Achieving a Zero Percent Reoperation Rate at 3 Years in a 50-Consecutive-Case Augmentation Mammaplasty Premarket Approval Study

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Background: Excessively high reoperation rates in breast augmentation premarket approval studies are a major concern of patients and the U.S. Food and Drug Administration. Over the past two decades, reoperation rates have remained between 13 and 20 percent at 3 years in three different premarket approval studies for three different types of implant devices, indicating that high reoperation rates are not device dependent. The hypothesis of this study was that implementing specific peer-reviewed and published processes can significantly reduce reoperation rates in a premarket approval study.
Methods: Fifty consecutive primary breast augmentation patients were enrolled in a premarket approval study for the Inamed Style 410 form stable, cohesive gel implant. All patients were treated specifically according to the premarket approval protocol. The series was monitored throughout the study by an independent clinical review organization and by a U.S. Food and Drug Administration inspection of the patient records on site at the author's practice. Specific content and processes were applied to patient management in patient education and informed consent, patient and surgeon decision-making processes, preoperative assessment and operative planning, implant selection based on individual patient tissue characteristics, surgical techniques, and postoperative care techniques.
Results: Follow-up was 100 percent (50 of 50 patients) at 1 year, 98 percent (49 of 50 patients) at 2 years (one patient could not be reached), and 94 percent (47 of 50 patients) at 3 years. No reoperations were performed on any patient followed at 3 years in the 50-consecutive-patient series.
Conclusion: Implementing the peer-reviewed and published processes described in this study, no reoperations were performed in a prospective 50-consecutive-case series of primary augmentation mammaplasty patients in a premarket approval study with 94 percent follow-up at 3 years. (*Plast. Reconstr. Surg.* 118: 1453, 2006.)

Premarket approval studies required for approval of breast implant devices are among the most stringent tests of outcomes data in augmentation mammaplasty. These studies follow detailed protocols defined by the U.S. Food and Drug Administration and are monitored closely by independent clinical review organizations and the U.S. Food and Drug Administration. To date, no published study exists in the peer-reviewed and indexed plastic surgery literature of a prospective, consecutive series of augmentation patients in a premarket approval study that specifically addresses reoperation rates following primary breast augmentation.

Reoperation rates are one of the most important outcome indicators for breast augmentation, because these rates reflect the quality of patient education, informed consent, decision-making processes, preoperative assessment, breast implant selection, surgical techniques, postoperative management, and management of complications and compromised outcomes. Excessively high reoperation rates may result from suboptimal implementation of any of the previously listed processes.

Excessively high reoperation rates in breast augmentation premarket approval studies are a major concern to patients and the U.S. Food and Drug Administration. Over the past two decades,

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reoperation rates have remained between 13 and 20 percent[1–3] at 3 years in three different premarket approval studies for three different types of implant devices, indicating that high reoperation rates are more a reflection of surgeon and patient processes than device inadequacies. Excessively high reoperation rates in these carefully monitored studies have been a factor in U.S. Food and Drug Administration rejection of breast implant devices that would have offered more choices and alternatives to patients and surgeons. The hypothesis of this study is that implementing specific peer-reviewed and published processes can significantly reduce reoperation rates.

PATIENTS AND METHODS

This study examines a prospective, consecutive series of 50 patients monitored by an independent clinical review organization and by the U.S. Food and Drug Administration in Inamed Corporation's (Santa Barbara, Calif.) premarket approval study for the Style 410 form stable, anatomical, cohesive gel implant. All patients in the series were enrolled, treated, and followed according to the U.S. Food and Drug Administration protocol for the study.

Patients' ($n = 50$) ages ranged from 19 to 60 years, with a mean of 35.2 years. Twenty patients were nulliparous and 30 were parous before their breast augmentation.

Patient education and informed consent followed the premarket approval protocol. In addition, all patients received the staged, repetitive education content and informed consent methods, decision support, and documentation described in previous publications in this *Journal*.[4,5]

Preoperative assessment followed the U.S. Food and Drug Administration protocol but also included tissue assessment methods[6] and decision support priorities and sequences[7] that prioritize long-term soft-tissue coverage of the implant device and base decisions of pocket location (soft-tissue coverage) and implant size on individual patient tissue characteristics.

Optimizing long-term soft-tissue coverage of the implant device is the highest priority in the decision-making process.[7] Choice of pocket location and specific treatment of the pectoralis major/breast parenchyma relationships were based on quantifiable soft-tissue parameters. Patients whose soft-tissue pinch thickness of the upper pole above the breast parenchyma was less than 2 cm had a choice of either conventional partial subpectoral placement (preserving all origins of the pectoralis along the inframammary fold) or dual-plane placement[8] (dividing pectoralis origins along the inframammary fold but preserving all medial origins along the sternum inferiorly to the sternal junction with the inframammary fold). Patients whose soft-tissue thickness at the inframammary fold was less than 0.5 cm were counseled to consider traditional partial retropectoral placement, preserving the origins of the pectoralis along the fold for additional coverage and accepting the tradeoffs of leaving those origins intact.[6,7]

All patients were allowed to choose implant size based on personal preferences and to define a specific number of grams they desired or an approximate bra cup size, acknowledging in informed consent documents that bra cup sizes are inconsistent and that the surgeon could not predictably deliver a specific bra cup size. Alternatively, the patient could choose to ask the surgeon to help select implant size based on the patient's individual tissue characteristics using the *t*issue characteristics of the *e*nvelope, *p*arenchyma, and *i*mplant and the *d*imensions and fill distribution dynamics of the implant (TEPID)[6] and the refined TEPID systems.[7] All 50 patients elected to choose implant size and pocket location based on their individual tissue characteristics to optimize long-term soft-tissue coverage and attempt to minimize potential long-term negative effects of the implant on tissues.

The specific group of implant devices was specified by the study protocol. The specific device used in all 50 patients was the full-height, moderate-profile version of the Style 410 implant. Implant pocket location was based on quantified soft-tissue parameters individual to each patient,[6–8] by measuring soft-tissue pinch thickness of the upper pole and soft-tissue pinch thickness at the inframammary fold. Implant size was selected using the TEPID[6,7] system, considering the following preoperative parameters: base width of the existing parenchyma, anterior pull skin stretch, and existing parenchyma contribution to stretched envelope fill. Decision parameters and sequences are detailed in other articles published in this *Journal*.[6,7]

Optimal inframammary fold location was determined using the volume and base width parameters of the implant selected, following the methods described in the TEPID[6] and the refined High Five systems.[7] This system specifies a desired postoperative nipple-to-inframammary fold based on the volume and base width of the implant selected. All implants were placed by means of the inframammary approach using a 5.5-cm-long in-

cision, placing the incision exactly at the level of the desired postoperative inframammary fold.

All patients received 1 g of cefotaxime (Claforan; Sanofi-Aventis Group, Bridgewater, N.J.) intravenously before surgery. No patient received postoperative antibiotics. All procedures were performed using general endotracheal and anesthetic techniques described previously.[9]

Surgical techniques in all cases emphasized no-touch techniques for rib periosteum and perichondrium and techniques of prospective hemostasis to minimize bleeding and prevent even minor blood staining of pocket tissues.[8,9] No blunt dissection was used in any area of any case during development of the implant pocket. All pocket dissection was performed with unipolar, handswitching, needlepoint electrocautery forceps.[9] Dimensions of the periprosthetic pocket were tailored to fit the base dimensions of the implant selected for each case. Before implant insertion, pockets were irrigated with sterile saline solution.

All implants were placed using a polyethylene introducing sleeve to minimize implant contact with the skin during introduction and to minimize focal pressure on any area of the implant during introduction. The full-height, anatomically shaped implant devices were positioned for optimal aesthetics and blending with the chest wall, and in most cases were not oriented exactly vertically, but in most cases were rotated off the vertical axis from 5 to 15 degrees right or left, depending on skeletal and soft-tissue anatomy.

The deep subcutaneous fascia was closed with 4-0 Prolene (Ethicon, Inc., Somerville, N.J.) and the skin with running subcuticular 5-0 Monocryl (Ethicon). At the conclusion of each procedure, a single strip of flesh-colored Dermicel tape (Johnson & Johnson, New Brunswick, N.J.) was placed over the incision. No patient in the series received any other type of bandage, strap, special bra, garment, drains, pain pumps, intercostal blocks, or other postoperative adjuncts. No patient received any type of narcotic pain medication or muscle relaxant postoperatively. The postoperative regimen described in the author's previous article detailing methods to achieve 24-hour recovery was applied to all patients in this series.[9] All patients were instructed and encouraged to go out to dinner the evening of their surgery and to resume full normal activity within 24 hours, avoiding only strenuous, aerobic, athletic activities for 2 weeks.

The premarket approval protocol required follow-up at 4 weeks, 6 months, 1 year, and annually thereafter to 10 years. Additional follow-up visits, serial photographs, and measurements were scheduled to study implant soft-tissue dynamics and soft-tissue response to the device over time. All patients in the series were required by the premarket approval protocol to have preoperative and serial postoperative magnetic resonance imaging scans every 2 years for 10 years.

Patient satisfaction was evaluated as part of a questionnaire at the 1-year follow-up visit, with 49 of 50 patients completing the questionnaire. A numeric scale was used for patients to rate their satisfaction levels, with 5 = extremely satisfied, 4 = very satisfied, 3 = satisfied, 2 = not very satisfied, and 1 = not satisfied. Patients were asked to respond to the following: (1) Please rate your degree of satisfaction with the size increase in your breasts resulting from your augmentation, and (2) Please rate the overall quality of your result, balancing improvements with tradeoffs.

RESULTS

Over the 3-year duration of the study, no intraoperative, perioperative, or postoperative complications occurred. No patient in the series developed hematoma, seroma, infection, grade 3 or 4 capsular contracture, or visible rippling or wrinkling in any area of the breast.

Follow-up was 100 percent (50 of 50 patients) at 1 year, 98 percent (49 of 50 patients) at 2 years, and 94 percent (47 of 50 patients) at 3 years. No reoperations were performed on any patient followed at 3 years in the 50-consecutive-patient series. Specifically, no grade 3 or 4 capsular contractures occurred; no patient underwent reoperation for size change, implant malposition, or any other reason. Implant size ranged from 195 to 310 g, with an average size in the series ($n = 50$) of 280 g.

Using the tissue measurement criteria described previously to prioritize optimal tissue coverage, combined with patients' requests based on informed consent mammographic and soft-tissue considerations, 40 patients had dual-plane[8] 1, seven had dual-plane 2, and three had dual-plane 3 type procedures.

In response to patient satisfaction question 1 regarding satisfaction with breast size 1 year after augmentation, with 49 of 50 patients responding, the average of the patient responses was 4.66 on a scale of 5. In response to patient satisfaction question 2 regarding satisfaction with the overall quality of the result 1 year after augmentation, with 49 of 50 patients responding, the average of the patient responses was 4.72 on a scale of 5.

Aesthetic results, detailed implant/soft-tissue interaction data, serial photographs, and serial

magnetic resonance imaging data from all patients in this 50-consecutive-case series are addressed in a separate article in preparation for submission to this *Journal*. The title of this pending article may change with further evaluation of data; thus, the article in preparation is not included in the references in this article. The data from all patients enrolled in this premarket approval study was submitted to the U.S. Food and Drug Administration by Inamed Corporation in December of 2004 and will become available to the public when the U.S. Food and Drug Administration schedules an Advisory Panel meeting to review the data.

DISCUSSION

During the three most recent U.S. Food and Drug Administration Advisory Panel hearings for silicone gel, saline, and silicone gel implants, Advisory Panel members, patients, and patient advocate groups have expressed concern over the 13 to 21 percent reported reoperation rates within 3 years following primary breast augmentation. Each of the past three U.S. Food and Drug Administration Advisory Panels has recommended that the U.S. Food and Drug Administration require surgeons and manufacturers to provide additional education to surgeons to increase patient awareness of potential risks and tradeoffs, and to address high reoperation rates. Although plastic surgery professional organizations have conducted numerous educational programs at national meetings and other venues, current surgeon education content and methods have not substantially impacted reoperation rates in premarket approval studies over the past 15 years.

When U.S. Food and Drug Administration Advisory Panel members have requested estimates of reasonable reoperation rates, manufacturers and surgeons have quoted reoperation rates from various retrospective studies—rates that are usually much lower than the premarket approval reoperation rates over the past 15 years. Members of U.S. Food and Drug Administration Advisory Panels, U.S. Food and Drug Administration scientists, and patient advocate groups have used 13 to 21 percent reoperation rates as evidence to deny approval for a medically unnecessary device used in a totally elective surgical procedure. The reoperation rates in this series of patients in a premarket approval study directly address those concerns and demonstrate that lower reoperation rates are possible in a premarket approval study.

Reducing reoperation rates in larger populations of breast augmentation patients requires increased surgeon implementation of proved processes. Surgeon and patient education are essential prerequisites to implementation of proved processes. The current 15-year record of reoperation rates in premarket approval studies suggests that significantly improving patient outcomes may require additional incentives for surgeons and patients, combined with improved selection of educational content, more effective methods of delivering that content, and more valid methods of testing to ensure delivery and implementation of the information. Improving implementation of proved processes that positively affect outcomes requires that entities delivering information and education to patients and surgeons (especially plastic surgery professional organizations and implant manufacturers) (1) acknowledge processes and content that are proved efficacious in reducing reoperation rates in stringently peer-reviewed and published studies and premarket approval studies, (2) base their education program content decisions on scientifically peer-reviewed and published processes instead of previous program evaluation results from surgeons stating what they may want to hear in educational venues, and (3) validate the methods used to deliver educational information by appropriate testing and outcomes analysis. Implementation further requires that incentives exist to ensure patient and surgeon accountability for reoperation rates and outcomes in breast augmentation.

An important question is whether the results achieved in this study are more the result of the surgical experience of the author compared with proved processes, and whether these results are reproducible by other surgeons. Although this article does not definitively answer this question, investigators in this same premarket approval study are reporting extremely low reoperation rates[10,11] using patient education and clinical processes similar to the processes reported in this article. Other surgeons with less than 10 years in practice are reporting low reoperation rates using similar processes.[7]

CONCLUSIONS

Implementing peer-reviewed and published processes described in this study,[4–9] no reoperations were performed in a prospective 50-consecutive-case series of primary augmentation mammaplasty patients in a premarket approval study with 94 percent follow-up at 3 years. Patient satisfaction with breast size and with the overall quality of their results was extremely high. This is the first prospective, consecutive case experience in

current peer-reviewed and published literature that documents a 0 percent reoperation rate in a premarket approval study of breast implants.

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DISCLOSURES

The author is an investigator in the premarket approval study described in the article and received financial support from the manufacturer for staff services during the study. A member of the author's family is an employee of a business entity that receives consulting fees and product royalty payments from Inamed Corporation for the author's breast implant designs and from Cardinal Snowden Pencer for the author's breast instrument designs. The study described in this article was monitored by an independent clinical review organization and by U.S. Food and Drug Administration inspectors at the author's practice location.

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