AUGMENTATION MANANAPLASTY

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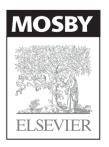
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AUGMENTATION MANAPLASTY

REDEFINING THE PATIENT AND SURGEON EXPERIENCE



JOHN B. TEBBETTS, M.D.





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DEDICATION

To Terrye and Kas.

INTRODUCTION

The patient experience in breast augmentation has been redefined during the past decade. Advances in every aspect of breast augmentation currently enable a majority of patients to be out to dinner the evening of their augmentation surgery, and enable up to 95% to return to full normal activities within 24 hours following surgery. Patients can expect this level of recovery with any type of currently available breast implant, and they can expect equal recovery with any currently described implant pocket location and with inframammary, periareolar, and axillary incision approaches.

Less than a decade ago, patients required some or all of the following after a breast augmentation procedure: compressive bandages, special straps or bras, drains, intercostal blocks, pain pumps, nerve stimulation devices, narcotic strength pain medications, muscle relaxants, motion exercises, restricted normal activities, and 1 to 2 weeks to return to full, normal activities. Today, improvements in every process in breast augmentation have made all of these postoperative measures completely unnecessary, allowing patients to experience dramatically different recovery.

Refinements in processes that have redefined patient recovery have also redefined patients' longer term outcomes and have reduced reoperation rates. Less than a decade ago, 15–20 percent reoperation rates within just 3 years following breast augmentation were documented in Food and Drug Administration (FDA) premarket approval application (PMA) studies. Currently, in large peer reviewed and published studies with up to 7 year followup, refined processes resulted in a 3% reoperation rate, and one 50 consecutive cases series in a recent PMA study documented a zero percent reoperation rate at 3 years.

These dramatic improvements for patients did not evolve from solution based thinking and designing new surgical techniques. The redefined patient experience resulted from process based thinking, reexamining all of the major process categories in breast augmentation, including patient education, informed consent, clinical evaluation, operative planning and implant selection, anesthetic techniques, surgical techniques, and postoperative care. Basic principles of process engineering and motion and time study, implemented by all of the world's most successful businesses, were invaluable as a framework to examine and improve processes in breast augmentation.

The processes described in this book have been refined over more than a decade and a half. Each process has been documented, implemented, and tested, collecting data that have been peer reviewed and published in *Plastic and Reconstructive Surgery*, the most respected professional journal in plastic surgery. This approach to process analysis, with outcomes confirmed by peer review, has produced an entirely different patient experience and redefined outcomes for breast augmentation patients.

The extent to which patients can benefit from these dramatic improvements depends on surgeon implementation of proved processes. The goal of this book is to provide surgeons a framework of proved processes to deliver a new level of patient experience and outcome in breast augmentation.

The history of breast augmentation is interesting. For more than four decades, many surgeons have considered breast augmentation a simple operation, basing clinical evaluation, implant selection, and surgical technique selections entirely on subjective parameters and surgeon preference of incision location, pocket location, and implant type. As recently as 2002, this type of approach produced up to 20% reoperation rates within 3 years following augmentation in FDA PMA studies. For more than three decades, the patient experience in augmentation remained largely unchanged. Implant options for patients declined when the "breast implant crisis" of the early 1990s prompted the FDA in the United States to remove silicone gel filled implants from the market, while a greater range of implant products remained available to patients in other parts of the world. Despite additional research supporting the safety and efficacy of silicone gel filled implants, FDA concerns regarding several additional issues including excessively high reoperation rates have delayed FDA approval of conventional and new designs of silicone gel filled devices. A majority of surgeons in the United States currently recommend and use round, smooth shell, saline filled implant devices, a design that was developed more than three decades ago.

While other medical technology fields have continually progressed with device and application innovations, breast augmentation has in some ways gone full circle in reverse.

New implant designs have not changed appreciably since 1994. Fewer implant alternatives are available to patients in the United States today compared to the 1980s. The obvious question is, "Why?"

Surgeons learn by apprenticeship. An apprenticeship educational model encourages solution based thinking. Solution based thinking is linear and algorithmic, defining a specific set of solution alternatives to address a surgical objective or problem. Solution based thinking compares one solution or technique to another, and potentially limits advancement by encouraging choices from currently available alternatives and channeling thought into a debate mode (one technique or solution versus another) instead of a continuous improvement mode (how do we improve processes to better apply every technique or implant solution).

Process based thinking, in contrast to solution based thinking, focuses on the processes and subprocesses that ultimately determine actions and outcomes. Instead of encouraging debate and choices between currently available solution alternatives (technique or implant), process based thinking encourages continuous improvement in the processes that determine optimal use of all solution alternatives. Instead of focusing on which technique or implant is currently "best", process based thinking encourages more optimal use of every available alternative by improving the processes of patient education, clinical evaluation, decision making, surgical execution, and postoperative management.

Process oriented thinking encourages surgeons to question every detail of every process, analyzing and seeking improvements in the details of each subprocess. More detailed analysis of processes stimulates lateral thinking that often sparks innovation. Analyzing the details of one process can stimulate surgeons to recognize seemingly small actions that, alone or in combination, may dramatically affect outcomes and results. For example, analyzing steps and movements in an augmentation operation using motion and time study principles (analyzing the steps in the operation process) to shorten operative and anesthesia times revealed surgical technical maneuvers that were inadvertently and unnecessarily increasing tissue trauma and bleeding. Optimizing one set of processes (eliminating unnecessary steps or movements during the operation) resulted in refinements and outcome improvements in another set of processes (surgical techniques).

Many businesses spend considerable resources to acquire and implement "best practices" (proved processes) that were developed by other companies and acquired through highly paid consultants. These companies then carefully and precisely implement the "best practices" and gather data to determine the effectiveness of each process before making

any changes to the best practices "recipe". Plastic surgeons often learn of new or improved processes in professional education venues or by reading professional journals. Instead of implementing the process exactly as described, plastic surgeons often only partially implement the processes as described, or make changes to the process based on personal preference or subjective opinion before gathering data on which to base changes in the process. The surgeon tendency to modify a proved recipe (best practice, proved process) before exactly implementing the proved process can dramatically slow improvements in the patient experience and outcomes.

Surgeon educational methods and venues have also remained largely unchanged for three decades. Highly effective education models developed and used by the world's most successful businesses require staged, repetitive educational encounters, assess the effectiveness of the education process by verification and testing, and base employee incentives and rewards on testing performance. In plastic surgery, education methods and venues seldom utilize staged, repetitive learning encounters. Testing to evaluate the effectiveness of education methods and information transfer is rare. Attendee opinions gleaned from educational venue evaluation forms often determines content and curriculum of future education venues and methods. Absent objective performance evaluations, surgeon incentives to change are limited, and limit progress for the patient and the patient's experience.

Surgeons rarely read any book cover to cover. Instead, surgeons usually access printed information when they need information about an operation that they are planning to perform in the near future. The primary limitation of all printed information for surgeons is the inability to assure transmission of essential information when the surgeon accesses only a single chapter or index reference. The only method to credibly address surgeons' needs is purposeful redundancy in a book, reiterating critical information in multiple locations to assure that the critical information is available to surgeon readers when they access limited content in a book.

This book focuses on proved processes that have a 15 year track record of delivering a redefined patient experience, improved outcomes, and lower reoperation rates in breast augmentation. Our responsibility as plastic surgeons is to our patients—to predictably deliver a continually improving level of patient experience and outcome. We have an opportunity to advance our patients' experience and outcome by applying process based thinking and best practices principles to our education methods and venues and our surgical practices. To the extent that this book can contribute to that effort, it will meet its objectives.