

# Indications for Extra Full Projection Anatomical Cohesive Silicone Gel Implants in Cosmetic and Reconstructive Breast Surgery

*Avelina I. Mario, MRCS, MD, Alexandra R. Molina, MRCS, MA (Cantab.),  
and Charles M. Malata, FRCS (Plast.)*

**Abstract:** In 2003, a new extra full projection (EFP) anatomic cohesive silicone gel breast implant was introduced onto the European market. This review presents the early experience of a single surgeon with this new implant over a 29-month period. Between 2003 and 2006, the McGhan Style 410 EFP breast implants were inserted for highly selected indications. Twenty-eight patients received a total of 47 EFP implants. Their age range was 23 to 66 years (mean: 46 years). The implant was used in 6 primary and 7 revisional cosmetic breast augmentation patients. The series included 9 postmastectomy breast reconstructions. In further, 6 patients the implant was used to revise existing breast reconstructions. After a mean follow-up period of 31 months, there were no infections, malrotations, or significant capsular contractures and no patients have required revisional implant surgery. The novel implant was successfully used to address specific challenges in cosmetic and reconstructive breast surgery. These included large skin envelopes in breast augmentation patients declining mastopexy, complicated implant exchanges, and suboptimal prosthetic breast reconstructions. This prosthesis may prove a useful addition to the range of breast implants available, especially when there is an overlap of challenging esthetic problems.

**Key Words:** breast reconstruction, cosmetic breast augmentation, silicone gel implants, extra full projection, breast implants, implant rupture, revision

(*Ann Plast Surg* 2008;61: 000–000)

Received for publication March 11, 2007; accepted February 19, 2008.  
From the Department of Plastic and Reconstructive Surgery, Addenbrooke's Hospital, Cambridge University Hospitals NHS Trust, Cambridge.  
Presented at the 40th Congress of the European Society for Surgical Research (ESSR), Konya, Turkey, May 2005; 10th Congress of European Societies of Plastic, Reconstructive and Aesthetic Surgery (ESPRAS), Vienna, September, 2005; and British Association of Plastic and Reconstructive Surgeons (BAPRAS), Summer Meeting, Sheffield, June 2006  
Disclaimer: The authors have no financial or other relationship to Inamed Aesthetics, the manufacturers of the implant studied. Inamed is one of many suppliers of implants used by the senior author.  
Reprints: C. M. Malata, Consultant Plastic and Reconstructive Surgeon, Addenbrooke's Hospital, Cambridge University Hospitals NHS Trust, Cambridge, CB2 2QQ. E-mail: cmalata@hotmail.com.  
Copyright © 2008 by Lippincott Williams & Wilkins  
ISSN: 0148-7043/08/6106-0001  
DOI: 10.1097/SAP.0b013e318174333e

**B**reast implants in the 21st century are technically reliable and provide a safe method for both cosmetic augmentation and postmastectomy breast reconstruction. After a period of uncertainty about their possible risks,<sup>1–4</sup> there has been a constant search for new and safer implants.<sup>5</sup> The main developments have been a renewed interest in saline-filled implants<sup>6,7</sup> and a general move from “liquid” to cohesive silicone gel breast implants.<sup>8–13</sup> In addition to assuring constancy of form,<sup>14</sup> higher cohesivity gels theoretically eliminated the risk of gel leakage in the event of rupture.<sup>15,16</sup> Since the year 2000, anatomically shaped implants have become popular<sup>17</sup> especially those composed of cohesive gel.<sup>10,12</sup>

Shape and projection are the most visible, objective parameters of an implant-augmented breast. Anatomic implants closely imitate the natural breast shape, with a low profile, superiorly, and increasing projection towards the lower pole. Ranges of differently projecting implants are available today. The implants discussed in this article address specifically the issue of projection.

Although excellent cosmetic results can be achieved with round or anatomic implants in most breast augmentation patients, frequently the surgeon is faced with patients with atrophic and ptotic breasts, with large empty skin envelopes refusing the scars, which would result from mastopexy. Another challenging group of patients are those undergoing capsulectomy many years after cosmetic augmentation, who often possess large breast pockets in the presence of ptotic breasts. Anatomic implants with extra full projection (EFP) could conceptually fulfil the esthetic needs of these patients. One of the challenges of prosthetic breast reconstruction is poor projection, especially in the nipple areolar area, often in association with excessive upper pole fullness. It is frequently difficult to achieve sufficient projection of the nipple areolar area to match the contralateral breast.<sup>18</sup> Theoretically, this deficiency could be addressed by the use of anatomic implants with increased lower pole projection.

This article reviews a single surgeon's experience with EFP anatomic cohesive silicone gel breast implants, highlighting the potential indications identified for this novel implant.

**PATIENTS AND METHODS**

All patients who received a McGhan 410 EFP cohesive gel implant (Inamed Esthetics, County Wicklow, Ireland) for either cosmetic or reconstructive breast surgery by the senior author (C.M.M.) between November 2003 and April 2006 were included in this study. All implants were placed in the subpectoral position for the primary cosmetic augmentation group and in the same pocket after capsulectomy. For breast reconstruction, the implant was sandwiched between the pectoralis major and latissimus dorsi muscles.

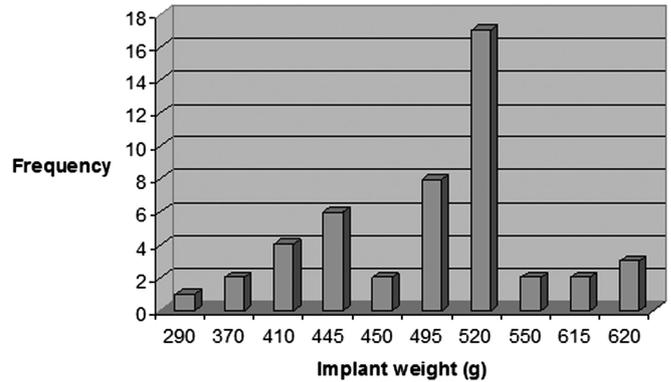
Case notes were reviewed and the patients were assessed in outpatient follow-up clinics. Preoperative and postoperative appearances were documented using standard medical photography. Four years after the first use of EFP implants, a final follow-up assessment questionnaire was sent to all patients to record their postoperative satisfaction. Parameters including shape and consistency were assessed using linear analogue scales, each with a maximum score of 10. All patients who underwent implant exchange were additionally asked to score the improvement in breast shape and overall outcome.

**RESULTS**

Over the 29-month period, 28 patients received a total of 47 EFP implants. Their age range was 23 to 66 years with a mean of 46 years. The patient clinic follow-up period averaged 31 months (range, 18–45 months). The EFP implant was used in 13 patients for cosmetic augmentation (26 breasts) and in 15 patients for postmastectomy breast reconstruction (21 breasts) (Table 1). The volumes of the implants used ranged from 370 g to 620 g, with 495 g and 520 g being the most frequently used sizes overall (Fig. 1). Most of the implants used were from the medium height category, and no low height prostheses were required (Table 2).

In the cosmetic augmentation group, 6 patients underwent primary augmentation and 7 underwent revisional implant exchange. In the primary cosmetic augmentation group, the indications for using EFP implants were a large skin envelope and patients with ptotic or atrophic breasts refusing to undergo skin reduction surgery (Fig. 2). The indications for revisional cosmetic surgery included visible wrinkling or ridging, excessive upper pole fullness, severe capsular contracture (Fig. 3), and implant rupture.

There was one immediate breast reconstruction with an EFP implant, although 8 patients underwent delayed or



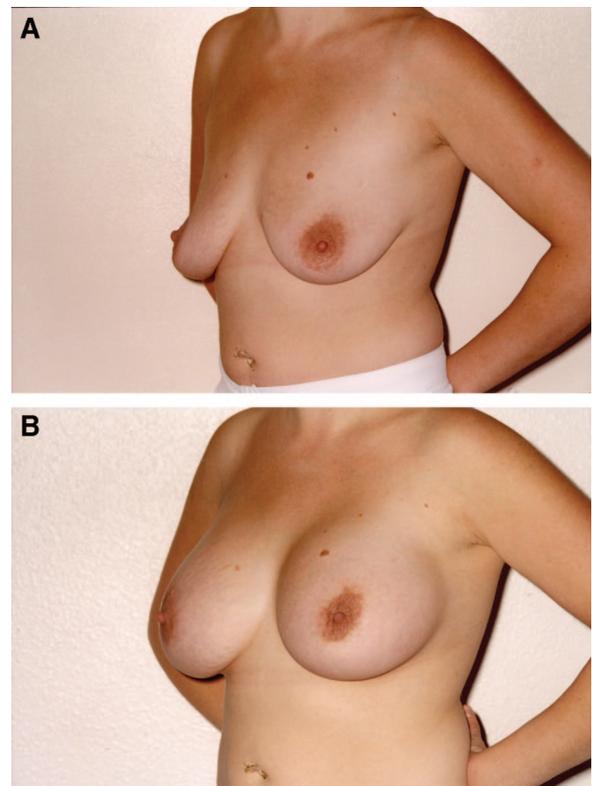
**FIGURE 1.** Frequency of EFP implant sizes used in cosmetic and reconstructive breast surgery.

**TABLE 2.** Heights of Extra Full Projection Implants Used

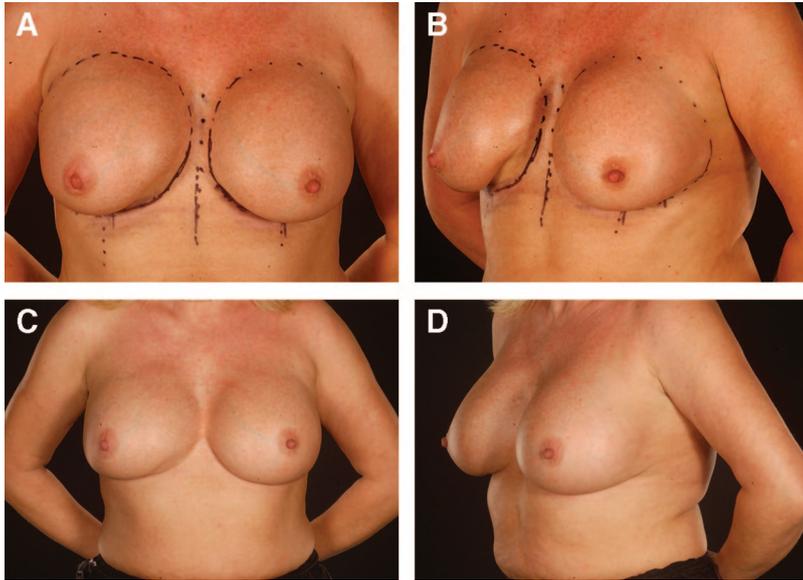
Implant Type	Frequency	Volume Range (g)
Full height (FX)	14	445–615
Medium height (MX)	33	370–620
Low height (LX)	0	N/A

**TABLE 1.** Indications for Extra Full Projection Implants

Indication	Patients	Breasts
Cosmetic augmentation	13	26
Primary surgery	6	12
Revisional surgery	7	14
Breast reconstruction	15	21
Immediate	1	1
Delayed/planned 2nd stage	8	11
Revision of existing reconstruction	6	9
Total	28	47



**FIGURE 2.** Preoperative (A, B) and postoperative (C, D) views of a 23-year-old cosmetic augmentation patient with glandular ptosis who declined mastopexy, instead opting for EFP implants (615 g FX).



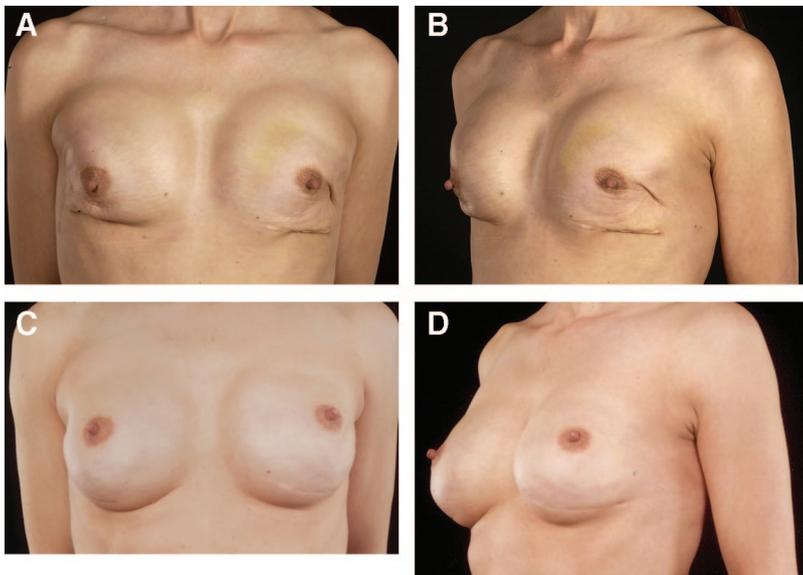
**FIGURE 3.** Preoperative (A, B) views of a 47-year-old with severe capsular contractures 25 years after breast augmentation. Appearances (C, D) after bilateral capsulectomies and implant exchange to 520 g MX implants.

planned second stage reconstructive procedures (11 breasts). Selected indications in this group included a large skin envelope and the need for projection to match the contralateral breast. Nine existing breast reconstructions in 6 patients were revised using the new implant (Table 1). The implant was used in 2 breasts within this group to augment a latissimus dorsi flap, and in 7 breasts for implant exchange. The indications for revision were suboptimal pre-existing reconstructions with significant capsular contractures (Fig. 4), poor projection of the nipple areolar area and implant displacement (Fig. 5).

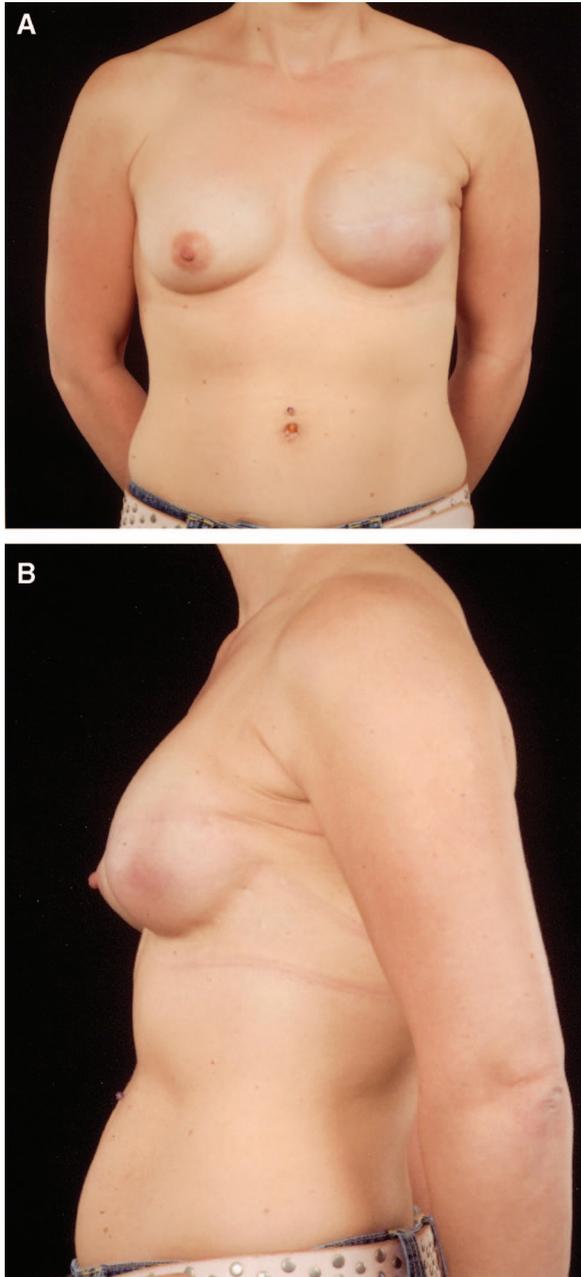
Postoperative problems (Table 3) were mainly identified in the patients undergoing revisional surgery. Two patients reported paraesthesia (affecting 3 breasts) and 1 patient complained of nipple hypersensitivity. In the revisional reconstructive group, one patient was treated empirically with

antibiotics after developing a pyrexia of unknown origin. Another complained postoperatively of tightness of the pectoralis major muscle and difficulties in shoulder abduction, which resolved with massage and anti-inflammatories. In the follow-up period there were no hematomas, infections, implant malpositions, malrotations, or significant capsular contractures (Baker grade III or IV). No patients have required revisional implant surgery to date.

The final assessment questionnaire was returned by 21 out of 28 patients (75%) after 2 mailings. Ninety percent of the respondents (19/21) were satisfied with the overall outcome (Fig. 6) of their surgery (mean satisfaction score = 8.9 of 10). Only 2 patients scored their satisfaction below 6. The first of these 2 patients deemed the initial result as excellent, but felt the reconstructed breast had reduced in size over time in relationship to the simultaneously augmented contralateral



**FIGURE 4.** This 46-year-old patient had severe grade IV contractures 20 years after bilateral subcutaneous mastectomies and implant reconstruction 20 years ago (A, B). Postoperative views (C, D) after total capsulectomies and insertion of 450 g FX implants.

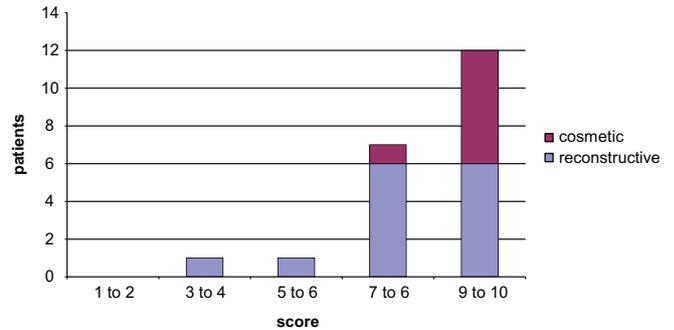


**FIGURE 5.** Preoperative (A) and postoperative (B) views of a 37-year-old patient who underwent revision of a delayed expander/implant reconstruction by exchange to a 410 g EFP implant. Note the correction of the low infra-mammary fold and improvement in lower pole projection.

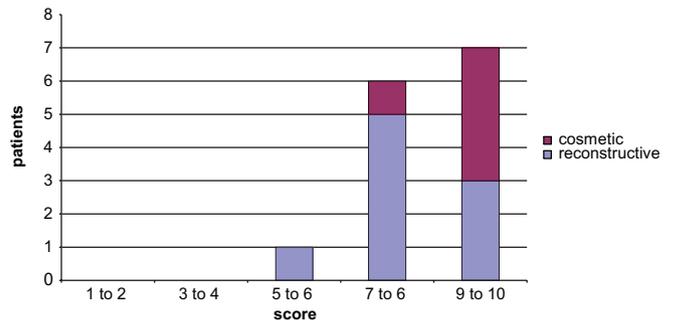
healthy breast. The second patient fell into the cosmetic primary augmentation group. She presented with postlactational atrophic breast tissue and underwent subpectoral placement of 495 g EFP implants, as per her request for maximal augmentation. Postoperatively she complained of descent of glandular tissue given her a pseudo “double-bubble” appearance. Both patients have been recalled for further consultation. In the 14 patients who underwent implant exchange to EFP prostheses, all scored their overall satisfaction with

**TABLE 3.** Complications Following Extra Full Projection Implants

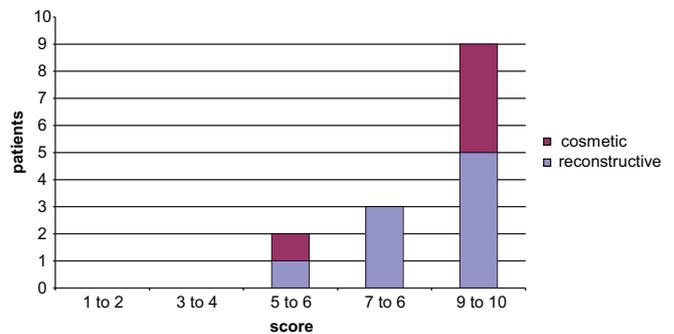
Complication	Patients	Breasts	Outcome
Nipple hypersensitivity	1	2	Not troublesome
Breast paraesthesia	2	3	Resolved in 2/3 breasts
Tightness of pectoralis muscle	1	1	Settled with massage and anti-inflammatories
Pyrexia of unknown origin	1	N/A	Resolved



**FIGURE 6.** Overall patient satisfaction with outcome of surgery.



**FIGURE 7.** Overall satisfaction with revision.



**FIGURE 8.** Satisfaction with shape after revision.

revision equal or above 6, with an average score of 8.4 (Fig. 7). Additionally, these women all rated the improvement of their breast shape as greater or equal to 6, with an average score of 8.3 (Fig. 8).

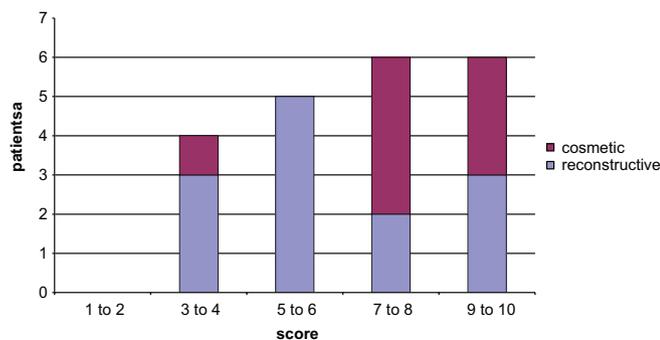


FIGURE 9. All patients consistency/softness.

In contrast to the above, the average score for breast softness/consistency was only 7 for the study group as a whole (Fig. 9). An analysis of the 7 patients, who scored their consistency below 6 revealed that all but one fell into the reconstructive group. The single cosmetic augmentation patient was the same patient mentioned above, who was dissatisfied with the overall outcome of her surgery. The 6 breast reconstruction patients not only had no breast tissue covering the implants, but had also all received adjuvant radiotherapy.

## DISCUSSION

Anatomic implants produce a natural breast shape, allowing differential projection of the nipple areolar area with respect to the upper pole. This effect can also be achieved with certain types of round implants, providing they are not overfilled: when placed beneath the pectoralis muscle these implants assume a more anatomic and natural shape. The disadvantages of anatomic implants include the possibility of malrotation,<sup>19</sup> which does not cause problems with round implants. In addition, there have been claims that although anatomic implants retain their shape in the supine patient, round implants sit back more naturally, closely imitating normal breast tissue.<sup>20,21</sup> However, we feel that anatomic implants more reliably produce a natural breast mound, and in our experience<sup>12</sup> have not been found to be associated with a greater number of complications than those reported for round prostheses.<sup>22</sup>

When a new style of implant is introduced onto the market, we do not advocate its immediate unrestricted use in preference to existing widely used prostheses. Enthusiasm for a new product should not override a surgeon's experience with familiar implants. Instead, as we have tried to emphasize in this study, it is important to identify carefully selected cases where the novel implant may fulfil a role that existing implants could not. Should early experience with these specific indications subsequently prove encouraging? One may choose to extend the use of the new prosthesis to a wider range of patients and indications. We have so far identified a number of potential niche indications, in which the new EFP implant could prove valuable.

The cosmetic breast surgeon is sometimes faced with patients, in whom even a full projection implant could not adequately fill the large skin envelope present. Such patients are often more amenable to the idea of an EFP implant than

to skin reduction surgery, usually because of the significant scars arising from mastopexy. Many women do not want to look as if they have undergone breast surgery or admit to cosmetic enhancement, but seek the benefits offered by breast augmentation. Occasionally, a patient simply has the desire to be bigger without the artificial "operated look" and the EFP implant, with its projection of up to 7.1 cm, can help in the quest for the larger but natural-looking breast.

The most common indications for revision of augmented breasts are capsular contracture and recurrent ptosis.<sup>24</sup> Long-standing cosmetic and reconstructive breast implants may develop serious complications, such as implant rupture or capsular contractures, which can only be resolved by total capsulectomies and implant exchange.<sup>4,25</sup> In this situation the surgeon is often left with a large empty pocket to fill—because of the deficit left by the explant and capsulectomy, compounded by the effects of age and gravity in this older group of patients.

In prosthetic breast reconstruction, the degree of projection of the contralateral breast must be considered when selecting the appropriate implant, as this will need to be matched to optimize esthetic outcome. After mastectomy, the inability to achieve natural-looking projection is one of the well-known shortcomings of implant reconstruction.<sup>18</sup> Many in this group of patients have ptotic or atrophic breasts, posing a further challenge to the surgeon attempting to achieve symmetry without the need for contralateral surgery. The EFP implant can help to achieve the highly desirable projection of the nipple areolar area required to match the contour of the opposite breast (Figs. 4, 5).

Many patients who receive breast implants, eventually develop breast ptosis and a descent of the inframammary fold, requiring either exchange for a larger implant, mastopexy, augmentation mastopexy, or the more recently described "power lift," ie, suturing of the posterior leaf of the capsule to the pectoralis major muscle.<sup>26</sup> The surgeon must accept that despite assisting the correction of ptosis in a previously augmented breast, the EFP implant in revisional surgery will be subject to the same the effects of gravity and, thus, result in further breast ptosis over time. By the very nature of their challenging indications, these implants are used at the larger end of the volume spectrum (in our study between 370 g and 620 g). Therefore, they may be more likely to stretch the soft tissues of the breasts in the long-term. This has, however, yet to be established as EFP implants have only been available for 5 years in Europe.

The novel EFP implant has helped to address specific challenges in cosmetic and reconstructive breast surgery. This preliminary study suggests that this implant may have a role to play in carefully selected cases, and opens a new window of opportunity to primary cosmetic augmentation patients with large skin envelopes who decline skin reduction surgery. In revisional cosmetic surgery, it may be used to salvage intractable complications in long-standing implants, notably severe capsular contractures and implant rupture. The EFP prosthesis also demonstrates its potential in selected breast reconstruction patients, by improving projection in the nipple areola region and, thus, symmetry with the contralat-

eral breast. Our early experience with this implant within these specific niche indications is encouraging.

In conclusion, extra full projection anatomic cohesive gel implants were useful in complex primary and revisional breast surgery, especially where there was overlap of different challenging esthetic problems. These prostheses were used safely without undue complications.

## REFERENCES

- Kessler DA. The basis of the FDA's decision on breast implants. *N Engl J Med*. 1992;326:1713–1715.
- Dunn K, Hall PN, Khoo C. Breast implant materials: sense and safety. *Br J Plast Surg*. 1992;45:315–321.
- Malata CM, Sharpe DT. On the safety of breast implants. *The Breast*. 1992;1:62–75.
- Spear SL, Malata CM. Silicone autoimmune disease: a systematic approach to patient management. In: Singletary SE, Robb G, eds. *Advanced Therapy of Breast Disease*. Hamilton: BC Decker Inc; 2000; 221.
- Spear SL, Mardini S. Alternative filler materials and new implant designs. *Clin Plast Surg*. 2001;28:435–443.
- Gutowski KA, Mesna GT, Cunningham BL. Saline-filled breast implants: a plastic surgery educational foundation multicenter outcomes study. *Plast Reconstr Surg*. 1997;100:1019–1027.
- Cunningham BL, Lokeh A, Gutowski KA. Saline-filled breast implant safety and efficacy: a multi-centre retrospective review. *Aesth Plast Surg*. 2000;25:440.
- Heitmann C, Schreckenberger C, Olbrisch RR. A silicone implant filled with cohesive gel: advantages and disadvantages. *Eur J Plast Surg*. 1998;21:329–332.
- Bogetti P, Boltri M, Balocco P, et al. Augmentation mammoplasty with a new cohesive gel prosthesis. *Aesth Plast Surg*. 2000;24:440–444.
- Heden P, Jernbeck J, Hober M. Breast augmentation with anatomical cohesive gel implants. *Clin Plast Surg*. 2001;28:531–532.
- Niechajev I. Mammary augmentation by cohesive silicone gel implants with anatomic shape: technical considerations. *Aesth Plast Surg*. 2001; 25:397–403.
- Fruhstofer BH, Hodgson EB, Malata CM. Early experience with an anatomical soft cohesive silicone gel prosthesis in cosmetic and reconstructive breast implant surgery. *Ann Plast Surg*. 2004;53:536–542.
- LeVier RR, Harrison MC, Cook RR, et al. What is silicone? *Plast Reconstr Surg*. 1993;92:163–167.
- Brown MH, Shenker R, Silver SA. Cohesive silicone gel breast implants in aesthetic and reconstructive breast surgery. *Plast Reconstr Surg*. 2005;116:768–779.
- Malata CM, Varma S, Scott M, et al. Silicone breast implant rupture: common/serious complication? *Med Prog Technol*. 1994;20:251–260.
- Peters W, Keystone E, Smith D. Factors affecting the rupture of silicone-gel breast implants. *Ann Plast Surg*. 1994;32:449–451.
- Hobar PC, Gutowski K. Experience with anatomic breast implants. *Clin Plast Surg*. 2001;28:553–599.
- Vasconez LO, Grotting JC, Calderon W, et al. Reconstruction of the breast: where do we fall short? An evolution of ideas. *Am J Surg*. 1984;48:103–110.
- Baekke JL. Warning about anatomical breast implants. *Plast Reconstr Surg*. 2000;106:740.
- Kisner WH. Round versus tear-drop breast prostheses: their superiority when supine. *Br J Plast Surg*. 1997;30:284–286.
- Hamas RS. The postoperative shape of round and teardrop saline-filled breast implants. *Aesthetic Surg J*. 1999;19:369–374.
- Handel N, Corday T, Gutierrez J, et al. A long-term study of outcomes, complications and patient satisfaction with breast implants. *Plast Reconstr Surg*. 2006;117:757–767.
- Sarwer DB, LaRossa D, Bartlett SP, et al. Body image concerns of breast augmentation patients. *Plast Reconstr Surg*. 2003;112:83–90. **AQ:2**
- Spear SL, Low M, Ducic I. Revision augmentation mastopexy: indications, operations and outcomes. *Ann Plast Surg*. 2003;51:540–546.
- Young VL, Brandon HJ, Watson ME. Silicone gel-filled breast implant integrity: a retrospective review of 478 consecutively explanted implants. *Plast Reconstr Surg*. 2000;105:1986–1989. **AQ:3-4**
- Rowe R, Freund. The autologous internal splint: A novel technique for the treatment of postaugmentation ptosis. *Aesthetic Surg J*. 25:587–592.

## AUTHOR QUERIES

### AUTHOR PLEASE ANSWER ALL QUERIES

1

AQ1—Kindly check whether the short title is OK as given at the top of every third page.

AQ5—Please define “FX”, “MX”, and “LX”.

AQ2—Please note that Ref. [23] is not cited anywhere in the text. Kindly insert its citation at an appropriate place or delete it from the reference list (you do not need to renumber any references).

AQ3—Please note that the text in Ref 24, “Frequency of EFP....,” was deleted because it did not appear to be part of that reference. Kindly check.

AQ4—Please note that the references 24, 25 and 26 have been renumbered as they were not in sequence.

---