

High- and Extra-High-Projection Breast Implants: Potential Consequences for Patients

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Summary: All breast implants can potentially have deleterious effects on patients' tissues. Limiting negative tissue consequences and potential uncorrectable deformities requires that surgeons be aware and educate patients regarding potential consequences of various implant designs. High-profile implants have been available for decades, and during the current decade, extra-high-profile implants have become available, but no valid peer-reviewed and published studies have compared the potential tissue consequences of these designs to those of other breast implant designs. Valid comparative studies are exceedingly difficult to perform because of the number of variables that must be addressed to establish valid comparative cohorts. Nevertheless, the potential occurrence of negative tissue consequences from high- and extra-high-profile implants in primary breast augmentation and breast augmentation reoperation cases is well known to experienced aesthetic breast surgeons. This article addresses potential negative effects on patients' tissues of high- and extra-high-profile breast implants used for breast augmentation. This Special Topic article is not structured or intended as a scientific article. It is written as a Special Topic and not an Editorial at the editor's request. The cases presented are selected examples to illustrate potential clinical eventualities. The rate of occurrence of uncorrectable tissue deformities relates directly to surgeon and patient awareness of the potential consequences of implant selection decisions and requests. To minimize risks of negative tissue consequences for patients, surgeon awareness, patient education, and optimal implant selection decision processes are essential. (*Plast. Reconstr. Surg.* 126: 2150, 2010.)

All breast implants can potentially have deleterious effects on patients' tissues. The frequency and severity of these changes relate directly to surgeons' and patients' willingness to prioritize preservation of tissues over arbitrary requests for breast projection or size.

Although many surgeons recognize that it is important for implant base width to not exceed the base width of the patient's parenchyma, to satisfy a patient's request for a specific size or volume, those same surgeons may resort to a higher projection implant with a narrower base width. High-profile and extra-high-profile implants have approximately one-third more volume for a specific base width compared with moderate-profile implants of the same base width. More volume and more projection cause more pressure on surrounding tissues, includ-

ing skin, subcutaneous tissue, breast parenchyma, muscle, and bone.

In a recent article published elsewhere analyzing 13 augmentation patients, the authors reported a small series of six primary and seven revision cases, and suggested that highly cohesive, extra-high-projection implants may be indicated for "large skin envelopes in breast augmentation patients declining mastopexy, [and]...complicated implant exchanges...."¹ Aside from the fact that no scientifically valid conclusions can be derived from a series this small, the conclusion of this article and the popularity of extra-high-projection implants in some parts of the world for primary breast augmentation should be a significant con-

From private practice.

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cern to patients and surgeons. Avoidance of permanent or uncorrectable tissue deformities depends on the willingness of surgeons to prioritize scientifically valid and proven processes for assessing patients' tissues above surgeon intuition, opinion, or any patient aesthetic requests.

These comments do not apply to the use of larger or more highly projecting implants in breast reconstruction, an environment in which tissues have already been irreversibly compromised by disease. In *primary* breast augmentation, the tissue environment and the decision processes by patient and surgeon are very different compared with reconstruction. In reconstruction, tissues are, by definition, already compromised or destroyed. In primary augmentation, a primary objective is to avoid tissue compromise, reoperation, and deformities resulting from a primary, medically unnecessary operation.

INDICATIONS FOR USE OF HIGH- AND EXTRA-HIGH-PROJECTION IMPLANTS

Proposed indications for high- and extra-high-profile implants are based largely on surgeon conjecture that these devices may be indicated for (1) "glandular ptotic" breasts, (2) "constricted lower pole" breasts, (3) "tuberous breast" deformities, (4) avoiding mastopexies in patient who do not want mastopexy scars, and (5) patients requesting more projection. These indications are based largely on subjective surgeon speculation validated by no more than selected, often short-term, before-and-after photographs. None is based on any published quantitative measurements or any scientifically valid long-term data confirming that high- and extra-high-profile implants are safe for tissues or aesthetically superior to less projecting implants.

This Special Topic article does not present valid, comparative, or quantitative scientific data to prove or disprove which implant devices may or may not produce tissue compromises. To do so would require (1) valid comparative cohorts that control for more than 50 variables, (2) possible violation of ethical and Helsinki guidelines by placing different implant types and projections on the two sides of a single patient, or (3) access to detailed premarket approval data on each specific type of implant that manufacturers claim is proprietary and have not released. This article presents issues and patient cases that exist, and encourages further study with release and accumulation of scientifically valid data to further define patient safety issues.

CURRENT LITERATURE

The numbers of high- and extra-high-profile implants in U.S. Food and Drug Administration premarket approval studies are too small for any valid conclusions about their safety and efficacy to be drawn, and adverse outcomes are not categorized by device projection in any current premarket approval data. No other valid scientific series (of rigor and monitoring equal to U.S. Food and Drug Administration premarket approval data) documents the long-term safety and potential negative or uncorrectable tissue consequences from extra-high-projection implants in breast augmentation patients.

Handel² succinctly described potential negative tissue effects of breast implants when he wrote, "The long-term presence of implants typically results in changes in breast anatomy and physiology, including parenchymal atrophy, tissue thinning, and diminished skin blood supply." The potential to limit these negative effects by specific tissue-based planning and implant selection processes has been addressed in published studies that reported the lowest reported reoperation rates and the absence of uncorrectable deformities with up to 7-year follow-up in series that limited implant size to 350 cc and in which no high- or extra-high-projection implants were used.³⁻⁹ Outcomes data in these studies prove the safety and efficacy of low- and moderate-profile implants. Equivalent published data do not exist for high- and extra-high-profile implants.

SURGEON AND PATIENT OBJECTIVES AND DECISION PROCESSES

Satisfying patient requests and delivering visually evident short-term results are important objectives for aesthetic surgeons. Protecting patients' tissues requires that size and projection requests are subordinate to a surgeon's primary objective of protecting the patient's tissues and preventing uncorrectable deformities or long-term tissue compromises, especially when performing a medically unnecessary procedure. Fulfilling a patient request for volume or doing what may seem necessary to correct a specific condition (e.g., glandular ptosis or constricted lower pole breast) should be tempered by an acknowledgment that the very forces exerted by an implant to push the breast envelope into a particular shape or dimension are the same forces that can cause irreversible, long-term tissue consequences and uncorrectable tissue deformities. Patient (and surgeon) education are vitally important to optimize deci-

sion processes and avoid a “cure” that is far worse than the disease.

CHALLENGING QUESTIONS AND CLINICAL OBSERVATIONS

Although surgeons’ opinions may promote the use of these devices, no current scientific *data* adequately define safe indications for use of high- and extra-high-profile devices in breast augmentation. Regardless of the size of published anecdotal series, absent quantified tissue measurements using clinical and imaging techniques and long-term follow-up comparable to U.S. Food and Drug Administration studies, those studies do not prove the safety of this type of device for primary breast augmentation.

Challenging questions remain unanswered by science. How much of the additional projection of a high-profile implant are lost to parenchymal atrophy or remodeling of the rib cage? When is the additional level of correction or improvement in shape worth the potential negative long-term consequences to tissues? How do long-term results compare with short-term results? What scientific study designs can be structured and implemented to definitively define the effects of breast implant designs on patients’ tissues? What should determine implant selection: long-term validated data, analysis of short-term photographs, or opinion not verified by data?

Surgeon opinion has established an unenviable track record of up to 25 percent reoperation rates in just 3 years after breast augmentation in U.S. Food and Drug Administration premarket approval studies. Of much greater concern is that surgeon opinion and intuition, in the context of patient wishes, may risk uncorrectable tissue compromises and deformities in breast augmentation patients. Many of those uncorrectable problems are caused by excessively large and excessively projecting implants in augmentation, often with the justification, “it’s what the patient wanted,” and without documentation that the patient was fully educated and understood the potential consequences of her requests on her tissues.

IMPLANT-SOFT-TISSUE DYNAMICS AND TISSUE CONSEQUENCES

Figure 1 is an illustrated flowchart summarizing potential negative tissue consequences related to breast implant size and projection. Greater size and/or projection of breast implants have greater potential negative effects on patients’ tissues. The weight and pressure of high- and extra-high-projection implants potentially causes more stretch-

ing and thinning of the breast envelope (skin and subcutaneous tissue) and more parenchymal atrophy compared with smaller or less projecting implants. Consequences to patients can be disastrous and can produce uncorrectable deformities and conditions that include parenchymal thinning, skin stretch, inability to lactate, sensory compromise, implant edge or shell visibility, visible traction rippling, and chest wall deformities. Regardless of what any patient requests, it is every physician’s first responsibility to do no harm to the patient.

More than 50 variables must be analyzed in comparative augmentation cohorts to achieve scientific validity in comparative clinical studies of various size and projection implants, making these studies virtually impossible to accomplish.³ Nevertheless, the management of many patients with high- and extra-high-profile implants has unequivocally demonstrated specific patterns of tissue compromises and uncorrectable deformities that are not observed when implants have been selected by valid and published processes.³⁻⁹

Capsular contracture provides surgeons an excellent clinical model with which to observe tissue effects of higher profile or projection implants, because a severe, spherical capsular contracture converts any low- or moderate-profile implant to a high- or extra-high-profile shaped device. The tissue effects of capsular contracture, especially more severe and longstanding contractures, relate directly to the forces generated by a dramatic increase in the projection (creating more focal pressure) and decrease in base width (focusing the pressure on a smaller area) that affect adjacent and underlying tissues. Figure 2 dramatically illustrates the disastrous consequences of a high-profile device with capsular contracture in an already thin patient. Surgeons cannot predictably control the wound-healing mechanisms that may produce capsular contracture, but surgeons can certainly observe the tissue consequences of more highly projecting implants, whether the implant was designed with additional projection or acquired the projection as the result of capsular contracture. Those observations provide insight and an opportunity to integrate the knowledge of potential tissue consequences into the decision processes of implant selection for primary augmentation.

Parenchymal atrophy and chest wall deformities are most apparent when a high- or extra-high-profile implant is removed (Figs. 3 and 4). The larger or more projecting the implant, the tighter the patient’s breast soft-tissue envelope; and the

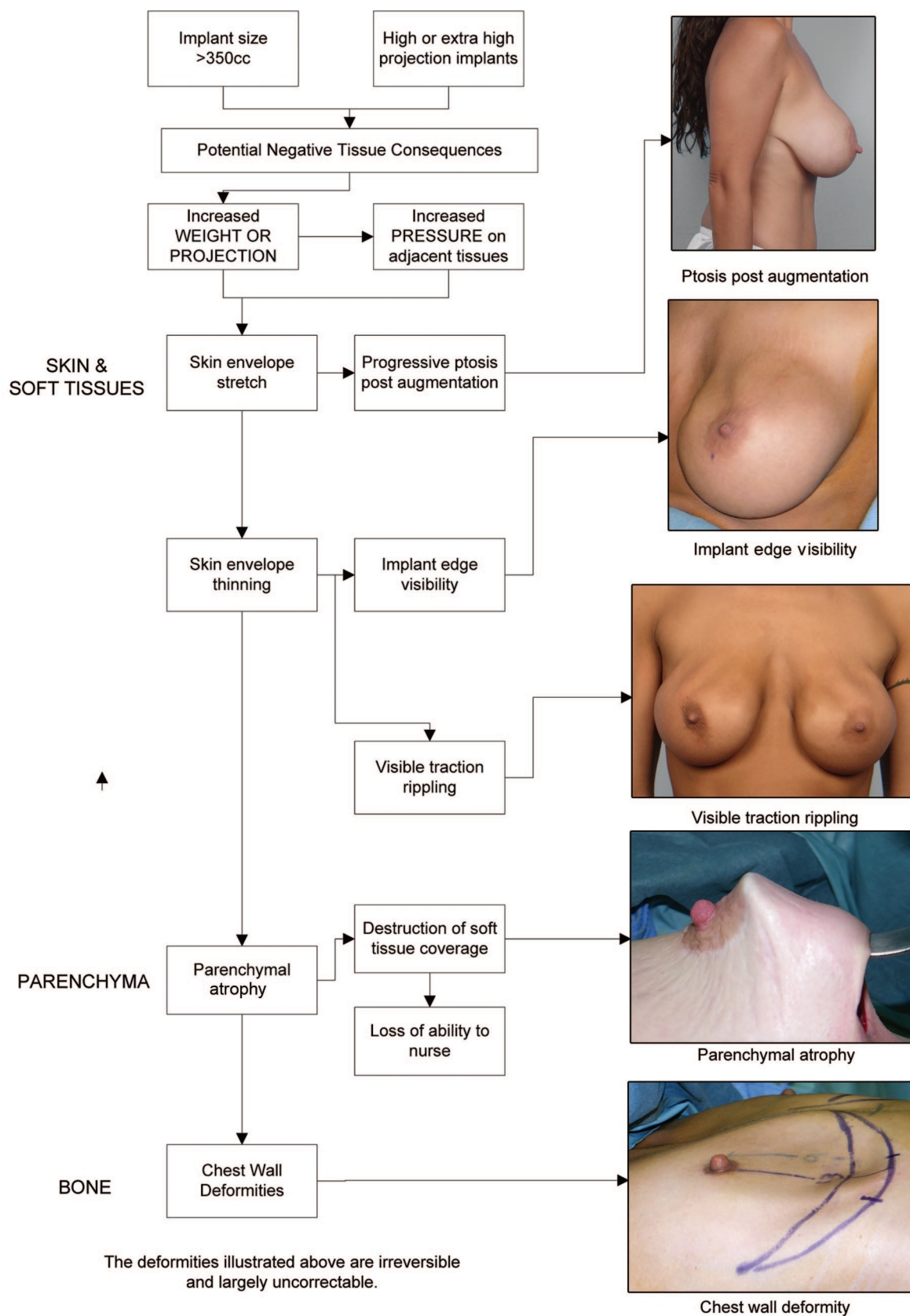


Fig. 1. Illustrated flowchart summarizing potential negative tissue consequences related to breast implant size and projection.

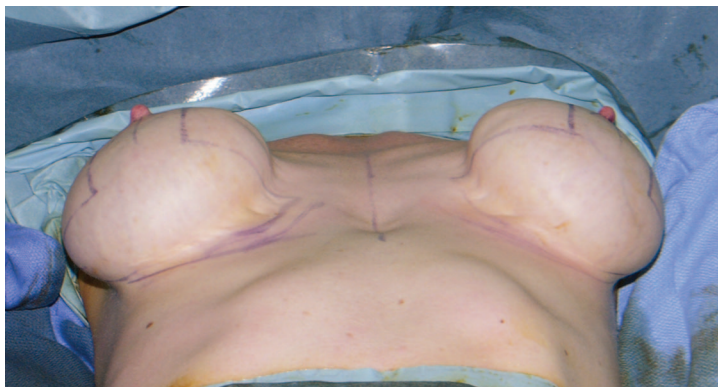


Fig. 2. A 30-year-old patient is shown 7 years after augmentation with a 325-cc high-profile implant. The effects of capsular contracture have increased the projection of the breast implant, focused pressure on the overlying parenchyma and underlying chest wall, caused obliteration of overlying parenchyma, caused dramatic skin envelope thinning, created radial-oriented stretch marks in the skin, and resulted in visible traction deformities to the thin overlying tissue. Similar tissue effects occur with breast implants as implant projection or size increases, or with tighter tissues or more cohesive filler materials.

firmer the implant filler material, the greater the pressure that the implant focuses on adjacent tissues and the greater the risk of these deformities.

Temporary improvement occurs with high- and extra-high-profile implants in patients with glandular ptosis and other conditions. However, as surgeons observe these patients over time and inventory the tissue problems of high- and extra-high-profile patients seeking revision surgery, many surgeons recognize that higher profile implants almost invariably deliver one or more of the following:

1. Focused, maximal pressure where consequences are most dire, in the already stretched and thinned skin of the lower pole, on overlying parenchyma, and on underlying chest wall.
2. Parenchymal pressure atrophy/thinning that cannot be corrected, may compromise lactation and sensation, but for which patients sometimes undergo reoperations with even larger implants, site changes, or attempts at thickening the envelope with acellular dermal matrix grafts or fat injection.
3. Stretch of lower pole skin that produces (a) a more ptotic, “lower but larger” or “rock in a sock” breast; (b) a dramatic increase in nipple-to-inframammary fold distance, (c) descent of the inframammary fold, or (d) a combination of (b) and (c) that produces a “bottomed-out” appearance.

4. Implant edge visibility and palpability.
5. Visible traction rippling.
6. Depression deformities of the rib cage, which reduce projection, create deformity, and are essentially uncorrectable.
7. Compromised tissue vascularity from stretch, resulting in higher risks if later mastopexy is required.²
8. Disproportionate underfill of the upper pole as a result of a narrower implant dimension.

Some surgeons believe that ideal indications for high- and extra-high-profile implants include glandular ptosis and constricted lower pole breasts. A key question is whether these deformities can be treated adequately and with less risk of negative tissue consequences with moderate-profile implants. Although anecdotal cases do not provide scientifically valid answers, they may nevertheless provide insight. Figures 5 and 6 illustrate changes that occurred following treatment of glandular ptosis with a larger and more projecting implant. Figure 7 illustrates changes that occurred following treatment of a constricted lower pole breast with a high-profile implant. These case examples illustrate the inevitable tissue consequences of larger and higher profile breast implants, even in cases where logical indications seem to exist. Case examples such as these are invaluable to help educate glandular ptosis patients who want a large, projecting implant in lieu of a mastopexy, and a wide range of patients who



Fig. 3. (Above) Severe thinning, stretch marks, and potential vascular compromise are evident intraoperatively, as minimal pressure from a retractor tip causes marked blanching of the skin envelope in a 39-year-old patient 4 years postoperatively with high-profile 375-cc implants. (Below) Parenchymal atrophy, skin stretch, and skin thinning are seen in a 26-year-old patient after explantation of 400-cc high-projection implants just 4 years after implantation. The severe parenchymal atrophy and stretch thinning of the soft-tissue envelope are uncorrectable.

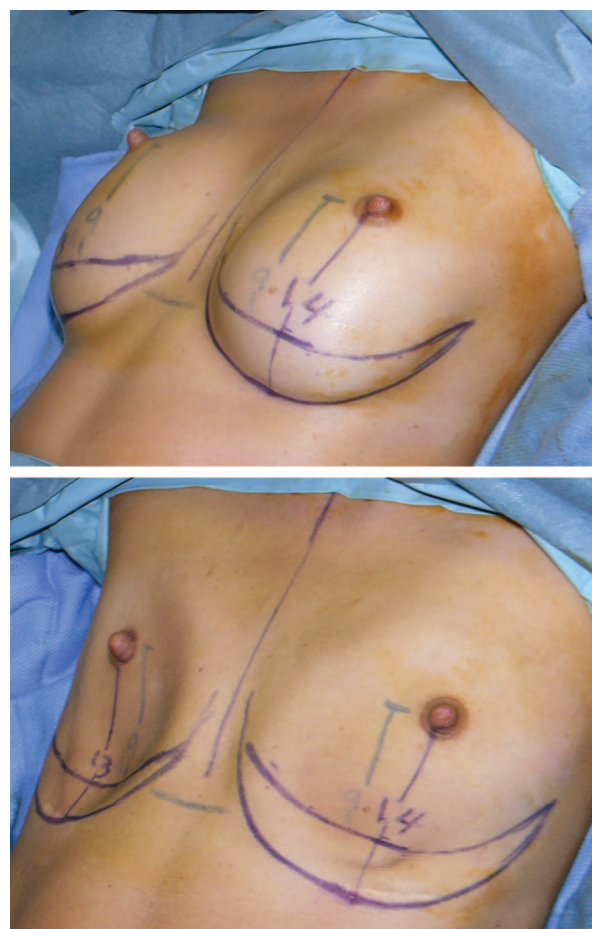


Fig. 4. Chest wall deformities, absence of parenchyma, and marked lower pole skin stretch and thinning. Bilateral chest wall deformities and depressions are evident in a 24-year-old patient at explantation of high-profile, 425-cc implants, placed at her request for increased projection, 5 years after primary augmentation. Breast parenchyma is virtually nonexistent. The inframammary scar, placed 9 cm below the nipple in the inframammary fold at the primary operation, is now located 13 cm below the nipple, quantifying the dramatic stretch of the lower pole skin caused by the implant.

request implants that are larger or more projecting than their tissues can tolerate.

Patients who experience these effects often suffer severe emotional and self-esteem issues, and many undergo multiple, additional operations in an attempt to correct problems that are often iatrogenic and avoidable. The elective and medically unnecessary nature of breast augmentation makes negative tissue compromises and uncorrectable deformities all the more illogical and unnecessary.

Each of the negative consequences listed previously is much greater in two specific groups of patients: (1) patients with a “tighter” skin envelope preoperatively, and (2) patients with a pre-

viously stretched and thinned envelope. The greatest risk to patients’ tissues from high- and extra-high-projection implants is using the implants in primary augmentation to force any patient’s tissues to a preconceived or desired result. Figure 4 dramatically illustrates the potential tissue consequences for patients who may request higher projection and a high- or extra-high-profile implant. Surgeons should be fully aware that the firmer or more cohesive the silicone gel filler of any implant, and/or the larger the implant, the greater the transmission of pressure to tissues by the implant. The weight and pressure effects of high- and extra-high-profile implants

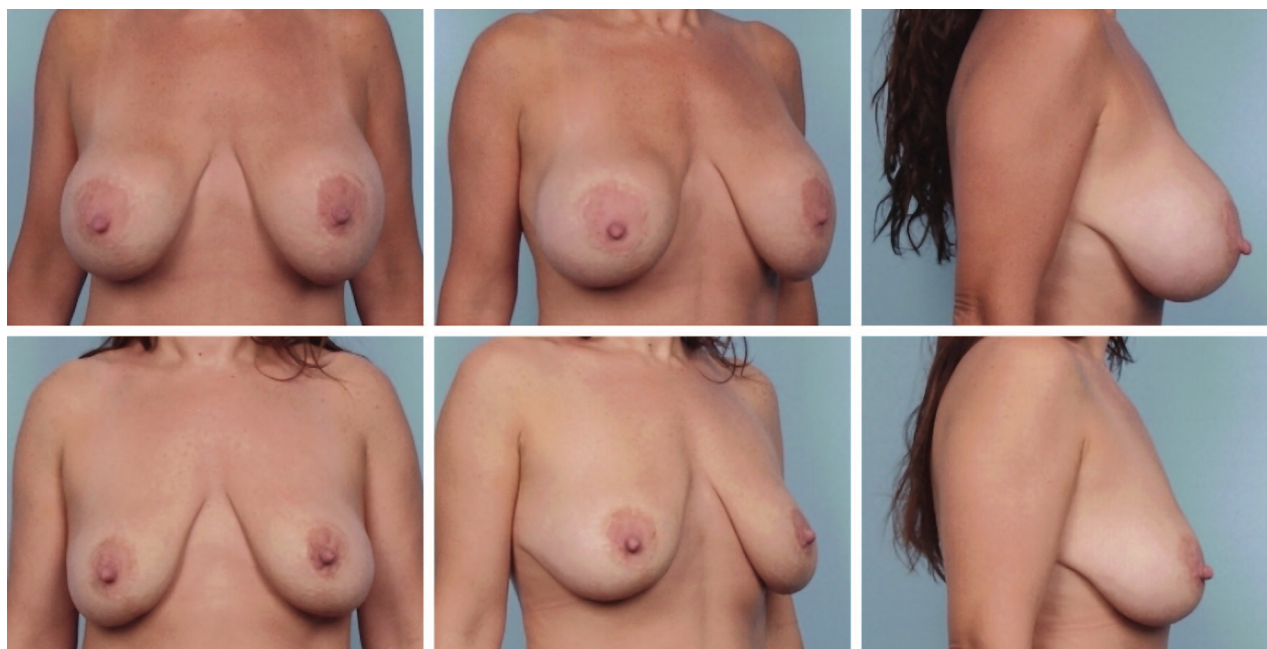


Fig. 5. (Above) Result 6 years after treatment of glandular ptosis with high-profile, 500-cc implants and a periareolar “mastopexy.” The result illustrates a larger breast that is lower on the torso, with disproportionate lower breast fill, inadequate upper breast fill, a stepoff from chest wall to breast, and medial and lateral traction webbing at the junction of inframammary fold skin with the torso. (Below) The patient, despite compromised tissues, is better served long-term by explantation of the large, highly projecting implants to minimize further tissue consequences.

can be equally detrimental to tissues that are thin and stretched from pregnancy or from previous implants. Delivering the advantages of any implant design with minimal compromises to patients' tissues requires that surgeons understand implant–soft-tissue dynamics and carefully consider indications for use of high- and extra-high-projection implants.

SUGGESTIONS FOR USE OF HIGH- AND EXTRA-HIGH-PROFILE IMPLANTS

To avoid uncorrectable tissue compromises and deformities for patients, surgeons should define indications for implant selection using quantified, scientifically valid data, not intuition and surgeon opinion. Requirements include measuring tissue characteristics including the thickness of parenchyma and dimensions of skin, using proved implant selection decision processes, and documenting changes in tissues over time that result from extra-high-projection implants using clinical measurements and breast imaging. This article does not define the level at which implant projection or filler material may adversely or irreversibly affect patients' tissues. Specific indications based on scientifically valid, comparative scientific data are needed. Based on 45 years of combined clinical experience, and prioritizing the safest out-

comes for augmentation and revision patients with the least compromises, our current indications for use of high- and extra-high-profile implants include the following:

1. High- or extra-high-projection implants are rarely indicated for primary breast augmentation or revision. Published series indicate that a wide range of primary augmentation can be adequately treated with moderate projection devices that may have a lower risk of long-term tissue compromises. These series currently document the lowest reoperation rates and rates of uncorrectable deformities in the medical literature for comparable series.^{3–9} In overly stretched envelopes and revision cases, staged envelope reduction and secondary placement of a smaller and less projecting implant may be a much better option for preventing damage to patients' tissues, and may incur less perioperative risks and provide optimal predictability. The cost of two procedures is inconsequential compared with the cost of irreversible tissue compromises and complications.
2. Highly cohesive, shaped implants are rarely an ideal choice for reoperation or revision because of the inability of surgeons to con-



Fig. 6. (Above) A 31-year-old patient with glandular ptosis who did not desire mastopexy and underwent augmentation with high-profile 375-cc implants (*center*), at 13 months postoperatively. The patient subsequently developed grade 3 capsular contracture (*below*) 23 months postoperatively, showing tissue thinning and webbing at the medial and lateral aspects of the inframammary fold skin. With relatively mild capsule contraction, implant edge visibility is present bilaterally in the upper medial aspect of the breasts because of skin thinning.

control the tissue environment in already compromised tissues. Previously stretched tissues (with or without vascular compromise) are more prone to further stretch and to the inability to control pocket dimensions—a combination that increases risks of implant malposition with shaped implants. If minimizing reoperations is the goal, round gel implants may be a better alternative for reoperations compared with shaped implants.

3. Highly cohesive, shaped implants greater than 400-cc volume, even in wider breasts

with more lax skin envelopes,^{2,3} are rarely indicated for primary or revision augmentation because implant weight in these cases virtually ensures more tissue stretch and less predictable implant position. Even if malposition rates are low, they are not low for reoperation patients who require exchange to a round implant when anatomical implant malposition occurs because of skin stretch around a shaped implant.

4. A highly cohesive, shaped implant, especially with high or extra-high projection, is



Fig. 7. An 18-year-old patient preoperatively (*above, left*), on the operating table (*above, right*) with 380-cc, high-profile, saline-filled implants filled to 440cc, and 2 years postoperatively (*below, left*). Six years later (*below right*), at age 24, following three additional operations, this patient had the potential for drastically negative tissue consequences even in young patients with ideal tissues and with a deformity that seemingly provides logical indications for a high-profile or extra-high-profile breast implant. The implant base width exceeds the base width of the atrophied parenchyma, inadequate soft-tissue coverage and tissue thinning have produced edge visibility, and the weight of the implant pulling on thin overlying tissues has produced severe traction rippling. Mastopexy to improve the configuration of the stretched envelope has added additional tradeoffs of scars and potentially compromised sensation while questionably (and transiently) improving breast aesthetics.

never indicated for any primary breast augmentation patient's tissues to force a patient's tissues to a desired result that exceeds an amount that can be substantiated to be safe by quantitative tissue measurements preoperatively and peer-reviewed and published data.³⁻⁹ Peer-reviewed and published processes demonstrate unequivocally that by applying tissue-based planning and implant selection, surgeons and patients can dramatically lower reoperation rates and exponentially reduce risks of uncorrectable tissue deformities.³⁻⁹ These studies conclusively demonstrate that nearly any primary augmentation problem can be optimally treated without using high- or extra-high-projection

breast implants while delivering the lowest reoperation rates and the most rapid recovery in the literature.

Although concerns and highly restricted indications for use of high- and extra-high-projection implants may seem excessive to some colleagues, these indications have delivered scientifically verified, peer-reviewed, and published patient outcomes that set benchmarks for dramatically improved patient recovery and reoperation rates and a low risk of permanent tissue compromise.³⁻⁹ Exceeding the parameters of these studies using large (>400 cc or >400 g) or high- and extra-high-projection implants requires that surgeons document the safety and efficacy of high- and ex-

tra-high-profile implants in comparable, scientifically valid studies.

POTENTIAL IMPROVEMENTS TO PROTECT PATIENTS' TISSUES

Data currently exist that could be tremendously helpful to base the selection of high- and extra-high-profile implants on valid data. Current U.S. Food and Drug Administration premarket approval data include serial magnetic resonance imaging and device-specific adverse events data. These data could document types and degrees of tissue changes from a range of implant types and sizes. Unfortunately, to date, implant manufacturers have consistently used proprietary rights explanations to avoid providing these data for independent device- and size-specific review. Surgeons and breast implant manufacturers who prioritize patients' tissues have an opportunity and a responsibility to take a closer and more scientific look at high- and extra-high-profile breast implants and work together to better define optimal, safe indications and limitations for the use of these devices.

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