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Abstract:

Disclosure

The author is an investigator in the PMA study described in the paper 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 paper was monitored by an independent clinical review organization and by FDA inspectors at the author's practice location.

Dear Dr. Rohrich:

Enclosed is a manuscript entitled "Achieving a Zero Percent Reoperation Rate at 3 Years in a 50 Consecutive Case Augmentation Mammoplasty PMA Study" that I would like to submit for review for publication in the Journal.

All data in this paper is original, has not been previously published and will not be submitted to any other journal.

Please feel free to contact me with any questions regarding this manuscript.

Thank you for your considering this manuscript.

Sincerely,

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**Achieving a Zero Percent Reoperation Rate at 3 Years in a 50 Consecutive
Case Augmentation Mammoplasty PMA Study**

**John B. Tebbetts, M.D.
Dallas, Texas**

Achieving a Zero Percent Reoperation Rate at 3 Years in a 50 Consecutive Case Augmentation Mammoplasty PMA Study

Abstract

Background

Excessively high reoperation rates in breast augmentation premarket approval (PMA) studies are a major concern to patients and the FDA. Over the past two decades, reoperation rates have remained between 13 and 20 percent at 3 years in three different PMA's for three different types of implant devices¹⁻³, indicating that high reoperation rates are not device dependent. The hypothesis of this study is that implementing specific peer reviewed and published processes can significantly reduce reoperation rates in a PMA study.

Methods

50 consecutive primary breast augmentation patients were enrolled in a premarket approval (PMA) study for the Inamed Style 410 form stable, cohesive gel implant. All patients were treated specifically according to the PMA protocol. The series was monitored throughout the study by an independent clinical review organization and by an FDA 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^{4,5}, patient and surgeon decision making processes^{4,5}, preoperative assessment and operative planning^{6,7}, implant selection based on individual patient tissue characteristics^{6,7}, surgical techniques^{8,9}, and postoperative care techniques⁹.

Results

Followup was 100% (50/50) patients at one year, 98% (49/50) at two years with one patient unable to reach, and 94% (47/50) at 3 years. No reoperations were performed on any patient followed at 3 years in the 50 consecutive patient series.

Conclusions

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 mammoplasty patients in a PMA study with 94% followup at 3 years.

Disclosure

The author is an investigator in the PMA study described in the paper 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 paper was monitored by an independent clinical review organization and by FDA inspectors at the author's practice location.

Achieving a Zero Percent Reoperation Rate at 3 Years in a 50 Consecutive Case Augmentation Mammoplasty PMA Study

Background

Premarket approval (PMA) studies required for approval of breast implant devices are of the most stringent tests of outcomes data in augmentation mammoplasty. These studies follow detailed protocols defined by the FDA and monitored closely by independent clinical review organizations (CRO) and the FDA. 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 PMA 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 application of any of the previously listed processes.

Excessively high reoperation rates in breast augmentation premarket approval (PMA) studies are a major concern to patients and the FDA. Over the past two decades, reoperation rates have remained between 13 and 20 percent¹⁻³ at 3 years in three different PMA's for three different types of implant devices, indicating that high reoperation rates are not device dependent. Excessively high reoperation rates in these carefully monitored studies have been a factor in FDA 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.

Methods

This study examines a prospective, consecutive series of 50 patients monitored by an independent CRO and by the FDA in Inamed Corporation's PMA study for the Style 410 form

stable, anatomic, cohesive gel implant. All patients in the series were enrolled, treated, and followed according to the FDA protocol for the study.

Patients' (n=50) age ranged from 19 to 60 years, with a mean of 35.2 years. 20 patients were nulliparous and 30 were parous prior to their breast augmentation.

Patient education and informed consent followed the PMA 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 FDA protocol, but also included tissue assessment methods⁶ and decision support priorities and sequences⁷ 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 cover of the implant device is the highest priority in the decision making process⁷. 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 (STPTUP) 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 placement⁸ (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, while 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 TEPID™⁶ and the refined TEPID™ systems⁷. All of the 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 of the 50 patients was the full height, moderate profile (FM) version of the Style 410 implant. Implant pocket location was based on quantified soft tissue parameters individual to each patient⁶⁻⁸, by measuring soft tissue pinch thickness of the upper pole (STPTUP) and soft tissue pinch thickness at the inframammary fold (STPTIMF). 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 (APSS), and existing parenchyma contribution to stretched envelope fill (PCSEF). Decision parameters and sequences are detailed in other publications 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 TEPID™ systems⁷. This system specifies a desired postoperative nipple-to-inframammary fold (N:IMF) based on the volume and base width of the implant selected. All implants were placed via the inframammary approach using a 5.5 cm. long incision, placing the incision exactly at the level of the desired postoperative inframammary fold.

All patients received 1 gram of cefotaxime (Claforan) IV prior to surgery. No patient received postoperative antibiotics. All procedures were performed using general endotracheal and anesthetic techniques described previously⁹.

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 forceps⁹. Dimensions of the periprosthetic pocket were tailored to fit the base dimensions of the implant selected for each case.

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 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 and the skin with running subcuticular 5-0 Monocryl. At the conclusion of each procedure, a single strip of flesh colored Dermicel tape 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 paper detailing methods to achieve 24-hour recovery was applied to all patients in this series⁹. 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 two weeks.

The PMA protocol required followup at 4 weeks, 6 months, 1 year, and annually thereafter to 10 years. Additional followup 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 PMA protocol to have preoperative and serial postoperative MRI scans every two years for 10 years.

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.

Followup was 100% (50/50) patients at one year, 98% (49/50) at two years, and 94% (47/50) at 3 years. No reoperations were performed on any patient followed at 3 years in the 50 consecutive patient series.

Aesthetic results, detailed implant-soft tissue interaction data, serial photographs, and serial MRI data from all patients in this 50 consecutive case series are addressed in other submissions to this Journal.

The data from all patients enrolled in this PMA study was submitted to the FDA by Inamed Corporation in December, 2004, and will become available to the public when the FDA schedules an Advisory Panel meeting to review the data.

Discussion

During the three most recent FDA Advisory Panel Hearings for silicone gel, saline, and silicone gel implants, advisory panel members, patients, and patient advocate groups have expressed concern over the 13-21% reported reoperation rates within 3 years following primary breast augmentation. Each of the past three FDA Advisory Panels has recommended that the FDA 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. While 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 PMA studies over the past 15 years.

When FDA 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 PMA reoperation rates over the past 15 years. Members of FDA advisory panels, FDA scientists, and patient advocate groups have used 13-21% 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 PMA study directly address those concerns, and demonstrate that lower reoperation rates are possible in a PMA study.

Reducing reoperation rates in larger populations of breast augmentation patients will require increased surgeon implementation of proved processes. Surgeon education is an essential prerequisite to implementation of proved processes. The current 15-year record of reoperation rates in PMA studies suggests that significantly improving patient outcomes may require additional incentives for surgeons and patients, combined with more effective educational content and methods.

An important question is whether the results achieved in this study are more the result of the surgical experience of the author compared to proved processes, and whether these results are reproducible by other surgeons. While this paper does not definitively answer this question, investigators in this same PMA study are reporting extremely low reoperation rates^{10,11} using patient education and clinical processes similar to the processes reported in this paper. Other surgeons less than 10 years in practice are reporting low reoperation rates using similar processes⁷.

Conclusions

Applying peer reviewed and published processes described in this study⁴⁻⁹, no reoperations were performed in a prospective 50 consecutive case series of primary augmentation mammoplasty patients in a PMA study with 94% followup at 3 years.

This is the first prospective, consecutive case experience in current peer reviewed and published literature that documents a zero percent reoperation rate in a PMA study of breast implants.

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