Techniques in Cosmetic Surgery

An Approach that Integrates Patient Education and Informed Consent in Breast Augmentation

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Informed consent requires surgeons to provide information about all available alternatives and their associated risks and tradeoffs to every prospective breast augmentation patient. The informed patient and surgeon then make decisions based on the information the patient has received, clinical parameters that may affect those decisions, and the patient’s willingness to accept specific risks and tradeoffs. During the authors’ 22 years of clinical practice, substantial changes have occurred in the requirements for adequate informed consent and the methods of ensuring that patients receive it.

The numbers of alternatives for augmentation and the relative benefits and risks of each method have changed substantially over the past two decades. Four specific areas of postoperative issues stimulated major changes in the authors’ approach to patient education and informed consent: 1) questions or dissatisfaction with implant size postoperatively, 2) questions about financial responsibility for costs associated with untoward events requiring reoperation postoperatively including capsular contracture or other problems, 3) spouses or other concerned parties rendering opinions postoperatively when they had not been involved in the informed consent process, and 4) criteria for whether reoperations were indicated, how many were indicated, and when implant removal without replacement might be most logical.

This paper describes an approach that integrates patient education and informed consent in stages by 1) providing detailed, highly specific written and verbal information, 2) utilizing a staged approach to education and informed consent that provides information and requires simultaneous, informed consent in stages, 3) repeating each critical topic at least two or three times during the process, requiring repetitive written documentation by the patient on at least three different occasions, 4) emphasizing patient accountability for choices selected, and 5) organizing the education and informed consent process so that it is clinically practical and also increases thoroughness and documentation while conserving surgeon time.

This staged, integrated system of patient education and informed consent uses a comprehensive set of informed consent documents that are available for downloading from the Plastic and Reconstructive Surgery Web site (www.plasreconsurg.org).

Before incorporating any of the informed consent documents or statements reported in this paper, each surgeon should seek review by the surgeon’s malpractice insurance carrier and by appropriate legal counsel to ensure compliance with state and federal laws applicable to the surgeon’s practice. These documents have evolved to prospectively address patient management issues that have occurred over the authors’ 22-year experience in augmentation. The documents are not endorsed by ASPS and do not necessarily represent the views of ASPS. (Plast. Reconstr. Surg. 110: 971, 2002.)

“It has been the universal experience of most medical malpractice insurance carriers, that of all the procedures in the plastic surgeon’s bag of tricks, it is surgery of the female breast that is the commonest generator of claims.” “Contrary to popular belief, informed consent is not just having a patient sign a piece of paper; it is a process. In the last five years most medical liability carriers have experienced a notable increase in claims that allege failure to obtain proper informed consent before treatment. Nowhere is this more important than in augmentation mammoplasty.” These statements by Dr. Mark Gorney emphasize the importance of thorough informed consent in augmentation mammoplasty for both patient and surgeon. This article addresses the authors’ clini-
cal experiences and evolution of the patient education and informed consent process in a 22-year practice of breast augmentation using every incision approach, pocket location, and type of implant available during that period.

The statements in this paper and the accompanying documents reflect the views of the authors based on a 22-year clinical experience. The documents are not endorsed by ASPS. They reflect the views of the authors, which are not necessarily those of ASPS. They should not be adopted verbatim without consultation with the members' malpractice carrier and legal counsel.

Before 1989, the senior author's preferred operation for most primary breast augmentation patients was the axillary, subpectoral approach. Information and consent forms consisted primarily of information provided by the State of Texas, professional societies, and our malpractice insurance carrier. After consulting with the surgeon and reviewing the consent form jointly, the patient signed a single operative consent form for augmentation. This early approach to informed consent changed markedly as the result of a) the 1992 "Breast Implant Crisis," b) increased clinical experience with a wide range of incision approaches, pocket locations, and implant types, and c) specific experiences that occurred postoperatively.

Clinical Experiences and Observations

The patient education and informed consent process has evolved based on the following observations from 22 years of clinical experience:

1) Regardless of the amount of written and verbal information provided patients, retention of that information is limited and decreases with time or the occurrence of untoward events.

2) Any process of informed consent is, to some extent, burdensome and boring to surgeons. Issues that arise postoperatively, however, can be substantially more burdensome compared with a well-organized, comprehensive, thoroughly documented informed consent process integrated with patient education so that the documentation requires no additional surgeon time commitment preoperatively.

3) Patients are increasingly aware of the wide range of alternative incision approaches, pocket locations, surgical techniques, and implant alternatives available. Informed consent law assigns an affirmative duty for surgeons to provide information to every patient about treatment alternatives (and no treatment) with the risks and benefits of each. There is no single best incision approach, pocket location, or implant type or shape; patients must be aware that each alternative or choice has inherent benefits and tradeoffs and that there are only different sets of tradeoffs and risks.

4) Information transferred to the patient is largely invalid if not completely and thoroughly documented. "Line-by-line" or individual paragraph documentation by patient initials more effectively documents a patient's understanding and consent compared with a single patient signature at the end of a lengthy document.

5) Patients often ask their surgeon to make decisions for them, but may easily forget the reasoning, risks, and tradeoffs associated with those decisions compared with decisions the patient makes herself and clearly documents line-by-line. This type of record is invaluable for reference in the event of untoward occurrences or postoperative questions. As Gorney points out, "Pursuant to some clearly articulated changes in legal policy by the United States Supreme Court, it is the prerogative of the patient, not the physician, to determine the direction in which it is believed his or her best interests lie."

6) Patients retain more information if the information is presented repetitively, at each stage documenting their understanding and acceptance of responsibility for risks, tradeoffs, or consequences associated with each topic and each choice they make.

7) Repetitive education and repetitive documentation of informed consent line-by-line or topic-by-topic more effectively verifies informed consent if challenged legally compared with a single educational event and informed consent document.

8) To be clinically practical, a repetitive education and informed consent process
must be well-organized, must incorporate information and documentation materials that are comprehensive but efficient, and must effectively use trained paramedical personnel to maximize surgeon time utilization.

9) Financial responsibilities associated with common postoperative problems are best discussed in detail preoperatively, definitively assigning responsibility for reoperation costs to either patient or surgeon and clearly documenting each party’s acceptance of responsibility for those costs.

10) Surgeons should preoperatively address any unpredictable or uncontrollable event that may increase risks of reoperations, complications, tissue compromises, or the necessity of implant removal in the future (e.g., implant size issues, capsular contracture, stretch deformities, infection). Patients should understand the remedial actions that are likely to be recommended for each type of occurrence, should understand when implant removal may be recommended to decrease further risks and costs, and should document their acceptance of these remedies in writing before their augmentation.

11) Any spouse or significant other who will be involved in patient decision-making processes or any discussions postoperatively of results or management of untoward events should be required to participate in the patient informed consent process preoperatively, or should refuse to be involved by informed consent document.

Four specific areas of postoperative issues stimulated major changes in our approach to patient education and informed consent: 1) questions or dissatisfaction with implant size postoperatively, 2) questions about financial responsibility for costs associated with capsular contracture or other problems postoperatively, 3) spouses or other concerned parties rendering opinions when they had not been involved in the informed consent process, and 4) criteria for whether reoperations were indicated, how many, and when implant removal without replacement might be most logical.

Overview of the Informed Consent Process

Table I outlines events in a staged, repetitive approach to patient education and informed consent, persons involved at each stage, and specific documents used at each stage of the process. Each of these documents is numbered and is available for download from the Plastic and Reconstructive Surgery Web site at www.plasreconsurg.org. Documents 1 through 10 are used in the authors’ practice for every augmentation patient. Additional documents are used for specific clinical circumstances and are self-explanatory.

The Initial Telephone Call to the Office

When a patient calls our office, a patient coordinator or patient educator answers all of the patient’s initial questions and provides basic information about augmentation and our practice. The patient then receives detailed, extensive written information. Each surgeon can individualize written information to fit the surgeon’s skills and preferences, additional professional societies’ materials, or other materials. During the initial call, office personnel emphasize the importance of thoroughly reading the information and listing questions before scheduling a consultation visit with a patient educator. Each patient is required to have a 45-minute to 1-hour consultation with a patient educator on a separate day before her consultation with the surgeon. This procedure ensures that 1) the patient will receive information and answers to questions, consider and discuss options, consider preferences and choices, and sign informed consent documents on multiple occasions, 2) the patient receives information on different days by different personnel with opportunity between consultations to carefully review and consider the information, and 3) the surgeon gets a more accurate and thorough assessment of the patient’s assimilation of knowledge and her consistency in stated goals and preferences.

Clarifying the Role of Other Parties

Any person other than the patient who will be involved in discussions of results, problems, or expectations postoperatively should become involved preoperatively. When other parties are involved in a patient’s choices, decision-making process, or in discussions with the office postoperatively regarding any aspect of the patient’s result, breast size, expectations, or
other issues, it is imperative to provide information to that person preoperatively and to clarify their role and expectations. Patients must understand that another person’s input is welcome, but all decisions regarding final surgical and implant decisions are based entirely on the patient’s written requests. To clarify these issues with the patient preoperatively, personnel discuss this issue in detail during the initial telephone call to the office, and ask that the other person(s) involved read all materials and be present during the patient educator and surgeon consultations. The patient and the other involved person(s) initial line items in a document entitled Will Anyone Else Be Involved at the patient educator and surgeon consultations. The documents convey a specific message to other involved parties—your involvement is welcome, but if you want to be involved in discussing or criticizing the outcomes of the surgery, become involved, informed, and openly discuss your objectives preoperatively.

The Patient Educator Consultation
To ensure a more flexible and unhurried environment for the patient and patient educator, the patient educator schedules consultations when the surgeon is not in the office. A Patient Educator Checklist (Document #1) lists essential information on a comprehensive range of topics. The patient educator follows this detailed, written outline for the consultation, discussing each topic with the patient, answering questions to help her better understand available alternatives and the tradeoffs and risks of each alternative. The patient educator assesses specific responses of the patient to questions structured to assess comprehen-
sion of information, decision-making abilities, the consistency of requests, possible hidden agendas, and suitability as a candidate for augmentation. The patient views before and after pictures and implant products in the presence of the patient educator to ensure an appropriate perspective for the patient, establishing an understanding that a picture cannot document tissue characteristics, and therefore a result cannot match any picture. The patient educator is invaluable to help the patient to use her knowledge to make choices.

Patients are not charged for patient educator consultations. The goal of the patient educator consultation is to personalize written information, clarify questions about the information, review pertinent topics, answer patient questions, and equip the patient to better communicate with the surgeon, define preliminary preferences, and screen unsuitable candidates for augmentation. Patients frequently share insightful information with patient educators that they may not share with the surgeon, information that sometimes is critical to the decision-making process.

After discussing all items on the checklist and answering patient questions, the patient educator asks the patient to define preliminary preferences based on her personal desires and the written and verbal information she understands, using a document entitled Preferences and Choices for Augmentation and Factors the Surgeon Cannot Control (Document #2). This document defines realistic, available alternatives, and helps the patient understand and focus on what realistic choices instead of unrealistic perceptions. This document also defines aspects of capsule formation, contracture, and tissue stretch that the surgeon cannot control. During this process, patients often provide additional information or insight that the patient educator can document for the surgeon before the surgeon sees the patient. If the patient seems tentative or confused about alternatives, the patient educator uses an Augmentation Decisions Flowchart (Document #3) that helps guide the patient step-by-step through available alternatives. At the conclusion of the patient educator consultation, the patient completes two additional, critical documents. The first document entitled How Did We Do Informing You? (Document #4) specifically addresses critical issues and questions that the patient must address appropriately to be a suitable candidate for augmentation. This document is purposefully repetitive and definitive because it a) asks the patient to confirm having read the initial written information, b) asks the patient to confirm her understanding of alternatives, choices, and surgical limitations from the initial written information, and c) strongly confirms the patient’s understanding and acceptance of tradeoffs, risks, factors beyond the surgeon’s control, and remedies and financial responsibility for possible untoward occurrences following surgery. The final document, Will There Be Anyone Else Involved—Part 1 (Document #5), requires the patient identify anyone else who will be involved in the decision-making process or in assessing and rendering opinions about outcomes postoperatively. If another person is present at the consultation or if another person will be involved, the patient receives the second part of this document, Will There Be Anyone Else Involved—Part 2 (Document #6). The patient is responsible for having the other person read, sign, and return this document at least 2 weeks before surgery.

At the conclusion of the patient educator consultation, the patient, patient educator, and a witness sign the Patient Educator Consultation Checklist verifying the discussions that occurred. On the Clinical Evaluation Sheet (Document #7), the patient educator transfers preliminary patient choices information and completes medical history information that is used later on the same sheet by the surgeon during the surgeon consultation. The patient initials the information on the Clinical Evaluation Sheet to reconfirm her preferences and understanding of important information.

The Surgeon Consultation—Final Choices

Patient and surgeon make final choices at the surgeon consultation. Patients understand that during their surgeon consultation, the surgeon will help them reconcile their desires and choices with their individual tissue characteristics to define realistic goals, expectations, and limitations. The surgeon is most qualified to interpret tissue characteristics and effects of implant–soft tissue dynamics that determine the long-term result and risk of complications and reoperations. During the surgeon consultation, the surgeon a) reviews basic information about which the patient has questions, b) reemphasizes potential complications, tradeoffs, and the planned
remedies and financial responsibilities for each, and c) makes objective measurements of tissue dimensions, thickness, and stretch characteristics. While explaining and demonstrating pertinent findings to the patient, the surgeon records pertinent information on a Clinical Evaluation Sheet (Document #7) that incorporates operative planning and implant selection information.5 The surgeon then reviews the patient’s preliminary choices document with the patient and finalizes those choices, providing additional information to ensure that the patient understands, accepts, and initial any changes to her initial choices. Finally the surgeon emphasizes the factors of tissue healing and tissue stretch that are determined by each patient’s healing mechanisms and are beyond the control of any surgeon, and defines financial responsibilities for reoperations that may be necessary for capsules or tissue stretch problems.

Patients must ultimately make choices of incision location, pocket location, and implant type and size—either alone, or asking the surgeon acting in good faith to help with the choices. In either case, the patient must clearly document whether she is making the choices (and accepting all responsibility), or whether she is asking the surgeon to make the choices, and accepting what the surgeon chooses. The patient defines preferences during the patient educator consultation, documented on the Preferences and Choices document (Document #2) and initials line-by-line items that detail remedies and assign financial responsibility for situations such as the patient later requesting a different implant type or size, the occurrence of capsular contracture, recurrent contracture, tissue stretch deformities, infection, and other potential complications. The documents also define criteria by which the surgeon will recommend implant removal without replacement. The surgeon finally completes a Surgeon Consultation Notes document (Document #8) that confirms the content and conclusions from the consultation. The patient and surgeon review digitally captured images of the patient’s breasts, and the surgeon completes a Patient Images Analysis (Document #9) that the patient initials. This document defines factors that will not change or may only partially improve.

When the Patient Schedules Surgery

When the patient schedules surgery, she receives a package of documents to read and sign. A General Disclosure and Consent for Breast Augmentation (Document #10) is a general consent form that lists basic requirements for consent required by state law in a standard form based on state requirements and insurance carrier requirements. A Verification of Informed Consent (Document #11) repeats and verifies essential items relating to patient choice and patient understanding and acceptance of potential eventualities. Depending on the patient’s specific history (e.g., a strong family history of breast cancer) or specific requests (larger than ideal implant for tissues or implant larger than 350 cc) or requirements for adequate fill of the existing envelope, the packet includes additional specialized informed consent documents (Documents 12 through 21). The packet also includes the implant manufacturer’s package insert, informed consent documents, and implant warranty information if the manufacturer provides them. A Disclosure, Consent, and Release of Liability for HIV Testing (Document #22) grants permission for HIV testing preoperatively. Finally, the packet includes Information about Anesthesia (Document 23), Information about Financial Policies (Document #24), and Outpatient Surgical Facility informed consent documents.

After reviewing these documents with the patient, the surgery scheduling coordinator or patient coordinator instructs the patient to take all of these documents home, read and reread them carefully, and discuss them with any other involved person. If the patient has questions or does not fully understand any portion of any document, the scheduling coordinator encourages the patient to schedule another office visit with the patient educator to clarify questions. The patient must return all of these documents signed and witnessed at least 2 weeks before surgery, with no exceptions allowed for any reason. If the documents are not returned or are not completely correct, the surgery scheduling coordinator reschedules surgery and schedules another office visit for the patient to correct deficiencies.

Actions Based on Written Requests

All operative planning and implant selection decisions are based entirely on the patient’s
written requests. Any change in any choice or decision by the patient can be made verbally to the surgeon or a member of our staff, but no verbal choice or decision will be acted on by the surgeon until the patient has modified and signed the appropriate documents. Any changes must be requested at least 1 week before surgery. If any verbal changes or requests are made the day of surgery or at any time during the week preceding surgery, surgery is canceled, and another consultation appointment is scheduled to clarify changes in choices or decisions. There are no exceptions to these rules for any reason. These policies have virtually eliminated last-minute changes resulting from apprehension, hidden agendas or uninformed, third party input—changes that frequently result in additional problems, questions, or misunderstandings postoperatively.

Criteria to Decline Prospective Augmentation Patients

Patient selection is critical to avoiding potential problems in breast augmentation. Each surgeon must individually determine criteria for rejecting augmentation candidates. Several credible reasons exist to counsel women not to have augmentation. Other rejection criteria are based on tissue limitations or other clinical limitations, psychological, or financial considerations that each surgeon must define. One effective method to defining rejection criteria focuses on actual patient rejections or postoperative problems. Each time the surgeon rejects a patient (or subsequently questioned whether the patient should have been rejected), and each time that any type of problem with a patient occurs postoperatively, the surgeon and personnel formulate three questions that might have helped identify the problem preoperatively. This list of questions is continually updated and condensed based on clinical experience. Office personnel and the surgeon integrate these questions into conversations with the patient at the initial telephone call, the patient educator consultation, and the surgeon consultation. Some questions are repetitive to ensure consistent answers. This process has proved that many problems can be avoided prospectively—provided the surgeon is willing to draw strict criteria and not deviate from those criteria. Criteria for patient selection are largely simple and logical. Establishing strict criteria that do not require surgeon enforcement (and therefore do not incur surgeon bias) has greatly improved surgeon time utilization and patient selection. Impact on practice volume and efficiency has only been positive; reinforcing the belief that one problem patient costs the practice far more than any positive effect that any patient may have on the practice.

Implementation

Integrating repetitive, staged informed consent and thorough documentation requires the following: 1) surgeon commitment of time and resources, 2) adequate personnel including a minimum of a patient care/scheduling coordinator and patient educator, 3) surgeon and personnel commitment to constant revision and updating of informed consent information and documentation. Although demanding, this implementation is within the resources of every practicing plastic surgeon that performs breast augmentation. Using the more comprehensive, integrated system described in this article, total surgeon and personnel time spent per patient rarely exceeds 90 minutes. In our practice, time savings when dealing with postoperative issues have been massive. Surgeon and personnel time commitment using this comprehensive, integrated system is no greater than the abbreviated system we used 10 years earlier, but the depth of patient education and the thoroughness of informed consent documentation are exponentially better.

Most patients appreciate comprehensive information and assistance with making informed decisions and choices. Patients who are unwilling to receive comprehensive information, unable to digest or comprehend the information, and/or unwilling to make definitive written commitments to their understanding and acceptance of inherent risks, tradeoffs, and potential problems and the financial responsibilities that may result are probably not suitable candidates for breast augmentation. Patients are more likely to understand and accept realistic alternatives and facts preoperatively. If questions or problems arise postoperatively, patients may misinterpret reality and facts as excuses.

Conclusions

Efforts to improve the informed consent process for breast augmentation patients have evolved over the past two decades. Currently, the authors’ staged, repetitive patient education and informed consent process includes:
1) Comprehensive, detailed printed information, provided and repeated preoperatively.

2) Information in a variety of formats, presented and discussed by more than one person.

3) Repeated opportunities for the patient to ask questions and clarify issues.

4) Multiple stage documentation of information provided the patient, explanation of choices, eventual patient choices, and repeated efforts to provide informed consent.

5) Multiple stage patient acknowledgment of the patient’s acceptance and understanding of choices, tradeoffs, risks, and complications.

6) An effort to educate third parties who may have input to the patient’s choices, decision-making process, or evaluation of results, and to define the role of third parties.

7) A system that bases choices of surgical and implant alternatives only on a patient’s written, documented requests rather than verbal requests.

8) Preoperatively defining remedies and assigning responsibility for costs for untoward postoperative events including implant size exchange, capsular contracture, tissue stretch deformities, and infection.

9) Preoperatively defining and patients accepting endpoints for recommending implant removal.

Implementation of the informed consent process discussed in this paper over the past 5 years in more than 1000 primary augmentation patients has drastically reduced problems and misunderstandings preoperatively and postoperatively, and dramatically improved patient communication. Surgeons who have seen the system and requested the documents have successfully integrated them into their practices. As facts, information, and surgical alternatives change, patient education and informed consent must change. This current system of providing information and obtaining informed consent is a work in progress that has progressively improved communication with patients and has improved the informed consent process. Colleagues may incorporate or adapt any of the documentation in this system that they find useful into their informed consent processes.

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REFERENCES