Cosmetic

Decision and Management Algorithms to Address Patient and Food and Drug Administration Concerns Regarding Breast Augmentation and Implants

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During the U.S. Food and Drug Administration's advisory panel hearings to evaluate the premarket approval for conventional silicone gel implants on October 14 and 15, 2003, panel members and patient advocate representatives focused on four specific areas of concern: reoperation rates in primary breast augmentation; levels, depth, and methods of patient education and informed consent; modes, frequency, and management of silicone gel implant device failures, including management of "silent" ruptures; and methods of monitoring and managing symptoms or symptom complexes that may or may not be associated with connective tissue disease or other undefined symptom complexes. These concerns, with a reported 20 percent reoperation rate for primary augmentation within just 3 years, and a lack of concise, definitive management protocols addressing these areas of concern may have contributed to the Food and Drug Administration's rejection of the premarket approval, despite the panel's recommendation for approval. This article presents decision and management algorithms that have been used successfully for 7 years in a busy breast augmentation practice (Tebbetts and Tebbetts). The algorithms have been further expanded and refined by a group of surgeons with diverse experiences and expertise to address the following clinical situations that coincide with concerns expressed by patients and the Food and Drug Administration: implant size exchange, grade III to IV capsular contracture, infection, stretch deformities (implant bottoming or displacement), silent rupture of gel implants, and undefined symptom complexes (connective tissue disease or other). In one practice (Tebbetts and Tebbetts) that uses the TEPID system (tissue characteristics of the *e*nvelope, *p*arenchyma, and *i*mplant and the

dimensions and fill distribution *dynamics* of the implant), implant selection is based on quantified patient tissue characteristics, pocket selection is based on quantified soft-tissue coverage, and anatomic saline implants have fill volumes that are designed to minimize shell collapse and fold fatigue; in this practice, the algorithms contributed to a 3 percent overall reoperation rate in 1662 reported cases with up to 7 years of follow-up, compared with a 20 percent reoperation rate at 3 years in the 2003 premarket approval study. (*Plast. Reconstr. Surg.* 114: 1252, 2004.)

During the U.S. Food and Drug Administration's advisory panel hearings on October 14 and 15, 2003, the panel members and patient advocate organization representatives voiced concerns about four specific areas regarding breast augmentation and breast implant devices: reoperation rates in primary breast augmentation; levels, depth, and methods of patient education and informed consent; modes, frequency, and management of silicone gel implant device failures, including management of "silent" ruptures; and methods of monitoring and managing symptoms or symptom complexes that may or may not be associated with connective tissue disease or other undefined symptom complexes.¹

These four areas of concern and the rates of reoperation that accompany primary breast

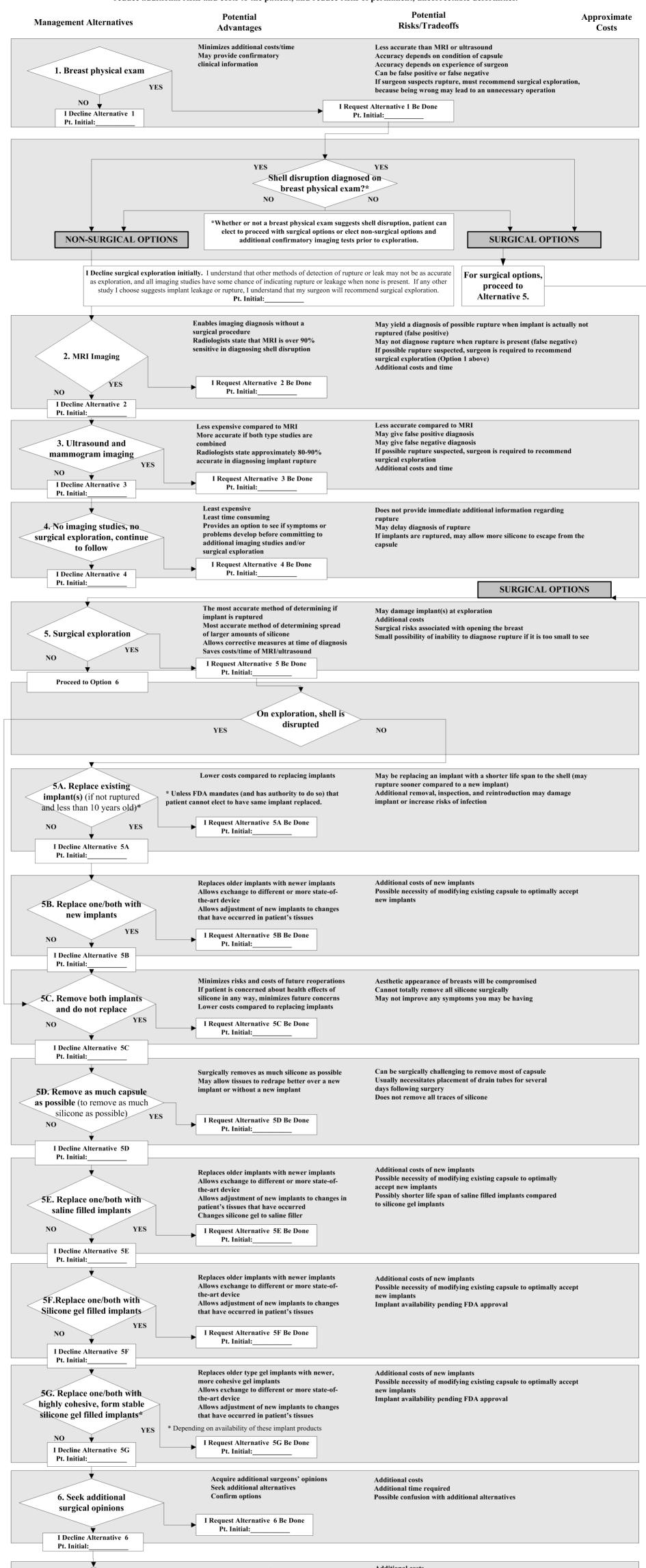
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Alternatives for Management of Concerns of Shell Disruption or Leaking Silicone Gel Implant The BASPI Workgroup, John B. Tebbetts, M.D., Moderator

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**Management alternatives are listed prioritizing alternatives most likely to reduce risks of additional operations, reduce additional risks and costs to the patient, and reduce risks of permanent, uncorrectable deformities.



Allows screening for possible leak or

Additional costs

7. Recommend MRI at 10 years and every 5 years thereafter, even if asymptomatic to screen for silent rupture		If positive, surgeon will recommend surgical exploration—see "Surgical Alternatives"
Pt. Initial:	Surg	eon actions:

1) Return all implants with shell disruption to manufacturer for analysis

2) Request a written report with results of analysis within 3 months from manufacturer

**If patient, surgeon, or patient's family are concerned about any aspect of silicone causing symptoms or possible associated conditions, see additional information and flowchart alternatives entitled "If Patient Has Symptoms or Concerns Related to Silicone"

Patient Name (please print):	Witness Name (please print):
Patient Signature:	Witness Signature:
Date:	Date:

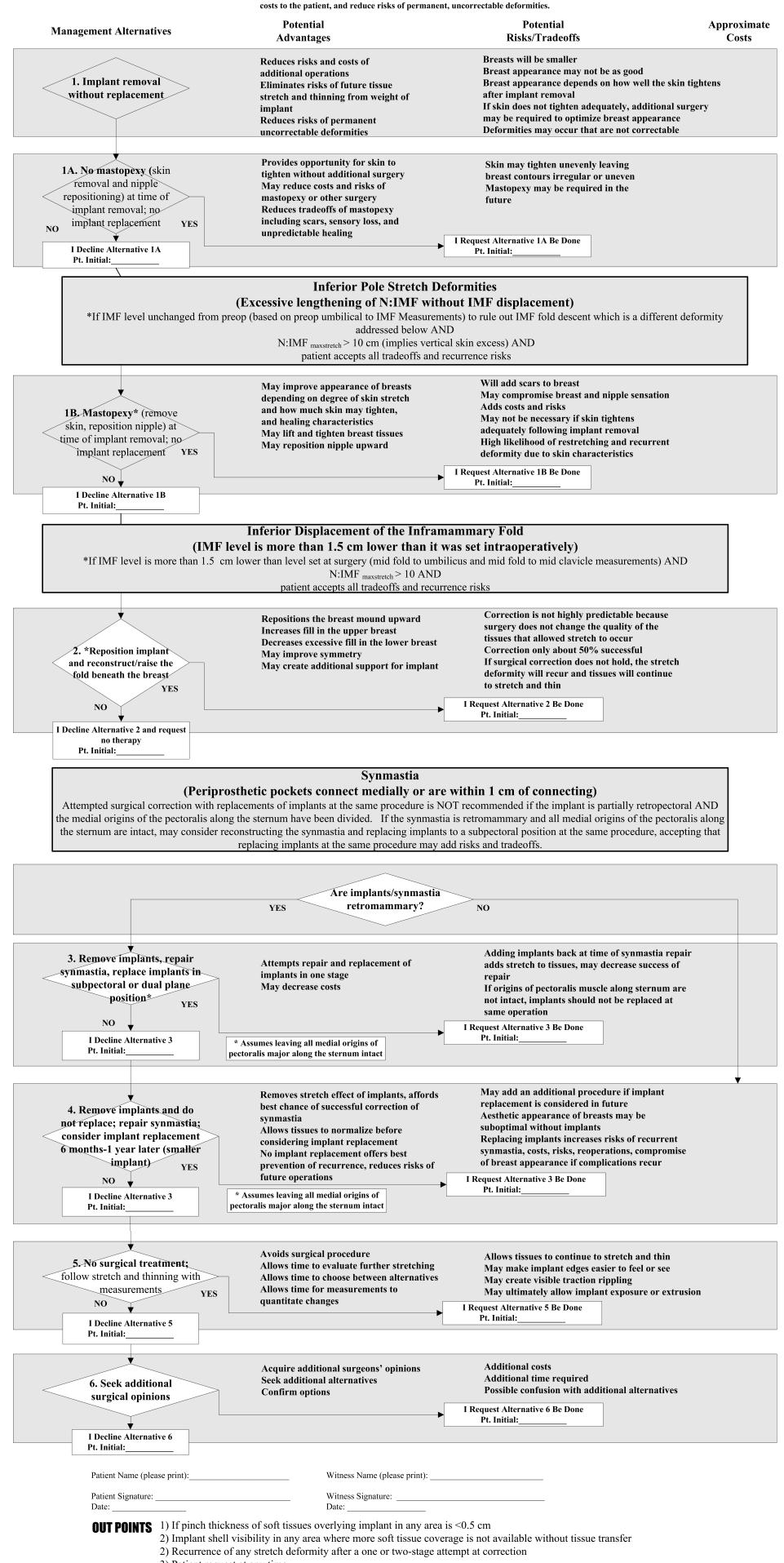
1) Patient requests removal without replacement at any time **OUT POINTS**

2) When available soft tissue coverage in any area of the breast is less than 0.5 cm pinch thickness (0.25 cm overlying implant)

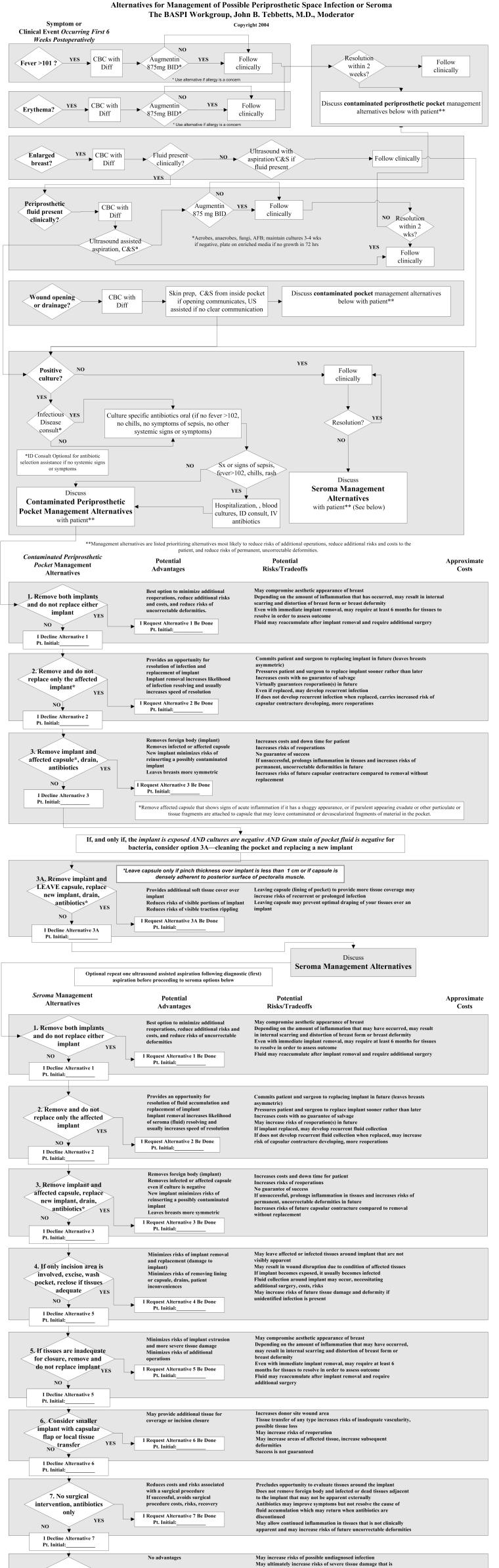
Alternatives for Management of Stretch Deformities and Implant Malposition The BASPI Workgroup, John B. Tebbetts, M.D., Moderator

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**Management alternatives are listed prioritizing alternatives most likely to reduce risks of additional operations, reduce additional risks and



3) Patient request at any time



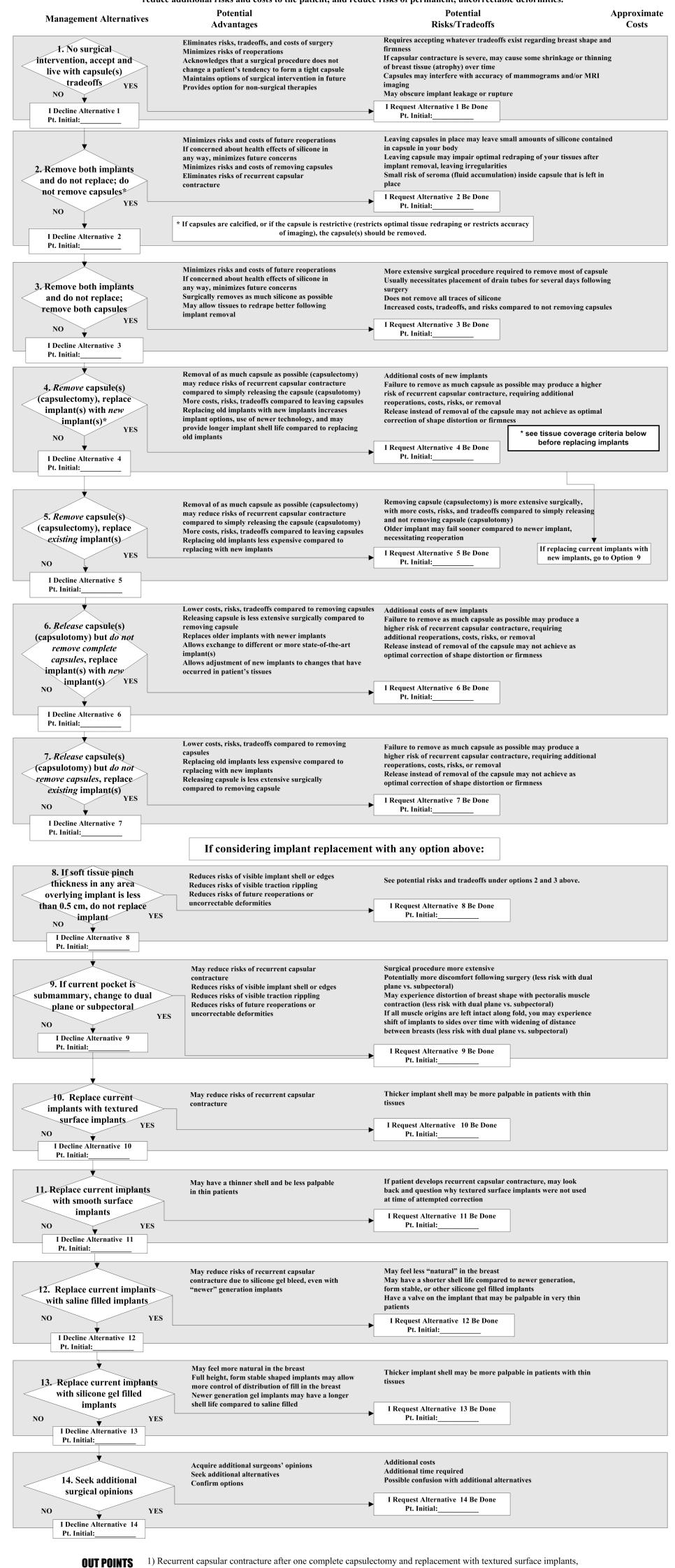
8. No treatment YES	I Request Alternative 8 Be Done Pt. Initial:	May cause stretch of tissues that produces an uncorrectable deformity or requires additional surgery		
9. Seek additional surgical opinions	Acquire additional surgeons' opinions Seek additional alternatives Confirm options I Request Alternative 9 Be Done Pt. Initial:	Additional costs Additional time required Possible confusion with additional alternatives		
I Decline Alternative 9 Pt. Initial:	Datiant Nama (alaona mint))	Witness Name (sloves with)		
	Patient Name (please print):	Witness Name (please print):		
	Patient Signature:	Witness Signature:		
	Date:	Date:		
OUT POINTS 1) Culture p	proved infection of the periprosthetic pocket			
2) Inadequa reclosure	2) Inadequate (<0.5 cm thick or severely indurated or inflammed) soft tissue coverage at the incision site for safe			
	patient requests removal without replacement			
Implant Replacement1) No replacement for 3-6 months with no evidence of infection A tissues in all areas of the breast 2) No replacement if the patient has had more than one episode of 3) No replacement if soft tissue pinch thickness in any area overly		e of infection in the affected breast		

Alternatives for Management of Capsular Contracture Grades 3 and 4 The BASPI Workgroup, John B. Tebbetts, M.D., Moderator

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**Management alternatives are listed prioritizing alternatives most likely to reduce risks of additional operations,

reduce additional risks and costs to the patient, and reduce risks of permanent, uncorrectable deformities.



or one conversion from submammary to dual plane or subpectoral

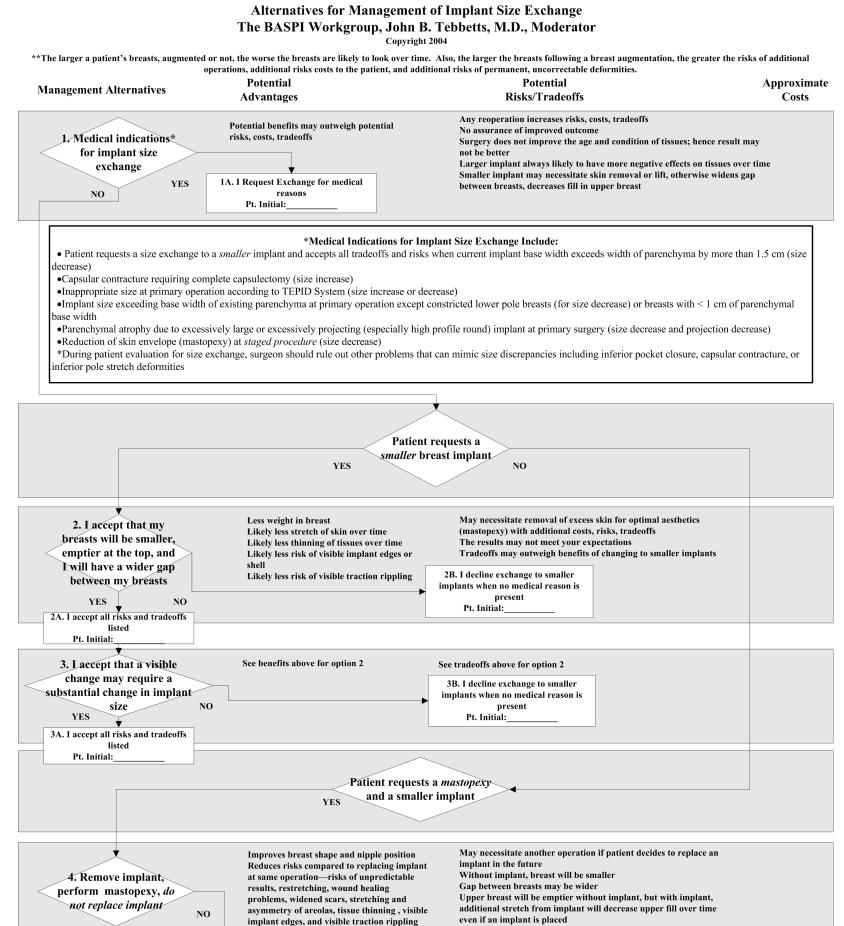
2) Soft tissue coverage over any area of the implant is less than 0.5 cm pinch thickness

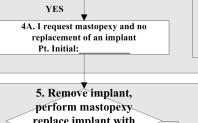
3) Patient requests implant removal without replacement at any time

information and flowchart alternatives entitled "If Patient Has Symptoms or Concerns Related to Silicone"









replace implant with new, smaller implant at same operation NO YES

◆ 5A. I request simultaneous mastopexy and implant replacement and accept all risks and tradeoffs listed Pt. Initial: Additional thinning of skin Additional shrinkage of existing breast tissue Possible sensory loss

Additional sagging of breasts

reoperation:

Possible visible traction rippling

Possible visible implant edges Deformities and compromises may be uncorrectable

Replacing an implant in a breast that has already proved it does not

support weight and sags, even if a smaller implant is placed, adds all of

the following potential risks and tradeoffs that can necessitate additional

×

Surgeon has more control over variables in

Pt. Initial:

May avoid another operation should patient

decide to replace implants after mastopexy

without implant replacement

Pt. Initial:

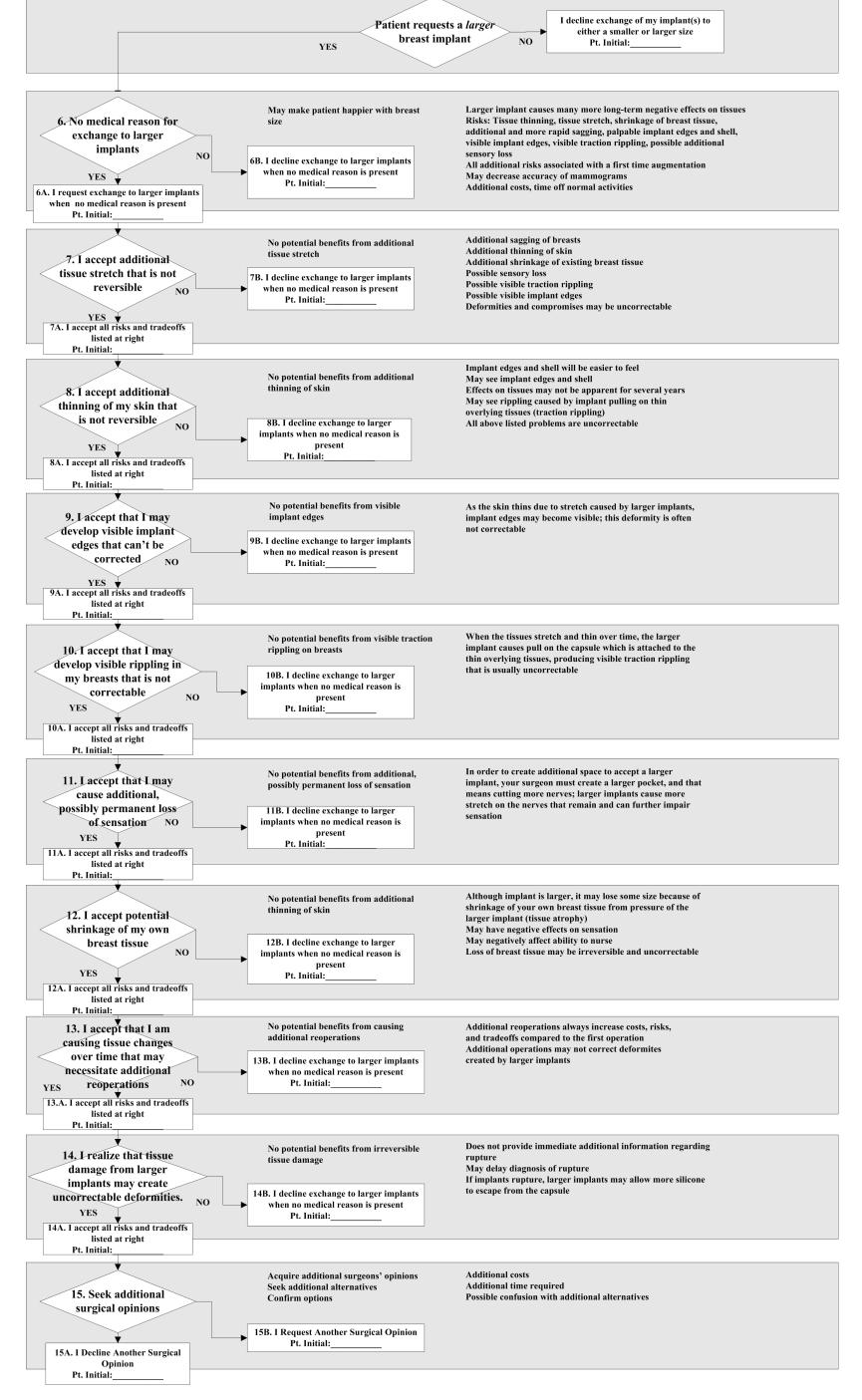
5B. I decline simultaneous mastopexy

and implant replacement

4B. I decline mastopexy and no replacement of an implant

mastopexy alone without simultaneous

implant replacement



OUT POINTS

If soft tissue coverage in any area of the breast is less than 0.5 cm pinch thickness, decline to replace with larger implants
If N:IMF is increased more than 20% compared to N:IMF set at primary surgery (if measurement data are available), decline to replace with larger implants
If any portion of the implant is visible or if visible rippling is present in any portion of the breast, decline to replace with larger size

implants

Patient Name (please print): Witness Name (please print):

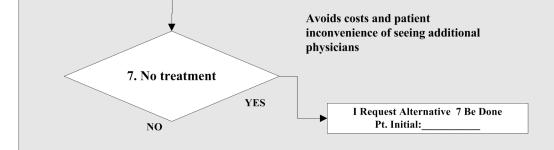
Patient Signature:	Witness Signature:
Date:	Date:

Alternatives for Management of Undefined Symptom Complexes The BASPI Workgroup, John B. Tebbetts, M.D., Moderator

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**Management alternatives are listed prioritizing alternatives most likely to reduce risks of additional operations, reduce additional risks and costs to the patient, and reduce risks of permanent, uncorrectable deformities.

and costs to the patient, and reduce risks of permanent, uncorrectable deformities.					
Management Alternatives	Potential Advantages	Potential Risks/Tradeoffs	Approximate Costs		
1. Patient presents with undefined symptoms or associated with CTDs YES	Identify and carefully document systemic or localized symptoms that may or may not relate to patient's breast implants Opportunity to offer patient referral to specialist for evaluation and opinion regarding any relationships of symptoms to her breast implants	None			
2. Refer to board certified rheumatologist and/or immunologist YES NO I Decline Alternative 2 Pt. Initial: If pt. declines #2, surgeon	Provides an opportunity for medical evaluation and diagnosis by board certified immunologist or rheumatologist May provide additional information to patient and plastic surgeon that may affect choices and decisions	Increases patient's costs and time expenditure Consultant may not be able or willing to definitively state whether symptoms are related to breast implants			
will recommend #4. 3. Consultant believes symptoms may be associated with patient's breast implants YES NO	Opportunity to get opinions from rheumatology, immunology, or other specialists regarding possible association of symptoms with patient's breast implants Opportunity for second opinion Opportunity to make more valid decisions regarding removal of breast implants	If consultant believes there is any possible a of symptoms with breast implants, surgeon recommend implants be removed and not re Consultant expertise may vary and surgeon judge consultant expertise I request/do not request (circle one) referral for another of surgeon, rheumatologist, immunologist—circle all yo Pt initial	will likely eplaced cannot pinion (plastic		
	Removing capsules and implants removes maximum possible amount of silicone from body Affords best opportunity to improve or eliminate symptoms if they are due to silicone in breast implants I Request Alternative 4 Be Done Pt. Initial: r saline implant should be reported on the form for FDA purposes.	Removing capsules prolongs surgical procedure, bleeding risks, and will likely cause more draina drain tubes following surgery Increases costs, risks, and time away from norms have implants removed May increase need for additional operations Depending on size of implants and patient tissue skin stretch from implants may require addition as lifting or nipple-areola repositioning for optin Permanent, uncorrectable deformities may occur implant removal due to patient healing character characteristics May not produce any change in symptoms if sym related to implants	ge requiring al activities to characteristics, al surgery such nal appearance r following ristics and tissue		
5. Remove both implants and do not replace, leave capsules NO ↓ YES I Decline Alternative 5 Pt. Initial:	Shorter operation time by not removing capsules, potentially less bleeding and less risk of prolonged drainage or fluid accumulation if capsules are not removed I Request Alternative 5 Be Done Pt. Initial:	May leave additional silicone in body that may be contained in the lining tissue that has formed around the implant and is not visible to a surgeon May not produce any change in symptoms if symptoms not related to implants			
6. Replace silicone gel filled implants with saline filled implants NO I Decline Alternative 6 Pt. Initial:	Reduces total amount of silicone in body May reduce potential for silicone gel bleed from gel implants	May not produce any change in symptoms not related to silicone gel Increases reoperations, costs, risks Increases reoperation risk for the future co implant removal without replacement If symptoms are related to silicone, presence shell of saline filled implants may make symptoms	mpared to e of silicone		



Refusing treatment makes surgeon unable to help the patient Symptoms may get worse or cause additional problems over time No opportunity for specialists to evaluate patient and provide additional information to help make better decisions

Patient Name (please print):	Witness Name (please print):
Patient Signature:	Witness Signature:
Date:	Date:



Board certified rheumatologist relates symptoms, findings or diagnosis to breast implants, or diagnoses CTD
Patient desires implant removal, regardless of findings of rheumatologist

augmentation in the augmentation core studies (average rate of 20 percent within just 3 years) have remained largely unchanged for more than a decade.^{2,3} Reoperation rates in premarket approval studies since 1992 have remained high while devices have changed from silicone to saline and back to silicone. Consistently high reoperation rates using different devices over more than a decade raise interesting questions: (1) To what extent are reoperation rates primarily device related, or (2) to what extent do patient and surgeon decisions and surgical techniques influence reoperation rates? A comparison of reoperation rates and panel concerns from the 1990 Food and Drug Administration's advisory panel hearings to those from the 2000 and 2003 hearings reveals that while implant devices may have changed (e.g., saline versus silicone), overall reoperation rates for primary augmentation have not changed appreciably. Understandably, scientists on the panel and patient advocacy representatives question why devices, reoperation rates, and outcomes have not improved substantially during the past decade. Interestingly, when panel members questioned surgeons and manufacturer representatives about the management of specific clinical entities that concerned the panel, clearly defined management solutions were not readily available. Testimony during the October 2003 panel hearings clearly defined a need for decision and management algorithms for clinical entities that concerned the advisory panel members.

For decades, the world's most successful businesses have understood and implemented the concept of "best practices," or "best" ways to perform business processes derived from processes that have proved effective in use.⁴ A "best practice" does not necessarily mean that the process is literally the "best"; instead, it suggests that a business practice or process "solution" is a method that has been implemented and has delivered consistently positive results. A wide range of medical specialties are currently deriving best practices for specific clinical situations using evidence-based medicine principles, by integrating individual clinical experience with the best available clinical evidence. This article presents decision and management algorithms that have been implemented for more 7 years in a busy augmentation practice and that have been further expanded and refined by a group of surgeons

with a wide range of experience and expertise. Combined with a staged, repetitive system of patient education,⁵ the TEPID⁶ system (*t*issue characteristics of the *e*nvelope, *p*arenchyma, and *i*mplant and the dimensions and fill distribution *d*ynamics of the implant) for implant selection and pocket location based on quantifiable, individual patient tissue characteristics, and anatomic saline implants with fill volumes designed to minimize shell collapse and fold fatigue,⁷ these algorithms have been a major factor contributing to an overall reoperation rate of 3 percent in 1662 patients with up to 7 years of follow-up in peer-reviewed and published studies.⁷⁻⁹

A NEED FOR BEST PRACTICES

More than 7 years ago, as we (Tebbetts and Tebbetts) focused on expanding and refining our patient education and informed consent practices,⁵ we adopted a best practices approach to help us and our personnel address specific clinical issues or problems. Problems or situations that rarely arise can often be the most challenging for patients, surgeons, and surgeons' personnel, because patient interaction, management, and clinical "solutions" are less defined compared with everyday clinical situations and issues. We realized that when faced with an issue or a difficult clinical situation or problem, if we had carefully prospectively defined and documented a process of addressing and managing the problem, management was much easier, more refined, less costly, and more comfortable for us, for our patients, and for their families. Having predefined management templates (decision and management algorithms) also allows the surgeon to focus on more sophisticated concerns and innovative solutions instead of having to rethink an entire process each time a problem occurs.

DECISION AND MANAGEMENT ALGORITHM FLOWCHARTS

As a first step to developing a best practices approach to managing issues and problems, we developed decision and management algorithms for specific clinical problems or issues that we had encountered during the past two decades. Developing decision and management algorithms is a stimulating and challenging process. Despite the fact that there exist alternative approaches to every clinical problem or issue, a flowchart-documented, algorithmic approach demands a "solution" rather than a list of alternatives that stimulate endless debate. A decision algorithm flowchart is a visible template that depicts one process that has proved clinically useful, and it can be easily changed or adjusted when new facts or data become available. Graphic representation of thought processes, decisions, and actions stimulates alternative thinking about problems or issues. A graphic algorithm flowchart helps surgeons define the sequence of decisions and the logic of management alternatives. In addition, the process stimulates surgeons to reexamine sacrosanct "answers" and develop even better solutions.

When issues or problems occur, the patient usually speaks first with the surgeon's personnel. The information the patient receives in response to his or her problem, concern, or issue can have a critical effect on the patient's comfort and confidence as the surgeon and the surgeon's staff address the problem. Decision and management algorithms are invaluable in training personnel-not necessarily to deliver definitive answers but to develop a basic knowledge of how problems will be approached when they arise. Consistency in decision-making and management processes builds confidence in surgeons' personnel, and that confidence transmits directly to patients when they most need confidence to deal with issues and adversity.

Defined processes to manage issues and problems are most effective when patients are aware of how an issue or problem will be managed *before* the issue or problem arises. As we (Tebbetts and Tebbetts) implemented our decision and management algorithms, we learned that their value increased exponentially when we used them to help educate our patients *preoperatively* about how we would manage each issue or problem postoperatively, offering them management alternatives and an opportunity to help make sometimes difficult decisions.

PATIENT EDUCATION AND INFORMED CONSENT

When a clinical situation or problem arises postoperatively, the more a patient knows from preoperative education about the problem, how it will be handled, who is responsible for costs, and the chances for correction, the more comfortably the patient can face the challenges. Preoperative informed consent materials and documents addressing the most common potential postoperative problems are available online from a previous publication.⁴ When a reoperation may be necessary, patients are often more stressed and face additional costs and risks compared with the primary operation. Before any reoperation procedure is undertaken, detailed information and informed consent documentation are arguably more critical and more challenging compared with those for the primary operation. Detailed decision and management algorithms that contain essential summary information about the potential benefits and risks help clarify the realistic choices or alternatives. They contain spaces for the patient to document his or her understanding and acceptance of choices at each decision-making stage, and they are invaluable in assuring optimal informed consent and guaranteeing the patient's involvement in the decision-making process. According to Mark Gorney, M.D., "it is the prerogative of the patient and not the physician to determine the direction in which it is believed his or her best interests lie," as the informed consent law mandates that patients be involved in the decisionmaking process.10 An integrated document that defines alternatives, provides information on potential risks and benefits, and documents the patient's choices and decisions helps the surgeon ensure optimal informed consent before a reoperation. More importantly, the documents can sometimes prevent unnecessary reoperations, such as implant size exchange operations, by providing patients with more definitive information about the risks and tradeoffs. By demanding that patients accept responsibility for their decisions, optimal informed consent documents sometimes encourage patients to reconsider their requests and decisions.

PRACTICAL CLINICAL INTEGRATION AND IMPLEMENTATION

Currently in our practice (Tebbetts and Tebbetts), each decision and management algorithm is integrated with (a) information provided to the patient in preoperative patient education and informed consent documents and (b) more detailed information and alternatives contained in additional education and informed consent documents when an issue or problem occurs. After providing the patient with detailed information addressing a specific clinical situation or problem, a patient educator and the surgeon review the information with the patient in detail. After the surgeon discusses and answers the patient's questions, the patient then re-reads and signs the informed consent document and defines his or her choices on the decision and management flowchart to verify his or her understanding and acceptance of the information and the choices made.

Reality sometimes demands difficult choices, none of which may seem ideal. One of the most difficult challenges in managing issues and problems is defining choices-translating a myriad of grey areas, unknowns, questions, wishes, and fears into realistic alternatives from which a patient may choose. A second challenge is helping the patient understand that there is no perfect choice, not at the primary operation and certainly not at a reoperation for an issue or problem. There are only different sets of tradeoffs, benefits, risks, and costs for each alternative. A clearly defined approach to management of each issue or problem and a practical, efficient system to optimize patient education and informed consent are invaluable. On first review, decision and management algorithms may seem complex, but they are only as complex as required to define the alternatives available to the patient according to the informed consent law.

MANAGEMENT AND DECISION ALGORITHM FLOWCHARTS: OBJECTIVES AND LOGIC

Each of the following flowcharts (Figs. 1 through 6) addresses a specific clinical problem or issue. They are not intended to be definitive. No "best practice" is ever definitive. Instead, each algorithm is a snapshot in time of a process that has proved clinically useful and effective—a template alternative that surgeons can examine, modify, individualize, and evolve according to surgeon and patient preferences and specific clinical situations. Each algorithm flowchart is a continuous work in progress that provides a basic set of alternatives from which to evolve better solutions.

For efficiency and to provide as much summary information as possible while outlining choices in flowchart form to help the patient make decisions, each decision and management flowchart incorporates two additional components: (1) a summary of potential benefits and tradeoffs associated with each decision and (2) a space for the patient to specifically accept or decline alternatives at each stage of the decision-making process, documented in writing by the patient's initials.

Each algorithm flowchart has six specific objectives that coincide with concerns expressed by patients and the Food and Drug Administration: (1) to minimize reoperations; (2) to prioritize alternatives that are most likely to reduce reoperations; (3) to define realistic choices for surgeon and patient; (4) to involve the patient in the decision-making process; (5) to define "out" points for removal without replacement in specific clinical situations; and (6) to provide thorough documentation of choices and assumption of responsibility for the choices. When examining any decision or management suggestion in the algorithm flowcharts, surgeons should carefully consider these priorities. In each flowchart, decisions and management alternatives are prioritized in a specific order to prevent additional reoperations with their inevitable risks and costs.

Every reoperation increases costs and risks. Reoperation rates approximating 20 percent are, at the least, highly questionable for medically necessary operations and are logically unjustifiable for any totally elective, primary cosmetic surgical procedure. An implant size change procedure, a common reoperation which may be a totally elective patient preference, increases risks and costs. If preoperative patient education and informed consent are optimal, and if choice of implant size is based on quantifiable tissue characteristics, reoperations for size change can be virtually eliminated.⁶⁻⁹ A reoperation is a reoperation, regardless of whether it is medically necessary or requested by the patient for aesthetic or personal reasons. Reoperations inarguably increase costs and risks that would not be present if the reoperation did not occur. While patients have a right to request the operations they choose, limiting medically unnecessary reoperations and reducing overall reoperation rates require that surgeons define and enforce strict indications for reoperations.

Implant removal without replacement is an alternative available to every surgeon and every patient before any reoperation is performed following breast augmentation, and it is the alternative most certain to minimize additional risks and costs of reoperations. If the choice of implant size has been based on quantifiable tissue dimensions and characteristics preoperatively, implant removal without replacement (in the absence of infection or severe inflam1256

mation) usually allows the breast to return to a form that approximates the effects of a pregnancy on the breast. Few patients or surgeons ever want to remove breast implants after the patient has experienced their benefits. In specific situations (e.g., multiple reoperations for capsular contracture, multiple attempts to salvage contaminated or infected implants, or severe stretching or thinning of overlying tissues with traction rippling or visible implant edges), implant removal without replacement is medically the best and most logical solution.

Genetic characteristics of patients' tissues that allow excessive stretching with even small implants, wound-healing predispositions that produce recurrent capsular contractures, and inflammatory processes around an implant are all factors that surgeons cannot predict or control. Patients should understand and document their acceptance of these facts before the primary augmentation. Then should any of these events occur, surgeons and patients will have discussed and agreed upon predefined "out" points preoperatively. Out points for implant removal without replacement are discussed in detail with patients preoperatively, and patients accept those out points in written informed consent documents.¹¹ When patients or surgeons choose not to define these out points, or choose not to remove and not to replace implants when irreversible tissue consequences are present, both the patient and the surgeon assume responsibility for the risk of deformities that may not be correctable.

DECISION AND MANAGEMENT ALGORITHMS

The six decision and management algorithm flowcharts address the following clinical issues or problems: implant size exchange (Fig. 1), grade III or IV capsular contracture (Fig. 2), infection (Fig. 3), stretch deformities (implant bottoming or displacement) (Fig. 4), silent rupture of gel implants (Fig. 5), and undefined symptom complexes that may be associated with connective tissue disease or other undefined problems (Fig. 6). Each algorithm has evolved in our (Tebbetts and Tebbetts) clinical practice for the past 7 years and has been effective in helping us address these issues, resulting in an overall reoperation rate of 3 percent, a deflation or implant failure rate of 0.78 percent, and a reoperation rate of 0.24 percent for size adjustment or exchange in 1662 cases reported in *Plastic and Reconstructive* Surgery with up to 7 years of follow-up.^{7–9} Each

algorithm addresses a specific clinical situation of concern to the Food and Drug Administration's advisory panel of 2003.

REFINING THE DECISION AND MANAGEMENT ALGORITHMS: A SURGEONS FOR PATIENTS INITIATIVE

Additional input from surgeons with a wide range of experiences and expertise could undoubtedly refine and improve the decision and management algorithms derived in a single practice. Ethical issues, medicolegal issues, variations in practice orientation and management, and issues addressing standards of practice could best be addressed by seeking input from other surgeons with expertise in each of these areas. Variations in practice occur as practices evolve. A broad range of innovative ideas, approaches, and expertise from surgeons in varying types of practices and with different levels of experience offers an opportunity to expand and improve decision and management processes, making the ultimate product more flexible and comprehensive.

To further improve and widen the scope of the decision and management algorithms, we (Tebbetts and Tebbetts) sought the input and expertise of the other authors of this article. To address patient and Food and Drug Administration concerns, the Breast Augmentation Surgeons for Patients Initiative (BASPI) focused on a single objective: reducing reoperation rates in breast augmentation. The participants who coauthored this article each prepared extensively by developing and submitting alternative decision and management solutions for each topic listed. During 2 days of intensive workgroup sessions and follow-up communications to verify revisions, key contributions from all participants' solutions were integrated to derive the final algorithms presented in this article.

The effort by this joint workgroup of plastic surgeons with diverse backgrounds and experiences was to develop decision and management algorithms to assist in reducing reoperation rates in breast augmentation and improve patient outcomes. All templates are optional, additional resources for surgeons to consider when addressing the specific clinical topics.

The Surgeons for Patients Initiative materials and solutions are designed to codify and present information and alternatives to make repetitive decision-making processes more efficient by defining templates for management that have proved effective in long-term clinical experience. Basic management templates allow surgeons to focus on more detailed specifics of each clinical situation and, it is hoped, improve reoperation rates and outcomes. The Initiative provides defined solutions that prove to patients, the Food and Drug Administration, and patient advocacy groups that defined alternatives and solutions exist to address their concerns regarding causes of reoperations.

These decision and management algorithms are not intended to define standards of practice. The templates are intended to delineate a set of options available to patients and surgeons, not to define or limit surgeons' or patients' choices. No component of any algorithm is intended to supplant any area of a surgeon's clinical decision making. These decision and management algorithms cannot and do not address all of the variables that may exist in any clinical situation, and in every situation they must be adjusted by the surgeon to fit the clinical issues.

All decision and management algorithms assume that the surgeon has obtained all pertinent baseline historical and medical background information pertaining to the clinical situation. Addressing the clinical options available to the patient and surgeon for optimal decision making and the requirements of informed consent requires the level of complexity presented in the algorithms. To limit complexity, the algorithms are not intended to address the management of unanticipated findings during surgery.

CONCLUSIONS

Defined management algorithms have proved invaluable to a wide range of businesses and professionals by optimizing business practices and addressing issues and problems. The decision and management algorithms presented in this article have been used successfully for 7 years in a busy breast augmentation practice, and they have been further expanded and refined by surgeons with a wide range of experiences and expertise to address the following issues and concerns that have been expressed by patients and the Food and Drug Administration: implant size exchange, grade III or IV capsular contracture, infection, stretch deformities (implant bottoming or displacement), silent rupture of gel implants, and undefined symptom complexes (connective tissue disease or other).

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