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

***Karol A Gutowski, MD, FACS***

*Instructional Course*

# Disclosures

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

**Levels of Evidence and Qualifying Studies (Therapeutic Studies):**

**I** High-quality, multi-centered or single-centered, randomized controlled trial with adequate power (N ≥ 100); or a systematic review of these studies

**II** Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies

**III** Retrospective comparative study; case-control study; or a systematic review of these studies

**IV** Case series

**V** Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles“

# 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

| Grade | Feel | Appearance |
|---|---|---|
| I | Soft | Natural |
| II | Little firm | Normal |
| III | Firm | Abnormal |
| IV | Hard, cold, painful | Distorted |

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

# Capsular Contracture

- Common cause of reoperation
  - Saline (Mentor & Allergan)
    - Augmentation up to 20%
    - Reconstruction up to 30%
  - Gel (Mentor & Allergan)
    - Augmentation up to 40%
    - Reconstruction up to 14%
- Common cause of implant removal
  - Saline (Mentor & Allergan)
    - Augmentation up to 15%
    - Reconstruction up to 30%
  - Gel (Mentor & Allergan)
    - Augmentation up to 33%
    - 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

Saline-Filled Breast Implants: A Plastic Surgery Educational Foundation Multicenter Outcomes Study

Karol A. Gutowski, M.D., Gregory T. Mesna, D.D.S., M.D., and Bruce L. Cunningham, M.D., M.S.
*Minneapolis, Minn.*

1997

Saline-Filled Breast Implant Safety and Efficacy: A Multicenter Retrospective Review

Bruce L. Cunningham, M.D., M.S., Adam Lokeh, M.D., and Karol A. Gutowski, M.D.
*Minneapolis, Minn.*

2000

# Capsular Contracture Over Time

COSMETIC

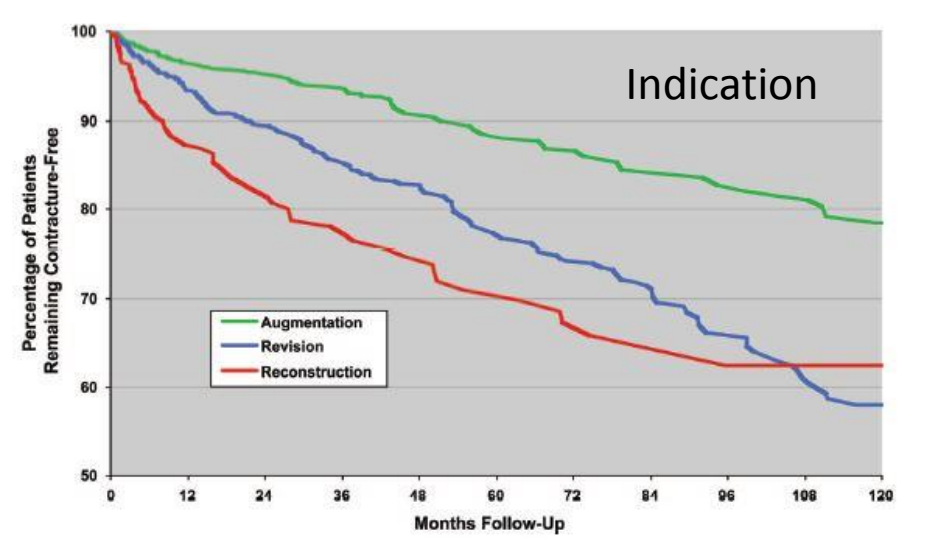
A Long-Term Study of Outcomes, Complications, and Patient Satisfaction with Breast Implants

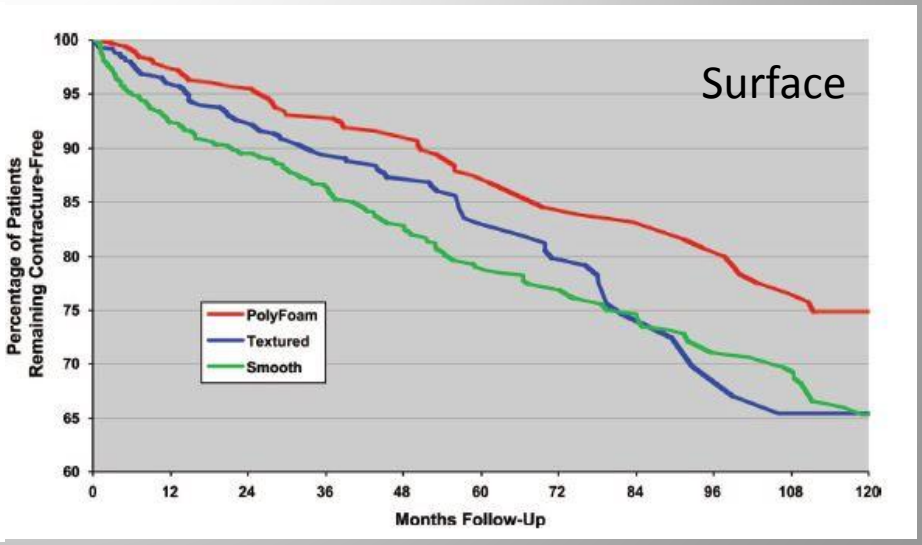
2006

Neal 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.

3495 saline or silicone gel implants in 1529 women for any indication



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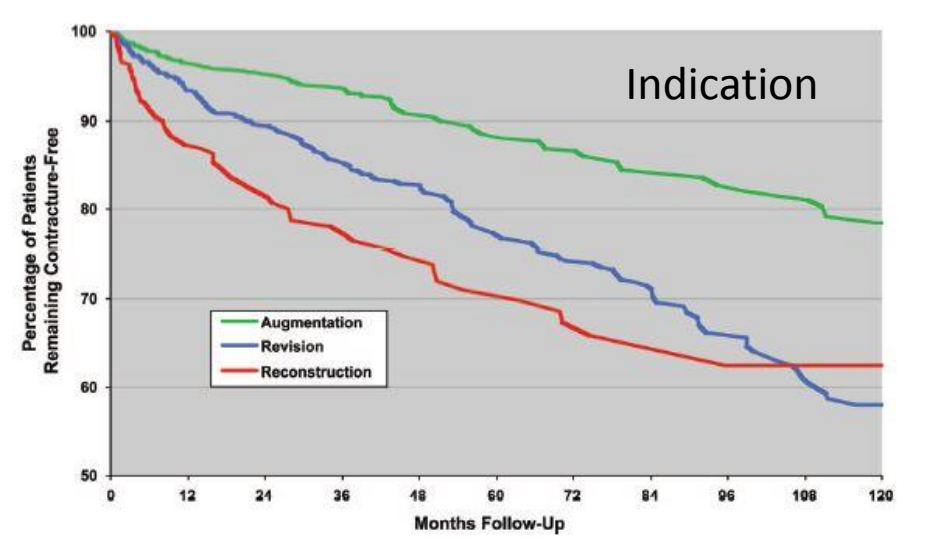
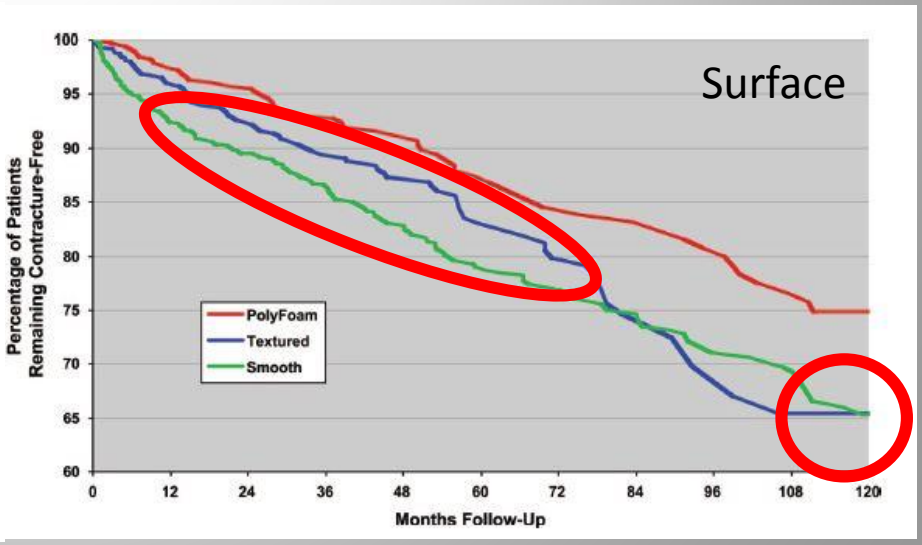
Is capsular contracture inevitable?



# Incidence: Allergan Saline

**Allergan Saline Implants**

| Procedure | 1 yr | 3 yr | 5 yr | 7 yr |
|---|---|---|---|---|
| • Augmentation | 7% | 9% | 11% | 16% |
| • Reconstruction | 13% | 25% | 36% | 43% |
| • Revision | 12% | NA | NA | NA |

- 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**

| Procedure | 1 yr | 3 yr | 5 yr | 7 yr | 10 yr |
|---|---|---|---|---|---|
| • Augmentation | 5% | 9% | 10% | 11% | 18% |
| • Reconstruction | 29% | 30% | 29% | 49% | 59% |
| • Revision | 15% | NA | NA | NA | NA |

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

# Incidence: Allergan Silicone Gel

**Allergan Silicone Gel Implants**

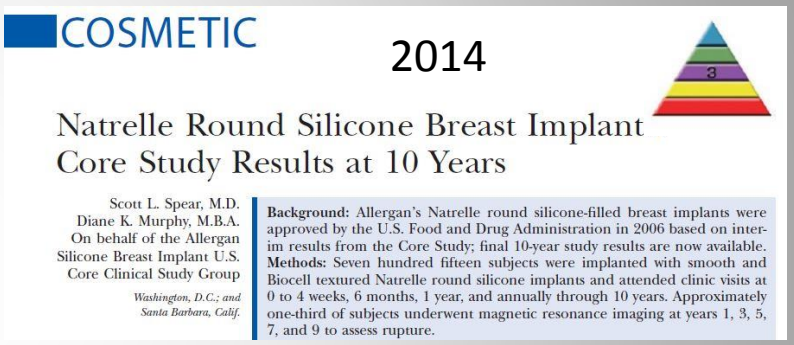
| Procedure | 7 yr |
| --- | --- |
| • Augmentation | 16% |
| • Reconstruction | 17% |

- Based on 3 studies done in the late 1990's
- For augmentation:
  - Mostly smooth, submuscular, IMF incision
- May not apply to current techniques

# Incidence: Allergan Silicone Gel

## Allergan Silicone Gel Implants: Final 10 Years

| Procedure | 10 yr |
|---|---|
| • Augmentation | 19% |
| • Reconstruction | 25% |



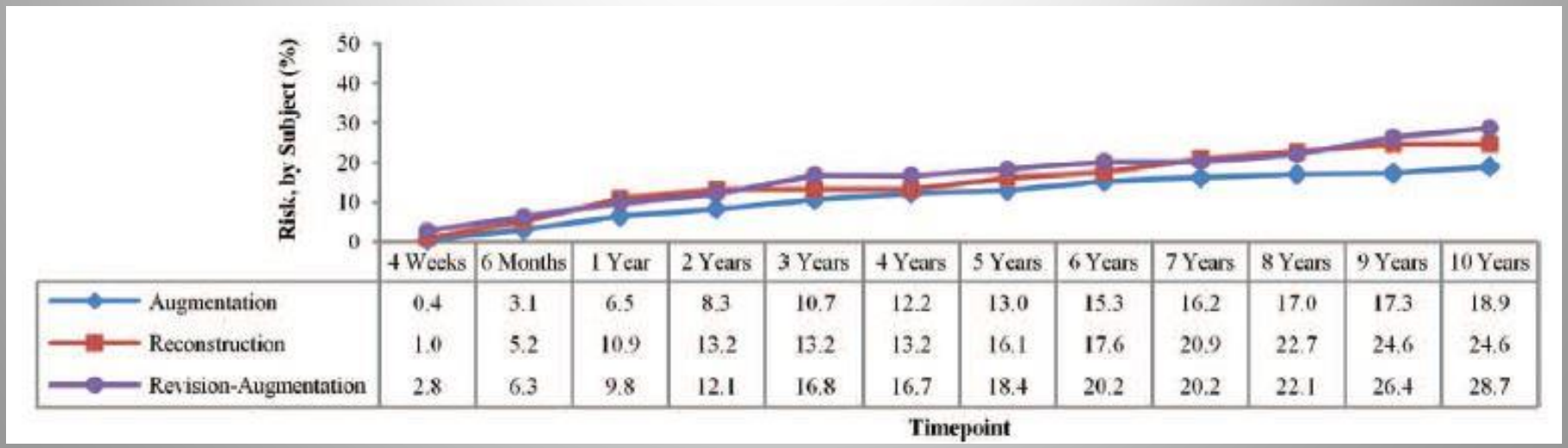
COSMETIC 2014

Natrelle Round Silicone Breast Implant Core Study Results at 10 Years

Scott L. Spear, M.D.
Diane K. Murphy, M.B.A.
On behalf of the Allergan Silicone Breast Implant U.S. Core Clinical Study Group

*Washington, D.C.; and Santa Barbara, Calif.*

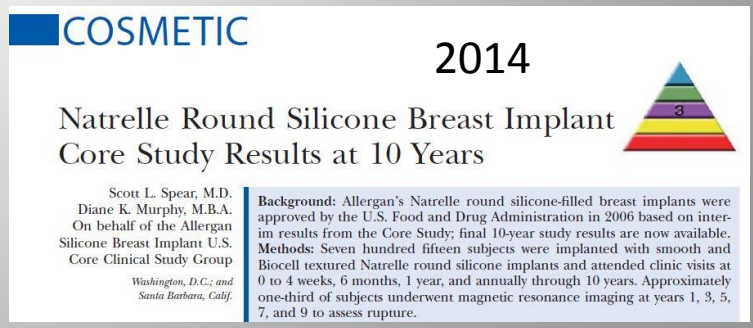
**Background:** Allergan's Natrelle round silicone-filled breast implants were approved by the U.S. Food and Drug Administration in 2006 based on interim results from the Core Study; final 10-year study results are now available. **Methods:** Seven hundred fifteen subjects were implanted with smooth and Biocell textured Natrelle round silicone implants and attended clinic visits at 0 to 4 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.




| | 4 Weeks | 6 Months | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years | 6 Years | 7 Years | 8 Years | 9 Years | 10 Years |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Augmentation | 0.4 | 3.1 | 6.5 | 8.3 | 10.7 | 12.2 | 13.0 | 15.3 | 16.2 | 17.0 | 17.3 | 18.9 |
| Reconstruction | 1.0 | 5.2 | 10.9 | 13.2 | 13.2 | 13.2 | 16.1 | 17.6 | 20.9 | 22.7 | 24.6 | 24.6 |
| Revision-Augmentation | 2.8 | 6.3 | 9.8 | 12.1 | 16.8 | 16.7 | 18.4 | 20.2 | 20.2 | 22.1 | 26.4 | 28.7 |

# 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%)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2014

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# 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


Breast Surgery

Ten-Year Results From the Natrelle 410 Anatomical Form-Stable Silicone Breast Implant Core Study

G. Patrick Maxwell, MD; Bruce W. Van Natta, MD; Bradley P. Bengtson, MD; and Diane K. Murphy, MBA

2015

# 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

# Incidence: Mentor Silicone Gel

**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

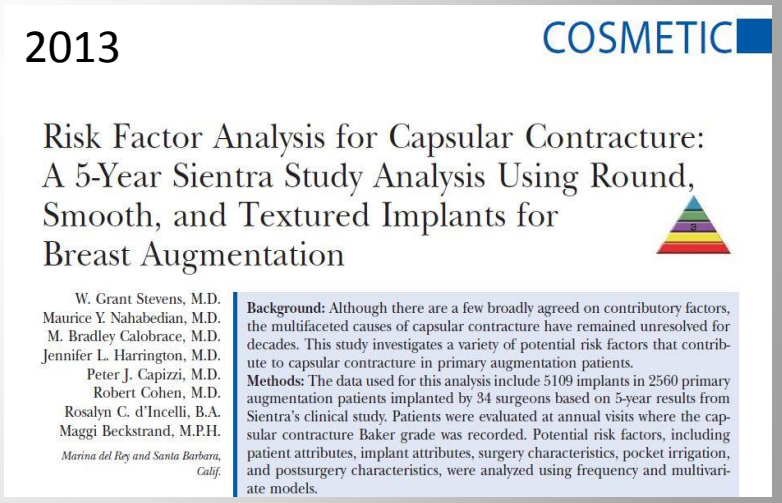
**Sientra Silicone Gel Implants**

| Procedure | 8 yr |
|---|---|
| • Augmentation | 11% |
| • Augmentation revision | 13% |
| • Reconstruction | 13% |
| • Reconstruction | 15% |

- 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 OR=4.7
  - Subglandular OR=4.6
  - Surgical Bra OR=3.7
  - Hematoma/seroma OR=2.9
  - Implant ≤355 cc OR=1.5
  - Periareolar incision OR=1.5



2013

COSMETIC

Risk Factor Analysis for Capsular Contracture: A 5-Year Sientra Study Analysis Using Round, Smooth, and Textured Implants for Breast Augmentation

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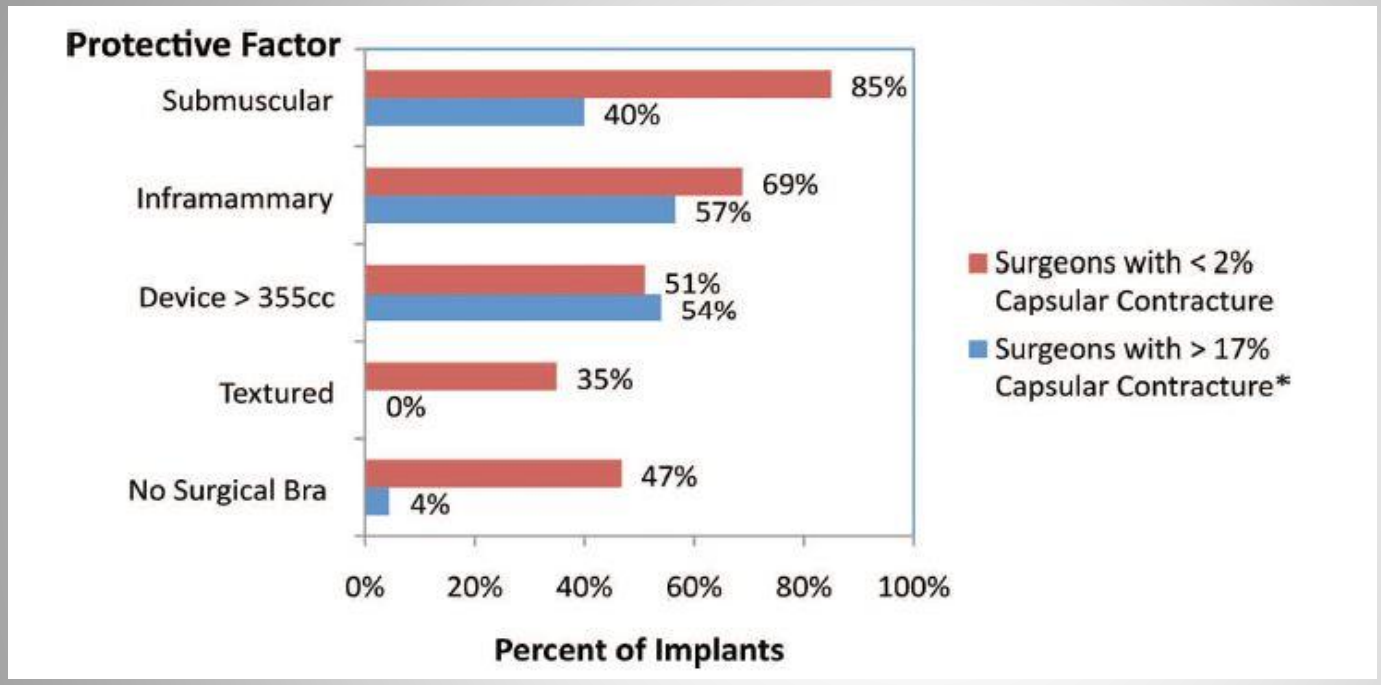
Robert Cohen, M.D.
Rosalyn C. d'Incelli, B.A.
Maggi Beckstrand, M.P.H.
*Marina del Rey and Santa Barbara, Calif.*

**Background:** Although there are a few broadly agreed on contributory factors, the multifaceted causes of capsular contracture have remained unresolved for decades. This study investigates a variety of potential risk factors that contribute to capsular contracture in primary augmentation patients.
**Methods:** The data used for this analysis include 5109 implants in 2560 primary augmentation patients implanted by 34 surgeons based on 5-year results from Sientra's clinical study. Patients were evaluated at annual visits where the capsular contracture Baker grade was recorded. Potential risk factors, including patient attributes, implant attributes, surgery characteristics, pocket irrigation, and postsurgery characteristics, were analyzed using frequency and multivariate models.

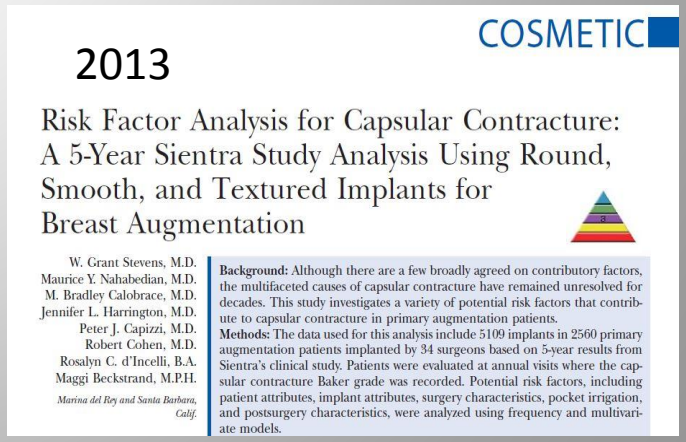
# Sientra Gel 5 Year Study




**Pocket Irrigation**

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

**Was not a factor in CC**



COSMETIC

2013

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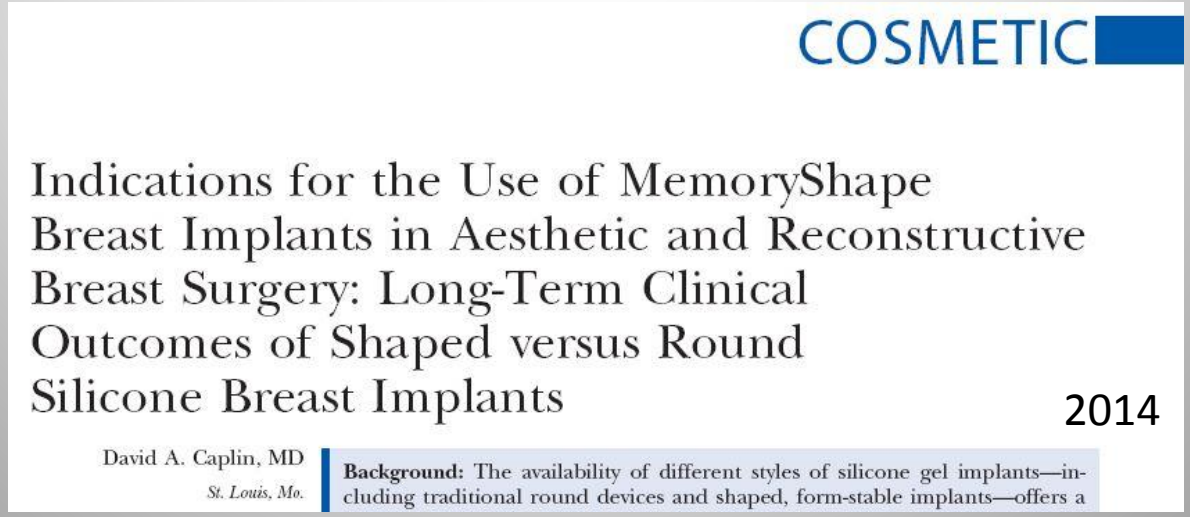
# Mentor Gel: Round vs Shaped

| Implant | Primary Augmentation | Revision Augmentation |
|---|---|---|
| MemoryShape (Shaped) | 3.4% | 11.3% |
| MemoryGel (Round) | 15.6% | 24.4% |



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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

David A. Caplin, MD

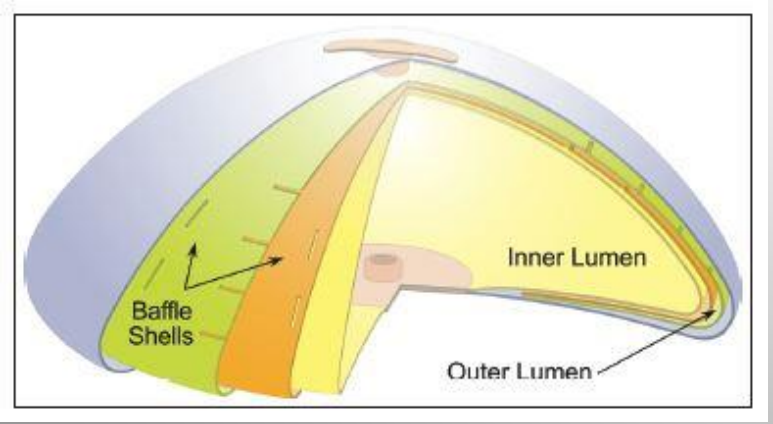
*St. Louis, Mo.*

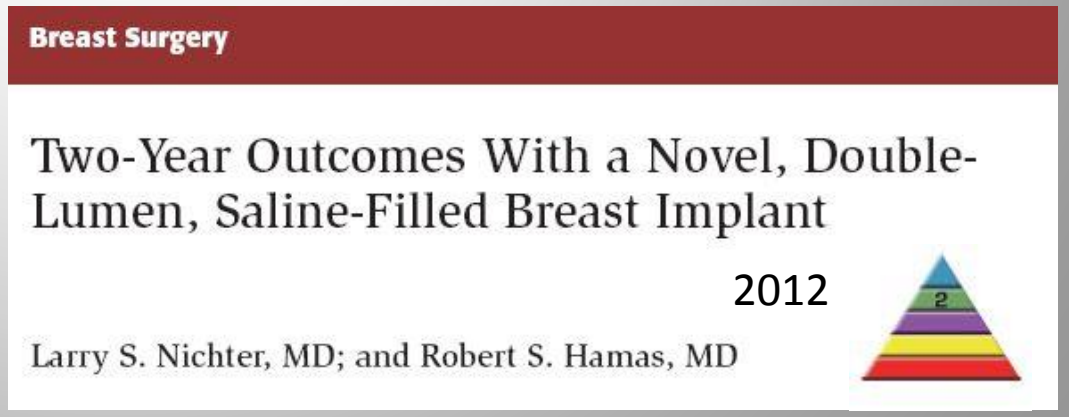
**Background:** The availability of different styles of silicone gel implants—including traditional round devices and shaped, form-stable implants—offers a

# Implant Type: IDEAL Implant

**New double-lumen saline filled implant**

| 1 Year | IDEAL | Allergan | Mentor |
|---|---|---|---|
| CC rate | 2.8% | 7.2% | 4.6% |



# Capsular Contracture: Prevention & Treatment

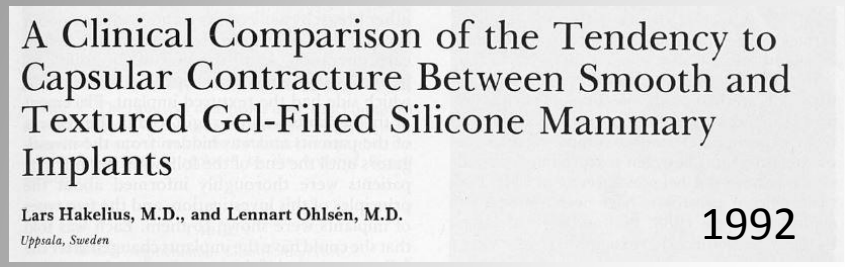
**Prevention**

- 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

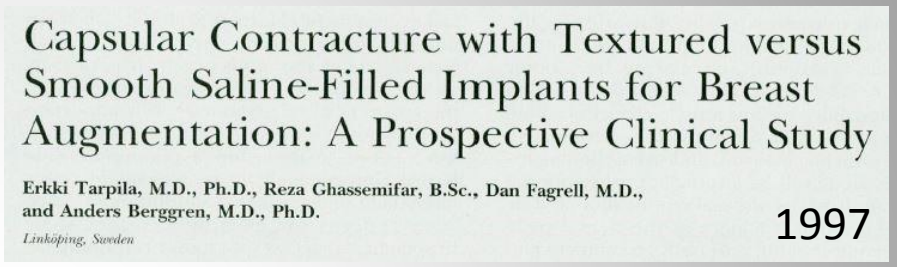


A Clinical Comparison of the Tendency to Capsular Contracture Between Smooth and Textured Gel-Filled Silicone Mammary Implants

Lars Hakelius, M.D., and Lennart Ohlsén, M.D.

*Uppsala, Sweden*

1992



Capsular Contracture with Textured versus Smooth Saline-Filled Implants for Breast Augmentation: A Prospective Clinical Study

Erkki Tarpila, M.D., Ph.D., Reza Ghassemifar, B.Sc., Dan Fagrell, M.D., and Anders Berggren, M.D., Ph.D.

*Linköping, Sweden*

1997

- **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

| Variables | Class I | Class II | Class III–IV | Total |
|---|---|---|---|---|
| Smooth, saline | 12 | 4 | 8 | 24 |
| Smooth, Betadine | 18 | 6 | 4 | 28 |
| Textured, saline | 21 | 1 | 6 | 28 |
| Textured, Betadine | 23 | 0 | 1 | 24 |

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

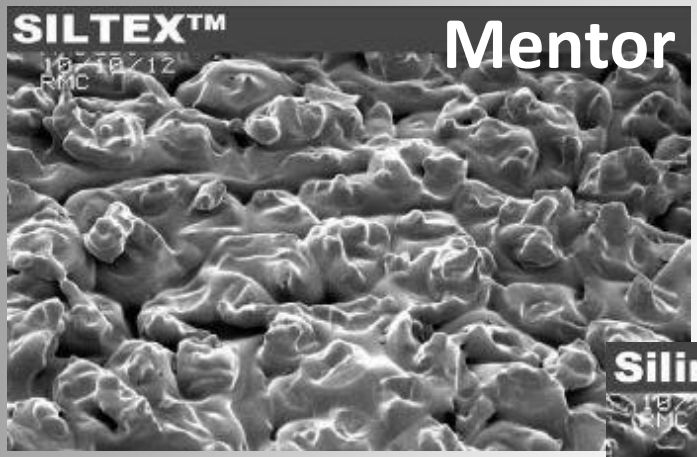
Boyd R. Burkhardt, M.D., and Christopher P. Demas, M.D.
*Tucson, Ariz.*

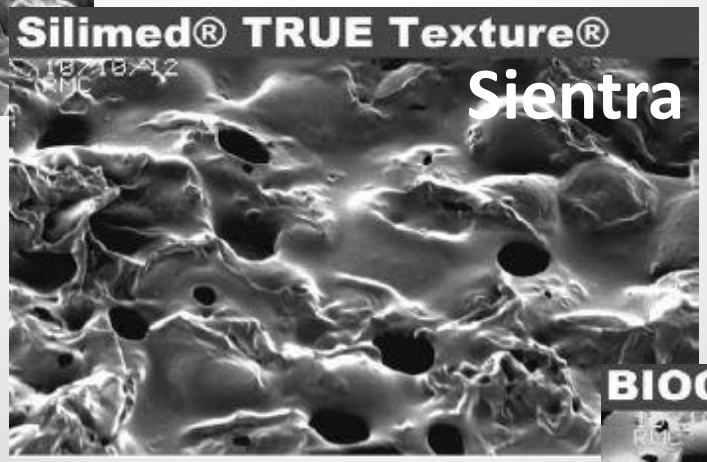
1994

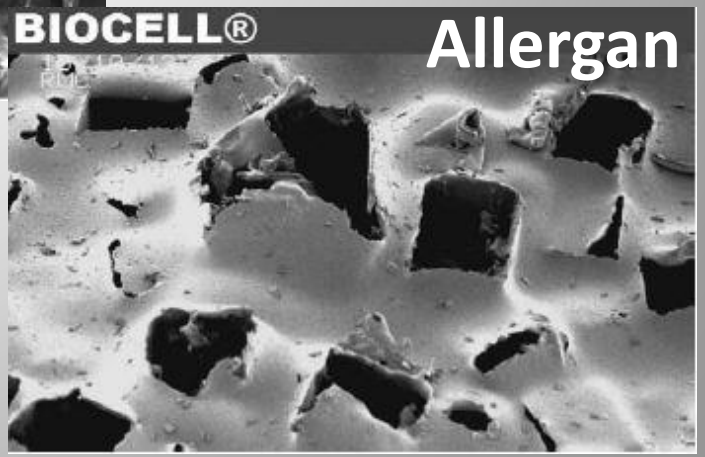
- **Saline Siltex (Mentor)**
- 56 patients
- Smooth + Betadine or saline
- Textured + Betadine or saline
- All periareolar & subglandular

- Most contractures in smooth group
- Betadine had no effect

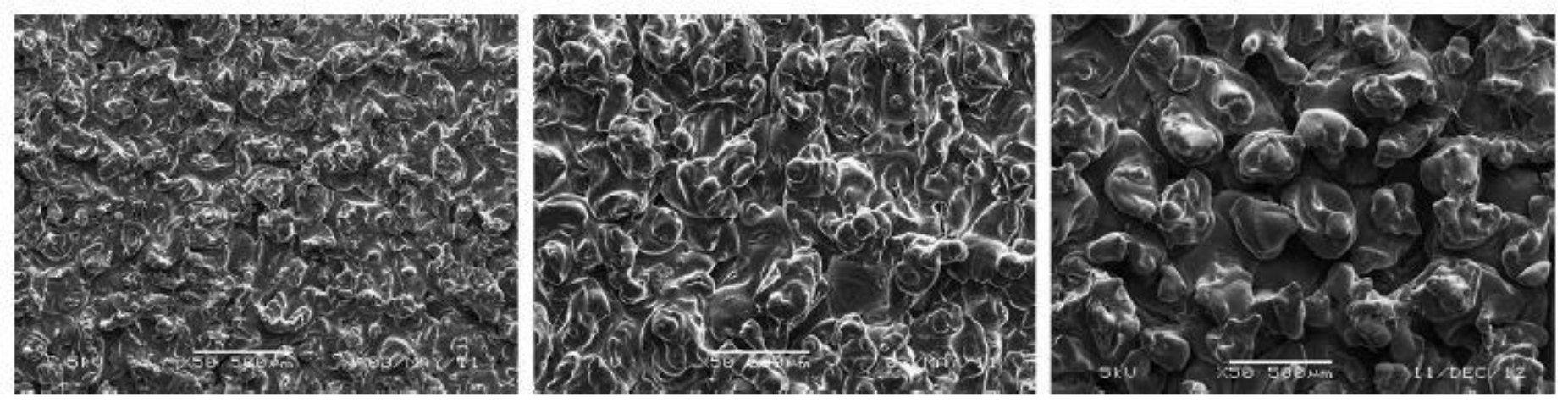
# Textured Surfaces NOT the Same



# Differences in Same Manufacturer



**Mentor**
**Round**
**MemoryGel**
**100 pores/inch**

**Mentor**
**Shaped**
**MemoryShape**
**65 pores/inch**

**Mentor**
**CPX**
**Tissue Expander**
**45 pores/inch**

COSMETIC

2014

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

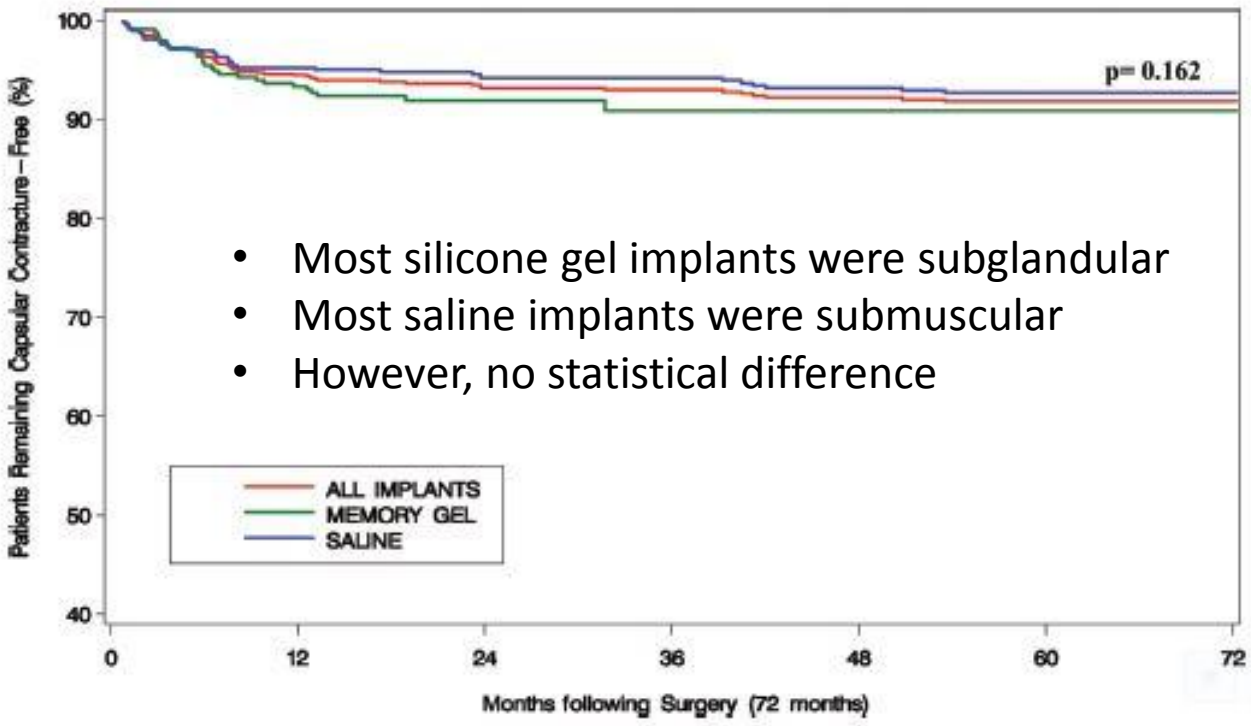
COSMETIC

2011

## A 15-Year Experience with Primary Breast Augmentation

Mark A. Codner, M.D.
Juan D. Mejia, M.D.
Michelle B. Locke, M.B.Ch.B., M.D.
Amy Mahoney, B.S.
Cornelius Thiels, B.S.
Farzad R. Nahai, M.D.
T. Roderick Hester, M.D.
Foad Nahai, M.D.
*Atlanta, Ga.; and Medellin, Colombia*

**Background:** This study evaluated patients who underwent primary breast surgery within a single group practice from 1994 to 2009. Reoperations were divided by reoperation reason into total reoperations and implant-specific reoperations. The authors hypothesized that the implant-specific reoperation rate will provide the most accurate measurement of complications caused by the breast implant device.
**Methods:** A total of 812 patients received the same brand of breast implant for primary breast augmentation or augmentation/mastopexy. Safety and efficacy data were recorded and complication rates were calculated. Statistics were applied using Kaplan-Meier estimated cumulative incidence calculations.
**Results:** This study included 482 patients with saline and 330 patients with silicone




- Most silicone gel implants were subglandular
- Most saline implants were submuscular
- However, no statistical difference

# Implant Surface

**Meta-analysis of 7 RCT**

- CC odds ratio 0.34 for Biocell vs smooth

**Meta-analysis, including 6 RCT (Subglanular)**

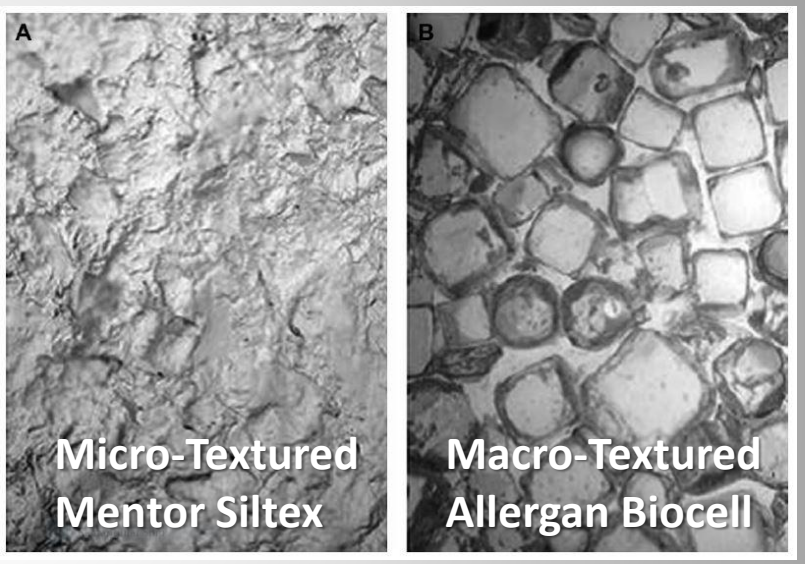
- CC higher with smooth vs textured at:
  - 1 year [RR = 4.16]
  - 3 years [RR = 7.2]
  - 7 years (RR = 2.98]

**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




# Textured for Subglandular Placement

COSMETIC

2006

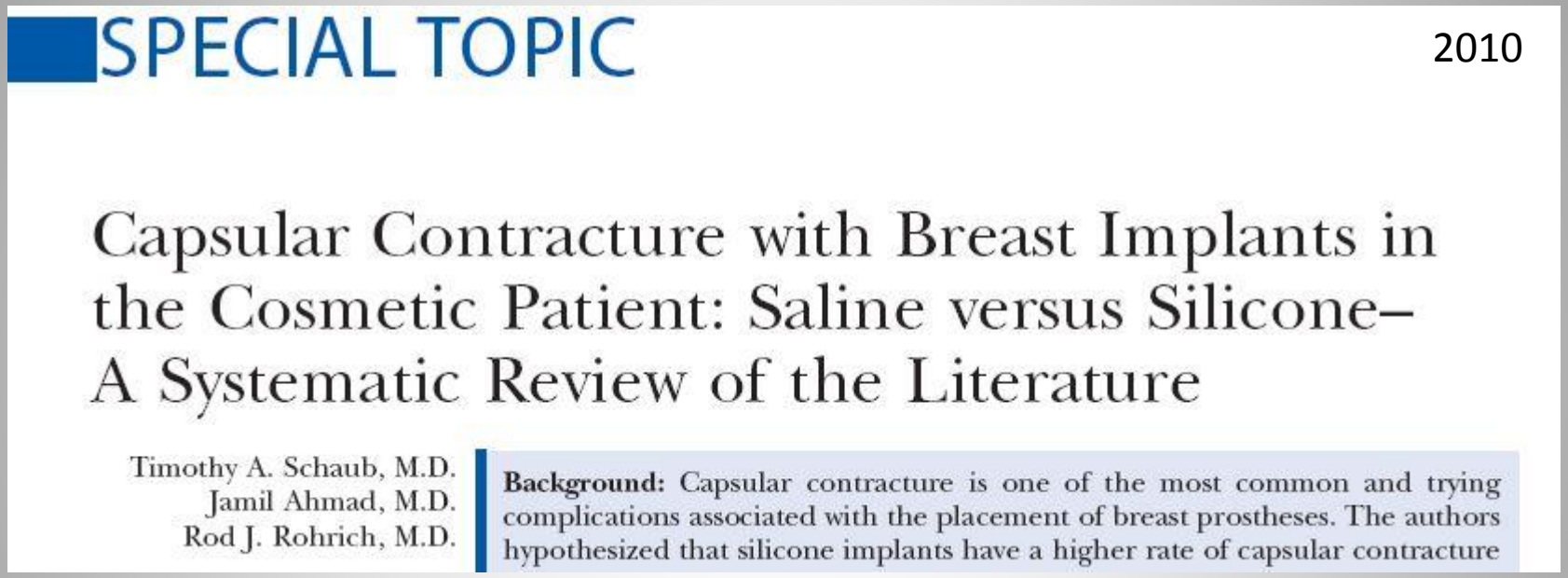
## Capsular Contracture in Subglandular Breast Augmentation with Textured versus Smooth Breast Implants: A Systematic Review

Chin-Ho Wong, M.R.C.S.
Miny Samuel, M.Sc., Ph.D.
Bien-Keem Tan, F.R.C.S.
Colin Song, F.R.C.S.
*Singapore*

**Background:** There are conflicting recommendations in the literature regarding the use of textured implants to reduce capsular contracture in subglandular breast augmentation. The authors reviewed the literature to evaluate the effectiveness of surface texturization in reducing capsular contracture.
**Methods:** The electronic databases MEDLINE, EMBASE and the Cochrane

Recommendation: Use textured implants for subglandular placement
Smooth implants may be appropriate for submuscular placement

# No Recommendations



SPECIAL TOPIC

2010

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 <u>lower</u> 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


**Breast Surgery**

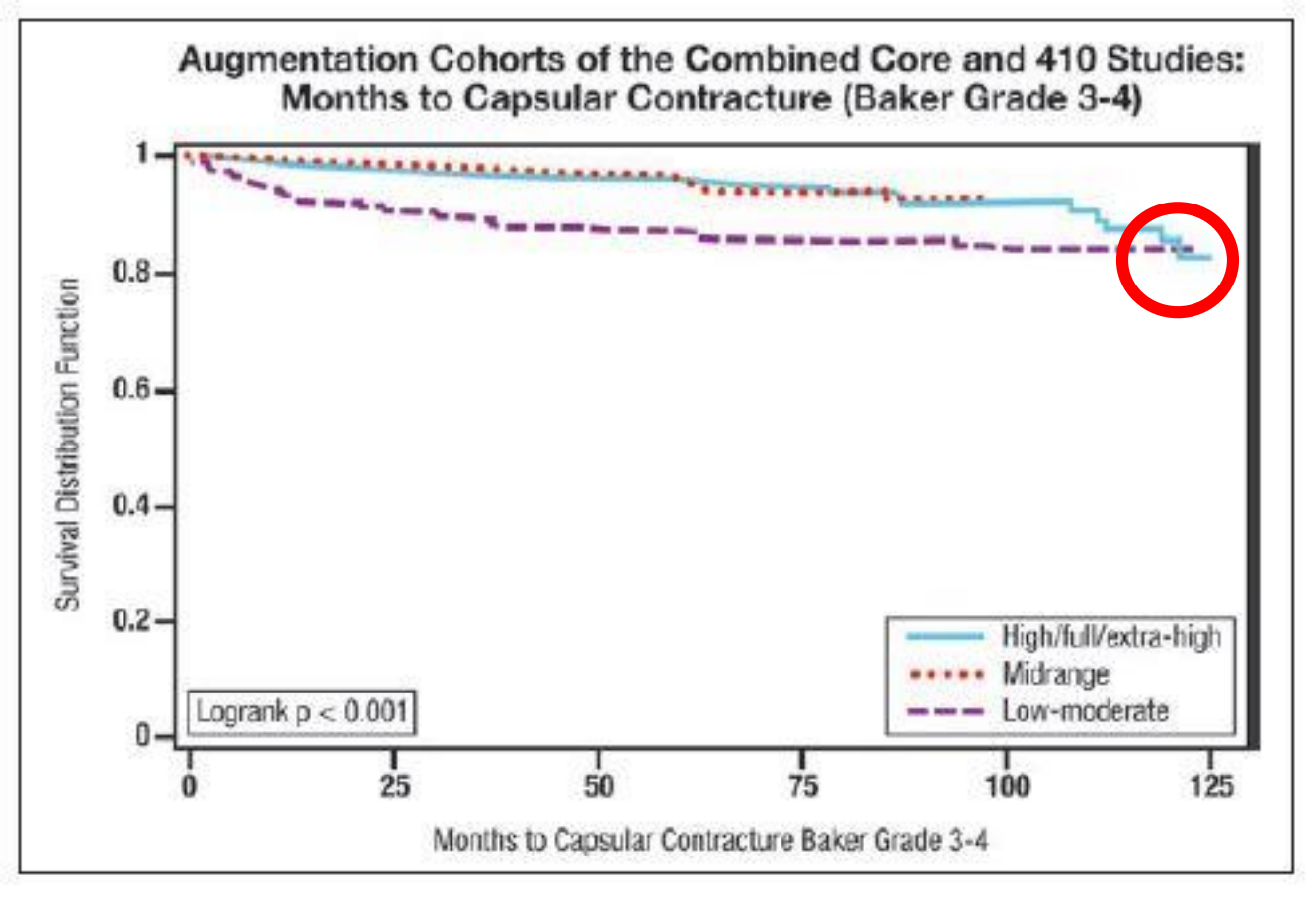
Clinical Trial Outcomes of High- and Extra High–Profile Breast Implants

2013

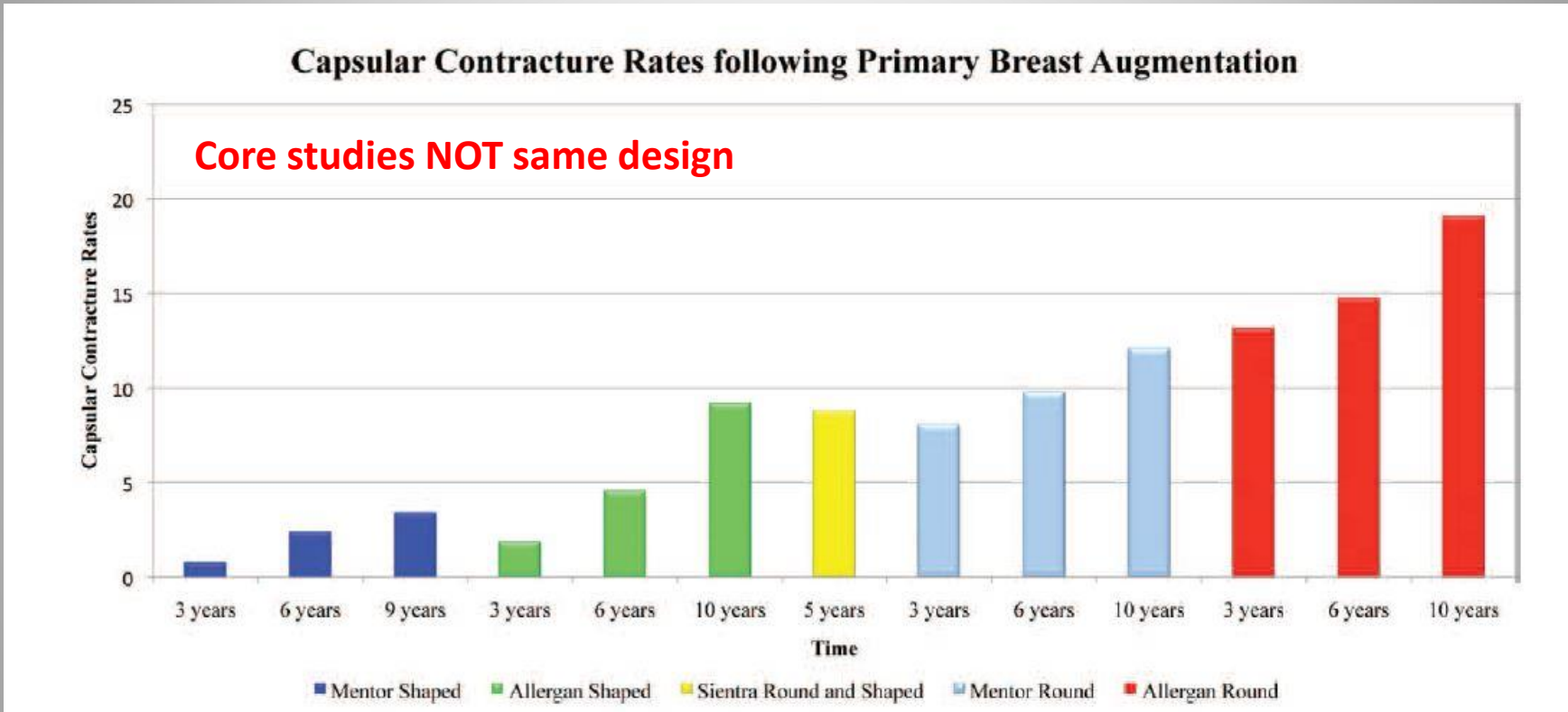
Joan A. Largent, MPH, PhD; Neal R. Reisman, MD, JD, FACS; Hilton M. Kaplan, MBBCh, FCSSA, PhD; Michael G. Oefelein, MD, FACS; and Mark L. Jewell, MD

# Implant Profile

May not matter after 10 years



# Core Studies Summary: CC




2015

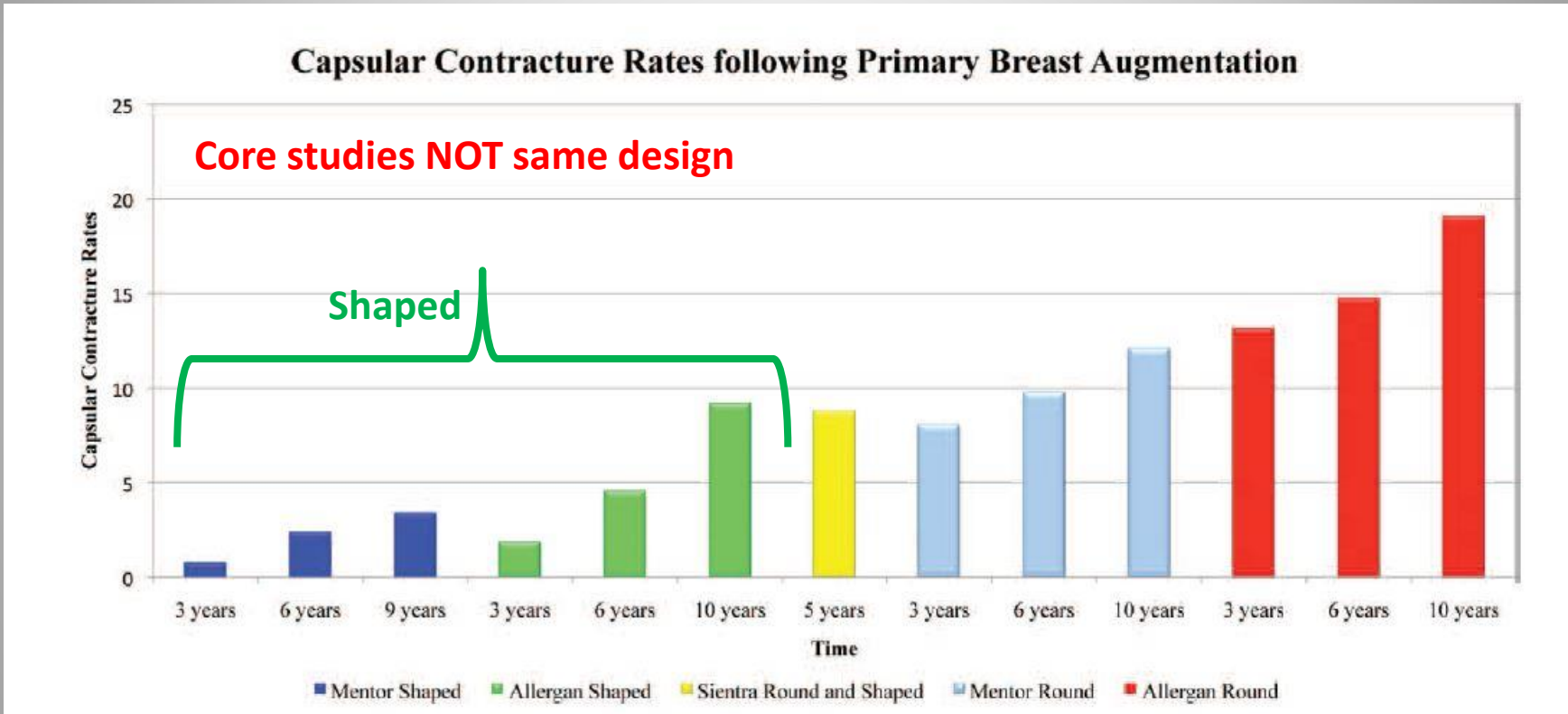
SPECIAL TOPIC

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

Brian M. Derby, M.D.
Mark A. Codner, M.D.
*Atlanta, Ga.*

**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 manufactur-

# Core Studies Summary: CC

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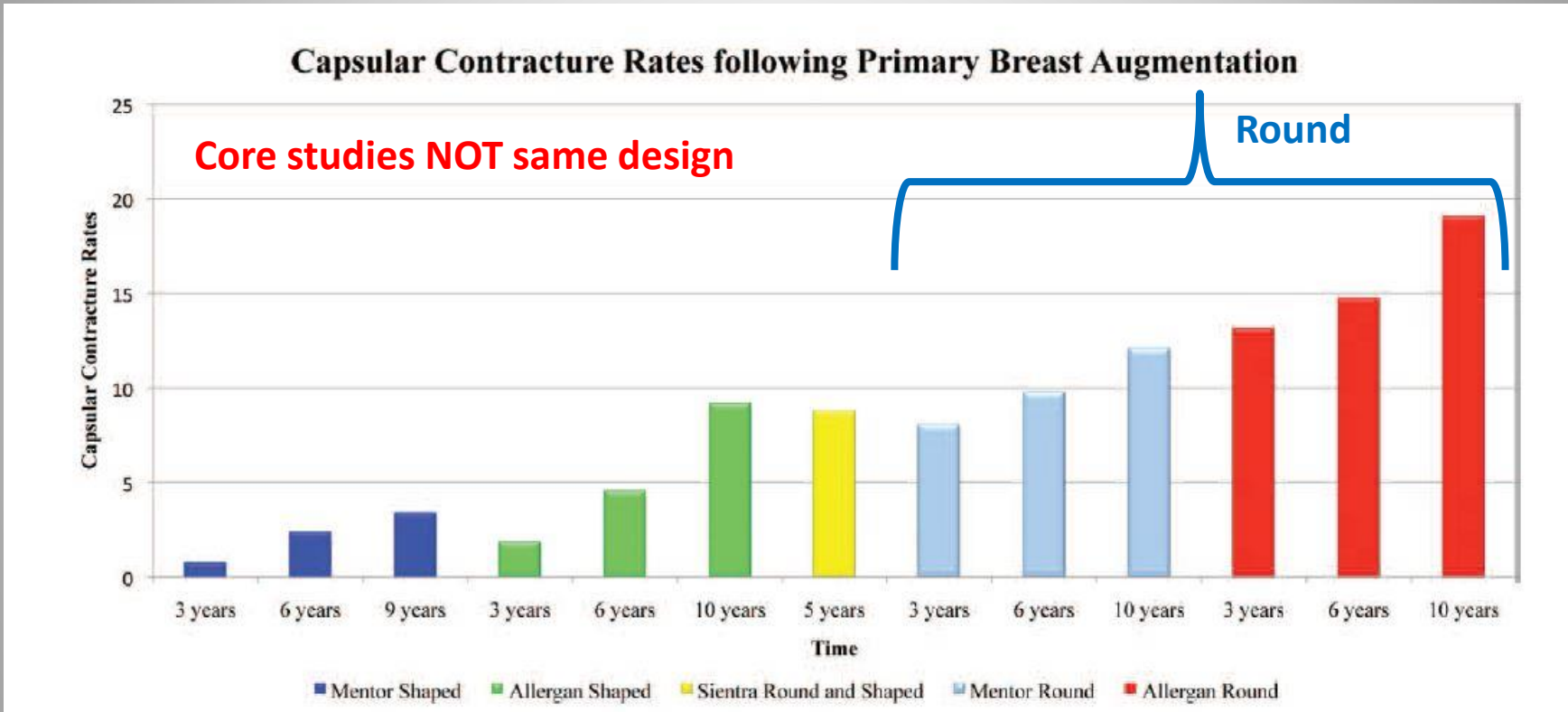


2015

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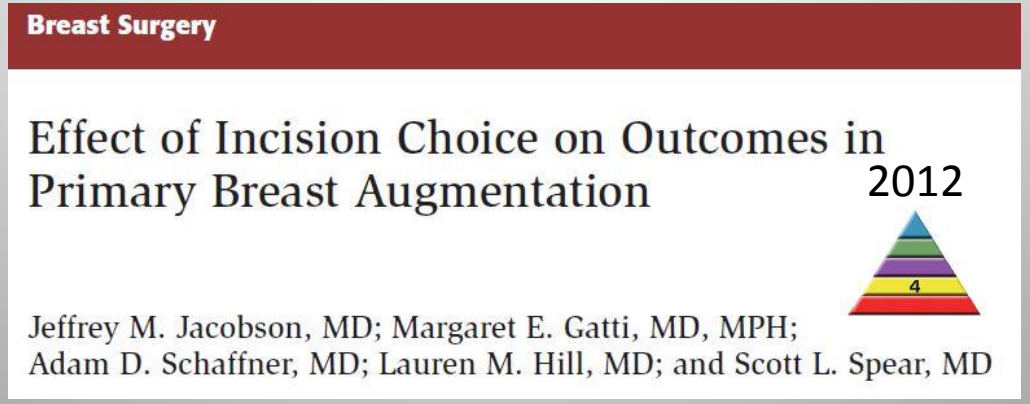
**Summary:** Evolution of silicone breast implant design has focused primarily on advances in implant fill, surface texture, and shape. Fifth-generation, shaped, form-stable, silicone breast implants from all three major implant manufactur-

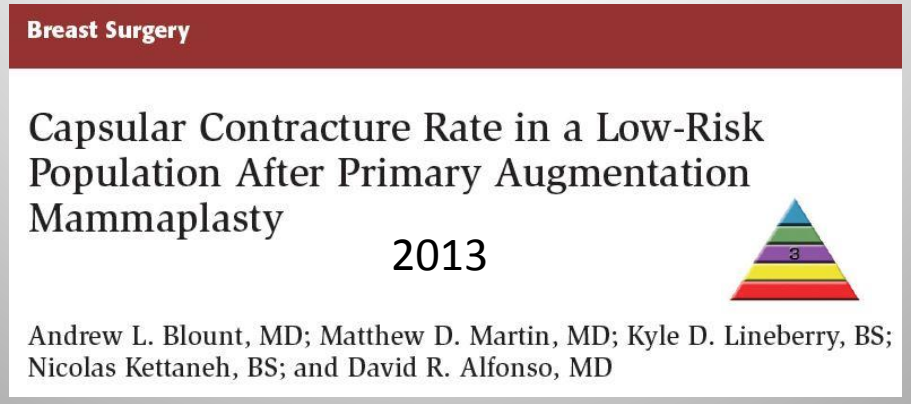
# Incision Site

- 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



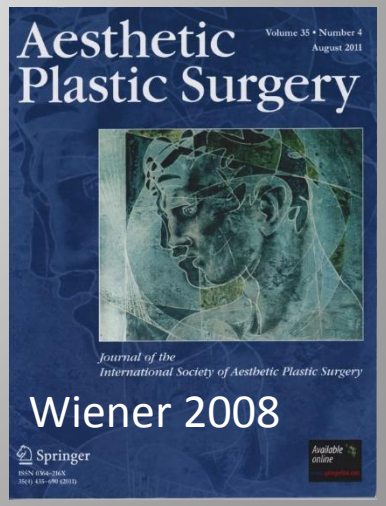
# Incision Site

- 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

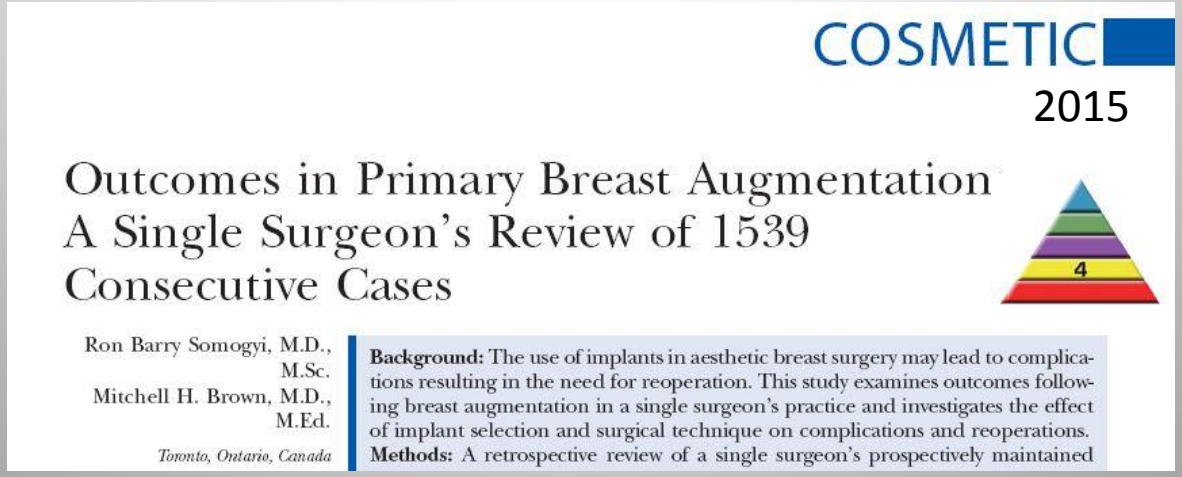
- Inframammary incision CC: 0.59%
- Periareolar incision CC: 9.5%
- Periareolar mastopexy CC: 8%
- “due to an increase in contamination of the breast pocket with intraductal material colonized by bacteria.”



Wiener 2008

# Optimizing Variables

- 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



COSMETIC

2015

Outcomes in Primary Breast Augmentation
A Single Surgeon's Review of 1539
Consecutive Cases

4

Ron Barry Somogyi, M.D., M.Sc.
Mitchell H. Brown, M.D., M.Ed.
*Toronto, Ontario, Canada*

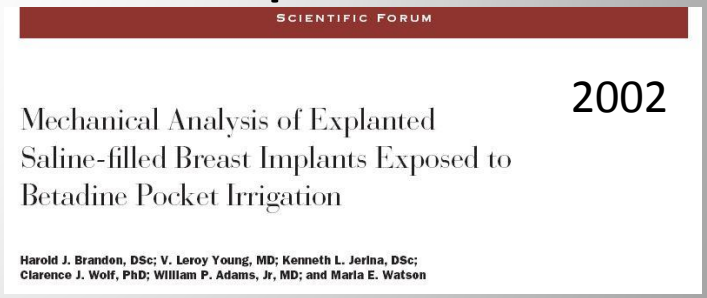
**Background:** The use of implants in aesthetic breast surgery may lead to complications resulting in the need for reoperation. This study examines outcomes following breast augmentation in a single surgeon's practice and investigates the effect of implant selection and surgical technique on complications and reoperations.
**Methods:** A retrospective review of a single surgeon's prospectively maintained

# Can we Agree on:

- Submuscular pocket
- Inframammary incision
- Textured implant
  - Unless submuscular pocket

# Pocket Irrigation: Betadine

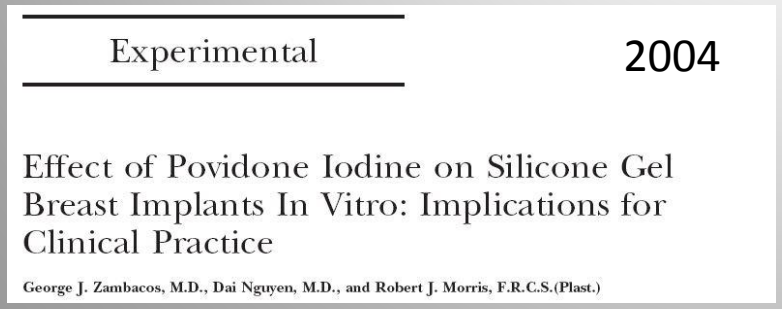
- Betadine rinse followed by saline (FDA OK)
- Leaving Betadine in the pocket (FDA NOT OK)
- Intraluminal Betadine (FDA NOT OK)
- FDA concerns of implant shell compromise
  - **Studies suggest it is safe**


SCIENTIFIC FORUM

2002

Mechanical Analysis of Explanted Saline-filled Breast Implants Exposed to Betadine Pocket Irrigation

Harold J. Brandon, DSc; V. Leroy Young, MD; Kenneth L. Jerina, DSc; Clarence J. Wolf, PhD; William P. Adams, Jr, MD; and Marla E. Watson


Experimental

2004

Effect of Povidone Iodine on Silicone Gel Breast Implants In Vitro: Implications for Clinical Practice

George J. Zambacos, M.D., Dai Nguyen, M.D., and Robert J. Morris, F.R.C.S.(Plast.)


BREAST

2007

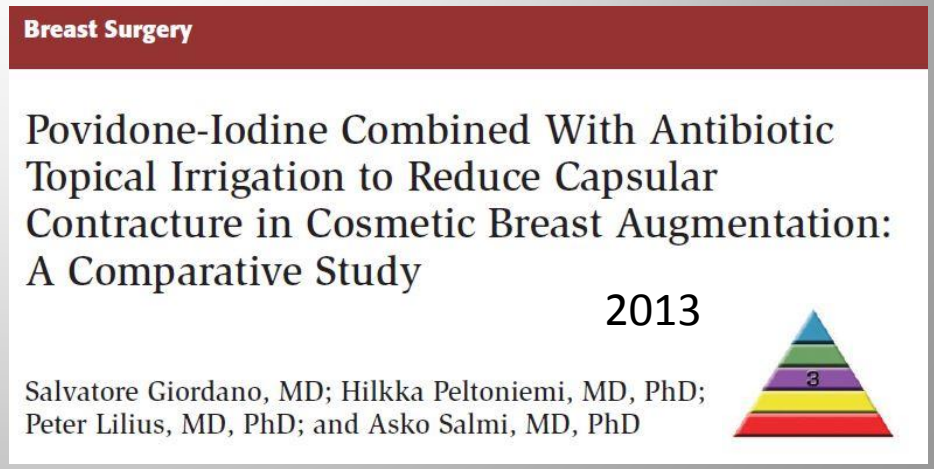
The Role of Betadine Irrigation in Breast Augmentation

Thomas C. Wiener, M.D.
*Houston, Texas*

**Background:** In the spring of 2000, the U.S. Food and Drug Administration issued a ban on the use of Betadine (povidone-iodine; Purdue Frederick, Stam-

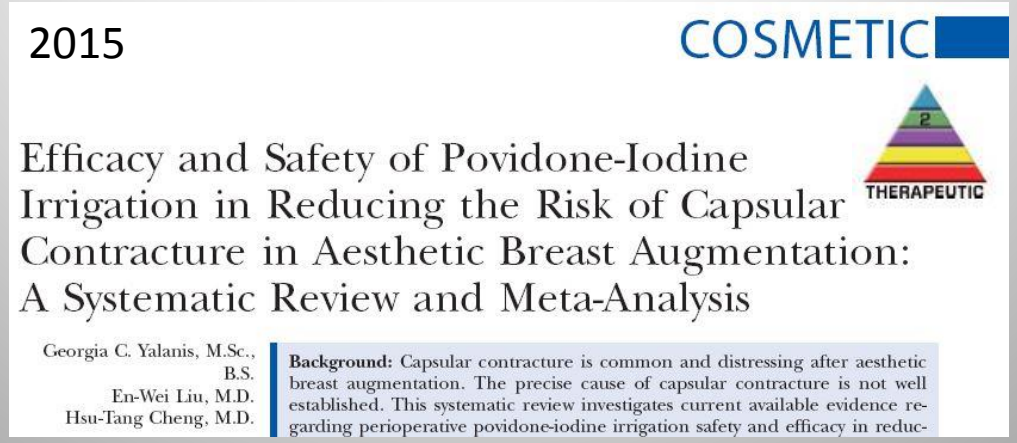
# Pocket Irrigation: Betadine + Abx

- 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%



# 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



2015

COSMETIC




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

Georgia C. Yalanis, M.Sc., B.S.
En-Wei Liu, M.D.
Hsu-Tang Cheng, M.D.

**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


Betadine Alone


+ Ascorbic Acid

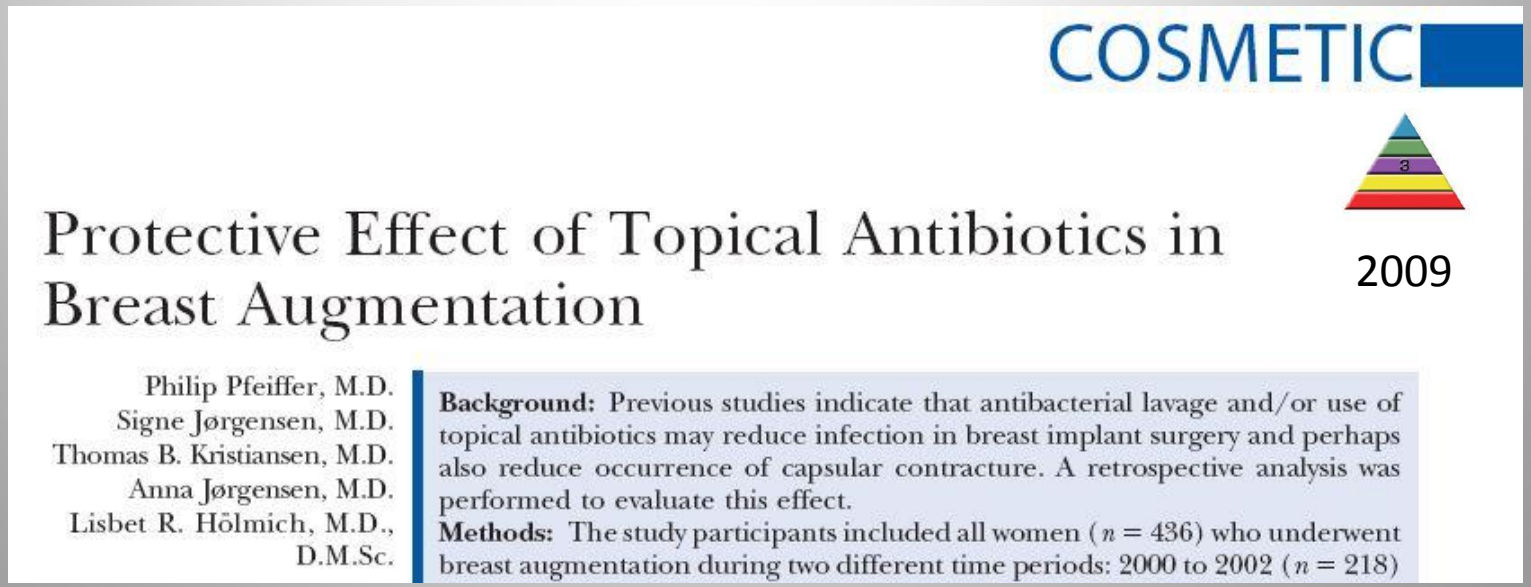

Betadine Neutralized

**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%)



COSMETIC

2009

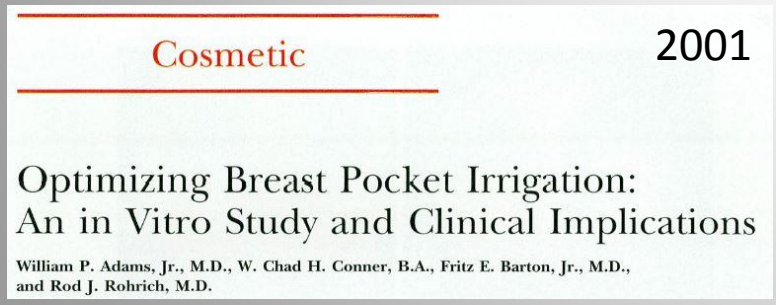
## Protective Effect of Topical Antibiotics in Breast Augmentation

Philip Pfeiffer, M.D.
Signe Jørgensen, M.D.
Thomas B. Kristiansen, M.D.
Anna Jørgensen, M.D.
Lisbet R. Hölmich, M.D., D.M.Sc.

**Background:** Previous studies indicate that antibacterial lavage and/or use of topical antibiotics may reduce infection in breast implant surgery and perhaps also reduce occurrence of capsular contracture. A retrospective analysis was performed to evaluate this effect.
**Methods:** The study participants included all women ($n = 436$) who underwent breast augmentation during two different time periods: 2000 to 2002 ($n = 218$)

# 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)


Cosmetic

2001

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

William P. Adams, Jr., M.D., W. Chad H. Conner, B.A., Fritz E. Barton, Jr., M.D., and Rod J. Rohrich, M.D.


COSMETIC

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

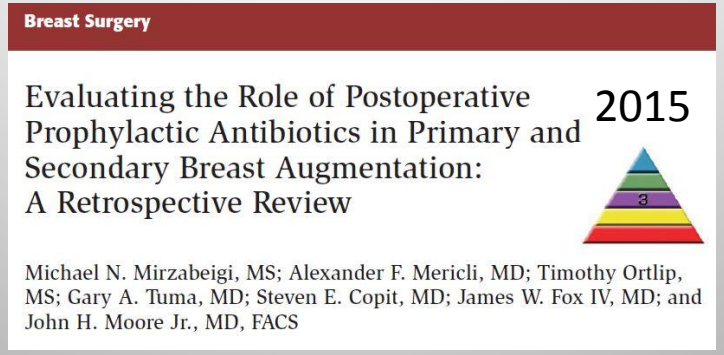
2006

William P. Adams, Jr., M.D.
Jose L. Rios, M.D.
Sharon J. Smith, R.N.

**Background:** Capsular contracture remains one of the most commonly reported complications in aesthetic and reconstructive breast patients. Previous in vitro studies from the authors' laboratory have recommended a new triple

# Postoperative Antibiotics

- 605 implants: 1º or 2º 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%

**The Role of Pocket Dissection in Breast Implant Contracture: A Single Surgeon's Review**

**Jason Jacoby, B.S.**
**Sean T. Lille, M.D**

2011

# Steroids

## 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.*

| Group | No. Patients | % With Firm Breasts‡ | % With Steroid-Related Complications | % With Discoloration | % With Atrophy | Follow-up in Months | |
|---|---|---|---|---|---|---|---|
| | | | | | | Mean | Range |
| No steroids† | 20 | 50.0 | 0 | 0 | 0 | 12.60 | 0.2 → 43 |
| Steroids around implant† | 21 | 52.4 | 0 | 0 | 0 | 23.74 | 2.5 → 40 |
| >20 mg Solu-Medrol* | 26 | 4.0 | 61.5 | 34.6 | 61.5 | 15.71 | 3.0 → 21.5 |
| 20 mg Solu-Medrol* | 24 | 4.2 | 8.3 | 4.2 | 4.2 | 6.33 | 1.0 → 12.2 |

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

# Steroids

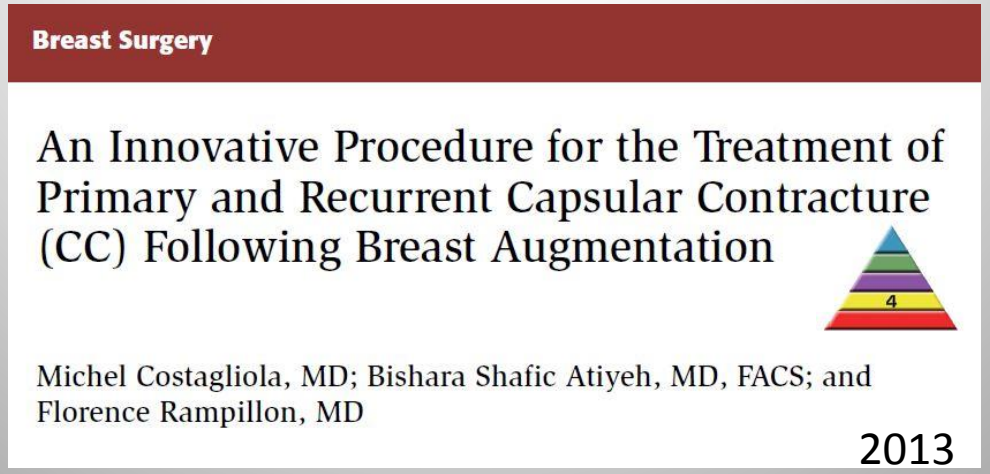
- Injected into saline implants
  - Drug delivery device
- In implant pocket

- Problems with tissue thinning & implant extrusion

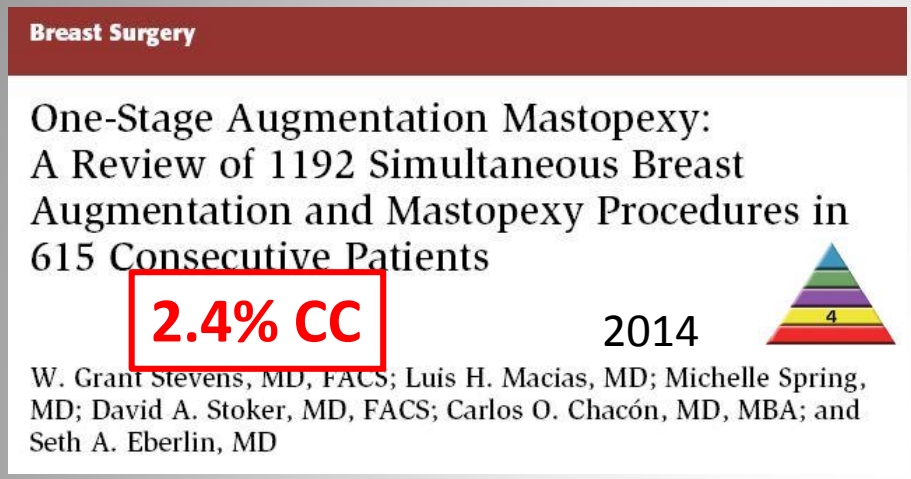
- Not recommended

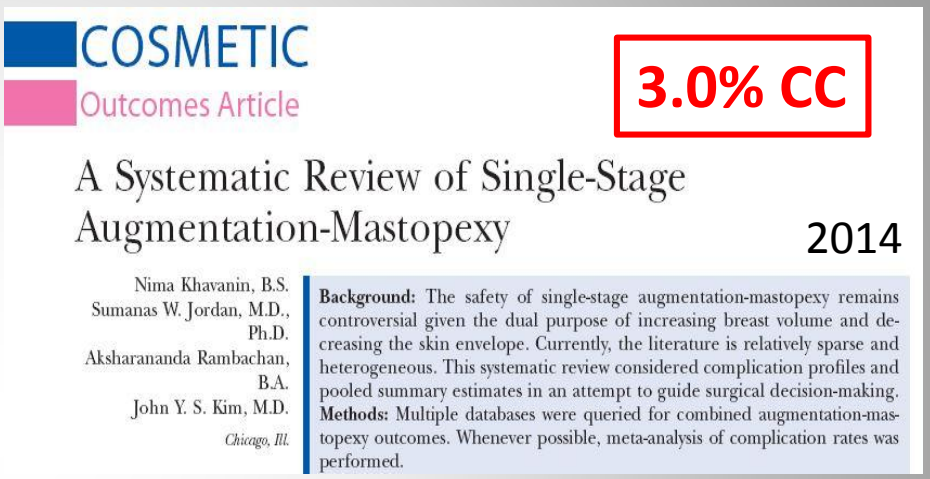
# Steroid Irrigation

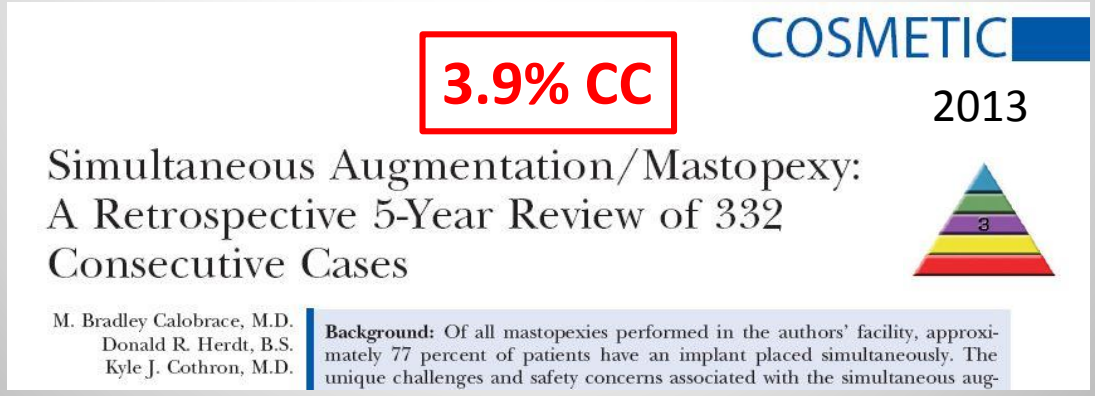
- 33 patients with established CC
- Capsulectomy & catheter irrigation x 2-3 days
  - Methylprednisolone (Solu-Medrol) 40 mg, 2 doses
- No recurrence at 2-10 years



# Combined Augmentation Mastopexy




- 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, inframmamry tissue
- Techniques to not touch skin or breast tissue
- Keep implant in original container and transfer to pocket with minimal handling

# Nipple Shield

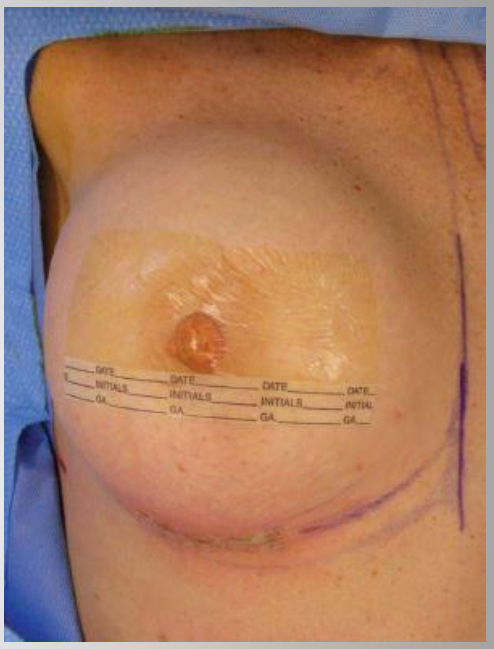
**Breast Surgery**

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


2012

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



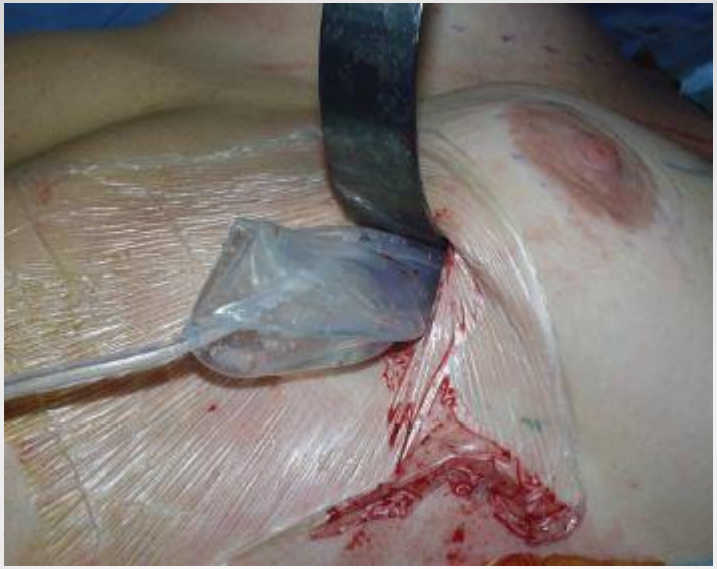
**LOP15: Nipple shields as additional tool to pocket irrigation in reducing capsular contracture after cosmetic breast augmentation**

*S. Giordano[1], A. Salmi[1]
[1]*Turku University Hospital, Plastic Surgery, Turku, Finland*

2015

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.*

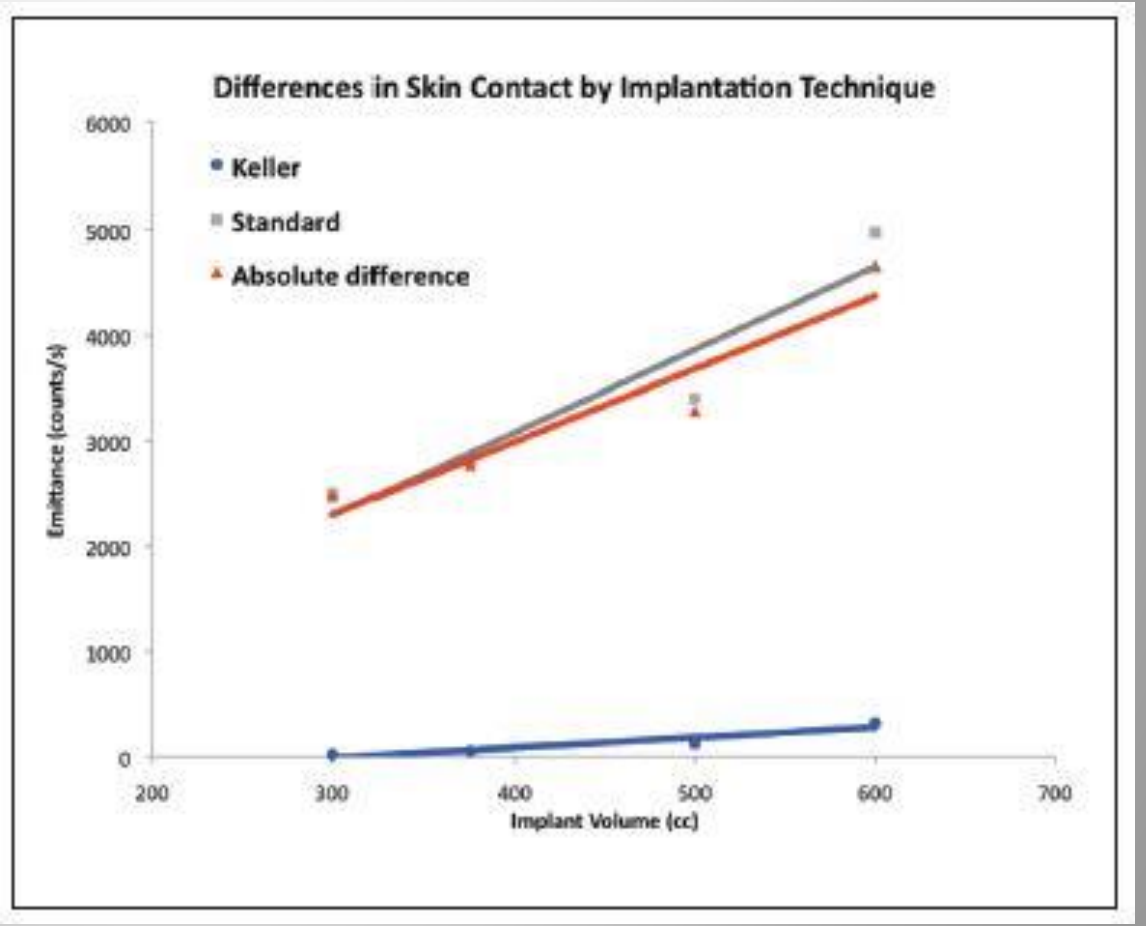
# Keller Funnel



Data submitted for publication

# Keller Funnel

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; Bahair 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

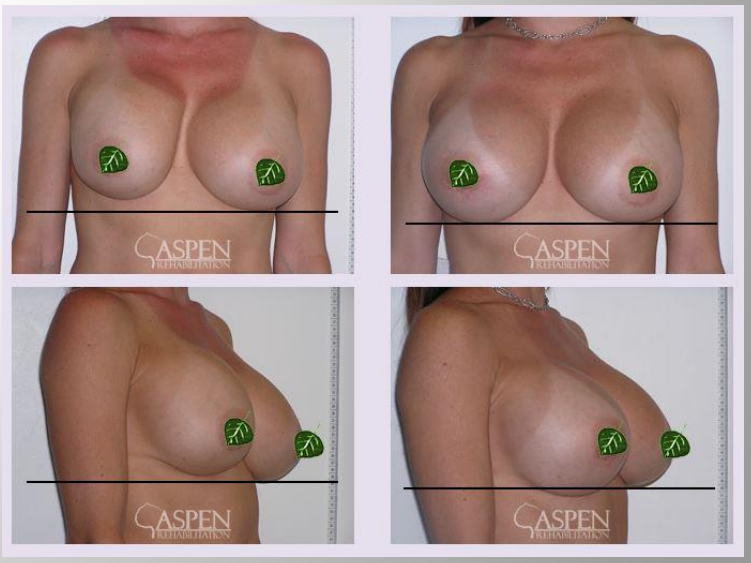
**Not recommended**

- 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

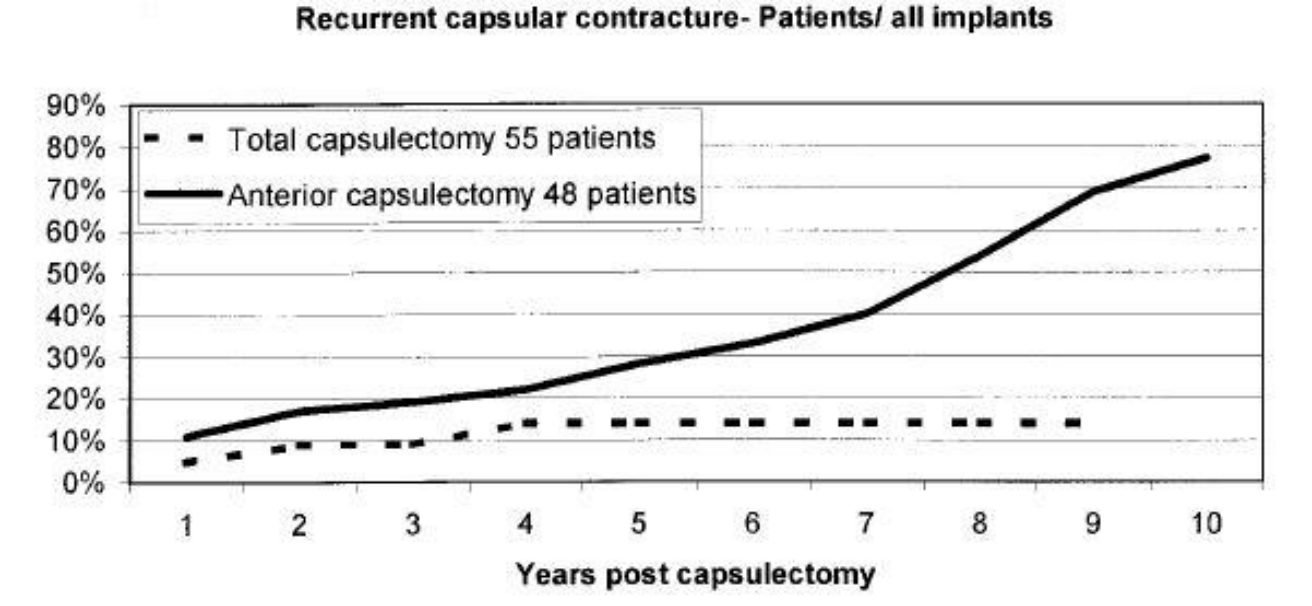
- LTU-904 Laser
- 10 min treatment per week x 6 weeks
- Average 50% improvement stiffness & comfort
- Surgery avoided in 31 of 33 patients (94%)

# Capsulectomy

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

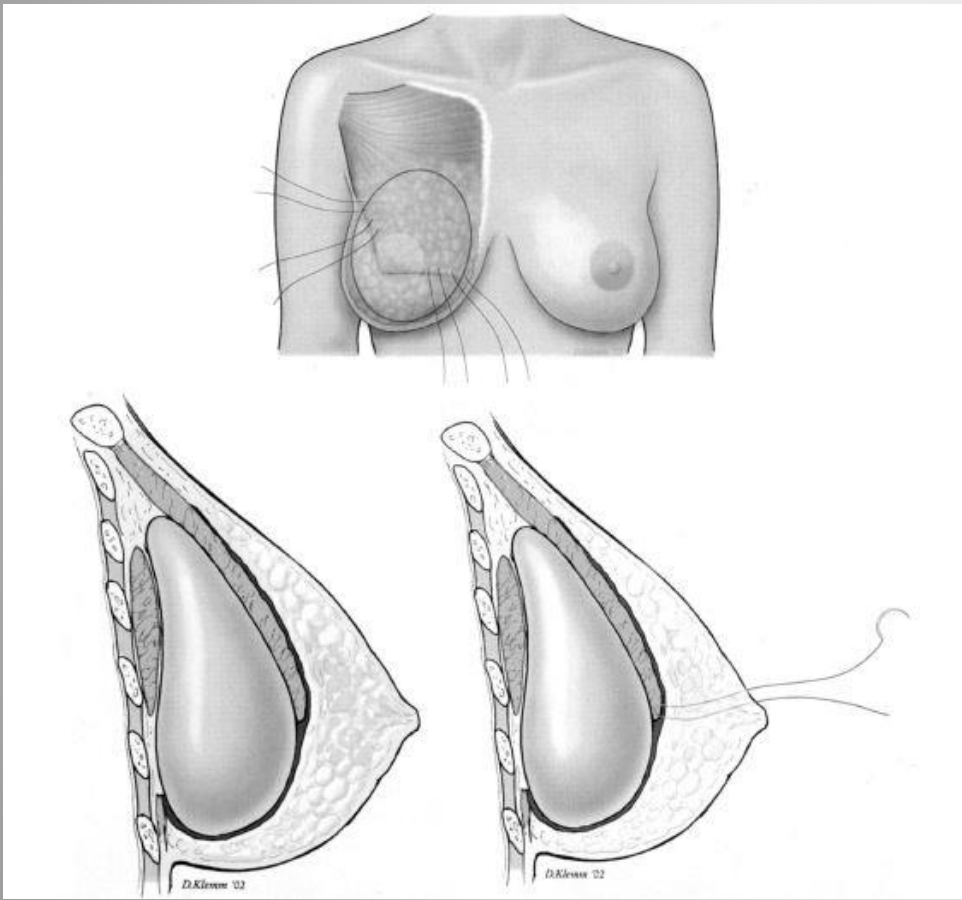
Nicholas Collis, B.Sc., F.R.C.S.(Ed.), and David T. Sharpe, O.B.E., M.A., F.R.C.S.
*West Yorkshire, England*

2000




Total (vs anterior) capsulectomy when possible

# Pocket & Capsule



- If subglandular
  - Capsulectomy
  - Submuscular pocket
  - Muscle sutures
  - ADM?

COSMETIC

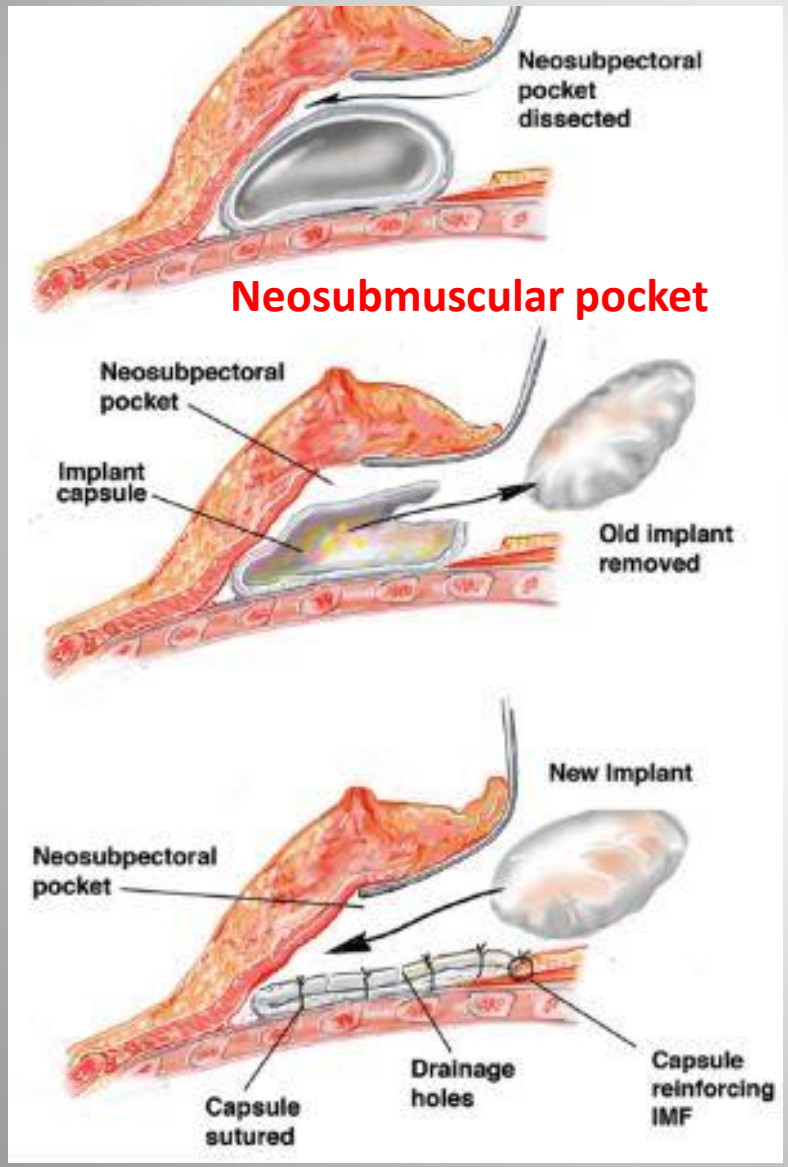
2003

The Correction of Capsular Contracture by Conversion to "Dual-Plane" Positioning: Technique and Outcomes

Scott L. Spear, M.D.
Mary Ella Carter, M.D.
Jason C. Ganz, M.D.
*Washington, D.C.*

Little has been published regarding the treatment of patients with long-established capsular contracture after previous submuscular or subglandular breast augmentation. This study reviews 7 years of experience in treating established capsular contracture after augmentation mammaplasty by relocating implants

# Pocket & Capsule




- If submuscular
  - Anterior capsulectomy

    ***versus***
  - Complete capsulectomy

    ***versus***
  - Neosubmuscular pocket
    - Between muscle & anterior capsule
    - Avoids intrathoracic penetration
  - ADM?

# Acellular Dermal Matrix

Anecdotal use and success

Short follow up, but seems convicing

**Supplemental Article**

## Acellular Dermal Matrix in Aesthetic Revisionary Breast Surgery


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

2013

BREAST

## 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.
*Dallas, Texas; Atlanta, Ga.; 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 6.3 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

**Supplemental Article**

## Acellular Dermal Matrix for Secondary Procedures Following Prosthetic Breast Reconstruction


Maurice Y. Nahabedian, MD; and Scott L. Spear, MD

# Acellular Dermal Matrix

| Acellular Dermal Matrix Group | Capsular Contracture,[a] n/N (%) | |
|---|---|---|
| | Preoperative | Postoperative |
| Strattice | 51/96 (53.1) | 0/96 (0) |
| AlloDerm | 45/57 (78.9) | 0/57 (0) |
| FlexHD | 10/19 (52.6) | 0/19 (0) |
| SurgiMend | 6/8 (75) | 2/8 (25.0) |
| NeoForm | 3/4 (75) | 1/4 (25) |
| DermaMatrix | 0/2 (0) | 0/2 (0) |
| Total | 115/186 (61.8) | 3/186 (1.6) |

| Baker Classification | Preoperative, n/N (%) | Postoperative, n (%) |
|---|---|---|
| I | 56/186 (30.1) | 176/186 (94.6) |
| II | 23/186 (12.4) | 14/186 (7.5) |
| III | 100/186 (53.8) | 3/186 (1.6) |
| IV | 14/186 (7.5) | 0/186 (0) |

**Follow up**

86% at least 2 years

50% at least 3 years

**Breast Surgery**

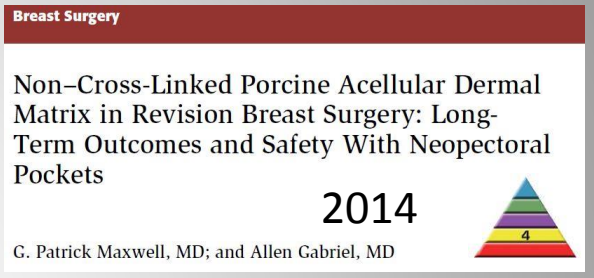
Efficacy of Acellular Dermal Matrices in Revisionary Aesthetic Breast Surgery: A 6-Year Experience

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

2015

# ADM: Strattice

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


Breast Surgery

Non–Cross-Linked Porcine Acellular Dermal Matrix in Revision Breast Surgery: Long-Term Outcomes and Safety With Neopectoral Pockets

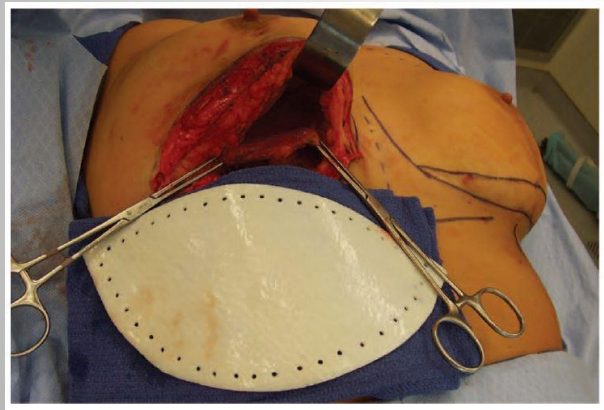
2014

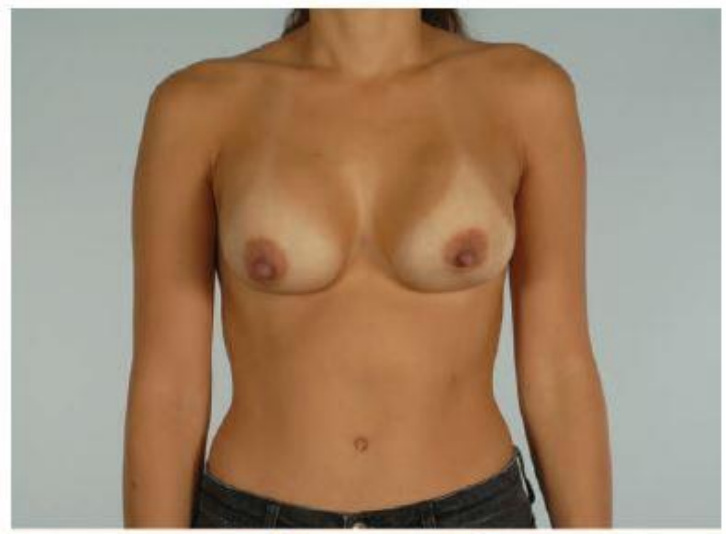
G. Patrick Maxwell, MD; and Allen Gabriel, MD

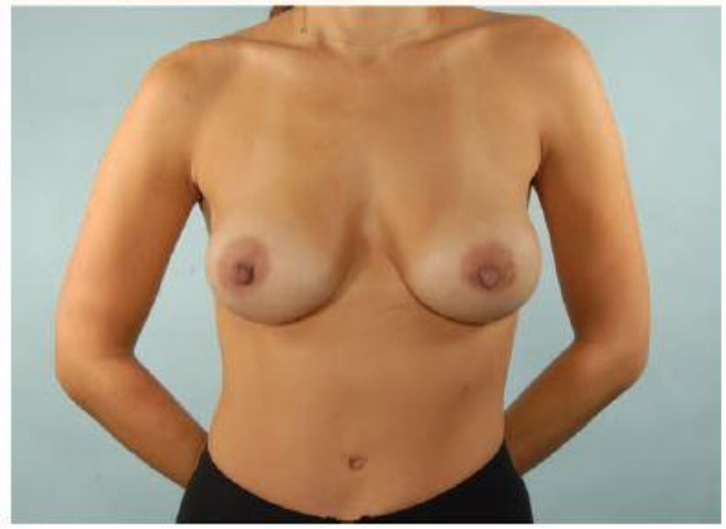
| Baker Classification | Before, No./Total No. (%) | After, No./Total No. (%) |
|---|---|---|
| I | 45/106 (41.5) | 99/106 (93.4) |
| II | 7/106 (6.6) | 7/106 (6.6) |
| III | 48/106 (46.2) | 0/106 (0) |
| IV | 6/106 (5.7) | 0/106 (0) |

# ADM: Strattice

- 25 breasts
- Mean 17 month follow up







COSMETIC

2013

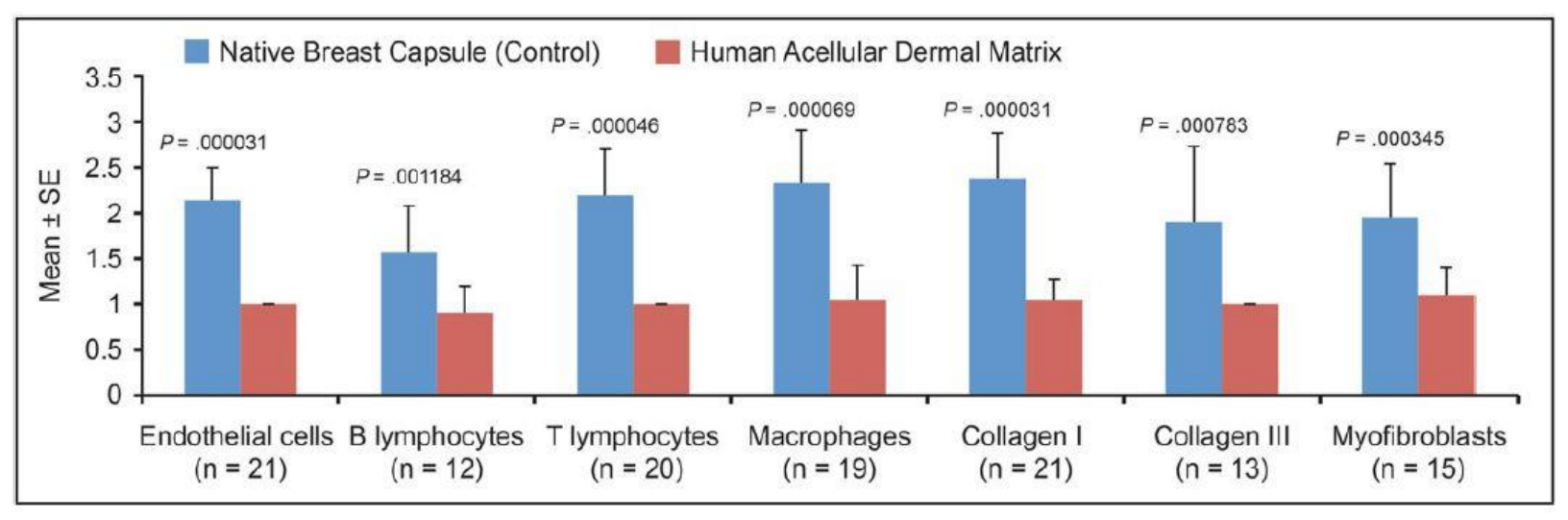

## Porcine Acellular Dermal Matrix (Strattice) in Primary and Revision Cosmetic Breast Surgery

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




**Breast Surgery**

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

COSMETIC


## Use of Dermal Matrix to Prevent Capsular Contracture in Aesthetic Breast Surgery

2012

T. Roderick Hester, Jr., M.D.
Bahair H. Ghazi, M.D.
Hunter R. Moyer, M.D.
Farzad R. Nahai, M.D.
Melissa Wilton, B.A.
Lou Stokes, L.P.N.

**Summary:** Capsular contracture remains a challenging complication of implant-based aesthetic breast surgery despite improvements in implant design. The lowering of capsular contracture rates noted with the past use of polyurethane foam–covered implants has increased awareness of the importance of the biologic response at the interface between the implant surface and breast tissue. Emerging evidence indicates that much like the polyurethane foam, acellular dermal matrices alter the biologic response at the surface interface, resulting in

# ADM Evidence

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

BREAST

2012

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 Oxnard, 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


SCIENTIFIC FORUM

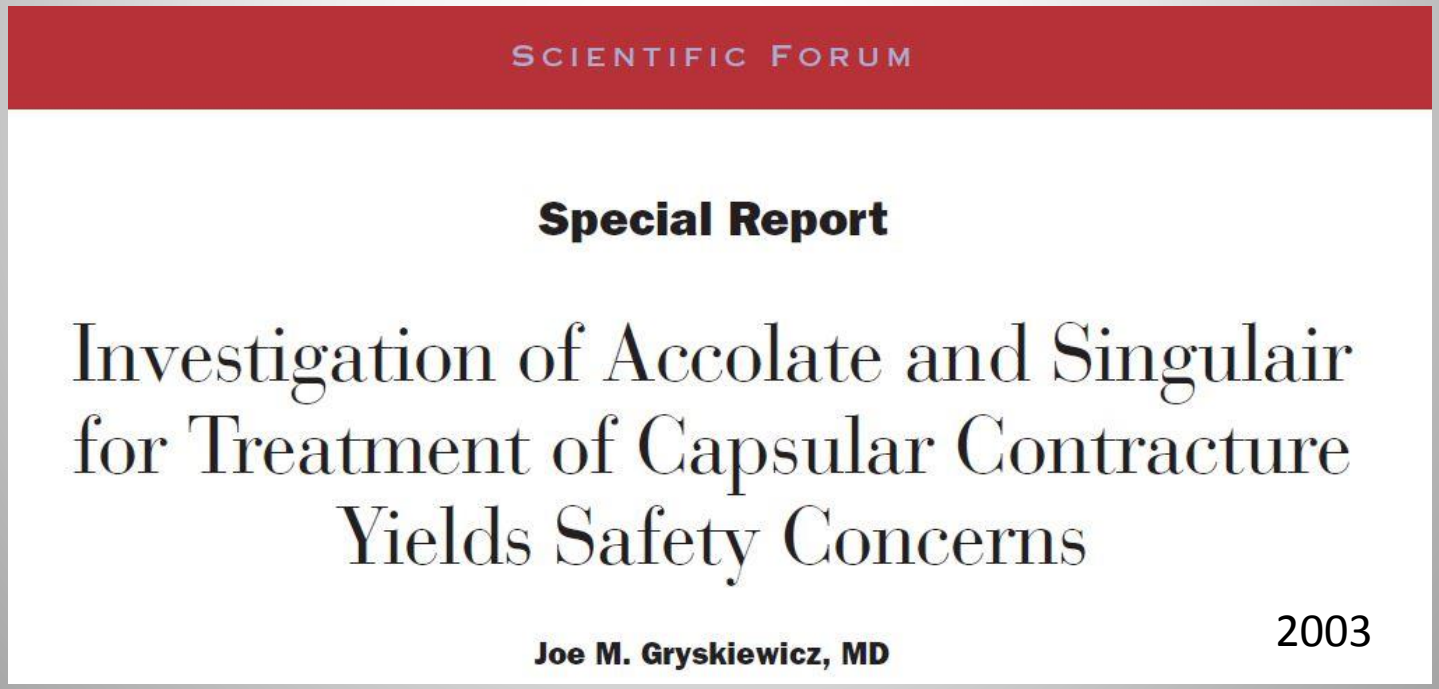
Zafirlukast (Accolate): A New Treatment for Capsular Contracture

S. Larry Schlesinger, MD; Richard Ellenbogen, MD; Michael N. Desvigne, MD; Steven Svehlak, MD; and Robert Heck, MD

2002

# Zafirlukast (Accolate) & Montelukast (Singulair)

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



SCIENTIFIC FORUM

**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


SCIENTIFIC FORUM

The Effect of Zafirlukast (Accolate) on Early Capsular Contracture in the Primary Augmentation Patient: A Pilot Study

Russell R. Reid, MD, PhD; Susan D. Greve, MS, RN; and Laurie A. Casas, MD

2005

# 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

| Study | Outcome | Follow-up (mo) | Side Effects |
|---|---|---|---|
| Schlesinger et al., 2002[1] | Case 1: Left, class III to class I in 3 mo<br>Case 2: Bilateral, class III to class I in 3 mo<br>Case 3: Left, class IV to class I in 1 mo<br>Case 4: Left, class IV to class I in 1 mo<br>Case 5: Left, class IV to class II in 3 mo; right, class IV to cloass III in 3 mo | One month in case 1; 5 mo in case 2; others not mentioned | Not reported |
| Reid et al., 2005[2] | In 6 mo<br>Complete response: 22 breasts<br>Partial response: 9 breasts<br>No response: 10 breasts<br>Long-term follow-up (mean, 16.5 mo)<br>Complete response: 30 breasts<br>Partial response: 4 breasts<br>No response: 7 breasts | Mean, 16.5 (range, 6–29) | No untoward effects of the drug |
| Scuderi et al., 2006[3] | 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[4] | 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 | | No untoward effects of the drug |
| Huang and Handel, 2010[5] | Completely improved: 7 patients (within days to 2 mo)<br>Improved: 5 patients (within days to 1 mo)<br>No change: 3 patients<br>Worsened: 2 patients<br>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?

# Questions?

Karol@DrGutowski.com

**Copy of this Presentation**

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[For Physicians]

Password: ASPS

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

***Karol A Gutowski, MD, FACS***

*Instructional Course*