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 (*t*issue characteristics of the *e*nvelope, *p*arenchyma, and *i*mplant and the dimensions and fill distribution *d*ynamics 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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DOI: 10.1097/01.PRS.0000136801.24005.D1

Alternatives for Management of Concerns of Shell Disruption or Leaking Silicone Gel Implant

The BASPI Workgroup, John B. Tebbetts, M.D., Moderator

****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.**

Management Alternatives	Potential Advantages	Potential Risks/Tradeoffs	Approximate Costs
1. Breast physical exam	Minimizes additional costs/time May provide confirmatory clinical information	Less accurate than MRI or ultrasound Accuracy depends on condition of capsule Accuracy depends on experience of surgeon Can be false positive or false negative If surgeon suspects rupture, must recommend surgical exploration, because being wrong may lead to an unnecessary operation	
YES → I Request Alternative 1 Be Done Pt. Initial:_____			
NO → I Decline Alternative 1 Pt. Initial:_____			
Shell disruption diagnosed on breast physical exam?* (YES / NO)			
*Whether or not a breast physical exam suggests shell disruption, patient can elect to proceed with surgical options or elect non-surgical options and additional confirmatory imaging tests prior to exploration.			
NON-SURGICAL OPTIONS			
I Decline surgical exploration initially. I understand that other methods of detection of rupture or leak may not be as accurate as exploration, and all imaging studies have some chance of indicating rupture or leakage when none is present. If any other study I choose suggests implant leakage or rupture, I understand that my surgeon will recommend surgical exploration. Pt. Initial:_____			
2. MRI Imaging	Enables imaging diagnosis without a surgical procedure Radiologists state that MRI is over 90% sensitive in diagnosing shell disruption	May yield a diagnosis of possible rupture when implant is actually not ruptured (false positive) May not diagnose rupture when rupture is present (false negative) If possible rupture suspected, surgeon is required to recommend surgical exploration (Option 1 above) Additional costs and time	
YES → I Request Alternative 2 Be Done Pt. Initial:_____			
NO → I Decline Alternative 2 Pt. Initial:_____			
3. Ultrasound and mammogram imaging	Less expensive compared to MRI More accurate if both type studies are combined Radiologists state approximately 80-90% accurate in diagnosing implant rupture	Less accurate compared to MRI May give false positive diagnosis May give false negative diagnosis If possible rupture suspected, surgeon is required to recommend surgical exploration Additional costs and time	
YES → I Request Alternative 3 Be Done Pt. Initial:_____			
NO → I Decline Alternative 3 Pt. Initial:_____			
4. No imaging studies, no surgical exploration, continue to follow	Least expensive Least time consuming Provides an option to see if symptoms or problems develop before committing to additional imaging studies and/or surgical exploration	Does not provide immediate additional information regarding rupture May delay diagnosis of rupture If implants are ruptured, may allow more silicone to escape from the capsule	
YES → I Request Alternative 4 Be Done Pt. Initial:_____			
NO → I Decline Alternative 4 Pt. Initial:_____			
For surgical options, proceed to Alternative 5.			
SURGICAL OPTIONS			
5. Surgical exploration	The most accurate method of determining if implant is ruptured Most accurate method of determining spread of larger amounts of silicone Allows corrective measures at time of diagnosis Saves costs/time of MRI/ultrasound	May damage implant(s) at exploration Additional costs Surgical risks associated with opening the breast Small possibility of inability to diagnose rupture if it is too small to see	
YES → I Request Alternative 5 Be Done Pt. Initial:_____			
NO → Proceed to Option 6			
On exploration, shell is disrupted (YES / NO)			
5A. Replace existing implant(s) (if not ruptured and less than 10 years old)*	Lower costs compared to replacing implants * Unless FDA mandates (and has authority to do so) that patient cannot elect to have same implant replaced.	May be replacing an implant with a shorter life span to the shell (may rupture sooner compared to a new implant) Additional removal, inspection, and reintroduction may damage implant or increase risks of infection	
YES → I Request Alternative 5A Be Done Pt. Initial:_____			
NO → I Decline Alternative 5A Pt. Initial:_____			
5B. Replace one/both with new implants	Replaces older implants with newer implants Allows exchange to different or more state-of-the-art device Allows adjustment of new implants to changes that have occurred in patient's tissues	Additional costs of new implants Possible necessity of modifying existing capsule to optimally accept new implants	
YES → I Request Alternative 5B Be Done Pt. Initial:_____			
NO → I Decline Alternative 5B Pt. Initial:_____			
5C. Remove both implants and do not replace	Minimizes risks and costs of future reoperations If patient is concerned about health effects of silicone in any way, minimizes future concerns Lower costs compared to replacing implants	Aesthetic appearance of breasts will be compromised Cannot totally remove all silicone surgically May not improve any symptoms you may be having	
YES → I Request Alternative 5C Be Done Pt. Initial:_____			
NO → I Decline Alternative 5C Pt. Initial:_____			
5D. Remove as much capsule as possible (to remove as much silicone as possible)	Surgically removes as much silicone as possible May allow tissues to redrape better over a new implant or without a new implant	Can be surgically challenging to remove most of capsule Usually necessitates placement of drain tubes for several days following surgery Does not remove all traces of silicone	
YES → I Request Alternative 5D Be Done Pt. Initial:_____			
NO → I Decline Alternative 5D Pt. Initial:_____			
5E. Replace one/both with saline filled implants	Replaces older implants with newer implants Allows exchange to different or more state-of-the-art device Allows adjustment of new implants to changes in patient's tissues that have occurred Changes silicone gel to saline filler	Additional costs of new implants Possible necessity of modifying existing capsule to optimally accept new implants Possibly shorter life span of saline filled implants compared to silicone gel implants	
YES → I Request Alternative 5E Be Done Pt. Initial:_____			
NO → I Decline Alternative 5E Pt. Initial:_____			
5F.Replace one/both with Silicone gel filled implants	Replaces older implants with newer implants Allows exchange to different or more state-of-the-art device Allows adjustment of new implants to changes that have occurred in patient's tissues	Additional costs of new implants Possible necessity of modifying existing capsule to optimally accept new implants Implant availability pending FDA approval	
YES → I Request Alternative 5F Be Done Pt. Initial:_____			
NO → I Decline Alternative 5F Pt. Initial:_____			
5G. Replace one/both with highly cohesive, form stable silicone gel filled implants*	Replaces older type gel implants with newer, more cohesive gel implants Allows exchange to different or more state-of-the-art device Allows adjustment of new implants to changes that have occurred in patient's tissues	Additional costs of new implants Possible necessity of modifying existing capsule to optimally accept new implants Implant availability pending FDA approval	
YES → I Request Alternative 5G Be Done Pt. Initial:_____	* Depending on availability of these implant products		
NO → I Decline Alternative 5G Pt. Initial:_____			
6. Seek additional surgical opinions	Acquire additional surgeons' opinions Seek additional alternatives Confirm options	Additional costs Additional time required Possible confusion with additional alternatives	
I Request Alternative 6 Be Done Pt. Initial:_____			
I Decline Alternative 6 Pt. Initial:_____			
7. Recommend MRI at 10 years and every 5 years thereafter, even if asymptomatic to screen for silent rupture	Allows screening for possible leak or rupture	Additional costs Additional time required If positive, surgeon will recommend surgical exploration—see "Surgical Alternatives"	
I Request Alternative 7 Be Done Pt. Initial:_____			
I Decline Alternative 7 Pt. Initial:_____			

Surgeon 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: _____

OUT POINTS

1) Patient requests removal without replacement at any time

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

**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.

Management Alternatives	Potential Advantages	Potential Risks/Tradeoffs	Approximate Costs
1. Implant removal without replacement	Reduces risks and costs of additional operations Eliminates risks of future tissue stretch and thinning from weight of implant Reduces risks of permanent uncorrectable deformities	Breasts will be smaller Breast appearance may not be as good Breast appearance depends on how well the skin tightens after implant removal If skin does not tighten adequately, additional surgery may be required to optimize breast appearance Deformities may occur that are not correctable	
1A. No mastopexy (skin removal and nipple repositioning) at time of implant removal; no implant replacement	Provides opportunity for skin to tighten without additional surgery May reduce costs and risks of mastopexy or other surgery Reduces tradeoffs of mastopexy including scars, sensory loss, and unpredictable healing	Skin may tighten unevenly leaving breast contours irregular or uneven Mastopexy may be required in the future	

NO → I Decline Alternative 1A Pt. Initial:_____

YES → I Request Alternative 1A Be Done Pt. Initial:_____

Inferior Pole Stretch Deformities
(Excessive lengthening of N:IMF without IMF displacement)

*If IMF level unchanged from preop (based on preop umbilical to IMF Measurements) to rule out IMF fold descent which is a different deformity addressed below AND
N:IMF $_{maxstretch}$ > 10 cm (implies vertical skin excess) AND
patient accepts all tradeoffs and recurrence risks

1B. Mastopexy* (remove skin, reposition nipple) at time of implant removal; no implant replacement	May improve appearance of breasts depending on degree of skin stretch and how much skin may tighten, and healing characteristics May lift and tighten breast tissues May reposition nipple upward	Will add scars to breast May compromise breast and nipple sensation Adds costs and risks May not be necessary if skin tightens adequately following implant removal High likelihood of restretching and recurrent deformity due to skin characteristics	

YES → I Request Alternative 1B Be Done Pt. Initial:_____

NO → I Decline Alternative 1B Pt. Initial:_____

Inferior Displacement of the Inframammary Fold
(IMF level is more than 1.5 cm lower than it was set intraoperatively)

*If IMF level is more than 1.5 cm lower than level set at surgery (mid fold to umbilicus and mid fold to mid clavicle measurements) AND
N:IMF $_{maxstretch}$ > 10 AND
patient accepts all tradeoffs and recurrence risks

2. *Reposition implant and reconstruct/raise the fold beneath the breast	Repositions the breast mound upward Increases fill in the upper breast Decreases excessive fill in the lower breast May improve symmetry May create additional support for implant	Correction is not highly predictable because surgery does not change the quality of the tissues that allowed stretch to occur Correction only about 50% successful If surgical correction does not hold, the stretch deformity will recur and tissues will continue to stretch and thin	

YES → I Request Alternative 2 Be Done Pt. Initial:_____

NO → I Decline Alternative 2 and request no therapy Pt. Initial:_____

Synmastia
(Periprosthetic pockets connect medially or are within 1 cm of connecting)

Attempted surgical correction with replacements of implants at the same procedure is NOT recommended if the implant is partially retropectoral AND the medial origins of the pectoralis along the sternum have been divided. If the synmastia is retromammary and all medial origins of the pectoralis along the sternum are intact, may consider reconstructing the synmastia and replacing implants to a subpectoral position at the same procedure, accepting that replacing implants at the same procedure may add risks and tradeoffs.

Are implants/synmastia retromammary?

YES → continue below

NO → skip to 4. Remove implants and do not replace; repair synmastia; consider implant replacement 6 months-1 year later (smaller implant)

3. Remove implants, repair synmastia, replace implants in subpectoral or dual plane position*	Attempts repair and replacement of implants in one stage May decrease costs	Adding implants back at time of synmastia repair adds stretch to tissues, may decrease success of repair If origins of pectoralis muscle along sternum are not intact, implants should not be replaced at same operation	

YES → I Request Alternative 3 Be Done Pt. Initial:_____

NO → I Decline Alternative 3 Pt. Initial:_____

* Assumes leaving all medial origins of pectoralis major along the sternum intact

4. Remove implants and do not replace; repair synmastia; consider implant replacement 6 months-1 year later (smaller implant)	Removes stretch effect of implants, affords best chance of successful correction of synmastia Allows tissues to normalize before considering implant replacement No implant replacement offers best prevention of recurrence, reduces risks of future operations	May add an additional procedure if implant replacement is considered in future Aesthetic appearance of breasts may be suboptimal without implants Replacing implants increases risks of recurrent synmastia, costs, risks, reoperations, compromise of breast appearance if complications recur	

YES → I Request Alternative 3 Be Done Pt. Initial:_____

NO → I Decline Alternative 3 Pt. Initial:_____

* Assumes leaving all medial origins of pectoralis major along the sternum intact

5. No surgical treatment; follow stretch and thinning with measurements	Avoids surgical procedure Allows time to evaluate further stretching Allows time to choose between alternatives Allows time for measurements to quantitate changes	Allows tissues to continue to stretch and thin May make implant edges easier to feel or see May create visible traction rippling May ultimately allow implant exposure or extrusion	

YES → I Request Alternative 5 Be Done Pt. Initial:_____

NO → I Decline Alternative 5 Pt. Initial:_____

6. Seek additional surgical opinions	Acquire additional surgeons' opinions Seek additional alternatives Confirm options	Additional costs Additional time required Possible confusion with additional alternatives	

I Request Alternative 6 Be Done Pt. Initial:_____

I Decline Alternative 6 Pt. Initial:_____

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

Patient Signature: _____ Witness Signature: _____
Date: _____ Date: _____

OUT POINTS

1) If pinch thickness of soft tissues overlying implant in any area is <0.5 cm
2) Implant shell visibility in any area where more soft tissue coverage is not available without tissue transfer
2) Recurrence of any stretch deformity after a one or two-stage attempt at correction
3) Patient request at any time

Alternatives for Management of Possible Periprosthetic Space Infection or Seroma
The BASPI Workgroup, John B. Tebbetts, M.D., Moderator

Symptom or Clinical Event *Occurring First 6 Weeks Postoperatively*

Fever >101 ? YES → CBC with Diff → Augmentin 875mg BID* → NO / YES → Follow clinically
* Use alternative if allergy is a concern

Erythema? YES → CBC with Diff → Augmentin 875mg BID* → NO / YES → Follow clinically
* Use alternative if allergy is a concern

Resolution within 2 weeks? → Follow clinically
Discuss **contaminated periprosthetic pocket** management alternatives below with patient**

Enlarged breast? YES → CBC with Diff → Fluid present clinically? → NO → Ultrasound with aspiration/C&S if fluid present → Follow clinically
YES

Periprosthetic fluid present clinically? → CBC with Diff → Ultrasound assisted aspiration, C&S*
Augmentin 875 mg BID → NO / YES → Follow clinically
*Aerobes, anaerobes, fungi, AFB; maintain cultures 3-4 wks if negative, plate on enriched media if no growth in 72 hrs
Resolution within 2 wks? NO / YES → Follow clinically

Wound opening or drainage? → CBC with Diff → Skin prep, C&S from inside pocket if opening communicates, US assisted if no clear communication → Discuss **contaminated pocket** management alternatives below with patient**

Positive culture? NO → Follow clinically; YES
YES → Infectious Disease consult* YES → Culture specific antibiotics oral (if no fever >102, no chills, no symptoms of sepsis, no other systemic signs or symptoms)
NO → *ID Consult Optional for antibiotic selection assistance if no systemic signs or symptoms
Follow clinically → Resolution? YES / NO → Discuss **Seroma Management Alternatives** with patient** (See below)
Sx or signs of sepsis, fever>102, chills, rash NO → Discuss **Contaminated Periprosthetic Pocket Management Alternatives** with patient**
YES → Hospitalization, , blood cultures, ID consult, IV antibiotics

**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.

***Contaminated Periprosthetic Pocket* Management Alternatives**	**Potential Advantages**	**Potential Risks/Tradeoffs**	**Approximate Costs**
1. Remove both implants and do not replace either implant	**Best option to minimize additional reoperations, reduce additional risks and costs, and reduce risks of uncorrectable deformities.**	**May compromise aesthetic appearance of breast Depending on the amount of inflammation that has occurred, may result in internal scarring and distortion of breast form or breast deformity Even with immediate implant removal, may require at least 6 months for tissues to resolve in order to assess outcome Fluid may reaccumulate after implant removal and require additional surgery**	
2. Remove and do not replace only the affected implant*	**Provides an opportunity for resolution of infection and replacement of implant Implant removal increases likelihood of infection resolving and usually increases speed of resolution**	**Commits patient and surgeon to replacing implant in future (leaves breasts asymmetric) Pressures patient and surgeon to replace implant sooner rather than later Increases costs with no guarantee of salvage Virtually guarantees reoperation(s) in future Even if replaced, may develop recurrent infection If does not develop recurrent infection when replaced, carries increased risk of capsular contracture developing, more reoperations**	
3. Remove implant and affected capsule*, drain, antibiotics	**Removes foreign body (implant) Removes infected or affected capsule New implant minimizes risks of reinserting a possibly contaminated implant Leaves breasts more symmetric**	**Increases costs and down time for patient Increases risks of reoperations No guarantee of success If unsuccessful, prolongs inflammation in tissues and increases risks of permanent, uncorrectable deformities in future Increases risks of future capsular contracture compared to removal without replacement**	

*Remove affected capsule that shows signs of acute inflammation if it has a shaggy appearance, or if purulent appearing exudate or other particulate or tissue fragments are attached to capsule that may leave contaminated or devascularized fragments of material in the pocket.

If, and only if, the *implant is exposed AND cultures are negative AND Gram stain of pocket fluid is negative* for bacteria, consider option 3A—cleaning the pocket and replacing a new implant

3A. Remove implant and LEAVE capsule, replace new implant, drain, antibiotics*	***Leave capsule only if pinch thickness over implant is less than 1 cm or if capsule is densely adherent to posterior surface of pectoralis muscle. Provides additional soft tissue cover over implant Reduces risks of visible portions of implant Reduces risks of visible traction rippling**	**Leaving capsule (lining of pocket) to provide more tissue coverage may increase risks of recurrent or prolonged infection Leaving capsule may prevent optimal draping of your tissues over an implant**	

Discuss **Seroma Management Alternatives**

Optional repeat one ultrasound assisted aspiration following diagnostic (first) aspiration before proceeding to seroma options below

***Seroma* Management Alternatives**	**Potential Advantages**	**Potential Risks/Tradeoffs**	**Approximate Costs**
1. Remove both implants and do not replace either implant	**Best option to minimize additional reoperations, reduce additional risks and costs, and reduce risks of uncorrectable deformities**	**May compromise aesthetic appearance of breast Depending on the amount of inflammation that may have occurred, may result in internal scarring and distortion of breast form or breast deformity Even with immediate implant removal, may require at least 6 months for tissues to resolve in order to assess outcome Fluid may reaccumulate after implant removal and require additional surgery**	
2. Remove and do not replace only the affected implant	**Provides an opportunity for resolution of fluid accumulation and replacement of implant Implant removal increases likelihood of seroma (fluid) resolving and usually increases speed of resolution**	**Commits patient and surgeon to replacing implant in future (leaves breasts asymmetric) Pressures patient and surgeon to replace implant sooner rather than later Increases costs with no guarantee of salvage May increase risks of reoperation(s) in future If implant replaced, may develop recurrent fluid collection If does not develop recurrent fluid collection when replaced, may increase risk of capsular contracture developing, more reoperations**	
3. Remove implant and affected capsule, replace new implant, drain, antibiotics*	**Removes foreign body (implant) Removes infected or affected capsule even if culture is negative New implant minimizes risks of reinserting a possibly contaminated implant Leaves breasts more symmetric**	**Increases costs and down time for patient Increases risks of reoperations No guarantee of success If unsuccessful, prolongs inflammation in tissues and increases risks of permanent, uncorrectable deformities in future Increases risks of future capsular contracture compared to removal without replacement**	
4. If only incision area is involved, excise, wash pocket, reclose if tissues adequate	**Minimizes risks of implant removal and replacement (damage to implant) Minimizes risks of removing lining or capsule, drains, patient inconveniences**	**May leave affected or infected tissues around implant that are not visibly apparent May result in wound disruption due to condition of affected tissues If implant becomes exposed, it usually becomes infected Fluid collection around implant may occur, necessitating additional surgery, costs, risks May increase risks of future tissue damage and deformity if unidentified infection is present**	
5. If tissues are inadequate for closure, remove and do not replace implant	**Minimizes risks of implant extrusion and more severe tissue damage Minimizes risks of additional operations**	**May compromise aesthetic appearance of breast Depending on the amount of inflammation that may have occurred, may result in internal scarring and distortion of breast form or breast deformity Even with immediate implant removal, may require at least 6 months for tissues to resolve in order to assess outcome Fluid may reaccumulate after implant removal and require additional surgery**	
6. Consider smaller implant with capsular flap or local tissue transfer	**May provide additional tissue for coverage or incision closure**	**Increases donor site wound area Tissue transfer of any type increases risks of inadequate vascularity, possible tissue loss May increase risks of reoperation May increase areas of affected tissue, increase subsequent deformities Success is not guaranteed**	
7. No surgical intervention, antibiotics only	**Reduces costs and risks associated with a surgical procedure If successful, avoids surgical procedure costs, risks, recovery**	**Precludes opportunity to evaluate tissues around the implant Does not remove foreign body and infected or dead tissues adjacent to the implant that may not be apparent externally Antibiotics may improve symptoms but not resolve the cause of fluid accumulation which may return when antibiotics are discontinued May allow continued inflammation in tissues that is not clinically apparent and may increase risks of future uncorrectable deformities**	
8. No treatment	**No advantages**	**May increase risks of possible undiagnosed infection May ultimately increase risks of severe tissue damage that is likely to produce permanent, uncorrectable deformities 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**	**Additional costs Additional time required Possible confusion with additional alternatives**	

Each alternative: YES → I Request Alternative N Be Done Pt. Initial:_____ ; NO → I Decline Alternative N Pt. Initial:_____

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

Patient Signature: _____ Witness Signature: _____

Date: _____ Date: _____

OUT POINTS

1) Culture proved infection of the periprosthetic pocket
2) Inadequate (<0.5 cm thick or severely indurated or inflammed) soft tissue coverage at the incision site for safe reclosure
3) Any time patient requests removal without replacement

Implant Replacement Criteria

1) No replacement for 3-6 months with no evidence of infection AND complete tissue resolution—normal soft tissues in all areas of the breast
2) No replacement if the patient has had more than one episode of infection in the affected breast
3) No replacement if soft tissue pinch thickness in any area overlying the implant is less than 0.5 cm

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

****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.**

Management Alternatives	Potential Advantages	Potential Risks/Tradeoffs	Approximate Costs
1. No surgical intervention, accept and live with capsule(s) tradeoffs	Eliminates risks, tradeoffs, and costs of surgery Minimizes risks of reoperations Acknowledges that a surgical procedure does not change a patient's tendency to form a tight capsule Maintains options of surgical intervention in future Provides option for non-surgical therapies	Requires accepting whatever tradeoffs exist regarding breast shape and firmness If capsular contracture is severe, may cause some shrinkage or thinning of breast tissue (atrophy) over time Capsules may interfere with accuracy of mammograms and/or MRI imaging May obscure implant leakage or rupture	
YES → I Request Alternative 1 Be Done Pt. Initial:_____			
NO → I Decline Alternative 1 Pt. Initial:_____			
2. Remove both implants and do not replace; do not remove capsules*	Minimizes risks and costs of future reoperations If concerned about health effects of silicone in any way, minimizes future concerns Minimizes risks and costs of removing capsules Eliminates risks of recurrent capsular contracture	Leaving capsules in place may leave small amounts of silicone contained in capsule in your body Leaving capsule may impair optimal redraping of your tissues after implant removal, leaving irregularities Small risk of seroma (fluid accumulation) inside capsule that is left in place	
YES → I Request Alternative 2 Be Done Pt. Initial:_____			
NO → I Decline Alternative 2 Pt. Initial:_____			
* If capsules are calcified, or if the capsule is restrictive (restricts optimal tissue redraping or restricts accuracy of imaging), the capsule(s) should be removed.			
3. Remove both implants and do not replace; remove both capsules	Minimizes risks and costs of future reoperations If concerned about health effects of silicone in any way, minimizes future concerns Surgically removes as much silicone as possible May allow tissues to redrape better following implant removal	More extensive surgical procedure required to remove most of capsule Usually necessitates placement of drain tubes for several days following surgery Does not remove all traces of silicone Increased costs, tradeoffs, and risks compared to not removing capsules	
YES → I Request Alternative 3 Be Done Pt. Initial:_____			
NO → I Decline Alternative 3 Pt. Initial:_____			
4. *Remove* capsule(s) (capsulectomy), replace implant(s) with *new* implant(s)*	Removal of as much capsule as possible (capsulectomy) may reduce risks of recurrent capsular contracture compared to simply releasing the capsule (capsulotomy) More costs, risks, tradeoffs compared to leaving capsules Replacing old implants with new implants increases implant options, use of newer technology, and may provide longer implant shell life compared to replacing old implants	Additional costs of new implants Failure to remove as much capsule as possible may produce a higher risk of recurrent capsular contracture, requiring additional reoperations, costs, risks, or removal Release instead of removal of the capsule may not achieve as optimal correction of shape distortion or firmness	* see tissue coverage criteria below before replacing implants
YES → I Request Alternative 4 Be Done Pt. Initial:_____			
NO → I Decline Alternative 4 Pt. Initial:_____			
5. *Remove* capsule(s) (capsulectomy), replace *existing* implant(s)	Removal of as much capsule as possible (capsulectomy) may reduce risks of recurrent capsular contracture compared to simply releasing the capsule (capsulotomy) More costs, risks, tradeoffs compared to leaving capsules Replacing old implants less expensive compared to replacing with new implants	Removing capsule (capsulectomy) is more extensive surgically, with more costs, risks, and tradeoffs compared to simply releasing and not removing capsule (capsulotomy) Older implant may fail sooner compared to newer implant, necessitating reoperation	If replacing current implants with new implants, go to Option 9
YES → I Request Alternative 5 Be Done Pt. Initial:_____			
NO → I Decline Alternative 5 Pt. Initial:_____			
6. *Release* capsule(s) (capsulotomy) but *do not remove complete capsules*, replace implant(s) with *new* implant(s)	Lower costs, risks, tradeoffs compared to removing capsules Releasing capsule is less extensive surgically compared to removing capsule Replaces older implants with newer implants Allows exchange to different or more state-of-the-art implant(s) Allows adjustment of new implants to changes that have occurred in patient's tissues	Additional costs of new implants Failure to remove as much capsule as possible may produce a higher risk of recurrent capsular contracture, requiring additional reoperations, costs, risks, or removal Release instead of removal of the capsule may not achieve as optimal correction of shape distortion or firmness	
YES → I Request Alternative 6 Be Done Pt. Initial:_____			
NO → I Decline Alternative 6 Pt. Initial:_____			
7. *Release* capsule(s) (capsulotomy) but *do not remove capsules*, replace *existing* implant(s)	Lower costs, risks, tradeoffs compared to removing capsules Replacing old implants less expensive compared to replacing with new implants Releasing capsule is less extensive surgically compared to removing capsule	Failure to remove as much capsule as possible may produce a higher risk of recurrent capsular contracture, requiring additional reoperations, costs, risks, or removal Release instead of removal of the capsule may not achieve as optimal correction of shape distortion or firmness	
YES → I Request Alternative 7 Be Done Pt. Initial:_____			
NO → I Decline Alternative 7 Pt. Initial:_____			

If considering implant replacement with any option above:

8. If soft tissue pinch thickness in any area overlying implant is less than 0.5 cm, do not replace implant	Reduces risks of visible implant shell or edges Reduces risks of visible traction rippling Reduces risks of future reoperations or uncorrectable deformities	See potential risks and tradeoffs under options 2 and 3 above.	
YES → I Request Alternative 8 Be Done Pt. Initial:_____			
NO → I Decline Alternative 8 Pt. Initial:_____			
9. If current pocket is submammary, change to dual plane or subpectoral	May reduce risks of recurrent capsular contracture Reduces risks of visible implant shell or edges Reduces risks of visible traction rippling Reduces risks of future reoperations or uncorrectable deformities	Surgical procedure more extensive Potentially more discomfort following surgery (less risk with dual plane vs. subpectoral) May experience distortion of breast shape with pectoralis muscle contraction (less risk with dual plane vs. subpectoral) If all muscle origins are left intact along fold, you may experience shift of implants to sides over time with widening of distance between breasts (less risk with dual plane vs. subpectoral)	
YES → I Request Alternative 9 Be Done Pt. Initial:_____			
NO → I Decline Alternative 9 Pt. Initial:_____			
10. Replace current implants with textured surface implants	May reduce risks of recurrent capsular contracture	Thicker implant shell may be more palpable in patients with thin tissues	
YES → I Request Alternative 10 Be Done Pt. Initial:_____			
NO → I Decline Alternative 10 Pt. Initial:_____			
11. Replace current implants with smooth surface implants	May have a thinner shell and be less palpable in thin patients	If patient develops recurrent capsular contracture, may look back and question why textured surface implants were not used at time of attempted correction	
YES → I Request Alternative 11 Be Done Pt. Initial:_____			
NO → I Decline Alternative 11 Pt. Initial:_____			
12. Replace current implants with saline filled implants	May reduce risks of recurrent capsular contracture due to silicone gel bleed, even with "newer" generation implants	May feel less "natural" in the breast May have a shorter shell life compared to newer generation, form stable, or other silicone gel filled implants Have a valve on the implant that may be palpable in very thin patients	
YES → I Request Alternative 12 Be Done Pt. Initial:_____			
NO → I Decline Alternative 12 Pt. Initial:_____			
13. Replace current implants with silicone gel filled implants	May feel more natural in the breast Full height, form stable shaped implants may allow more control of distribution of fill in the breast Newer generation gel implants may have a longer shell life compared to saline filled	Thicker implant shell may be more palpable in patients with thin tissues	
YES → I Request Alternative 13 Be Done Pt. Initial:_____			
NO → I Decline Alternative 13 Pt. Initial:_____			
14. Seek additional surgical opinions	Acquire additional surgeons' opinions Seek additional alternatives Confirm options	Additional costs Additional time required Possible confusion with additional alternatives	
YES → I Request Alternative 14 Be Done Pt. Initial:_____			
NO → I Decline Alternative 14 Pt. Initial:_____			

OUT POINTS

1) Recurrent capsular contracture after one complete capsulectomy and replacement with textured surface implants, 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

**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: _____

Alternatives for Management of Implant Size Exchange
The BASPI Workgroup, John B. Tebbetts, M.D., Moderator

**The larger a patient's breasts, augmented or not, the worse the breasts are likely to look over time. Also, the larger the breasts following a breast augmentation, the greater the risks of additional operations, additional risks costs to the patient, and additional risks of permanent, uncorrectable deformities.

Management Alternatives	Potential Advantages	Potential Risks/Tradeoffs	Approximate Costs

1. Medical indications* for implant size exchange

Potential benefits may outweigh potential risks, costs, tradeoffs

Any reoperation increases risks, costs, tradeoffs
No assurance of improved outcome
Surgery does not improve the age and condition of tissues; hence result may not be better
Larger implant always likely to have more negative effects on tissues over time
Smaller implant may necessitate skin removal or lift, otherwise widens gap between breasts, decreases fill in upper breast

YES → 1A. I Request Exchange for medical reasons
Pt. Initial:_____

NO

***Medical Indications for Implant Size Exchange Include:**

- Patient requests a size exchange to a *smaller* implant and accepts all tradeoffs and risks when current implant base width exceeds width of parenchyma by more than 1.5 cm (size decrease)
- Capsular contracture requiring complete capsulectomy (size increase)
- Inappropriate size at primary operation according to TEPID System (size increase or decrease)
- Implant size exceeding base width of existing parenchyma at primary operation except constricted lower pole breasts (for size decrease) or breasts with < 1 cm of parenchymal base width
- Parenchymal atrophy due to excessively large or excessively projecting (especially high profile round) implant at primary surgery (size decrease and projection decrease)
- Reduction of skin envelope (mastopexy) at *staged procedure* (size decrease)
- *During patient evaluation for size exchange, surgeon should rule out other problems that can mimic size discrepancies including inferior pocket closure, capsular contracture, or inferior pole stretch deformities

Patient requests a *smaller* breast implant

YES

NO

2. I accept that my breasts will be smaller, emptier at the top, and I will have a wider gap between my breasts

Less weight in breast
Likely less stretch of skin over time
Likely less thinning of tissues over time
Likely less risk of visible implant edges or shell
Likely less risk of visible traction rippling

May necessitate removal of excess skin for optimal aesthetics (mastopexy) with additional costs, risks, tradeoffs
The results may not meet your expectations
Tradeoffs may outweigh benefits of changing to smaller implants

NO → 2B. I decline exchange to smaller implants when no medical reason is present
Pt. Initial:_____

YES → 2A. I accept all risks and tradeoffs listed
Pt. Initial:_____

3. I accept that a visible change may require a substantial change in implant size

See benefits above for option 2

See tradeoffs above for option 2

NO → 3B. I decline exchange to smaller implants when no medical reason is present
Pt. Initial:_____

YES → 3A. I accept all risks and tradeoffs listed
Pt. Initial:_____

Patient requests a *mastopexy* and a smaller implant

YES

4. Remove implant, perform mastopexy, *do not replace implant*

Improves breast shape and nipple position
Reduces risks compared to replacing implant at same operation—risks of unpredictable results, restretching, wound healing problems, widened scars, stretching and asymmetry of areolas, tissue thinning , visible implant edges, and visible traction rippling
Surgeon has more control over variables in mastopexy alone without simultaneous implant replacement

May necessitate another operation if patient decides to replace an implant in the future
Without implant, breast will be smaller
Gap between breasts may be wider
Upper breast will be emptier without implant, but with implant, additional stretch from implant will decrease upper fill over time even if an implant is placed

NO → 4B. I decline mastopexy and no replacement of an implant
Pt. Initial:_____

YES → 4A. I request mastopexy and no replacement of an implant
Pt. Initial:_____

5. Remove implant, perform mastopexy replace implant with new, smaller implant at same operation

May avoid another operation should patient decide to replace implants after mastopexy without implant replacement

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 reoperation:
Additional sagging of breasts
Additional thinning of skin
Additional shrinkage of existing breast tissue
Possible sensory loss
Possible visible traction rippling
Possible visible implant edges
Deformities and compromises may be uncorrectable

NO → 5B. I decline simultaneous mastopexy and implant replacement
Pt. Initial:_____

YES → 5A. I request simultaneous mastopexy and implant replacement and accept all risks and tradeoffs listed
Pt. Initial:_____

Patient requests a *larger* breast implant

YES

NO → I decline exchange of my implant(s) to either a smaller or larger size
Pt. Initial:_____

6. No medical reason for exchange to larger implants

May make patient happier with breast size

Larger implant causes many more long-term negative effects on tissues
Risks: Tissue thinning, tissue stretch, shrinkage of breast tissue, additional and more rapid sagging, palpable implant edges and shell, visible implant edges, visible traction rippling, possible additional sensory loss
All additional risks associated with a first time augmentation
May decrease accuracy of mammograms
Additional costs, time off normal activities

NO → 6B. I decline exchange to larger implants when no medical reason is present
Pt. Initial:_____

YES → 6A. I request exchange to larger implants when no medical reason is present
Pt. Initial:_____

7. I accept additional tissue stretch that is not reversible

No potential benefits from additional tissue stretch

Additional sagging of breasts
Additional thinning of skin
Additional shrinkage of existing breast tissue
Possible sensory loss
Possible visible traction rippling
Possible visible implant edges
Deformities and compromises may be uncorrectable

NO → 7B. I decline exchange to larger implants when no medical reason is present
Pt. Initial:_____

YES → 7A. I accept all risks and tradeoffs listed at right
Pt. Initial:_____

8. I accept additional thinning of my skin that is not reversible

No potential benefits from additional thinning of skin

Implant edges and shell will be easier to feel
May see implant edges and shell
Effects on tissues may not be apparent for several years
May see rippling caused by implant pulling on thin overlying tissues (traction rippling)
All above listed problems are uncorrectable

NO → 8B. I decline exchange to larger implants when no medical reason is present
Pt. Initial:_____

YES → 8A. I accept all risks and tradeoffs listed at right
Pt. Initial:_____

9. I accept that I may develop visible implant edges that can't be corrected

No potential benefits from visible implant edges

As the skin thins due to stretch caused by larger implants, implant edges may become visible; this deformity is often not correctable

NO → 9B. I decline exchange to larger implants when no medical reason is present
Pt. Initial:_____

YES → 9A. I accept all risks and tradeoffs listed at right
Pt. Initial:_____

10. I accept that I may develop visible rippling in my breasts that is not correctable

No potential benefits from visible traction rippling on breasts

When the tissues stretch and thin over time, the larger implant causes pull on the capsule which is attached to the thin overlying tissues, producing visible traction rippling that is usually uncorrectable

NO → 10B. I decline exchange to larger implants when no medical reason is present
Pt. Initial:_____

YES → 10A. I accept all risks and tradeoffs listed at right
Pt. Initial:_____

11. I accept that I may cause additional, possibly permanent loss of sensation

No potential benefits from additional, possibly permanent loss of sensation

In order to create additional space to accept a larger implant, your surgeon must create a larger pocket, and that means cutting more nerves; larger implants cause more stretch on the nerves that remain and can further impair sensation

NO → 11B. I decline exchange to larger implants when no medical reason is present
Pt. Initial:_____

YES → 11A. I accept all risks and tradeoffs listed at right
Pt. Initial:_____

12. I accept potential shrinkage of my own breast tissue

No potential benefits from additional thinning of skin

Although implant is larger, it may lose some size because of shrinkage of your own breast tissue from pressure of the larger implant (tissue atrophy)
May have negative effects on sensation
May negatively affect ability to nurse
Loss of breast tissue may be irreversible and uncorrectable

NO → 12B. I decline exchange to larger implants when no medical reason is present
Pt. Initial:_____

YES → 12A. I accept all risks and tradeoffs listed at right
Pt. Initial:_____

13. I accept that I am causing tissue changes over time that may necessitate additional reoperations

No potential benefits from causing additional reoperations

Additional reoperations always increase costs, risks, and tradeoffs compared to the first operation
Additional operations may not correct deformites created by larger implants

NO → 13B. I decline exchange to larger implants when no medical reason is present
Pt. Initial:_____

YES → 13.A. I accept all risks and tradeoffs listed at right
Pt. Initial:_____

14. I realize that tissue damage from larger implants may create uncorrectable deformities.

No potential benefits from irreversible tissue damage

Does not provide immediate additional information regarding rupture
May delay diagnosis of rupture
If implants rupture, larger implants may allow more silicone to escape from the capsule

NO → 14B. I decline exchange to larger implants when no medical reason is present
Pt. Initial:_____

YES → 14A. I accept all risks and tradeoffs listed at right
Pt. Initial:_____

15. Seek additional surgical opinions

Acquire additional surgeons' opinions
Seek additional alternatives
Confirm options

Additional costs
Additional time required
Possible confusion with additional alternatives

15B. I Request Another Surgical Opinion
Pt. Initial:_____

15A. I Decline Another Surgical Opinion
Pt. Initial:_____

OUT POINTS

1) If soft tissue coverage in any area of the breast is less than 0.5 cm pinch thickness, decline to replace with larger implants
2) 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
3) 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

****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.**

Management Alternatives	Potential Advantages	Potential Risks/Tradeoffs	Approximate Costs
1. Patient presents with undefined symptoms or associated with CTDs	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	
YES			
2. Refer to board certified rheumatologist and/or immunologist	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	
YES → I Request Alternative 2 Be Done Pt. Initial:_____			
NO → I Decline Alternative 2 Pt. Initial:_____			
If pt. declines #2, surgeon will recommend #4.			
3. Consultant believes symptoms may be associated with patient's breast implants	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 association of symptoms with breast implants, surgeon will likely recommend implants be removed and not replaced Consultant expertise may vary and surgeon cannot judge consultant expertise	
YES			
NO → I request/do not request (circle one) referral for another opinion (plastic surgeon, rheumatologist, immunologist—circle all you desire) Pt initial_____			
OUT POINT **4. Remove* both implants and capsules, do not replace**	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	Removing capsules prolongs surgical procedure, may increase bleeding risks, and will likely cause more drainage requiring drain tubes following surgery Increases costs, risks, and time away from normal activities to have implants removed May increase need for additional operations Depending on size of implants and patient tissue characteristics, skin stretch from implants may require additional surgery such as lifting or nipple-areola repositioning for optimal appearance Permanent, uncorrectable deformities may occur following implant removal due to patient healing characteristics and tissue characteristics May not produce any change in symptoms if symptoms not related to implants	
YES → I Request Alternative 4 Be Done Pt. Initial:_____			
NO → I Decline Alternative 4 Pt. Initial:_____			
*Removal of a silicone or saline implant should be reported on the manufacturer's explant form for FDA purposes.			
5. Remove both implants and do not replace, leave capsules	Shorter operation time by not removing capsules, potentially less bleeding and less risk of prolonged drainage or fluid accumulation if capsules are not removed	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	
YES → I Request Alternative 5 Be Done Pt. Initial:_____			
NO → I Decline Alternative 5 Pt. Initial:_____			
6. Replace silicone gel filled implants with saline filled implants	Reduces total amount of silicone in body May reduce potential for silicone gel bleed from gel implants	May not produce any change in symptoms if symptoms not related to silicone gel Increases reoperations, costs, risks Increases reoperation risk for the future compared to implant removal without replacement If symptoms are related to silicone, presence of silicone shell of saline filled implants may make symptoms worse	
YES → I Request Alternative 6 Be Done Pt. Initial:_____			
NO → I Decline Alternative 6 Pt. Initial:_____			
7. No treatment	Avoids costs and patient inconvenience of seeing additional physicians	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	
YES → I Request Alternative 7 Be Done Pt. Initial:_____			
NO			

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

Patient Signature: _____ Witness Signature: _____
Date: _____ Date: _____

OUT POINTS
1) Board certified rheumatologist relates symptoms, findings or diagnosis to breast implants, or diagnoses CTD
2) 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 TEPID[6] 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, algorith-

mic 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 decision-making 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 inflam-

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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REFERENCES

1. U.S. Food and Drug Administration. General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee meeting transcript. Washington, D.C.: October 14-15, 2003. Available at http://www.fda.gov/ohrms/dockets/ac/03/transcripts/3989T1.htm. Accessed January 13, 2004.
2. U.S. Food and Drug Administration. General and Plastic Surgery Devices Panel meeting transcript. Washington, D.C., February 18, 1992.
3. U.S. Food and Drug Administration. General and Plastic Surgery Devices Panel meeting transcript. Washington, D.C.: March 1-3, 2000.
4. Hiebeler, R., Kelly, T. T., and Ketteman, C. *Best Practices: Building Your Business with Customer-Focused Solutions*. New York: Simon and Schuster, 1998. Pp. 7-228.
5. Tebbetts, J. B. An approach that integrates patient education and informed consent in breast augmentation. *Plast. Reconstr. Surg.* 110: 971, 2002.
6. Tebbetts, J. B. A system for breast implant selection based on patient tissue characteristics and implant–soft-tissue dynamics. *Plast. Reconstr. Surg.*: 109: 1396, 2002.
7. Tebbetts, J. B. Patient acceptance of adequately filled breast implants. *Plast. Reconstr. Surg.* 106: 139, 2000.
8. Tebbetts, J. B. Dual plane breast augmentation: Optimizing implant–soft-tissue relationships in a wide range of breast types. *Plast. Reconstr. Surg.* 107: 1255, 2001.
9. Tebbetts, J. B. Achieving a predictable 24-hour return to normal activities after breast augmentation: Part II. Patient preparation, refined surgical techniques, and instrumentation. *Plast. Reconstr. Surg.* 109: 293, 2002.
10. Gorney, M. Preventing litigation in breast augmentation. *Clin. Plast. Surg.* 28: 607, 2001.
11. Tebbetts, J. B. "Out points" criteria for breast implant removal without replacement and criteria to minimize reoperations following breast augmentation. *Plast. Reconstr. Surg.* 114: 1258, 2004.