

Special Topic

Breast Implants: Saline or Silicone?

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Aesthetic Surgery Journal
30(4) 557–570
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DOI: 10.1177/1090820X10380401
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Abstract

The United States has seen significant shifts in the breast implant market over the past five decades. From the moratorium on silicone gel breast implants in 1992 to their approval in 2006, there have been many developments in their manufacturing and usage. Meanwhile, saline breast implants have remained somewhat unchanged, still offering a few distinct advantages but none of the technological innovation of the silicone gel models. In this article, the authors review the current state of silicone gel and saline implants, as well as the advantages and disadvantages of each. Much of the current data on complications of gel and saline implants are examined, as well as some practical implications associated with the use of each implant type.

Keywords

breast implants, silicone

Accepted for publication August 12, 2009.

BACKGROUND

Over the past five decades, significant shifts have occurred in the breast implant market in the United States. Silicone gel implants have gone from a 1992 moratorium to approval in 2006, with many developments in manufacturing and usage in between. Meanwhile, saline implants have remained somewhat unchanged, offering a few distinct advantages—but without the technological innovation of silicone gel. Silicone gel implants currently dominate the worldwide breast implant market, yet they have only a small margin over sales of saline implants in the US. Even this small margin is remarkable, though, considering the fact that they were available in the US only for medical studies between 1992 and 2006.

The silicone gel implant was first introduced in 1961. This early model featured a silicone gel fill inside a silicone elastomer shell. Its development was a natural improvement on earlier, less-effective methods of augmentation, including direct injection of silicone into the breast itself (which would inevitably clump and harden, leaving the breast misshaped). The first-generation elastomer shells of silicone gel implants were quite thick. Some had patches on the posterior surface, made of polyethylene terephthalate (Dacron) or perforated silicone, to encourage tissue ingrowth and prevent implant migration. These patches were subsequently found to be unnecessary and detracted from implant performance by creating a stress point at which the elastomer could tear. The patches were removed in the early 1970s. This first generation of silicone implants was filled with highly-viscous silicone gel. Implants

were commonly placed in the subglandular space and had a high rate of capsular contracture (CC), with some centers reporting between 30% and 70%.¹

Also developed in the late 1960s was a silicone implant with a polyurethane cover. This layer was initially designed for fixation purpose, but was found to result in a decreased (or delayed) incidence of CC. The polyurethane coat ultimately tended to delaminate from the silicone elastomer shell and slowly deteriorate, which reduced its beneficial effect and increased concerns about possible adverse health effects. No detrimental health effects were found, but polyurethane-covered implants were nevertheless withdrawn from the market by Bristol-Meyers around 1991.²

The saline implant was first introduced in 1965, gaining popularity in the 1970s when early silicone gel implant patients were experiencing high rates of CC. Saline was marketed as a softer implant, but some varieties carried a 2% to 3% yearly deflation rate.^{3,4} Second-generation silicone gel implants with thinner shells and less viscous gel were also developed in the 1970s. The improvement in the feel of these implants, as well as the concurrent high failure rate of the saline implants, led to a renewed popularity of the silicone gel implant. These thinner shells, however,

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Table 1. Silicone Gel Breast Implant Development

Generation	Date	Features
First	1960s	Thick shell, viscous gel, Dacron patch
Second	1970s	Thin shell, less viscous gel, no patch
Third	1980s	Thicker, barrier-coated shells and textured surface implants
Fourth	1992 to present	Stricter manufacturing standards
Fifth	1993 to present	More cohesive gel and form-stable devices

Developed from information provided in Adams WP, Potter J. Breast implants: materials and manufacturing past, present, and future. In: Spear SL, editor. *Surgery of the Breast: Principles and Art*. 2nd ed. Philadelphia: Lippincott Williams & Wilkins; 2006:424-437.

ultimately proved less durable than earlier models. The late 1970s also brought the innovation of subpectoral placement, which improved the CC rate and resulted in a more natural appearance.

By the late 1980s and early 1990s, many women with thinner-shelled, second-generation silicone gel implants were experiencing various complications, including implant failure, CC, and other local problems.⁵ Some thought there might be a connection between silicone implants and an increased incidence of connective tissue disease. Because of the local complications and concerns about systemic health risk, the Food and Drug Administration (FDA) called for a brief moratorium on all silicone gel implants, followed by limitations on their cosmetic applications that lasted 14 years.⁶ The crux of the problem was the absence of comprehensive safety data to assess the risk of local and systemic disease associated with silicone implants.

While silicone gel implants were restricted in the US, their placement and development continued virtually unrestrained in most other countries. By the late 1980s, a third generation of silicone gel implants with stronger shells was introduced. These shells featured an additional barrier layer to reduce the problem of “gel bleed,” in which silicone oil and other low molecular weight moieties diffuse across the elastomer shell and out of the implant. The late 1980s also brought the introduction of textured surface implants, which were developed in an effort to reduce CC rates. The intent of the textured designs was to mimic the biomechanical effects of the polyurethane cover, without any of its potential negatives. Some refer to a fourth generation of de facto implants being developed coincident with the 1992 US FDA moratorium by virtue of refinements in the manufacturing process, which resulted in tighter specifications, lower tolerances for variability, and better quality control. A fifth generation of implants followed, containing more cohesive (or highly cross-linked) silicone gel. These models were introduced in Europe in 1993 (Table 1).

Silicone gel and saline breast implants were already in use in the US when Congress empowered the FDA to regulate medical devices in 1976. In 1999, the FDA required that all currently-marketed saline implants be formally evaluated and approved. By this time, earlier versions of saline implants with high rupture rates had been withdrawn from the market or improved. The manufacture of the silicone elastomer shell had evolved several times, including improving the fill valves and switching from a platinum-cured formulation to the current, more durable room-temperature vulcanized (RTV) model. Both Inamed (now Allergan) and Mentor saline implants were formally approved in 2000.

Saline implants were never under a cloud of controversy to the same degree as silicone gel implants, but they also have not yielded the same innovations. In terms of changes and improvements, several shaped saline implants were introduced around the same time as the shaped gel implants in 1993, and they remain useful options for patients choosing a saline implant.

VARIOUS PERSPECTIVES

The choice of an implant for breast augmentation has implications for both the patient and surgeon. To better analyze the multiple factors that influence implant choice, we examine the issue from a various points of view, including the perspective of both patient and surgeon.⁷⁻⁹ We also scrutinize the choice based on implications from a financial, safety, performance, and practical standpoint.

Patient Perspective

From the patient's perspective, many factors influence the decision about which implant type to select for augmentation and these factors vary according to the patient's personal priorities. Some considerations that enter into the decision process are the look and feel of the implant, the expense (both initial and maintenance), and the safety and complication rates associated with the implant. As an analogy to the saline versus silicone choice, we often compare the implants to cars. The saline implant is like a Volvo, a car developed and marketed as the gold standard of safety, whereas the silicone gel implant is like a BMW, a car designed and marketed as the gold standard of performance. They are both excellent cars, just as saline and silicone gel are both excellent implant choices. Both implants are safe and both perform well, but there are differences. Although silicone gel offers some aspects of better performance (namely a look and feel that more closely mimics natural breast tissue), saline implants sidestep all concerns over rupture and gel exposure. With this in mind, patients seem better able to grasp both the safety and performance differences between the two choices and make an informed decision based on which elements are most important to them.

Financial Perspective

Patients seeking breast augmentation are almost always concerned about costs. The retail cost of silicone gel breast implants is roughly twice that of saline implants. Depending on which aspects of the implant are most important to the individual patient, this cost may prove significant. Further costs associated with implant surveillance are also higher for silicone, as routine office visits and possibly diagnostic testing are required to evaluate implant integrity in the long term. In its approval of silicone implants, the FDA required the manufacturer, in its labeling literature, to recommend follow-up magnetic resonance imaging (MRI) at three years postoperatively and then every two years thereafter. Each patient is also required to sign an informed consent for silicone gel implants, acknowledging this recommendation. Many patients seem to feel that this represents an excessive burden, especially as insurance will likely not cover the cost of these tests. Although it is not explicitly stated in the FDA requirements for approval, the recommendation of an MRI every two years implies the need for a physician's office visit for follow-up and evaluation of test results. These recommendations represent an increased time and financial investment in the long term. Furthermore, even if patients are not required to pay out of pocket for follow-up physician visits, those visits have the practical effect of costing physicians revenue-earning time. We will explore this potential cost to physicians in a later section.

Although saline implants have fewer surveillance needs (because their failure is obvious), they appear to have a slightly higher rupture rate and may represent an increased likelihood of early replacement in a small percentage of patients (Tables 2 and 3).¹⁰

Safety Perspective

Although numerous studies have shown no increase in connective tissue disease associated with silicone gel implant rupture, some women are still fearful of silicone gel implants.¹¹⁻¹³ There are numerous Web sites claiming that silicone implants have detrimental health effects, and although the evidence for this seems totally anecdotal, these claims serve to perpetuate this fear.

There are some realistic risks to silicone gel rupture—namely, that silicone gel will leak outside the breast capsule and enter the local tissue. In microscopic amounts, this silicone is believed to be innocuous. In larger amounts, the silicone can potentially result in a palpable mass. In either case, this finding has been exceedingly rare recently and only isolated cases have been reported.⁹ Silicone gel has also been reported to enter the local lymphatics, at times resulting in an enlarged node. These findings can be disconcerting but have not been shown to cause any systemic symptoms or diseases.¹²

Saline implants remain the gold standard of safety, as they eliminate any silicone gel exposure concerns. Their

Table 2. Allergan Responsive Silicone Gel vs Saline Complications (Six Years vs 10 Years)

Complication	Silicone six year, %	Saline 10 year, %
Reoperation	28.0	26.0
Capsular contracture	14.8	11.5
Deflation/rupture	5.5	7.0
Malposition	5.2	9.2
Asymmetry	3.0	12.2
Wrinkling	1.2	13.7
Palpability/visibility	1.6	12.1

Table 3. Mentor Silicone MemoryGel vs Saline Complications (Six Years vs Seven Years)

Complication	Silicone six year, % ^a	Saline seven year, % ^b
Reoperation	19.4	25
Capsular contracture	9.8	11
Deflation/rupture	1.1	16

^aData are for Soft Touch, a registered trademark of Allergan, Inc. Soft Touch implants are not yet available in the US.

^bData are for Style 510, not yet available in the US.

rupture is completely harmless and this represents peace of mind for some women. Because of the harmless (and obvious) nature of device rupture in these cases, saline implants require a much less rigorous consent process.

Both silicone gel and saline breast implant patients have been studied to determine whether implants present a risk for breast or other cancers, difficulty in breastfeeding, exposure to platinum, and adverse effects in offspring. None of these risks has been shown to be increased in women with either type of breast implant.¹³⁻²⁰

Performance Perspective

Although silicone gel and saline implants each have distinct features that may suit a patient's needs, the data regarding performance of the implants are largely in favor of silicone gel. Gel implants, when compared to saline products by the same manufacturer, have been shown in core studies to have lower rates of rupture, malposition, and asymmetry than their saline counterparts. CC rates were found to be nearly equal at three years, as were reoperation rates in both the silicone gel and saline groups. CC at more than five years seems to be slightly more common with the silicone gel implant (Tables 2 and 3).^{12-15,21}

Data collected on form-stable implants (in limited use in the US but in wide use worldwide) suggest that they outperform round implants in every category (Table 4). US data collected by Allergan and Canadian usage data collected by Mentor seem to indicate that both the Allergan

Table 4. Allergan Style 410 Complications at Three Years Postaugmentation

Complication	Allergan 410, %	Silicone, %	Saline, %
Reoperation	12.5	20.6	21.1
Capsular contracture	1.9	8.3	8.7
Asymmetry	0.8	2.8	10.1
Removal/replacement	4.7	7.5	7.6
Deflation/rupture	0.7	1.2	5.0
Malposition	2.6	3.1	8.2
Loss of nipple sensation	NA	1.2	8.4
Wrinkling	0.5	0	10.5
Palpability/visibility	NA	0	9.2

Developed from information provided in Walker PS, Walls B, Murphy DK. Natrelle saline-filled breast implants: a prospective 10-year study. *Aesthetic Surg J* 2009;29(1):19-25, and Spear SL, Murphy DK, Slicton A, Walker PS, for the Inamed Silicone Breast Implant U.S. Study Group. Inamed silicone breast implant core study results at 6 years. *Plast Reconstr Surg* 2007;120(7):8S-16S.

Table 5. US vs European Data on Allergan Style 410 Implant Complications²²⁻²⁴

Complication	US three years, %	Europe five to nine years, %
Capsular contracture	1.9	5.6
Asymmetry	0.8	< 1
Removal/replacement	4.7	7.5
Deflation/rupture	0.7	1
Malposition	2.6	< 1
Wrinkling	0.5	< 1
Palpability/visibility	NA	< 1

Developed from information provided in Cunningham B, McCue J. Safety and effectiveness of Mentor's MemoryGel Implants at 6 years. *Aesthetic Plast Surg* 2009;33:440-444, and US Food and Drug Administration. *Summary of Safety and Effectiveness Data*. <http://www.fda.gov/cdrh/pdf3/p0.30053b.pdf> and <http://fda.gov/cdrh/pdf2/p020056b.pdf>.

Style 410 and the Mentor Contour Profile Gel (CPG) implants have superior performance and safety data as compared to the current round silicone gel and saline implants.²² The safety data from European and Canadian studies on Style 410 highly-cohesive silicone gel implants with up to nine years of follow-up support this conclusion as well²²⁻²⁴ (Table 5).

Surgeon Perspective

As implant-based breast reconstruction and augmentation have grown in popularity, the choices available to the plastic surgeon have also increased. Beginning with saline implants, there is a choice of seven different types. These

include moderate-, moderate plus-, or high-profile round implants (moderate profile implants with smooth or textured surfaces are available from both Mentor and Allergan), as well as anatomic implants in moderate height, full height, and full height with full projection (Mentor Contour Moderate and High Profile or Allergan styles 363, 468, and 163).

This is in contrast to the much larger and more varied array of silicone gel implants. Even in the US, where silicone implant availability is restricted as compared to Europe, the implant choices are still more diverse. Allergan offers five options for round implants in low, medium, medium-high, high, and extra projection (with some available in both smooth and textured surface). Mentor offers a similar lineup, with three options in terms of projection (also with some in either smooth or textured surface). Mentor's offering of anatomic silicone gel implants (available only for study use in the US) includes low-, moderate-, and full-height options for each of the low-, moderate-, moderate plus-, and high-projection implants. Allergan's anatomic implants (available also only in studies in the US) are also available in low, medium, high, and extra projection, as well as low, medium, and high height for every projection choice (Table 6). Add to this the many options not yet available in the US, and the possibilities grow even further. European choices include implants with a "softer" (or less cohesive) form-stable matrix, a variable cohesive matrix designed to support the nipple-areolar complex at the apex of the breast with a slightly firmer gel in that area, and a form-stable implant with a convex posterior surface to mimic the chest wall and avoid a visible or palpable implant edge. In addition, several implant manufacturers offer varieties of adjustable implants that allow expansion with an inner saline reservoir while maintaining the feel and shape of a silicone gel implant with an outer gel layer.

At the present time, in the authors' current practice, approximately 80% of implants for cosmetic augmentation are silicone gel. Including reconstructive patients, the percentage of gel implants is closer to 90%.

SILICONE GEL ADVANTAGES

Although silicone gel breast implants have been controversial at times, the advantages of their natural weight and feel, as well as their ability to be molded and shaped, have outweighed concerns over past problems and kept them at the top of the implant market. Round silicone gel implants have always had a more breast-like consistency than saline and have better resisted visible or palpable rippling in patients with a thin tissue envelope. Now that form-stable implants are likely to become widely available, a surgeon's ability to provide a more natural-looking breast will be further enhanced. With form-stable implants, surgeons will have a much more powerful tool to help patients with small breasts and thinner skin envelopes achieve a natural result.²⁵ Figures 1 through 8 illustrate the visible differences between contoured saline, round silicone gel, and

Table 6. Saline and Silicone Gel Implant Choices

Allergan ^a	
Saline	Silicone
Round (smooth)	Round (smooth or textured surface)
Moderate profile	(responsive or soft-touch firmness) ^b
Moderate plus profile	Moderate profile
High profile	Moderate plus profile
Round (textured)	High profile
Moderate profile	Round (smooth surface)
Contoured (textured)	Intermediate profile
Style 163 (full height/full projection)	Extra projection
Style 468 (full height/moderate projection)	Contoured (textured)
Style 363LF (low height/full projection)	Low height
	Moderate height
	Full height
	Low projection
	Moderate projection
	Full projection
	Extra projection
	Style 510 ^c
Adjustable (Allergan 150)	Adjustable (Allergan 150)
Mentor ^d	
Saline	Silicone
Round (smooth)	Round (smooth or textured surface)
Moderate profile	Moderate profile
Moderate plus profile	Moderate plus profile
High profile	High profile
Round (textured)	Contoured
Moderate profile	Low height
Contoured	Moderate height
Moderate profile	Tall height
High profile	Moderate projection
Adjustable (spectrum)	Moderate plus projection
Smooth	High projection
Textured round	
Textured contoured	

^aDeveloped from information provided in Bengtson BP, Van Natta BW, Murphy DK, et al. Style 410 highly cohesive silicone breast implant core study results at 3 years. *Plast Reconstr Surg* 2007;120(7):40S-48S.

^bSoft Touch is a registered trademark of Allergan, Inc. and is not yet available in the US.

^cStyle 510 is not yet available in the US.

^dDeveloped from information provided in Heden P, Bone B, Murphy DK, Slicton A, Walker PS. Style 410 cohesive silicone breast implants: safety and effectiveness at 5 to 9 years after implantation. *Plast Reconstr Surg* 2006;118:1281-1287.

contoured, form-stable silicone gel in patients with a thin soft tissue envelope. Note the rounded look of both the round saline and silicone gel implants compared to the more natural look of the contoured saline and the form-stable silicone gel implants. For patients who desire a less round look, the form-stable implant is an option.

Form-stable implants require a larger incision for placement (current recommendations are for an incision between 5 and 5.5 cm) and require care in handling to avoid permanently misshaping or fracturing the gel. Gel fracture has been found to occur with excessive deforma-

tion of an implant resulting from an attempt to place it through a small incision, but it is a rare occurrence, and the effect of a fracture in the gel is largely unknown and likely of little consequence.

The increased stability and cohesivity of silicone gel as compared to saline has led to the belief that silicone exerts a more minimal stretching and deforming force on overlying tissue. As a patient moves, local forces governed by gravity and inertia are exerted on the implant. The more the implant deforms, the more these forces are transmitted to surrounding tissue. Although data indicate that the inci-

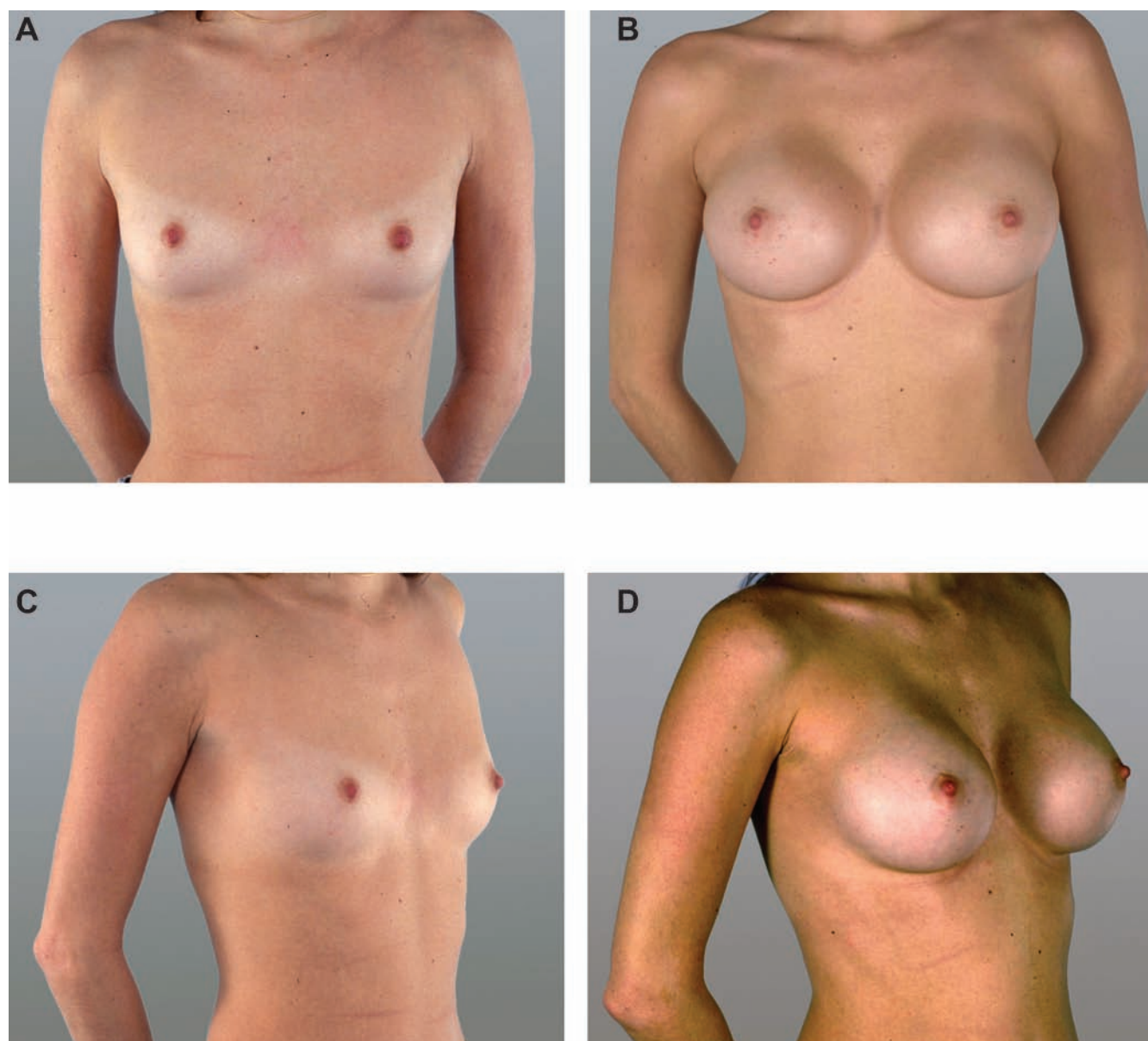


Figure 1. (A, C) A 29-year-old woman who presented for breast augmentation. (B, D) Three months after augmentation with smooth, round saline implants (Allergan 68MP) filled to 240 cc and placed subpectorally from a transaxillary approach.

dence of malposition is indeed increased with saline implants over silicone implants (Table 3), studies have not been sophisticated enough to detect whether this implant property is the reason. However, the FDA moratorium in 1992 contained an exception for placement of silicone gel implants in the correction of ptosis, an early recognition of the probable decreased “stretching” caused by silicone gel implants.

SALINE ADVANTAGES

Although silicone gel implants are undoubtedly technologically more advanced and saline has a firmer, less natural feel, saline implants do have some distinct advantages. First, they require almost no long-term surveillance. Once patients are informed of the consequences of rupture (namely, visible deflation, accompanied by nearly instantaneous resorption of the saline contents), they can be

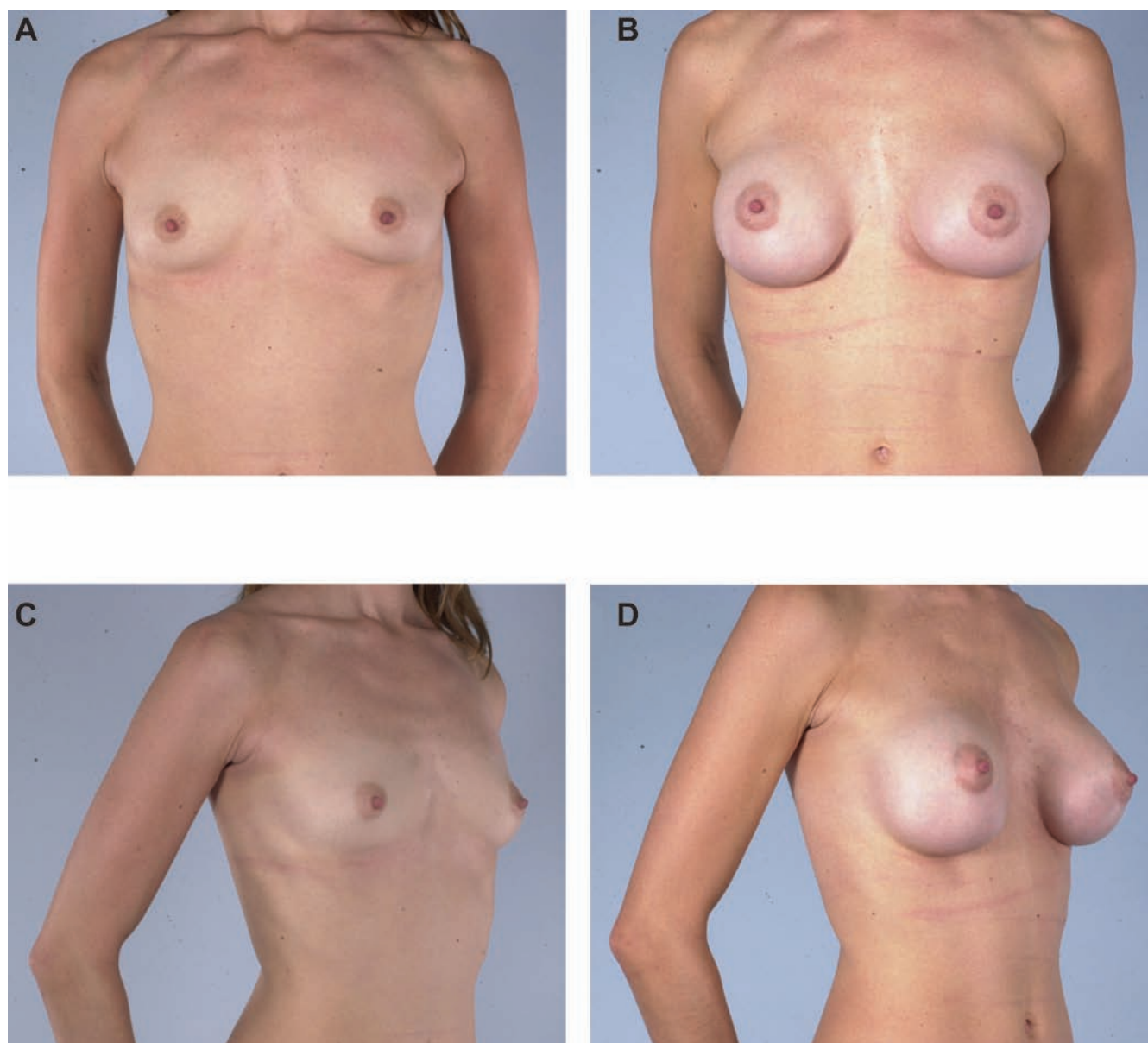


Figure 2. (A, C) A 32-year-old woman who presented for breast augmentation. (B, D) Five months after augmentation with contoured saline implants (Allergan 363LF) filled to 300 cc and placed subpectorally.

trusted to be aware of this occurrence. Device malfunction is clinically much more obvious than with a silicone gel implant, which may require physical exam, sonography, mammography, MRI, and even surgery to determine its integrity.

Saline implants also have the advantage of being inserted in the collapsed state. This allows them to be easily inserted through small and sometimes remote incision sites (as in the case with a periareolar incision in a patient with a small areola) or via a transaxillary or transumbilical incision.

Saline implants have some degree of adjustability, giving the surgeon slightly more flexibility by allowing fine-tuning of volume within a narrow range. With all saline implants (but especially contoured saline implants), options for over- or underfilling are limited, as these implants become increasingly firm, round, and less “breast shaped” with increased fill volumes. Visible rippling and risk of failure can increase with underfilling, thus further limiting the versatility of saline implants. The low viscosity of saline also makes the shape of the implant less resistant to local

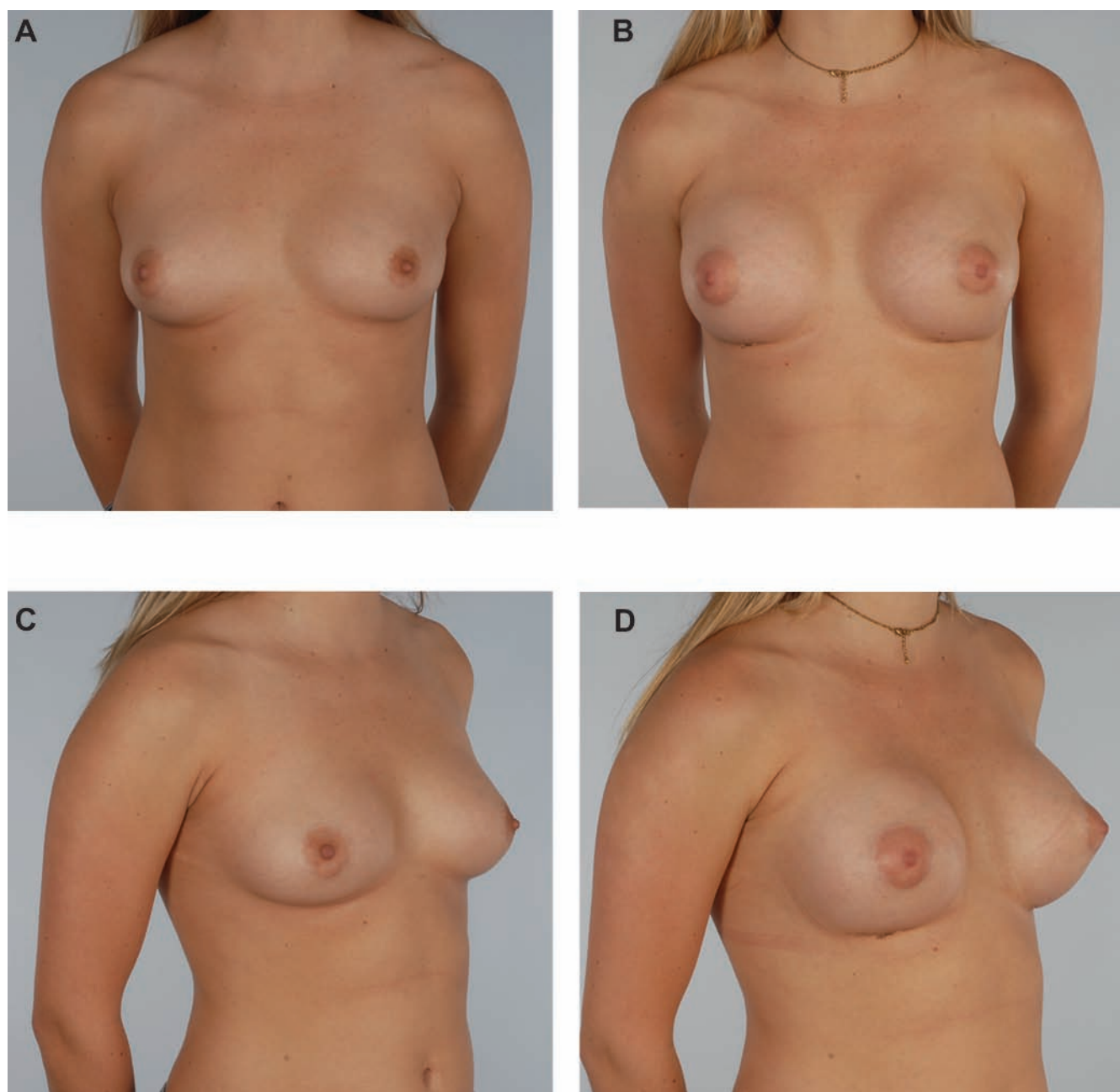


Figure 3. (A, C) A 28-year-old woman who presented for breast augmentation. (B, D) One month after augmentation with round 300 cc silicone implants (Allergan style 115) and placed subpectorally.

tissue pressure. A patient with a constricted skin envelope in the lower pole may therefore achieve less lower pole projection with a saline implant than with a form-stable silicone gel implant. This difficulty in controlling the distribution of the fill in a saline breast implant gives the surgeon less control over the breast shape.

PRACTICE IMPLICATIONS

An ongoing result of the FDA's approval of silicone gel implants is the continuation of the large premarket approval studies, as well as the initiation of new, even larger post-market surveillance studies to confirm their safety. Even for

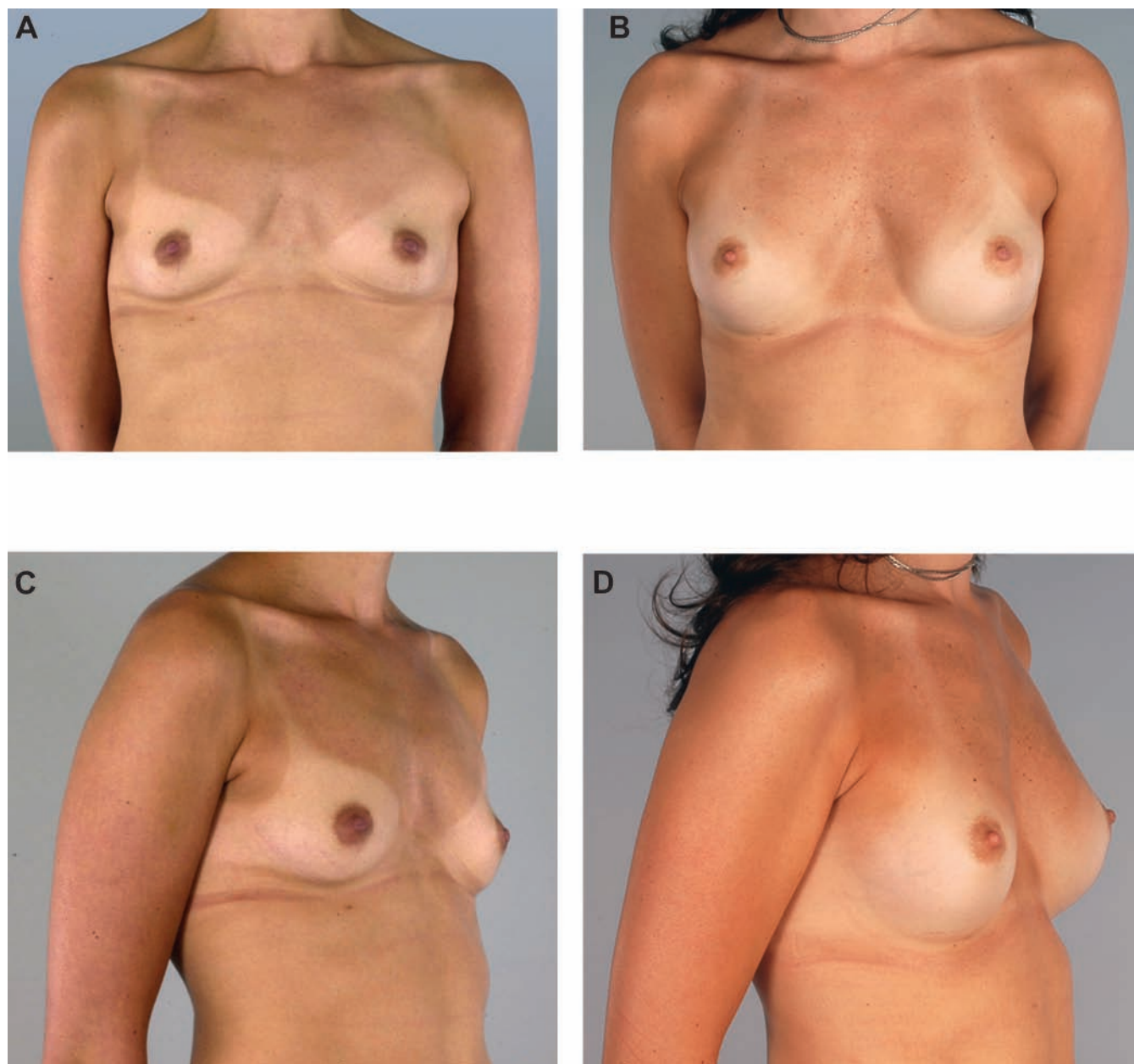


Figure 4. (A, C) A 26-year-old woman who presented for breast augmentation. (B, D) Six months after augmentation with form-stable gel implants (Allergan style 410MM, 245 g) placed subpectorally.

plastic surgeons not participating in manufacturer-sponsored surveillance studies, it is common practice for surgeons to evaluate silicone gel implant patients on a yearly or biyearly basis to examine the implant and check for problems such as capsular contracture or rupture.

If a surgeon places silicone implants at the rate of 100 pairs of implants a year and normally sees patients in the

office approximately 100 days per year (2 days per week, 50 weeks per year), he or she will need to see roughly one patient per office day in follow-up, per year of implants he or she has placed. That would not be a problem for the first two or three years, but after five years, the number of follow-up patients needing to be seen becomes more substantial.

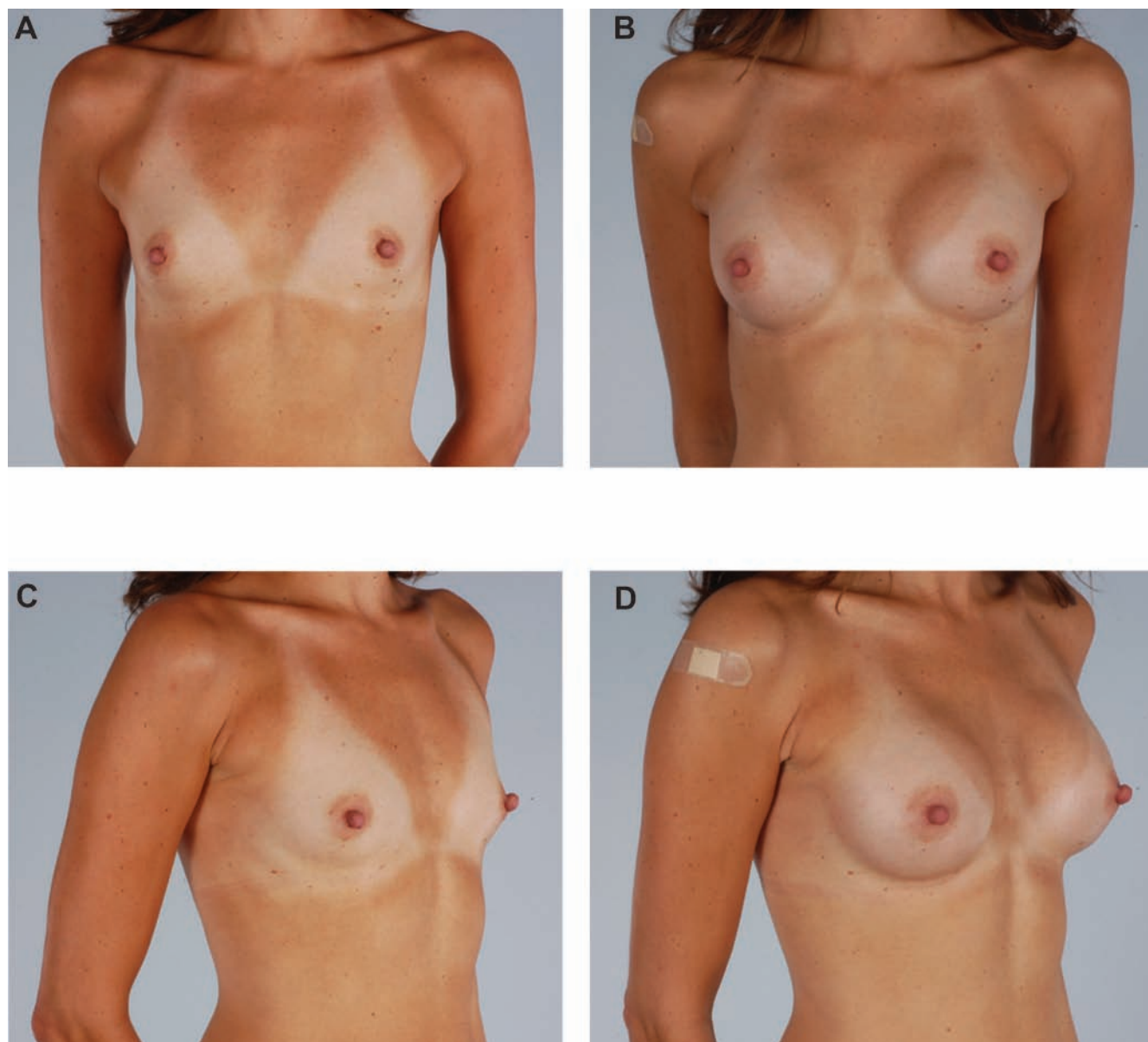


Figure 5. (A, C) A 30-year-old woman who presented for breast augmentation. (B, D) Two years after augmentation with smooth, round saline implants (Allergan 68MP) filled to 340 cc and placed subpectorally from a transaxillary approach.

Now consider a practice at 15 years. The surgeon has now placed silicone implants in roughly 1500 patients and, to keep up with yearly follow-up, he or she will now need to see 15 long-term follow-up patients during every clinic day. Even if the surgeon switches to two-year follow-up, seven or eight women will need to be seen every clinic day. By the time a surgeon has been in practice for 22

years and has placed silicone gel implants in close to 2200 patients, 22 patients would need to be seen every clinic day to keep up with routine surveillance. This represents a significant manpower burden. It also raises the question of who is going to pay for these visits. Should patients or surgeons pay for surveillance of the implants? Over the course of several years of implant operations, charging for

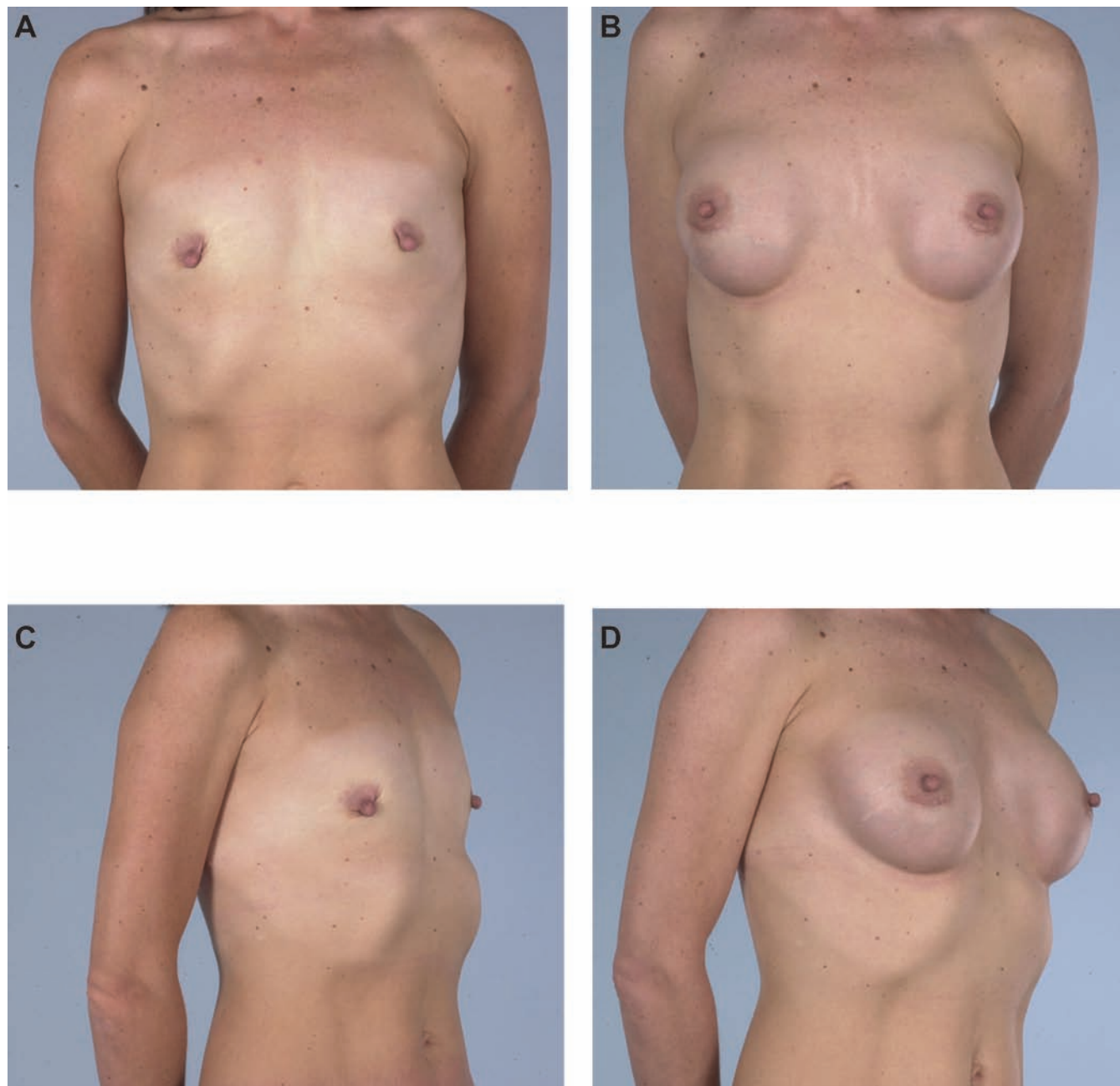


Figure 6. (A, C) A 35-year-old woman who presented for breast augmentation. (B, D) Two months after augmentation with contoured saline implants (Allergan 363LF) filled to 260 cc and placed subpectorally.

the time spent on surveillance may ultimately become the only feasible way for a surgeon to manage the situation.

Future innovations may ease this situation, and some patients may not be compliant with long-term surveillance, but as it stands, routine yearly screening for rupture or contracture of a silicone gel implant will have important implications.

CONCLUSIONS

Plastic surgeons in the US are practicing in an exciting time, when silicone gel has returned to the marketplace and new implant innovations are on the horizon. Although silicone gel is undoubtedly the leader in performance and innovation, saline still has a useful place as an alternative

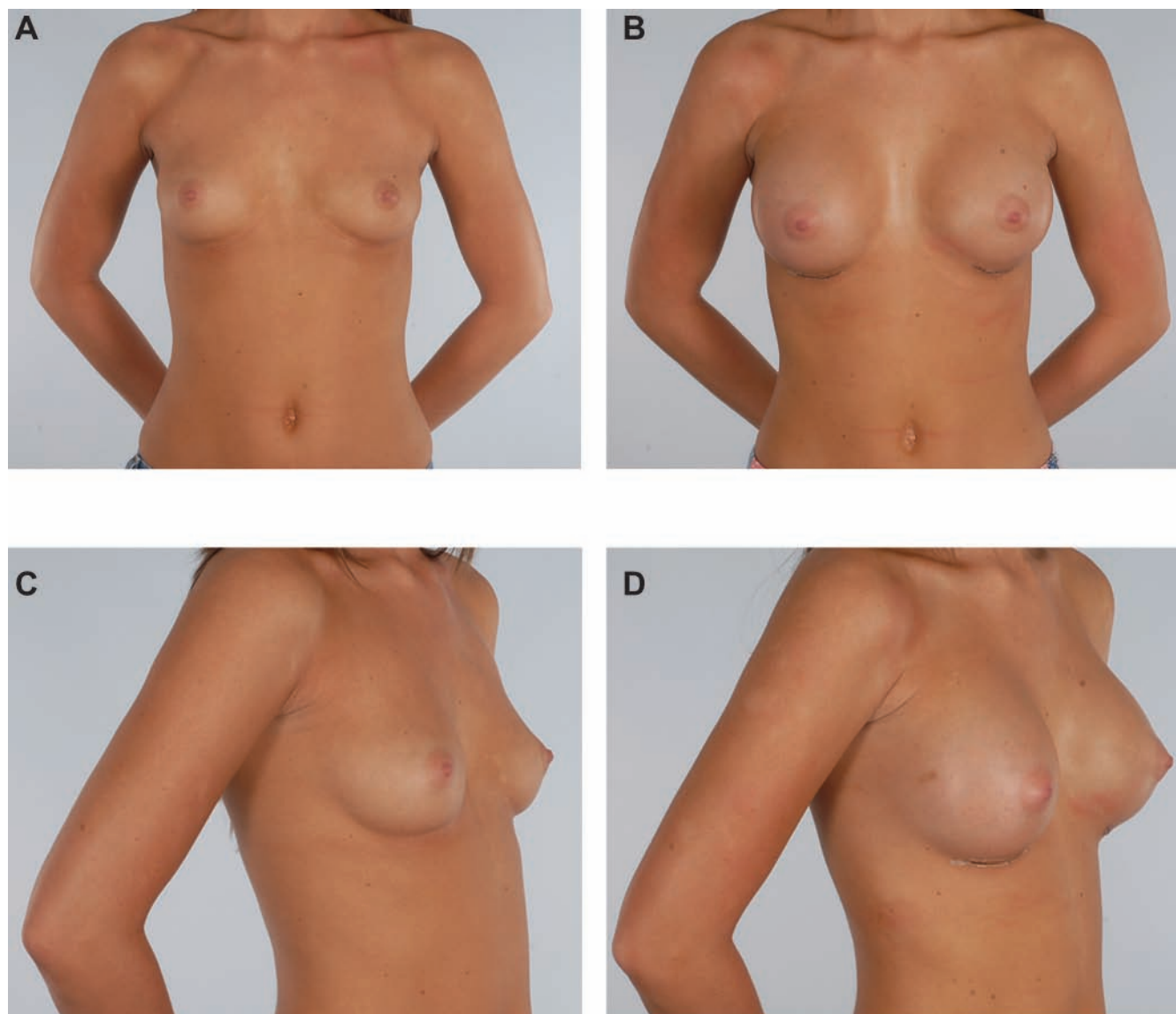


Figure 7. (A, C) A 38-year-old woman who presented for breast augmentation. (B, D) One month after augmentation with round 300 cc silicone implants (Allergan style 120) and placed subpectorally.

for breast augmentation. With the availability of high-performance, form-stable silicone gel implants, the ability of surgeons to create a more natural-appearing result should be enhanced. However, as silicone gel implant usage continues to grow, surgeons will have to accommodate more follow-up and surveillance into their practice.

As implant choices have evolved, certain concepts have proven useful. When the main determinant for patient satisfaction is the shape and feel of the implant (and in cases where the implant might be especially visible), a silicone gel implant is the better choice. In cases where the primary concerns are

safety (real or perceived), minimal access incisions, and ease of monitoring, saline may prove to be a better choice.

Disclosures

Dr. Spear is a paid consultant for Allergan.

Funding

The authors received no financial support for the research and/or authorship of this article.

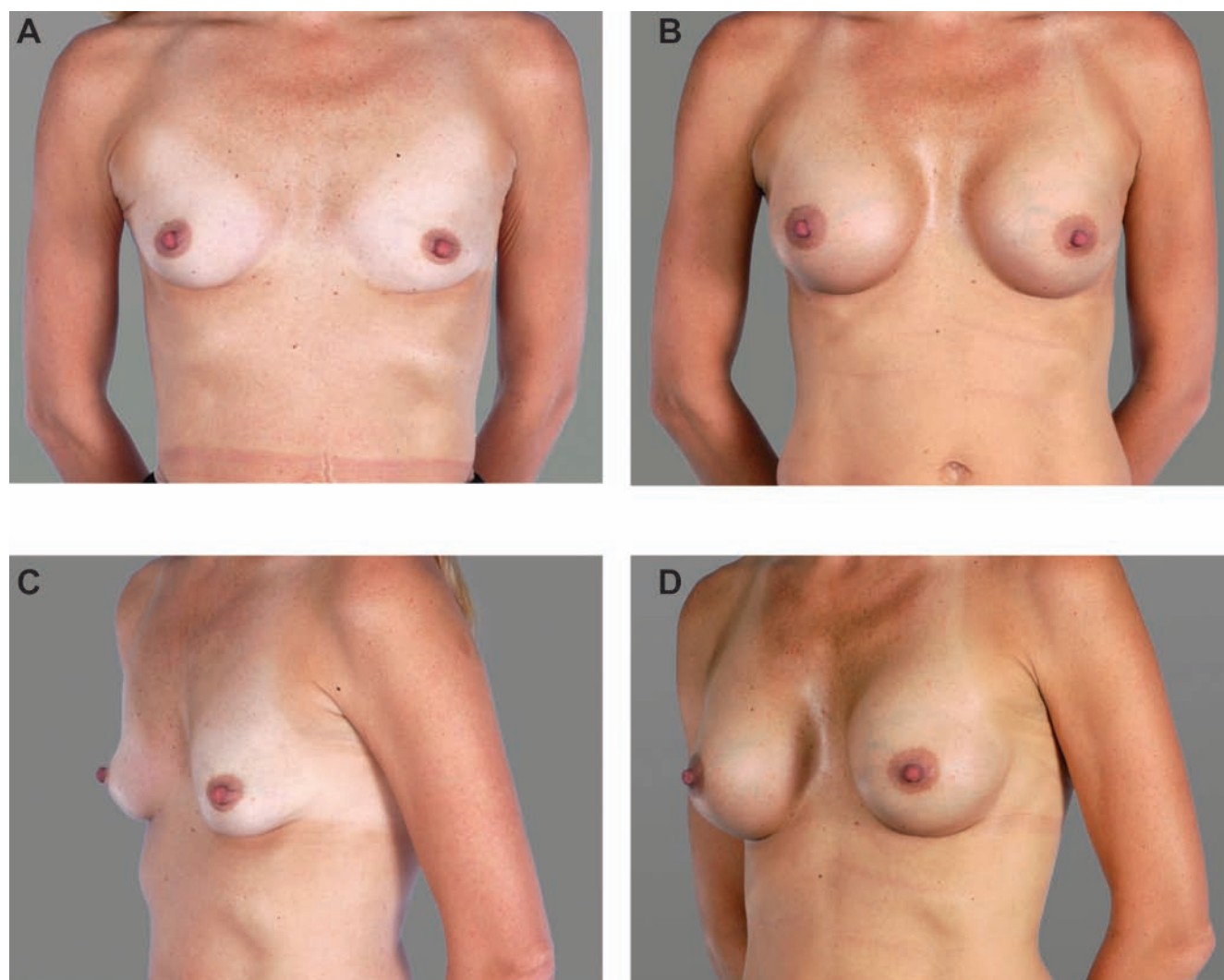


Figure 8. (A, C) A 39-year-old woman who presented for breast augmentation. (B, D) Three months after augmentation with form-stable gel implants (Allergan style 410MM, 290 g) placed subpectorally.

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