Reducing Capsular Contracture in Breast Augmentation: What’s the Evidence?

Karol A Gutowski, MD, FACS

Instructional Course
RTI Surgical (ADM Maker) - Advisor
Suneva Medical - Instructor
Angiotech/Surgical Specialties - Advisory Board

May use brand names due to lack of distinguishing generic names
Questions

• What is your CC rate?
• What do you do?
• What don’t you do?
• What questions do you want answered?
Objectives

Evidence-based review of options available to reduce the incidence of capsular contracture

• Understand patient selection
• Describe implant selection
• Refine intraoperative technique
• Options for treating capsular contracture
Levels of Evidence and Qualifying Studies (Therapeutic Studies):

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>High-quality, multi-centered or single-centered, randomized controlled trial with adequate power ($N \geq 100$); or a systematic review of these studies</td>
</tr>
<tr>
<td>II</td>
<td>Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies</td>
</tr>
<tr>
<td>III</td>
<td>Retrospective comparative study; case-control study; or a systematic review of these studies</td>
</tr>
<tr>
<td>IV</td>
<td>Case series</td>
</tr>
<tr>
<td>V</td>
<td>Expert opinion; case report or clinical example; or evidence based on physiology, bench research or &quot;first principles&quot;</td>
</tr>
</tbody>
</table>
Disclaimers

• Limited to augmentation
  – More variables in reconstruction
  – Same principles may apply

• Focus on more recent studies
  – Newer generation implants
  – More likely to use current techniques

• Individual surgeon’s case series
  – Tend to under report CC

• Variability in reporting technique details
  – Pocket irrigation
  – No touch technique
  – Pocket dissection
Etiology

- Bacterial contamination in 2/3rds of Baker III/IV capsules
- Emerging evidence of biofilms
- Nonbacterial causes
  - Hematoma
- Common inflammatory pathway
## Baker Grade

<table>
<thead>
<tr>
<th>Grade</th>
<th>Feel</th>
<th>Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Soft</td>
<td>Natural</td>
</tr>
<tr>
<td>II</td>
<td>Little firm</td>
<td>Normal</td>
</tr>
<tr>
<td>III</td>
<td>Firm</td>
<td>Abnormal</td>
</tr>
<tr>
<td>IV</td>
<td>Hard, cold, painful</td>
<td>Distorted</td>
</tr>
</tbody>
</table>

Unless otherwise mentioned, will only refer to Grade III & IV
Capsular Contracture

• Common cause of reoperation
  – **Saline** (Mentor & Allergan) Augmentation up to 20%
  – **Saline** (Mentor & Allergan) Reconstruction up to 30%
  – **Gel** (Mentor & Allergan) Augmentation up to 40%
  – **Gel** (Mentor & Allergan) Reconstruction up to 14%

• Common cause of implant removal
  – **Saline** (Mentor & Allergan) Augmentation up to 15%
  – **Saline** (Mentor & Allergan) Reconstruction up to 30%
  – **Gel** (Mentor & Allergan) Augmentation up to 33%
  – **Gel** (Mentor & Allergan) Reconstruction up to 21%
Saline Implants: 1980’s

- 995 and 882 saline implants, >90% augmentation
- Mean 6 year and 13 year follow up
- CC risk factors (20% and 20%)
  - Subglandular, antibiotics* in pocket, no steroid in implant, no antibiotics in implant
  - Subglandular, implant >450 cc

* Not triple antibiotics
Capsular Contracture Over Time

A Long-Term Study of Outcomes, Complications, and Patient Satisfaction with Breast Implants

3495 saline or silicone gel implants in 1529 women for any indication
Capsular Contracture Over Time

Is capsular contracture inevitable?

A Long-Term Study of Outcomes, Complications, and Patient Satisfaction with Breast Implants

Neil Handel, M.D., Tracy Cordray, M.D., Jaime Gutierrez, M.D., J. Arthur Jensen, M.D.

Los Angeles, Calif.

Background: Breast implants have been used worldwide for more than 40 years. Despite extensive clinical experience, there is continued concern about the safety of these devices. The purpose of this study was to compare the efficacy, complication rates, frequency of reoperation, and degree of patient satisfaction with different types of implants.
Incidence: Allergan Saline

<table>
<thead>
<tr>
<th>Procedure</th>
<th>1 yr</th>
<th>3 yr</th>
<th>5 yr</th>
<th>7 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Augmentation</td>
<td>7%</td>
<td>9%</td>
<td>11%</td>
<td>16%</td>
</tr>
<tr>
<td>Reconstruction</td>
<td>13%</td>
<td>25%</td>
<td>36%</td>
<td>43%</td>
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<tr>
<td>Revision</td>
<td>12%</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
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</tbody>
</table>

- Based on 3 studies done in the 1990’s
- For augmentation:
  - Mostly textured, submuscular, PA or IMF incision
- May not apply to current techniques
## Incidence: Mentor Saline

### Mentor Saline Implants

<table>
<thead>
<tr>
<th>Procedure</th>
<th>1 yr</th>
<th>3 yr</th>
<th>5 yr</th>
<th>7 yr</th>
<th>10 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Augmentation</td>
<td>5%</td>
<td>9%</td>
<td>10%</td>
<td>11%</td>
<td>18%</td>
</tr>
<tr>
<td>Reconstruction</td>
<td>29%</td>
<td>30%</td>
<td>29%</td>
<td>49%</td>
<td>59%</td>
</tr>
<tr>
<td>Revision</td>
<td>15%</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

- Based on 2 studies done in the 1990’s
- For augmentation:
  - Mostly textured, submuscular, PA or IMF incision
- May not apply to current techniques
Allergan Silicone Gel Implants

Procedure 7 yr
• Augmentation 16%
• Reconstruction 17%

• Based on 3 studies done in the late 1990’s
• For augmentation:
  – Mostly smooth, submuscular, IMF incision
• May not apply to current techniques
Allergan Silicone Gel Implants: Final 10 Years

Procedure  10 yr
• Augmentation  19%
• Reconstruction  25%

Background: Allergan’s Natrelle round silicone-filled breast implants were approved by the U.S. Food and Drug Administration in 2006 based on interim results from the Core Study: final 10-year study results are now available. Methods: Seven hundred fifteen subjects were implanted with smooth and Biocell textured Natrelle round silicone implants and attended clinic visits at 6 to 8 weeks, 6 months, 1 year, and annually through 10 years. Approximately one-third of subjects underwent magnetic resonance imaging at years 1, 3, 5, 7, and 9 to assess rupture.
Natrelle Augmentation Subgroup Analysis

- **Core Study not designed to capture CC risk factors**
  - Caution with drawing conclusions

- **Implant Surface**
  - Subglandular & submuscular: Textured (17.2%) vs smooth (19.9%)
  - Subglandular only: Texture (20.2%) vs smooth (37.0%) NOT SIGNIFICANT

- **Incisions**
  - Inframammary (17.4%) & periareolar (18.6%) vs Axillary (23.6%) \( (p = 0.077) \)
  - Axillary smooth (34.6 %) vs textured (14.8%)

- **The lowest CC rates at 10 years**
  - Inframammary submuscular smooth (10.2 %) or textured (14.2 %) implants
  - Periareolar submuscular textured implants (13.9%)

- **The highest CC rates at 10 years**
  - Transaxillary subglandular smooth (50%, \( n=2 \))
  - Periareolar subglandular smooth (36.2%)
  - Inframammary subglandular smooth (35.6%)
Allergan Natrelle 410 Silicone Gel

- Pooled data: 2 similar, ongoing, prospective, multicenter trials
- 5059 primary augmentation patients
- Median follow-up 4.1 years
- Significant risk factors for CC
  - Subglandular [RR=2.9]
  - Older device
  - Age
  - Periareolar incision

Risk Factor Analysis for Capsular Contracture, Malposition, and Late Seroma in Subjects Receiving Natrelle Style 410 Form-Stable Silicone Breast Implants

Patricia McGuire, MD; Neal R. Reisman, MD, JD, FACS; James Zins, MD; Diane K. Murphy, MBA

2015
Implant Type: Allergan 410

• 941 augmentation & reconstruction patients
• Many variables make comparison with past studies difficult
• 10 year CC rates:
  – 9% augmentation
  – 12% augmentation revision
  – 15% reconstruction
  – 27% reconstruction revision
Implant Type: Allergan 410

• Natrelle 410 shaped form-stable implants had lower CC rate than round gel implants
  – 51% lower for augmentation (9% vs 19%)
  – 59% lower for augmentation revision (12% vs 29%)

• Similar to Mentor 6 year data of form-stable Contour Profile Gel (CPG) implant compared to smooth round gel implants
Mentor Silicone Gel Implants

Procedure 3 yr
• Augmentation 8%
• Reconstruction 8%

• Based on 1 study done in the late 1990’s
• For augmentation:
  – Mostly smooth, submuscular, IMF incision
• May not apply to current techniques
Incidence: Sientra Gel

Sientra Silicone Gel Implants

<table>
<thead>
<tr>
<th>Procedure</th>
<th>8 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Augmentation</td>
<td>11%</td>
</tr>
<tr>
<td>Augmentation revision</td>
<td>13%</td>
</tr>
<tr>
<td>Reconstruction</td>
<td>13%</td>
</tr>
<tr>
<td>Reconstruction</td>
<td>15%</td>
</tr>
</tbody>
</table>

- For augmentation:
  - Mostly smooth, submuscular, IMF incision
- Pocket irrigation common
Sientra Gel 5 Year Study

- 5109 implants, 2560 1º augmentations, 34 surgeons
- 265 CC in 179 patients (7.6% by device)
- Independent factors for CC
  - Smooth \( \text{OR} = 4.7 \)
  - Subglandular \( \text{OR} = 4.6 \)
  - Surgical Bra \( \text{OR} = 3.7 \)
  - Hematoma/seroma \( \text{OR} = 2.9 \)
  - Implant \( \leq 355 \text{ cc} \) \( \text{OR} = 1.5 \)
  - Periareolar incision \( \text{OR} = 1.5 \)
Pocket Irrigation

- Antibiotic: 61%
- Betadine: 11%
- Steroid: 10%

Was not a factor in CC
## Mentor Gel: Round vs Shaped

<table>
<thead>
<tr>
<th>Implant</th>
<th>Primary Augmentation</th>
<th>Revision Augmentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>MemoryShape (Shaped)</td>
<td>3.4%</td>
<td>11.3%</td>
</tr>
<tr>
<td>MemoryGel (Round)</td>
<td>15.6%</td>
<td>24.4%</td>
</tr>
</tbody>
</table>

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### Indications for the Use of MemoryShape Breast Implants in Aesthetic and Reconstructive Breast Surgery: Long-Term Clinical Outcomes of Shaped versus Round Silicone Breast Implants

2014

*Background:* The availability of different styles of silicone gel implants—including traditional round devices and shaped, form-stable implants—offers a...
Implant Type: IDEAL Implant

New double-lumen saline filled implant

<table>
<thead>
<tr>
<th></th>
<th>IDEAL</th>
<th>Allergan</th>
<th>Mentor</th>
</tr>
</thead>
<tbody>
<tr>
<td>CC rate</td>
<td>2.8%</td>
<td>7.2%</td>
<td>4.6%</td>
</tr>
</tbody>
</table>

Breast Surgery

Two-Year Outcomes With a Novel, Double-Lumen, Saline-Filled Breast Implant

Larry S. Nichter, MD; and Robert S. Hamas, MD

2012
Capsular Contracture: Prevention & Treatment

### Prevention
- Implant choice
  - Smooth vs textured
  - Shaped vs round
- Incision choice
- Implant pocket
- Pocket irrigation
  - Betadine
  - Antibiotics
- Surgical technique
  - No touch methods

### Treatment
- Nonsurgical
  - Medication
  - Ultrasound
- Capsule modification
  - Closed capsulotomy
  - Anterior vs complete capsulectomy
- Pocket site change
- ADM placement
- Different implant
- Prevention
Textured vs Smooth: Same Patient

- **Silicone Gel**
  - 25 patients
  - Smooth on one side
  - Textured on one side
  - All subglandular
  - 1 year: **Textured much softer**

- **Saline**
  - 21 patients
  - Smooth on one side
  - Textured on one side
  - All subglandular
  - 1 year: **No difference**
Textured vs Smooth: Same Patient +/- Betadine

The Effect of Biocell Texturing and Povidone-Iodine Irrigation on Capsular Contracture Around Saline-Inflatable Breast Implants

Boyd R. Burkhardt, M.D., and Edward Eades, M.D.
Tucson, Arizona
1995

- Saline Biocell (McGhan)
- 60 patients
- Smooth + Betadine or saline
- Textured + Betadine or saline
- All periareolar & subglandular

The Effect of Siltex Texturing and Povidone-Iodine Irrigation on Capsular Contracture Around Saline Inflatable Breast Implants

Boyd R. Burkhardt, M.D., and Christopher P. Demas, M.D.
Phoenix, Ariz
1994

- Saline Siltex (Mentor)
- 56 patients
- Smooth + Betadine or saline
- Textured + Betadine or saline
- All periareolar & subglandular

- Most contractures in smooth group
- Betadine had no effect
Textured Surfaces NOT the Same

Mentor
Silimed® TRUE Texture®
Sientra
BIOCCELL®
Allergan
Differences in Same Manufacturer

Mentor Round MemoryGel
100 pores/inch

Mentor Shaped MemoryShape
65 pores/inch

Mentor CPX Tissue Expander
45 pores/inch

The Design and Engineering of the MemoryShape Breast Implant

M. Bradley Calobrace, MD
Louisville, Ky

Summary: The recent approval of MemoryShape implant by the Food and Drug Administration introduces a novel implant available to the surgeon for cosmetic
Smooth vs Textured

812 patients
Pocket irrigation unknown

- Most silicone gel implants were subglandular
- Most saline implants were submuscular
- However, no statistical difference
Meta-analysis of 7 RCT
- CC odds ratio 0.34 for Biocell vs smooth

Meta-analysis, including 6 RCT (Subglanular)
- CC higher with smooth vs textured at:
  - 1 year [RR = 4.16]
  - 3 years [RR = 7.2]
  - 7 years (RR = 2.98)

Number needed to treat
- 2 long-term trials, subglandular & submuscular
- 9 patients needed to treat with Biocell round, or 7 patients with a Biocell anatomic, rather than with smooth round implant, to prevent 1 Baker grade III/IV CC over 10 years

Slightly increased risk of
- Non-adherance
- Double capsule
- Late seroma
Recommendation: Use **textured** implants for **subglandular** placement

**Smooth** implants may be appropriate for **submuscular** placement
Capsular Contracture with Breast Implants in the Cosmetic Patient: Saline versus Silicone—A Systematic Review of the Literature

Timothy A. Schaub, M.D.
Jamil Ahmad, M.D.
Rod J. Rohrich, M.D.

Background: Capsular contracture is one of the most common and trying complications associated with the placement of breast prostheses. The authors hypothesized that silicone implants have a higher rate of capsular contracture

- **Lack of current prospective data** comparing saline & silicone implants
- Therefore can’t make data-driven recommendations regarding:
  - Pocket, fill type, surface
- Textured implants (saline and silicone) have **tendency** for less contracture
- Submuscular plane (saline and silicone) has **tendency** for less contracture
Implant Profile

CC risk lower in:

- High-profile vs low- to moderate-profile (RR = 0.21)
- Midrange-profile and full/high/extra high–profile vs low- to moderate-profile breast
  - Midrange (RR = 0.49)
  - Full/high/extra high (RR = 0.55)
- Subpectoral versus subglandular placement
- Younger patients
Implant Profile

May not matter after 10 years
Core Studies Summary: CC

Core studies NOT same design

Capsular Contracture Rates following Primary Breast Augmentation

2015

Textured Silicone Breast Implant Use in Primary Augmentation: Core Data Update and Review

Summary: Evolution of silicone breast implant design has focused primarily on advances in implant fill, surface texture, and shape. Fifth-generation, shaped, form-stable, silicone breast implants from all three major implant manufacturer.
Core Studies Summary: CC

Core studies NOT same design

Capsular Contracture Rates following Primary Breast Augmentation

2015

Textured Silicone Breast Implant Use in Primary Augmentation: Core Data Update and Review
Core Studies Summary: CC

Core studies NOT same design

Capsular Contracture Rates following Primary Breast Augmentation

Time

3 years 6 years 9 years 3 years 6 years 10 years 5 years 3 years 6 years 10 years 3 years 6 years 10 years

Capsular Contracture Rates

Mentor Shaped Allergan Shaped Sientra Round and Shaped Mentor Round Allergan Round

2015

SPECIAL TOPIC

Textured Silicone Breast Implant Use in Primary Augmentation: Core Data Update and Review

Summary: Evolution of silicone breast implant design has focused primarily on advances in implant fill, surface texture, and shape. Fifth-generation, shaped, form-stable, silicone breast implants from all three major implant manufacturers...
Incision Site

- 183 primary augmentations, mean follow-up 1.2 years
- Betadine + triple antibiotic irrigation + IV antibiotics
- CC rates:
  - 6.4% transaxillary
  - 2.4% periareolar
  - 0.5% inframammary
Incision Site

- 856 primary augmentations, mean follow-up 1.4 years
- Variable pocket irrigation
- Overall CC 2.8%
  - Antibiotic irrigation decreased CC (3.9% vs 0.4%)
  - Tobacco users had more CC (5.5% vs 1.9%)
  - Saline implants had more CC than silicone gel (4.3% vs 1.3)
- Recommend IMF & submuscular placement, antibiotic irrigation
Incision Site

- Inframammary incision CC: 0.59%
- Periareolar incision CC: 9.5%
- Periareolar mastopexy CC: 8%
- “due to an increase in contamination of the breast pocket with intraductal material colonized by bacteria.”
• 1539 patients with 3078 implants
• 596 shaped textured gel, 192 round textured gel
• 236 round smooth gel implants, 515 round smooth saline
• Follow-up average 18 months
• Lower CC rates:
  – Textured shaped gel implants
  – Submuscular pocket
Can we Agree on:

- Submuscular pocket
- Inframammary incision
- Textured implant
  - Unless submuscular pocket
Pocket Irrigation: Betadine

- Betadine rinse followed by saline (FDA OK)
- Leaving Betadine in the pocket (FDA NOT OK)
- Intraluminal Betadine (FDA NOT OK)
- FDA concerns of implant shell compromise
  - Studies suggest it is safe
Pocket Irrigation: Betadine + Abx

- 330 inframammary dual-plane augmentations
  - **Group A**: Cephalothin 1.5 g IV + cephalexin 750 mg PO BID x 7 days
  - **Group B**: Cefuroxime 750 mg IV + levofloxacin 500 mg PO QD x 5 days + pocket irrigation
    - 25 mL 10% povidone-iodine + cefuroxime 750 mg + gentamicin 80 mg in 15 mL saline

- CC at 2 year follow up
  - Group A: 6%
  - Group B 0.6%

Breast Surgery

Povidone-Iodine Combined With Antibiotic Topical Irrigation to Reduce Capsular Contracture in Cosmetic Breast Augmentation: A Comparative Study

Salvatore Giordano, MD; Hilkka Peltoniemi, MD, PhD; Peter Lilius, MD, PhD; and Asko Salmi, MD, PhD

2013
Betadine Irrigation

- Meta-analysis of four studies
  - 1191 patients Betadine irrigation
  - 595 patients saline irrigation
- Less CC with Betadine
  - 2.3% vs 8.9%
- Implant rupture <1%
- Low study methodologic quality limits recommendation for standard of practice

Efficacy and Safety of Povidone-Iodine Irrigation in Reducing the Risk of Capsular Contracture in Aesthetic Breast Augmentation: A Systematic Review and Meta-Analysis

Background: Capsular contracture is common and distressing after aesthetic breast augmentation. The precise cause of capsular contracture is not well established. This systematic review investigates current available evidence regarding perioperative povidone-iodine irrigation safety and efficacy in reduc-
Betadine + Marcaine NOT Compatible

• Common to place long-acting anesthetic in pocket
• Bupivacaine is pH balanced
  – Sensorcaine: NaOH + HCl
  – Marcaine: Ascorbic acid
• Marcaine (not Sensorcaine) may neutralize antimicrobial effects of Betadine

Incompatibility of Betadine Mixed with Marcaine as an Irrigant for Breast Implant Pockets

Elizabeth Hall-Findlay 2013
Antibiotic Irrigation: Cephalosporin Only

- 414 patients: ½ had irrigation with cephalothin
- Double lumen textured implants
- No difference in CC (8% vs 6%)
Triple Antibiotic Irrigation

- 335 patients, mean follow-up 14 months (6 - 75 months)
- No control group – compared to historical controls
- 50,000 U bacitracin + 1 g cefazolin + 80 mg gentamicin in 500 cc NS
- No touch techniques + postop antibiotics
- CC rates:
  - 1.8% primary breast augmentation (n=248)
  - 0% augmentation-mastopexy (n=24)
  - 9.5% breast reconstruction (n=63)

Optimizing Breast Pocket Irrigation: An in Vitro Study and Clinical Implications

Enhancing Patient Outcomes in Aesthetic and Reconstructive Breast Surgery Using Triple Antibiotic Breast Irrigation: Six-Year Prospective Clinical Study
Postoperative Antibiotics

- 605 implants: 1° or 2° breast augmentation
- 1% CC at mean 3.8 year follow up
- Protocol:
  - 1 g cefazolin IV (or clindamycin)
  - Bacitracin irrigation
  - Smooth Mentor saline or silicone gel implants
  - 3 days of antibiotics (52%) vs none (48%)
- No reduction in CC, infection, or complication rate
Electocautery vs Blunt Dissection

Brief Communication

• 615 cases
• 51% visualized dissection with electrocautery
  – CC 0.64%
• 49% blind Dingman blunt dissection
  – CC 6.4%
Capsular Contracture and Steroid-Related Complications After Augmentation Mammaplasty

A Preliminary Study

Thomas J. Carrico, M.D., and I. Kelman Cohen, M.D.

Richmond, Va.

<table>
<thead>
<tr>
<th>Group</th>
<th>No. Patients</th>
<th>% With Firm Breasts</th>
<th>% With Steroid-Related Complications</th>
<th>% With Discoloration</th>
<th>% With Atrophy</th>
<th>Follow-up in Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>No steroids†</td>
<td>20</td>
<td>50.0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>12.60 0.2 → 43</td>
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<tr>
<td>Steroids around implant†</td>
<td>21</td>
<td>52.4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>23.74 2.5 → 40</td>
</tr>
<tr>
<td>&gt;20 mg Solu-Medrol*</td>
<td>26</td>
<td>4.0</td>
<td>61.5</td>
<td>34.6</td>
<td>61.5</td>
<td>15.71 3.0 → 21.5</td>
</tr>
<tr>
<td>20 mg Solu-Medrol*</td>
<td>24</td>
<td>4.2</td>
<td>8.3</td>
<td>4.2</td>
<td>4.2</td>
<td>6.33 1.0 → 12.2</td>
</tr>
</tbody>
</table>

* Within inflatable implant
† Gel or inflatable implant
‡ Classified as Baker III or IV
Steroids

• Injected into saline implants
  – Drug delivery device

• In implant pocket

• Problems with tissue thinning & implant extrusion

• Not recommended
Steroid Irrigation

- 33 patients with established CC
- Capsulectomy & catheter irrigation x 2-3 days
  - Methylprednisolone (Solu-Medrol) 40 mg, 2 doses
- No recurrence at 2-10 years
Does not appear to dramatically increase risk of CC?

Place implant, close pocket, then do mastopexy
No Touch Technique

- Breast tissue is not sterile
  - Cx (+) in axillary, periareolar, inframammary tissue
- Techniques to not touch skin or breast tissue
- Keep implant in original container and transfer to pocket with minimal handling

Breast Surgery

The Breast: A Clean-Contaminated Surgical Site

Sophie Bartsich, MD; Jeffrey A. Ascherman, MD, FACS; Susan Whittier, MD; Caroline A. Yao, MD; and Christine Rohde, MD, FACS
Nipple Shield

Risk of Breast Implant Bacterial Contamination From Endogenous Breast Flora, Prevention With Nipple Shields, and Implications for Biofilm Formation

Roger N. Wixtrom, PhD, DABT; Ross L. Stutman, MD; Renee M. Burke, MD; Amy K. Mahoney, BS; and Mark A. Codner, MD

- NAC covered with adhesive shield
- 35% had + bacterial cultures

LOP15: Nipple shields as additional tool to pocket irrigation in reducing capsular contracture after cosmetic breast augmentation
*S. Giordano¹, A. Salmi¹
¹Turku University Hospital, Plastic Surgery, Turku, Finland

No Shield: 5% CC, n=60
Shield: 0% CC, n=105
Skin Barrier

IDEAS AND INNOVATIONS

A Simple Barrier Drape for Breast Implant Placement

Kenneth C. Shestak, M.D.
Morad Askari, M.D.
Pittsburgh, Pa.
Keller Funnel

$100 to $130

One case use

Data submitted for publication
27-fold reduction in skin contact

Breast Surgery

Contamination in Smooth Gel Breast Implant Placement: Testing a Funnel Versus Digital Insertion Technique in a Cadaver Model

2012

Hunter R. Moyer, MD; Bahaier Ghazi, MD; Neil Saunders, MD; and Albert Losken, MD
Capsular Contracture: Prevention & Treatment

**Prevention**
- Implant choice
  - Smooth vs textured
  - Shaped vs round
- Incision choice
- Implant pocket
- Pocket irrigation
  - Betadine
  - Antibiotics
- Surgical technique
  - No touch methods

**Treatment**
- Nonsurgical
  - Medication
  - Ultrasound
- Capsule modification
  - Closed capsulotomy
  - Anterior vs complete capsulectomy
- Pocket site change
- ADM placement
- Different implant
- Prevention
Capsular Contracture Surgery

Do something different
• Remove capsule
• New implant
• New pocket
• Use all other techniques
• Add ADM?
• Recurrent CC
  – When to stop & remove implant
  – Offer fat grafting?
Closed Capsulotomy

Not recommended

• Implant rupture
• Hematoma
• Implant pseudoherniation
• Low success long-term
Ultrasound

- Specific protocol
- Disrupts biofilm
- Allows antibiotic to work
- Not as useful for Baker 4
- No good published studies

- Prophylaxis trials
Low-Level Laser Therapy

- LTU-904 Laser
- 10 min treatment per week x 6 weeks
- Average 50% improvement stiffness & comfort
- Surgery avoided in 31 of 33 patients (94%)

J Johnson, P Glat, W Scarlett
2015
Capsulectomy

Recurrence of Subglandular Breast Implant Capsular Contracture: Anterior versus Total Capsulectomy

Nicholas Collis, B.Sc., F.R.C.S.(Ed.), and David T. Sharpe, O.B.E., M.A., F.R.C.S.

West Yorkshire, England

Total (vs anterior) capsulectomy when possible
Pocket & Capsule

- If subglandular
  - Capsulectomy
  - Submuscular pocket
  - Muscle sutures
  - ADM?
Pocket & Capsule

- If submuscular
  - Anterior capsulectomy
  - Complete capsulectomy
  - Neosubmuscular pocket
    - Between muscle & anterior capsule
    - Avoids intrathoracic penetration
  - ADM?
Acellular Dermal Matrix

Anecdotal use and success
Short follow up, but seems convincing

Supplemental Article

Acellular Dermal Matrix in Aesthetic Revisionary Breast Surgery

G. Patrick Maxwell, MD; and Allen Gabriel, MD

2013

Treatment of Capsular Contracture Using Complete Implant Coverage by Acellular Dermal Matrix: A Novel Technique

Angela Cheng, M.D., Chrisovalantis Lakhiani, B.S., Michel Saint-Cyr, M.D.; Buffalo, Toronto, Atlantic, CA; and Rochester, Minn.

Background: Capsular contracture is a frequent complication of breast reconstruction that affects 2.8 to 15.9 percent of patients. Use of acellular dermal matrix has been reported for treatment of contracture, with a recurrence rate of 6.5 percent, but this was limited to partial implant coverage only. The authors describe a novel surgical technique using acellular dermal matrix to completely cover the implant anteriorly to treat and prevent capsular contracture.

Supplemental Article

Acellular Dermal Matrix for Secondary Procedures Following Prosthetic Breast Reconstruction

Maurice Y. Nahabedian, MD; and Scott L. Spear, MD
Acellular Dermal Matrix

Follow up
86% at least 2 years
50% at least 3 years

<table>
<thead>
<tr>
<th>Acellular Dermal Matrix Group</th>
<th>Capsular Contracture, n/N (%)</th>
<th>Capsular Contracture, n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperative</td>
<td>Postoperative</td>
</tr>
<tr>
<td>Stratitce</td>
<td>51/96 (53.1)</td>
<td>0/96 (0)</td>
</tr>
<tr>
<td>AlloDerm</td>
<td>45/57 (78.9)</td>
<td>0/57 (0)</td>
</tr>
<tr>
<td>FlexHD</td>
<td>10/19 (52.6)</td>
<td>0/19 (0)</td>
</tr>
<tr>
<td>SurgiMend</td>
<td>6/8 (75)</td>
<td>2/8 (25.0)</td>
</tr>
<tr>
<td>NeoForm</td>
<td>3/4 (75)</td>
<td>1/4 (25)</td>
</tr>
<tr>
<td>DermaMatrix</td>
<td>0/2 (0)</td>
<td>0/2 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>115/186 (61.8)</td>
<td>3/186 (1.6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baker Classification</th>
<th>Preoperative, n/N (%)</th>
<th>Postoperative, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>56/186 (30.1)</td>
<td>176/186 (94.6)</td>
</tr>
<tr>
<td>II</td>
<td>23/186 (12.4)</td>
<td>14/186 (7.5)</td>
</tr>
<tr>
<td>III</td>
<td>100/186 (53.8)</td>
<td>3/186 (1.6)</td>
</tr>
<tr>
<td>IV</td>
<td>14/186 (7.5)</td>
<td>0/186 (0)</td>
</tr>
</tbody>
</table>

Efficacy of Acellular Dermal Matrices in Revisionary Aesthetic Breast Surgery: A 6-Year Experience

G. Patrick Maxwell, MD; and Allen Gabriel, MD
ADM: Strattice

- Non-cross-linked porcine ADM
- Neosubpectoral pocket
- Triple antibiotic irrigation
- At least 1 year follow up, mean 3 years

<table>
<thead>
<tr>
<th>Baker Classification</th>
<th>Before, No./Total No. (%)</th>
<th>After, No./Total No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>45/106 (41.5)</td>
<td>99/106 (93.4)</td>
</tr>
<tr>
<td>II</td>
<td>7/106 (6.6)</td>
<td>7/106 (6.6)</td>
</tr>
<tr>
<td>III</td>
<td>48/106 (46.2)</td>
<td>0/106 (0)</td>
</tr>
<tr>
<td>IV</td>
<td>6/106 (5.7)</td>
<td>0/106 (0)</td>
</tr>
</tbody>
</table>
ADM: Strattice

- 25 breasts
- Mean 17 month follow up

Porcine Acellular Dermal Matrix (Strattice) in Primary and Revision Cosmetic Breast Surgery

Scott L. Spear, M.D.
Jeremy C. Sinkin, M.D.
Ali Al-Attar, M.D., Ph.D.
Washington, D.C.

Background: Although acellular dermal matrix materials have been in use for over a decade in primary and secondary breast reconstruction and in some cosmetic breast surgery, little has been published on the outcomes of these materials for cosmetic applications.
Acellular Dermal Matrix

Decreased inflammation in capsule tissue

Further Evidence that Human Acellular Dermal Matrix Decreases Inflammatory Markers of Capsule Formation in Implant-Based Breast Reconstruction

Mimi Leong, MD, MS, FACS; C. Bob Basu, MD, MPH, FACS; and M. John Hicks, MD, DDS, PhD

2015
ADM: Strattice

- 70 breasts with CC & 1.3 year follow up
- All had antibiotic irrigation
- 4% CC recurrence
ADM Evidence

• Most studies in reconstructive surgery
• Mostly short term case reports for aesthetic breast surgery

The Role of Acellular Dermal Matrices in Capsular Contracture: A Review of the Evidence

C. Bob Basu, M.D., M.P.H.
Lynn Jeffers, M.D.
Houston, Texas, and Ozanum, Calif.

Summary: Despite advances in breast implant surgery, capsular contracture remains a challenging sequela of reconstructive and cosmetic breast implant surgery. Although there are established modalities for treatment, most recently, acellular dermal matrix products have been suggested to have a role in preventing or diminishing the pathologic process of capsular contracture. In this article, the author presents a review of the literature to highlight the level of evidence on the role of acellular dermal matrices in the treatment of capsular contracture. (Plast. Reconstr. Surg. 130 (Suppl. 2); 118S, 2012.)
Zafirlukast (Accolate) & Montelukast (Singulair)

• Leukotrienes (LTs)
  – Produced by leukocytes
  – Promote inflammation & smooth muscle contraction

• Mechanism of Action
  – Block LTs at final inflammatory pathway
Zafirlukast (Accolate)

- 3 year experience
- Decrease CC rate from 4% to 1%
- 20 mg BID x 2-3 months
- Best for early cases (< 6 months)
- 10% success in cases > 1 year

Letter to the Editor

A New Treatment for Capsular Contracture

2002
Zafirlukast (Accolate)

- Case reports of CC regression
- Baker III & IV resolved or improved within 3 months
Zafirlukast (Accolate) & Montelukast (Singulair)

- Liver failure & death associated with Accolate
- Not seen with Singular

Special Report

Investigation of Accolate and Singulair for Treatment of Capsular Contracture Yields Safety Concerns

Joe M. Gryskiewicz, MD

2003
Zafirlukast (Accolate)

• Primary, submuscular, smooth saline implants
• 41 of 74 (55%) of breasts had early CC
  – Started on Accolate 20 mg BID up to 6 months
  – 76% responded
  – Response maintained beyond 1 year
  – Confounders: Drains, Vitamin E, massage, lymphatic drainage
Montelukast (Singulair)

- 19 patients with existing CC
- Singulair (10 mg QD) + massage BID
  - 11% worse
  - 16% no change
  - 26% improved
  - 37% completely improved
  - 11% prevented from having CC formation (given after surgery for CC)
- Baker II had better improvement than III & IV
# Summary Antileukotriene Agents

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcome</th>
<th>Follow-up (mo)</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schlesinger et al.,</td>
<td>Case 1: Left, class III to class I in 3 mo</td>
<td>One month in case 1; 5 mo in</td>
<td>Not reported</td>
</tr>
<tr>
<td>2002&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Case 2: Bilateral, class III to class I in 3 mo</td>
<td>case 2; others not mentioned</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Case 3: Left, class IV to class I in 1 mo</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Case 4: Left, class IV to class I in 1 mo</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Case 5: Left, class IV to class II in 3 mo; right, class IV to class III</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>in 3 mo</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Reid et al., 2005<sup>2</sup> | In 6 mo  
  Complete response: 22 breasts  
  Partial response: 9 breasts  
  No response: 10 breasts  
  Long-term follow-up (mean, 16.5 mo)  
  Complete response: 30 breasts  
  Partial response: 4 breasts  
  No response: 7 breasts | Mean, 16.5 (range, 6–29) | No untoward effects of the drug |
| Scuderi et al., 2006<sup>3</sup> | Reduction in mammary compliance of 10.59% after 1 mo, 17.10% after 3 mo, and 23.49% after 6 mo | Not mentioned | No major complications; only 1 patient experienced hypertension |
| Scuderi et al., 2007<sup>4</sup>  | Group A (zafirlukast): reduction in mammary compliance of 7.69% after 1 mo, 16.78% after 3 mo, and 24.01% after 6 mo | Not mentioned | No major complications; only 1 case presented hypertension |
|                        | Group B (vitamin E): reduction in mammary compliance of 0.32% after 1 mo, 0.95% after 3 mo, and 2.09% after 6 mo |                                |                                                        |
| Huang and Handel, 2010<sup>5</sup> | Completely improved: 7 patients (within days to 2 mo)  
  Improved: 5 patients (within days to 1 mo)  
  No change: 3 patients  
  Worsened: 2 patients  
  Prevented: 2 patients | Mean, 19 (range, 5–36) | Only one patient reported fatigue |
Recommendations
Recommendations: Antibiotics

- 2 g cefazolin (or clindamycin) IV within 60 min
- Repeat if longer than 4 hour procedure
- No post-op antibiotics
  - May not apply if drains in place
  - Consider antibiotics until drains removed

- Prophylaxis for future procedures involving mucosal breach?
  - Not recommended due to lack of data
Recommendations: Technique

- Nipple shield
- Inframammary incision
- Submuscular or dual plane pocket
- Minimize bleeding during pocket dissection
  - Avoid dissection into breast tissue
- Pocket irrigation
  - Triple antibiotic
  - Betadine
Recommendations: Technique

• No touch principles
  – Glove change (no talc) before handling implant
  – Introduction sleeve (Keller Funnel)?
  – Minimize time implant is exposed
  – New instruments for incision closure

• No Drains

• Multi-layer tissue closure
Recommendations: Medications

• Singulair (Cost?)
  – Dose x 2 to 3 months
  – Inform patient “off label” use

• Steroid irrigation
  – Bad history
  – Select cases of recurrent CC?
Recommendations: Implants

• Implant choice
  – Shaped (form stable) implants may have lower CC
  – Rotation, cost, firmness, etc
  – Specific fit for size
• Submuscular – Smooth or textured
• Subglandular – Consider textured over smooth
  – Seroma, ALCL, double capsule
Recommendations: AMD

• Promising
  – Which product?
  – Cost
  – Other risks?
Lack of Good Data

• Smoking
  – Possible risk factor

• Vit E 2000 IU QD
  – Low risk

• Massage & implant displacement exercises
  – Smooth surface implants

• Papaverine hydrochloride 150 mg BID
Manufacturer CC Warranties

• **Allergan** Confidence Plus
  – Primary & revision augmentation
  – All silicone gel implants
  – No charge replacement implant (any style)
  – Baker III/IV within 10 years
  – Can replace contralateral implant

• **Mentor** Warranty
  – Primary augmentation
  – All silicone gel implants
  – No charge replacement implant
  – Baker III/IV within 3 years
  – Can replace contralateral implant
  – **10 years** + $3500 if Enhanced Warranty ($200)

• **Sientra** CapCon Care Program
  – Primary augmentation by BC/BE plastic surgeon
  – TRUE **Texture** silicone gel implants only
  – No charge replacement implant
  – Baker III/IV within 2 years
  – Same style, 1 size up or down
  – Affected side only

• Rupture warranties still apply
Will anyone change practice?