ORIGINAL ARTICLES

The Pocket Protector: A New Breast Implant Device

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Introduction: *Although strides have been made to improve breast augmentation surgery, they have focused on the use of single implant devices, necessitating adjustments to the type of operation performed and implants used. And although some breast types obtain excellent results, many others are less than optimal. By developing a thin synthetic expanded polytetrafluoroethylene device, the Pocket Protector, that lines the breast pocket by integrating with the body without a capsule formation, smooth-surfaced gel (or saline) implants can remain soft and provide improved augmentation mammoplasty results. Even patients with Baker class III and IV breasts refractory to all types of revisional surgery can achieve soft, natural breasts after revision with the Pocket Protector.*

Materials and Methods: *Augmentation mammoplasty and revision mammoplasty, often with capsulectomy, with the Pocket Protector was performed on 38 patients with smooth gel or saline implants. Since the initial prototype in April 1995, data have been collected with each patient to evaluate the efficacy of this device.*

Results: *Patients involved in the current study have yielded soft, natural-feeling breasts in the normal anatomic position. Two patients who experienced a flu syndrome in the immediate postoperative period developed refractory seromas necessitating removal of the expanded polytetrafluoroethylene. Both cases have subsequently been successfully revised with Pocket Protectors and smooth-gel implants. Three patients with very thin tissues experienced rippling in spite of using smooth-gel implants.*

Discussion: *The net result yields a soft, ripple-free (or near ripple-free) breast. Additionally, gel implants inside the Pocket Protector are potentially shielded from the body, should the implants rupture. Implants are easily exchangeable if necessary without need for capsulectomy or capsulotomy. It may also represent an implant device appropriate to treat breasts refractory to traditionally attempted augmentations, such as subcutaneous mastectomy. Although the first case performed in April 1995 has remained successful, most of the experience has been gathered over the past year. This preliminary paper presents the experience with the past 38 cases.*

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Breast augmentation surgery has generally been accomplished with implants designed to approximate additional breast volume. With few exceptions, such as the polyurethane coating on the former Meme implant, most shells have been made out of silicone rubber.[1–3] The implant has generally been filled with saline or silicone gel, though a few other materials (eg, soy oil, peanut oil, "bio-oncotic" gels, hydrogel) have been tested. In recent years, studies on patients with implants have focused on the content regarding the implant's effect on the body.[4,5] In spite of the many problems associated with silicone-gel implants—their potential for rupture, granuloma formation, extracapsular spread, capsular calcification, periprosthetic infections—contemporary studies have not implicated them as a causative agent for immune conditions on their own.[6–22] And in spite of the tremendous controversy over silicone gel and the psychological and physical symptoms attributed to it, many of the real problems related to breast implants concern the external shell rather than its contents.[23] Although fewer capsular contractures are reported with saline implants and general satisfaction, increased problems of tissue rippling have been reported, as well as a significant number of deflations.[24,25] Also, saline implants, probably by virtue of the tendency to overinflate, are generally more palpable compared with normal breast tissue or silicone-gel augmented breasts. Some breasts do well with saline implants, above or below the pectoralis muscle, but a subset of breasts has unique problems. These breasts are generally fairly thin and have a potential pocket space significantly larger than the desired volume for augmentation. In such a breast, a smooth implant

might reduce rippling but would have a higher risk for encapsulation. A textured implant, even a textured gel implant, above the muscle, and even as a partial subpectoral placement, would have a high risk of rippling. As such, I suggest that this large subset of patients has 2 problems that are better treated by 2 implant devices, one to maintain pocket integrity and the other to approximate natural breast tissue.

For years, advances in breast augmentation surgery have focused on the technique, the implant, or both. Technique variations have largely dealt with the position of the incision, methods of dissection, position of the pocket, preparation of the pocket, and handling of the implant. The implant design has largely focused on shape, content, and surface but has always involved a single prosthetic device.[26–44]

One of the problems with breast augmentation surgery is that there are significantly different categories of breast types. In simple terms, breasts for augmentation can be classified as 2 primary types. Type A breasts have a relatively small potential pocket space, such that the desired implant nearly fills the potential space. Type B breasts have a large potential pocket space, such that the desired volume of increase is substantially smaller than the potential space. A type A breast might commonly be seen on a young nulliparous patient, whereas a type B breast might be found on an older woman or a multiparous patient. Additionally, each type may present with either adequate tissue cover or thin tissue cover.

Although patients with type A breasts generally do well with smooth or textured implants because the implant fills the pocket and therefore stents it open, patients with type B breasts are more problematic with the currently available implants. Textured saline or gel implants have been used fairly successfully to reduce capsule contracture.[45] However, a significant amount of rippling occurs, particularly in thinner patients. Submuscular placement may reduce rippling, but in such patients total submuscular placement results in a ''breast hanging off the muscle'' appearance, and a partial submuscular placement, as generally recommended for such cases, only partly conceals rippling. Smooth silicone-gel implants provide the softest, most natural result with minimal rippling, but they do little to keep the pocket open. Massage had been recommended, yet statistically 40–50% of such augmentations resulted in capsule contracture. Double lumen implants with steroids and pocket lavage or injection with steroids has been used as well, though not always successfully and frequently with serious complications, such as tissue atrophy leading to dehiscence.

With this in mind, and having had experience with expanded polytetrafluoroethylene (e-PTFE), it became apparent that it might be fortuitous to develop 2 implant devices to effect the desired results.[46,47] Smooth silicone gel still remains the softest, most natural-feeling breast tissue augmentation material. e-PTFE is considered one of the safest synthetic implant materials. Nonetheless, e-PTFE does not have the elastic properties of silicone rubber and would not serve well as a coating on the implant. However, e-PTFE could be designed into a bladder and serve as a liner for the potential breast pocket. By achieving tissue ingrowth into the material, the pocket is stabilized and thus remains patent. Microporous (20–100 μm in porosity) e-PTFE does not elicit concentric scar tissue formation but rather tissue ingrowth of blood vessels and connective tissue into its interstices. An optimal thickness should provide adequate ingrowth and tensile strength while being thin enough to avoid being palpable. As such, we have arrived at a material that is .35 mm thick with 40 μm in porosity. The body rapidly grows into the material, and within 3 months there is no evidence of foreign body reaction and, as such, no degradation with chemical or structural change of the material.[46–49]

By virtue of these unique properties, the Pocket Protector should provide the following benefits to augmentation mammoplasty: (1) prevent capsule contracture; (2) allow for placement of a smooth-surfaced silicone-gel implant, thus achieving optimal softness and natural feel; (3) prevent or minimize rippling; (4) provide a barrier against potential infection; (5) provide a barrier in case of possible gel rupture; (6) provide an internal brassiere to prevent sagging; (7) allow for easy exchange of implant, if necessary (eg, increase or decrease size); and (8) allow for improved results with traditionally difficult cases, such as subcutaneous mastectomy.

Materials and Methods

As of the submission of this paper, the Pocket Protector has been implanted in 38 patients. The patients represented a fairly broad base of cases, from primary augmentation to those who had multiple revisions. Data were collected for several aspects of the operation, following the patients for subsequent sequelae.

All patients were evaluated before surgery, and laboratory evaluation or medical clearance was obtained as indicated. Patients were photographed and

marked in a standing position before the operation. The mammoplasty procedure was performed via the areola or inframammary fold incision. Electrocautery was the primary tool for capsulectomy and dissection of the potential pocket, using an extended electrode with
?4 a SAF-T-VAC device. All patients received the Pocket Protector. The configuration of the material's width and porosity evolved arriving at its current form by patient 4. The very first patient received a Pocket Protector made from 1-mm soft-tissue patch material from W. L. Gore, sewn together by Surgiform Inc. Subsequent trials were performed with material manufactured by the C. R. Bard Peripheral Vascular Devices division. Patients 2 and 3 had e-PTFE material that was slightly thinner (patient 2) and slightly stiffer (patient 3). The current composition of the e-PTFE at .35 mm thick and 40 μm in porosity was established by the results of patient 4. The material is fashioned as a flat posterior sheet 18–20 cm long and 15–16 cm wide with the base slightly wider than the superior aspect. The anterior component is stretched in a dome shape and currently sewn to the posterior sheet at the Surgiform Inc lab. The volume approximates 850 mL as a medium size. A large size approximates 1200 mL.

Currently, the Pocket Protector is loaded into the Pocket Protector Placer and sterilized to facilitate placement of the device. The Pocket Protector Placer is a tube that houses the Pocket Protector. Four Keith needles attached to the 4 peripheral points of the Pocket Protector by double-strand nylon suture are correspondingly held in place on the outside of the Pocket Protector Placer device. The needles are passed through the superior, left, right, and inferior points of the breast from inside the pocket, exiting externally where the needles are removed and the suture is secured around a soft foam-rubber bolster.

It should be noted that the device has received Food and Drug Administration (FDA) clearance for the material, and, indeed, the FDA recognizes that it can be used within the breast pocket. The FDA, though it recognizes the safety of the material, does not have enough information yet to allow the manufacturer to market its efficacy.

Patients opting to receive the Pocket Protector are provided with a video presentation as well as additional written material to aid in the informed consent. The first several patients were videotaped responding to the informed consent. I no longer use this procedure.

Once the Pocket Protector is positioned and the right, left, and inferior aspects are secured, smooth silicone-rubber–surfaced prostheses—gel or saline—are inserted within the Pocket Protector. By partially filling (150–200 mL) the Pocket Protector with antibiotic fortified saline solution before implant insertion, the prosthesis inserts more easily. The superior aspect is secured on its bolster after placement of the implant to minimize the risk of tearing the material during retraction and implant placement.

The patients were subsequently monitored, and data collection continued providing individual and cumulative results.

Results

The cumulative results are as follows (total of 38 patients):

Patient characteristics

Age implanted, years

- <20 ($n = 0$)
- 20–30 ($n = 3$)
- 30–40 ($n = 7$)
- 40–50 ($n = 14$)
- 50–60 ($n = 10$)
- >60 ($n = 4$)

Preoperative status

- Primary augmentation ($n = 8$)
- Secondary augmentation ($n = 7$)
- Revision following capsulectomy ($n = 21$)

Previous implant status

- Intact ($n = 39$)
- Partial rupture ($n = 8$)
- Complete rupture ($n = 9$)
- Not applicable ($n = 20$)

Baker classification

- Class I ($n = 9$)
- Class II ($n = 0$)
- Class III ($n = 10$)
- Class IV ($n = 11$)
- N/A (primary case) ($n = 8$)

Breast type

- A ($n = 3$)
- B ($n = 35$)

Tissue thickness

- Full ($n = 6$)
- Moderate ($n = 16$)
- Thin ($n = 16$)

Breast pathologies

- Lesions removed for biopsy ($n = 1$)
- Granulomas ($n = 4$)
- Other (subsequent mastectomy) ($n = 1$)
- None ($n = 32$)

Procedure variables

Operation materials

- Pocket Protector ($n = 38$)
- Smooth gel implant ($n = 35$)
- Smooth saline ($n = 3$)

Pocket Protector size

- Medium ($n = 38$)
- Large ($n = 0$)

Implant manufacturer

Mentor ($n = 31$)
McGhan ($n = 7$)

Implant volume, milliliters

200–250 ($n = 4$)
251–300 ($n = 8$)
301–350 ($n = 20$)
351–400 ($n = 23$)
401–450 ($n = 15$)
451–500 ($n = 4$)
501–550 ($n = 1$)

Anesthesia

General ($n = 23$)
Intravenous sedation + local ($n = 15$)

Preoperative preparation

Betadine ($n = 38$)

Incision

Areolar ($n = 34$)
Inframammary ($n = 4$)

Position

Prepectoral ($n = 38$)

Pocket preparation

Betadine (with saline rinse) ($n = 38$)

Drains used

None ($n = 38$)

Pocket Protector placement

Suture secured via external stab ($n = 5$)
Suture secured over external bolster ($n = 28$)
Suture secured internally ($n = 4$)
No suture secured ($n = 1$)

Pocket Protector insertion site

Closed ($n = 4$)
Not closed ($n = 34$)

Postsurgical outcomes

Implant class

Class 1, soft ($n = 38$)
Class 2 contracture ($n = 0$)
Class 2 contracture ($n = 0$)
Class 2 contracture ($n = 0$)

Adverse effects

Hematoma ($n = 1$)
Seroma ($n = 4$)
Rippling ($n = 3$)
Infection (viral flu syndrome) ($n = 2$)
Scarring ($n = 1$)

Summary of Results

Two patients, both of whom had flu symptoms, developed severe seromas bilaterally and ultimately had the e-PTFE material removed. The first patient also had the implants removed; however, with the second patient, the implants were sterilized and left in the pocket with drains, knowing that a capsule contracture was likely to occur but that at least a mound would remain while adequate time passed and revision could be performed. All cultures were negative. All other patients tolerated the procedure well and ultimately had positive outcomes with soft, natural breasts.

Two patients experienced localized swelling 1 or 2 weeks after the procedure. Both patients reported a vigorous motion or activity followed by a noticeable pain and swelling. In the first patient, the areolar incision was opened, a small lateral pocket of blood-tinged serum was aspirated, and a clot was removed, thereby exposing a small bleeder that was simply cauterized. The patient had an uneventful recovery and was still soft and asymptomatic 10 months later. The second patient was treated by aspiration through the areola incision with a 3-mm liposuction cannula. Sixty milliliters of bloody fluid was removed without any further negative sequelae.

In spite of receiving smooth-surfaced silicone-gel implants, 3 patients with very thin skin exhibited some rippling. Still, all patients revealed soft, Baker class I breasts and, except for 1 patient who was displeased with some slight rippling, were uniformly happy with their results.

Two thirds of the patients were between 40 and 60 years of age. Most patients had revision surgery for problems with their current implants. Five of the patients had primary surgery. The majority of implants were between 300 and 450 mL in volume. All of the Pocket Protectors were medium size, averaging 850 mL in potential capacity.

The Pocket Protector was used in a variety of cases, from primary augmentation to several cases that had been treated with multiple procedures and various implants, including the newer textured implants—both saline or silicone-gel filled. Capsules that were encountered varied from very thin to thick and calcified. Previous implant status varied from intact to ruptured and confined within the capsule or spreading into adjacent tissues. Often silicone granulomas were resected outside the confines of the capsule.

Discussion

Several years ago, Bill Gore left the Dupont Corporation with an idea to make Teflon into a stretchable material. Eventually, he and his son succeeded and founded W. L. Gore and Associates. Their principal product, Gore-Tex, or e-PTFE, has 3 general product categories: industrial, clothing, and medical. After reviewing an article written by H. Bryan Neel in 1983, I contacted a representative at W. L. Gore's Medical Division in Flagstaff, Ariz.[48] In September 1983 we met at their facility, where they provided me a tour of the plant. We spent several hours discussing the material, its past and current uses and potential ideas for future use, particularly in the area of plastic surgery—a field they had yet to enter.

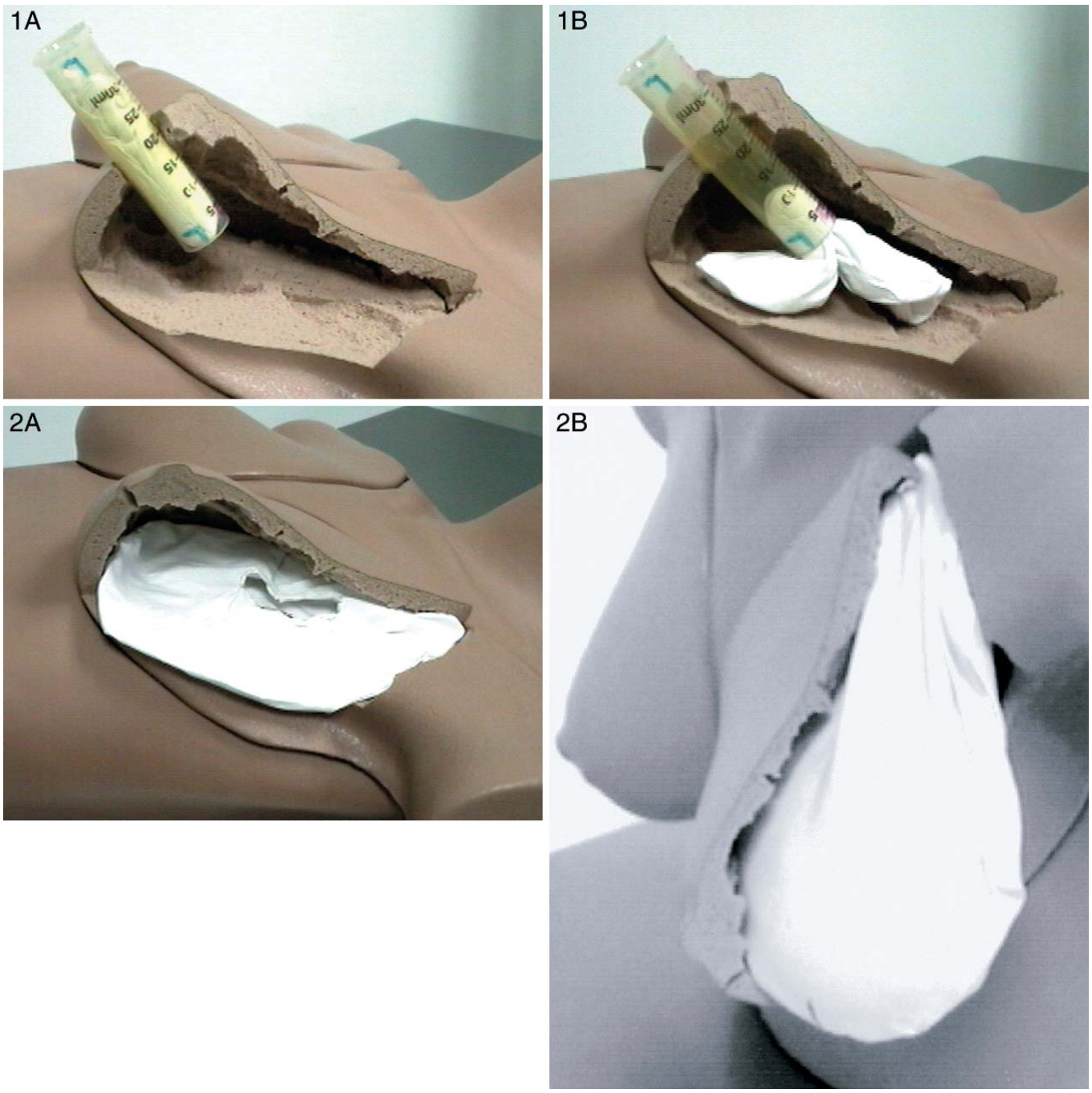
Shortly after returning to Los Angeles, I implanted Gore-Tex Soft Tissue Patch over a nasal dorsum. One week later, I implanted silicone-rubber cheek implants coated with the same material in another patient. Despite some claims by others, these were the first documented uses of e-PTFE for plastic surgical uses.[46] To date, I may still be one of the only doctors commonly using e-PTFE bonded to silicone-rubber facial implants. The FDA approved the use of Gore's e-PTFE for facial implant material in 1994.

I suggested that e-PTFE might be useful in resolving some of the existing problems with the current mammary prostheses. First, however, because I trained in otolaryngology and head and neck surgery, I sought additional training in breast surgery. In particular, I am indebted to W. Roy Morgan, MD, for the courses he organized on cosmetic breast surgery through the American Society of Cosmetic Breast Surgery. I attended additional breast courses made available through the American Academy of Cosmetic Surgery. Eventually, after adequately performing several breast augmentation procedures, I convinced McGhan Medical that e-PTFE could be a valuable tool for solving the "capsule contracture" problem plaguing the industry.

I implanted several custom-designed smooth-surface silicone-gel implants partially coated with e-PTFE. Although many of the prostheses did well (remained soft), a few developed capsule contractures. When I later had the duty to perform the capsulectomy and revision mammoplasty, I found that virtually no scar tissue over the e-PTFE area. However, the e-PTFE does not stretch as does silicone rubber; therefore, coating it onto the prosthesis defeats its purpose, essentially placing a "capsule" onto the prosthesis. I then realized that although silicone-gel implants had excellent tissue-imitating characteristics, they could not be relied upon to prevent capsular contracture. Of course, it can be argued that capsule contracture has been significantly diminished with the use of either textured surface implants or the current saline implants. Still, some patients seem to be refractory to any of these implants, or if they do well with a textured implant, it is not infrequent that rippling may occur.

e-PTFE has a long record for safety as well as excellent tissue characteristics that allow for tissue ingrowth without scar-tissue formation.[49–56] A bladder that is developed to line the potential pocket space could potentially provide patency for the pocket, and the silicone-gel implant imitates natural breast tissue without concern about capsular contraction (Figures 1 and 2). Indeed, results of testing to date validate this observation.

Although the Pocket Protector was conceived as a device to prevent capsule contracture, particularly in type B breasts, it has, so far, proved useful in all types of augmentation mammoplasty, including revision cases refractory to other treatments and simple primary augmentations in patients with type A or B breasts (Figures 3 and 4). The particular design of the Pocket Protector uniquely allows for tissue ingrowth without capsule formation. This provides an integrated synthetic barrier that maintains pocket patency by preventing concentric scar formation and preventing the newly created raw surfaces of the pocket from reattaching to



Figures 1 and 2. *Anatomic model representing the position of a prototype Pocket Protector filled with a silicone-gel implant.*

each other. Consequently, a more ideal implant can ultimately be placed within the breast pocket, ultimately achieving optimally natural appearing and feeling results. Implants can be placed in the prepectoral plane, avoiding the occasional unnatural results, distortion upon muscle contraction, or the trauma associated with elevating the muscle away from the chest wall (Figure 5).

The combination of thinness and porosity provides for an exceptionally supple material without significantly compromising the tensile strength. Thus, this allows for placement of a smooth-walled silicone-gel (or saline) implant. Such implants are considerably less likely to cause significant rippling compared with textured surface implants. Nonetheless, the modern

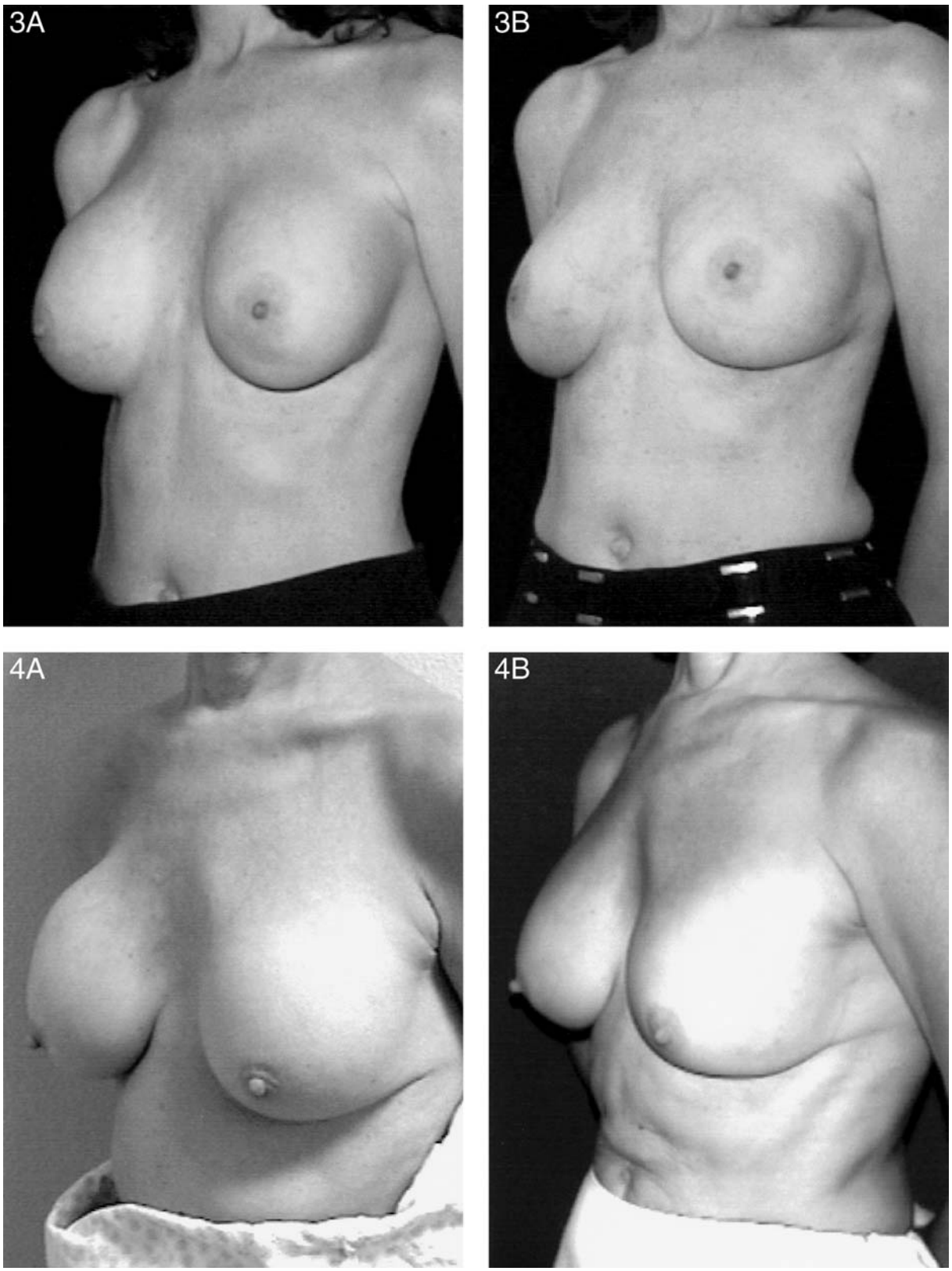
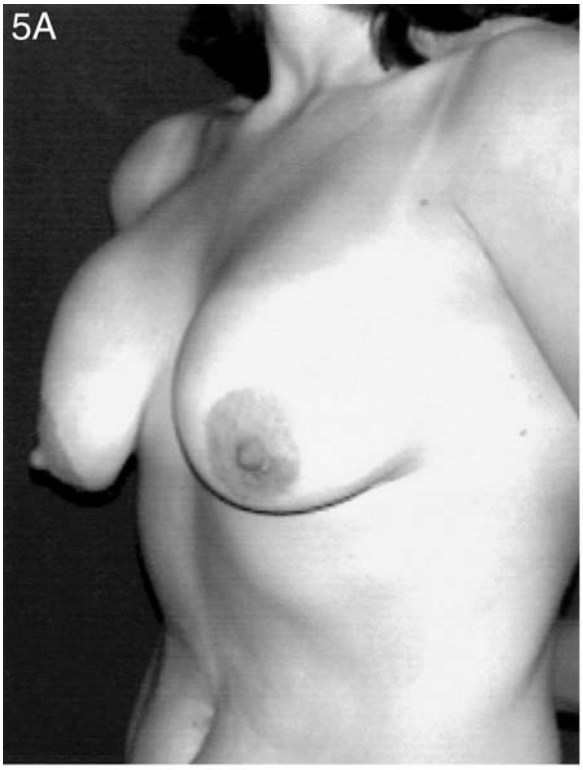


Figure 3. *(A) A 54-year-old patient after 4 previous mammoplasty procedures. She presented with Baker class IV capsule contracture and right ruptured gel implants. (B) Same patient's breasts remain soft and natural 14 months after bilateral capsulectomy, revision mammoplasty in prepectoral position with Pocket Protector, and 360-mL smooth silicone-gel implant.*

Figure 4. *(A) A 60-year-old patient after 5 previous mammoplasty procedures. Baker class IV capsule contracture and bilateral ruptured gel implants. (B) Same patient's breasts remain soft and natural 10 months after bilateral capsulectomy, revision mammoplasty in prepectoral position with Pocket Protector, and 250-mL smooth gel implants.*



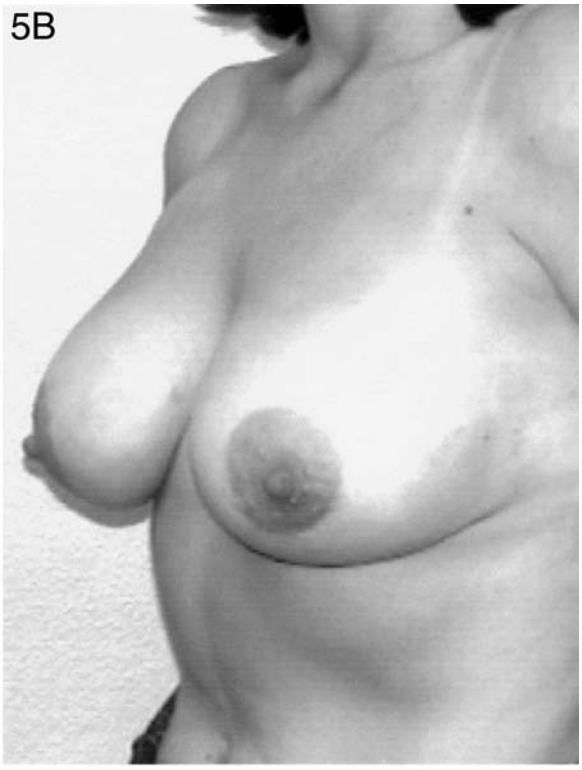


Figure 5. *(A) A 34-year-old patient with submuscular saline implants and distorted appearance (breast hanging over muscle). (B) Same patient 6 months after revision to prepectoral position with Pocket Protector.*

Figure 6. *A 56-year-old patient 8½ years after primary augmentation with Pocket Protector and 270-mL smooth gel-filled implant demonstrating softness (lack of capsule contraction).*

silicone-gel implants have a shell that is considerably thicker (though, admittedly, less permeable) than those of the past. Ultimately, a thinner shell (maintaining its integrity and decreased permeability) would provide a more ideal implant regarding palpability or rippling.

The first Pocket Protector prototype was tested in April 1995 as a primary operation on a patient with type B breasts. One-millimeter Gore-Tex Soft Tissue Patch material was sewn together as a bladder and implanted with a McGhan-style 40 270-mL smooth gel implant. The patient's breasts continue to remain natural in appearance and soft to palpation (Figure 6). After adequate time to follow-up this patient, Surgiform Inc and I applied for a patent, which was ultimately granted on November 14, 2000 (US Patent 6,146,418). Subsequently, recognizing that 1-mm Gore-Tex Soft Tissue Patch was much too thick to be useful, we spent considerable time developing the optimally structured material, eventually arriving at an e-PTFE .35 mm thick and 40 μm in porosity. This provides a material of adequate tensile strength yet minimal palpability, even under very thin skin or if folded upon itself. It also provides adequate porosity to allow for sufficient tissue adherence. These current Pocket Protector parameters have been used since September 2002 (patient 4). As previously noted, C. R. Bard Peripheral Vascular Division currently manufactures the e-PTFE to these
?5 standards.

Although there have been some problems and complications that will be discussed, none of the patients has exhibited capsule contracture.

The 2 most significant complications resulted in removal of the Pocket Protectors and, in 1 case, the mammary prostheses. Each of the patients had a flu syndrome and developed refractory seromas with negative cultures. In the first case, the patient exhibited
?6 fever (101.8), body aches, and pains the day after surgery. These adverse effects eventually abated; however, fluid continued to build up after initially appearing to resolve. The breasts were explored. It should be noted that although e-PTFE is very safe, if it becomes contaminated (bacteria, virus, or other contaminate), particularly in light of its porosity, then the material will not be accepted as an implant and cannot be cleaned and salvaged. Also, because of the hyperemia of the fresh wound (the breast pocket) and its immunocompromised state (freshly traumatized), the area is naturally more susceptible to any blood-borne contaminate during the early healing phases (first 3 months).

In the first case, the breast pocket was explored 2 weeks after surgery. Both breasts exhibited a tenacious greenish transudate that failed to grow out any bacteria, mycobacteria, or fungus. At that time the decision was made to remove all implant materials, including the silicone-gel mammary prosthesis and insert drains. The drains were subsequently removed, and the patient healed. However, pending revision, she remained quite disfigured (and unhappy with her surgeon) and relied upon an external prosthesis. Her tissues healed remarkably well, and revision surgery with a Pocket Protector and new gel implants was achieved 7 months after explantation.

In the second case, the seroma formation appeared 2 weeks after the operation but also in conjunction with significant flulike symptoms. Initially, attempts were made to salvage the implants by aspirating with a liposuction cannula via a small entry site in the areolar incision. All cultures remained negative. After several weeks of attempting conservative care, the left breast developed an infection—probably from contamination via aspiration. The decision was made to remove the e-PTFE. This time, however, the pocket was cleaned, drains were placed, and the breast implants were replaced after sterilization to maintain breast volume. Of course, this resulted in an expected bilateral capsular contracture, but at least the patient had breast mounds (and remained reasonably happy with her surgeon) and understood that revision surgery would be performed after adequate time for healing (6–12 months).

When performing a Pocket Protector revision for capsular contracture, it is generally advised to perform a total capsulectomy. This allows for fresh ''raw'' surfaces to grow into the e-PTFE. However, if the patient is particularly thin in certain areas, it is probably prudent to leave strategic sections of scar tissue attached to the underlying breast tissues so as not to thin out the tissues too much and risk damage or excessive thinning to those areas. Because the bulk of the capsule is being removed, there should be more than ample opportunity for tissue adherence. It is most important to have tissue adherence to the Pocket Protector around the perimeter, because this will ensure the prevention of the potential space from closing down upon itself and confining the implant.

In 3 particularly thin patients, some annoying rippling appeared despite the use of smooth silicone-gel implants. In 1 case, a larger McGhan smooth gel implant was exchanged for a slightly smaller Mentor smooth gel implant. The shell on the Mentor implant was slightly thinner, and some palpable ripples, though still present, were considerably less noticeable. Still,

even the current shell on the Mentor implant was thicker than desirable and left some visible rippling on 2 other patients. When implants on this patient were exchanged 6 months after the initial procedure (total capsulectomy and revision with Pocket Protector), the e-PTFE maintained pocket patency with peripheral adherence and showed no visible signs of scarring or any irregularity.

One of the patients exhibited some superior pole rippling but was ecstatic with her result. Her breasts had been rock hard and quite deformed for years. She had also complained of a general sense of malaise, but after her revision with the Pocket Protector she stated she had "increased energy" and felt as though a "veil had been lifted." Of course, this most likely is the result of removing "contaminated" subcapsular material (ruptured gel) along with the tainted capsule. With her renewed sense of health and improved appearance, the rippling she experienced was inconsequential (Figure 7).

The third patient with rippling exhibited a small horizontal crease on the medial aspect of each breast. She had Mentor 400-mL smooth moderate-profile gel implants. Her breasts were quite soft and felt natural; however, the rippling was very bothersome to her. She would likely benefit from a thinner-walled silicone-gel implant that would not be palpable through her thin tissues. Whether this is ultimately correctable will depend on the availability of such implants; otherwise, an exchange to a high-profile implant with greater relative fill may be advisable.

The Pocket Protector itself has not been palpable with the exception of a few individual spots where the seamed edge was excessively gathered into the tissues, causing a slightly palpable ridge.

As noted in the results, no drains were used. It should be noted that electrocautery dissection with a SAF-T-VAC facilitates the development of the breast pocket and minimizes bleeding. Thus, drains have not been necessary, though arguably they might have had possible benefit in the cases of refractory seroma without evidence of infection.

Although I envision that this product should be particularly useful to patients who are postpartum or older who have lost a modest amount of volume and want a minimal (200–250 mL) increase, so far most patients opt for implants of 350–450 mL (Figure 8). It makes sense that patients with more difficult and desperate problems are more likely to avail themselves of a new and, it is hoped, promising procedure. Naturally, success in these most difficult patients influences the decision making in the primary augmentation patient.

Also, this would seem to be an ideal implant for the patient with type B breasts, although saline implants might be adequate for patients with type A breasts. Still, the Pocket Protector has served well for patients with type A breasts (Figure 9). Potentially, even in these patients, the Pocket Protector serves as a liner; therefore, should it ever become necessary or desirable, the patient need only have the implants exchanged without the necessity of having more extensive revision surgery, such as capsulectomy or capsulotomy.

Furthermore, although I had envisioned the Pocket Protector's potential benefit in the difficult reconstructive case of subcutaneous mastectomy, I am pleased to have had the opportunity to already test it and see that it worked (Figure 10). Subcutaneous mastectomy carries considerable risk for reconstructive problems, particularly high rates of capsular contracture. There has been significant concern about its ability to reduce cancer risk as well.[57] Still, with the advent of a relatively simple and reliable reconstructive alternative, it might be worthwhile to re-explore improved methods of subcutaneous mastectomy as a prophylaxis against cancer in high-risk individuals. Arguably, a multitude of in vitro and in vivo studies can be performed.

Conclusion

I have suggested that the Pocket Protector would contribute the following benefits to augmentation mammoplasty: (1) prevent capsule contracture; (2) allow for placement of a smooth-surfaced silicone-gel implant, thus achieving optimal softness and natural feel; (3) prevent or minimize rippling; (4) provide a barrier against potential infection; (5) provide a barrier in case of possible gel rupture; (6) provide an internal brassiere to prevent sagging; (7) allow for easy exchange of implant, if necessary (eg, increase or decrease size); and (8) allow for improved results with traditionally difficult cases, such as subcutaneous mastectomy.

Most of these benefits have so far been supported by the findings, but more cases, long-term analysis, and further in vitro studies are warranted. Additional study will be necessary to support benefits 4, 5, and 6. For benefit 4, it is expected that once there is tissue ingrowth into the e-PTFE, then it should be less likely that a periprosthetic infection could occur, but this remains to be proven. A simple animal model could support this conjecture as well as long-term outcome analysis.

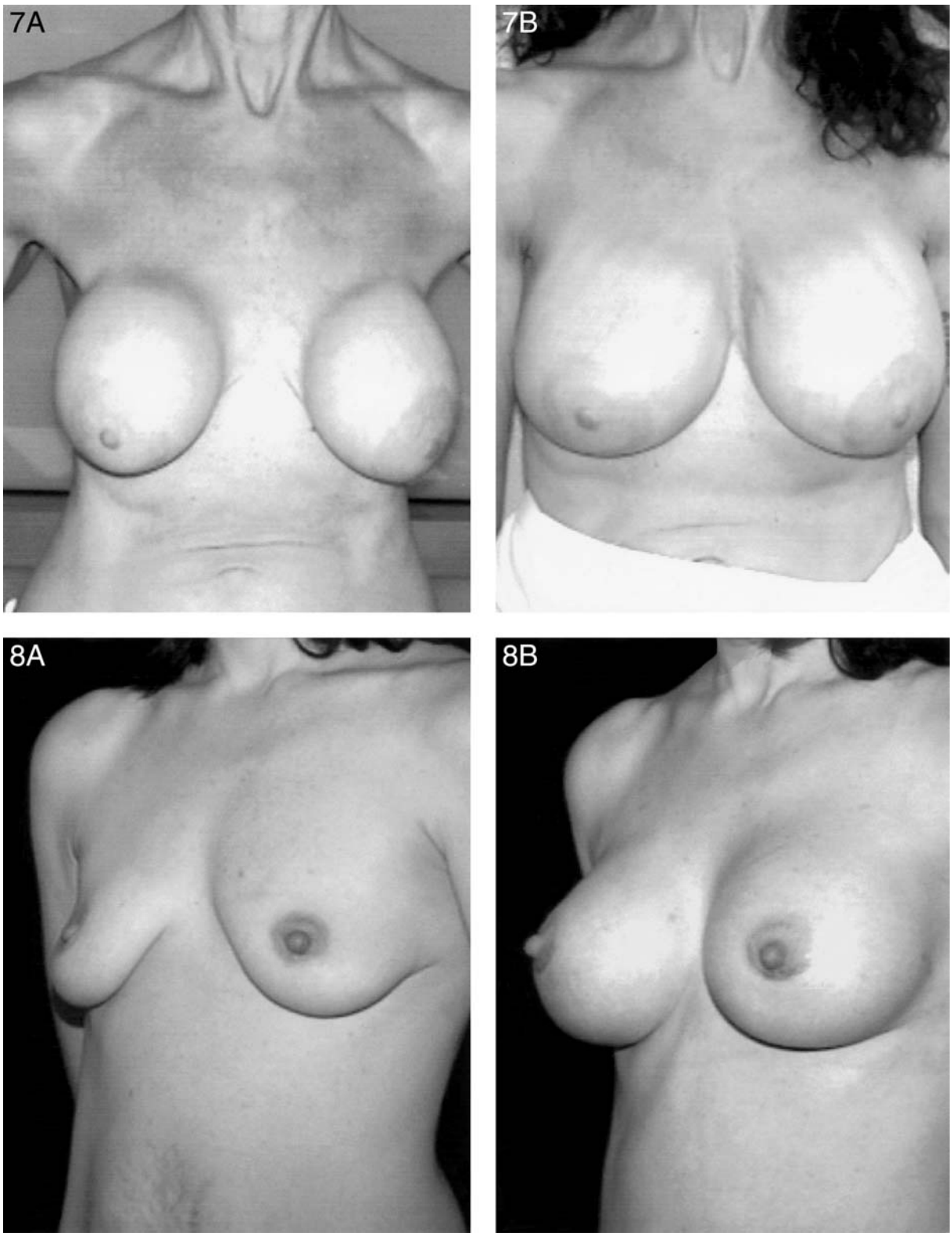


Figure 7. *(A) A 54-year-old patient demonstrating bilateral capsule contracture with calcified capsule and ruptured gel implants. (B) Same patient with smooth gel-filled implants within Pocket Protectors presents with some superior rippling; however, her breasts are soft and she feels generally better.*

Figure 8. *(A) A 36-year-old multiparous patient demonstrating moderate loss of breast volume relative to increase in skin pocket. (B) Same patient after augmentation with Pocket Protector and smooth gel-filled implant.*

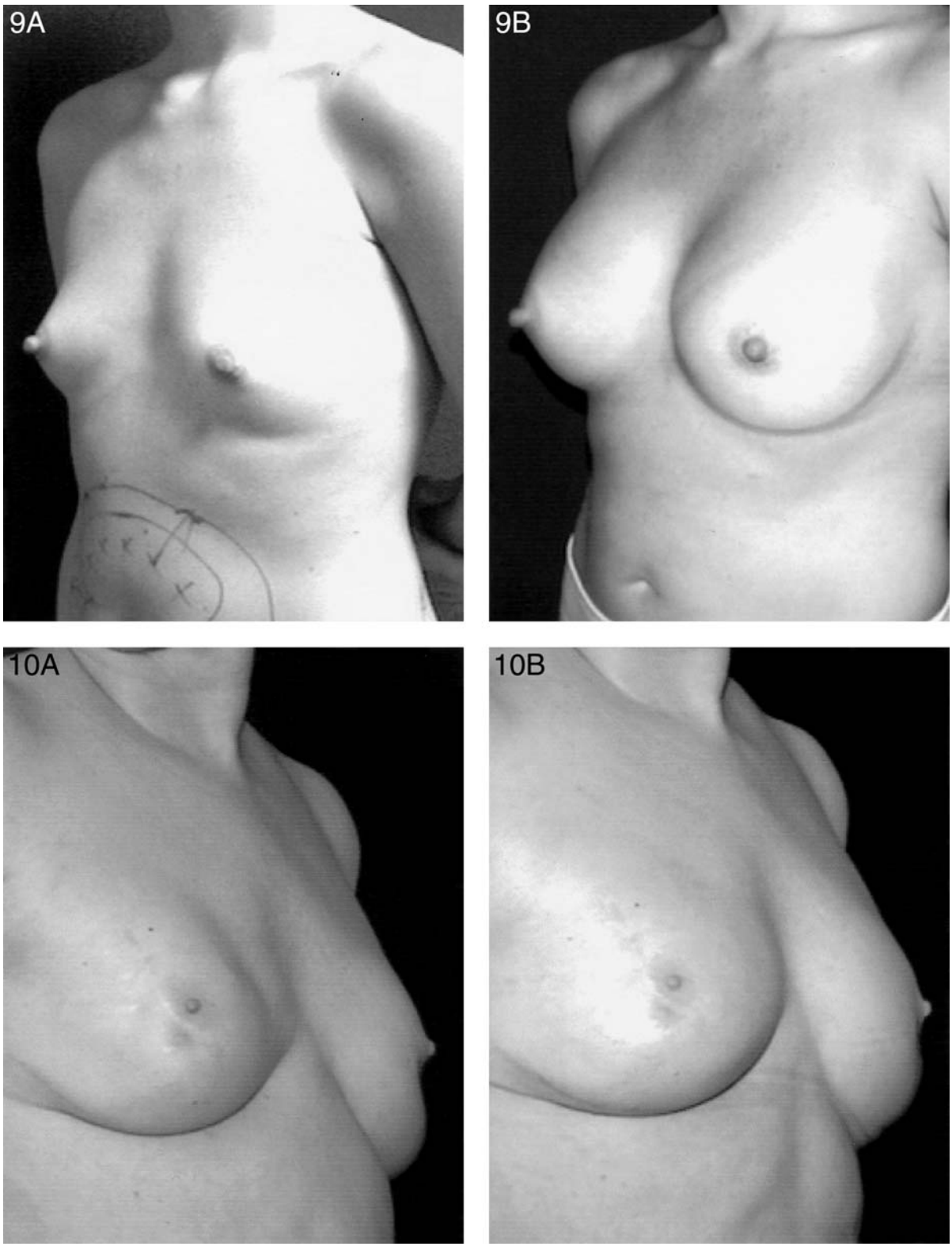


Figure 9. *(A) A 29-year-old patient with primary mammary hypoplasia, type A breasts. (B) Same patient's breasts remain soft; 10 months postoperative with Pocket Protector and 350-mL smooth gel implant.*

Figure 10. *(A) A 56-year-old patient after subcutaneous mastectomy and 2 previous implant procedures. Baker class IV capsule contracture. (B) Same patient's breasts remain soft 7 months after bilateral capsulectomy, revision mammoplasty in prepectoral position with Pocket Protector, and 350-mL smooth gel implants.*

Regarding benefit 5, it makes sense that if the pocket maintains its patency, rupture of the implant would not spread outside the confines of the e-PTFE. e-PTFE integrated with body should represent a formidable barrier to the possible spread of silicone gel beyond the breast pocket. Recent concerns by the FDA about ruptured implants and the possible spread to distal sites should be ameliorated by use of the Pocket Protector, perhaps improving the chances of approving silicone gel for general use. This would still require additional in vitro or long-term outcome analysis.

Finally, benefit 6—an internal brassiere—will be evaluated by simple long-term analysis.

Thus, a new surgical device, the Pocket Protector, has been presented for consideration as a means to improve the current state-of-the-art breast enhancement with prosthetic devices. Although saline devices have decreased the incidence of capsule contracture, they are definitely more artificial to palpation than soft gel implants and run the risk of deflation. Textured implants, particularly gel, work well on many patients; however, a significant number of patients (with thinner tissues) may experience adverse events from rippling. Submuscular augmentation can decrease some of these problems but can also result in distortion of the breast with or without muscle contraction. Also, patients with type B breasts who request modest increases in volume are not particularly aided by single implants that do not, or cannot, maintain the pocket patency. Meanwhile, the public, and apparently the FDA, remain confused and concerned about potential risks of ruptured gel. e-PTFE has a long history as an exceptionally safe implant material. Our goal should be to provide a safe procedure with the most natural results. This preliminary evaluation suggests that the Pocket Protector affords our patients and us this opportunity.

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