida II, presented with postlactational micromastia after breast-feeding for one year in each instance. **Right** One year after bilateral submuscular placement of 325 (350) Mentor style 1600 prostheses. Note the natural tissue drape and appropriate projection

Figure 3) Left 26-year-old (1.73 m, 66 kg [5'8", 145 lb]) para 0, gravida 0, RN presented with right implant ptosis as a result of the development of too large a subglandular space, extending caudad to the inframammary fold. **Right** One year after right capsulotomy and placement of a 250 (250) Mentor Style 1600 prosthesis. Note the corrected inframammary fold compared with the nonaugmented left breast

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 capsulotomy and bilateral submuscular textured inflatables.

- Unilateral capsular contracture – 6%, treated by capsulectomy and reinsertion 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 capsulotomy 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 capsulotomy and bilateral submuscular placement of textured inflatables.

Submuscular group (less than one-third of this series):

- Bilateral capsular contractures – 1%, treated by capsulotomy and placement of submuscular textured inflatables with no recurrence of capsular contracture.
- Unilateral capsular contracture – 2%, treated by capsulotomy and submuscular replacement with a less than 1% recurrence of capsular contracture. These were treated after an additional healing interval by capsulotomy 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 premarketing application submissions made in 1989 and approve the textured inflatable prosthesis for unrestricted use in Canada.

ACKNOWLEDGEMENTS: The author is indebted to numerous colleagues, through personal observation and/or communication, including: John Bostwick III MD, Boyd Burkhardt MD, Bob Flow-ers MD, Carl Hartrampf MD, Rod Hester MD, Pierre Langlois MD, Edward Malmed MD, Pat Maxwell MD, Jacques Papillon MD, Gerald Rheault MD, Gaston Schwarz MD, Scott L Spear MD, William A Stuart MD, Edward S Truppman MD.

REFERENCES

1. Jenny H. The areolar approach to augmentation mammoplasty. *Int J Aesth Plast Surg* 1967;5:85.
 2. Benelli L. A new periareolar mammoplasty: The "round block" technique. *Aesth Plast Surg* 1990;14:2-93.
 3. Vidal C. Intramural research data. Goleta, California: Mentor/Heyer-Schulte Corp.
 4. Biggs TM, Yarish RS. Augmentation mammoplasty: Retropectoral versus retromammary implantation. *Clin Plast Surg* 1988;15:549.
 5. Vinnik CA. Spherical contracture of fibrous capsules around breast implants. *J Plast Reconstr Surg* 1976;58:555.
 6. Vistnes LM, Ksander GA, Kosek J. Study of encapsulation of silicone rubber implants in animals: A foreign body reaction. *J Plast Reconstr Surg* 1978;62:580.
 7. Questions and answers about breast implants. Physician update on aesthetic surgery. Long Beach, California: American Society for Aesthetic Plastic Surgery Inc, Summer 1992.
 8. Position statement regarding saline-filled breast prostheses and patient information update recommended for informed consent. Arlington Heights, Illinois: American Society of Plastic and Reconstructive Surgeons, January 1993.
-