

Breast Augmentation: Surgical Decisions & Complications

Karol A Gutowski, MD, FACS

Instructional Course

plastic
surgery

THE MEETING

Los Angeles

September 23-27, 2016



AMERICAN SOCIETY OF
PLASTIC SURGEONS



THE PLASTIC SURGERY
FOUNDATION



Disclosures

Angiotech/Surgical Specialties - Advisory Board

AxcelRx Pharmaceuticals - Advisory Board

Suneva Medical - Instructor

Will use brand names for ease of understanding

Objectives

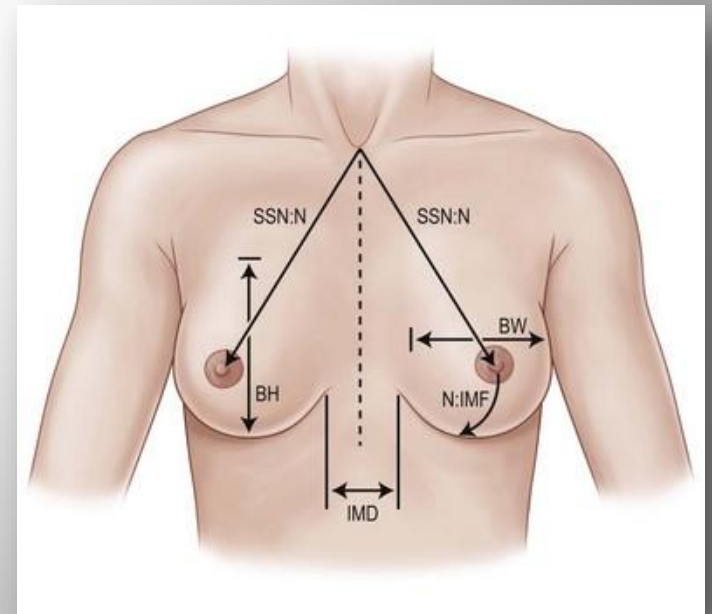
- Incision selection
- Pocket selection
- Implant selection
 - Saline vs gel
 - Smooth vs textured
- Preventing complications
 - Malposition, capsular contracture
- Anesthesia & analgesia

Too Many Implant Options?



Implant Size Selection

- Do NOT promise a cup size
 - Victoria's Secret has larger cups sizes
- Use a measurement system
 - Sternal Notch to Nipple
 - Upper Pole Pinch
 - Base Width
 - Areolar Diameter
 - Nipple to IMF (stretch)
 - Inter Mammary Distance

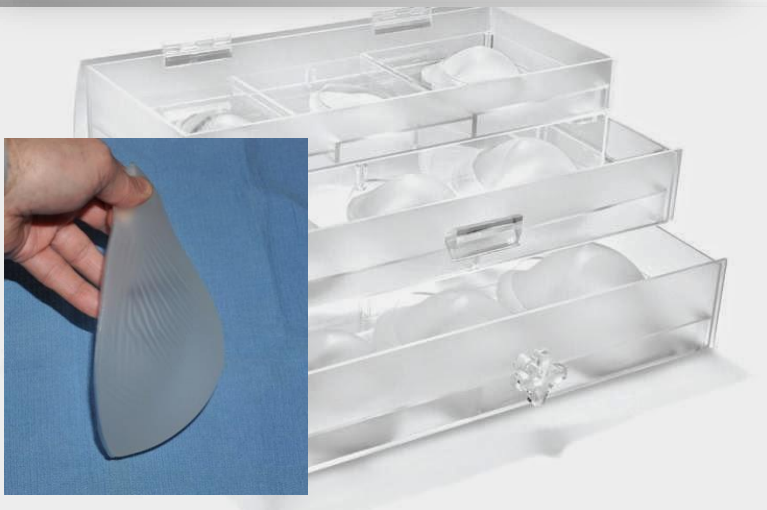


Size Selection: What Else Helps

The Rice Test

This is the most popular way to determine your breast implant size at home, before the consultation with your surgeon.

You will start to get an idea of how you would look with different sizes of breast implants.

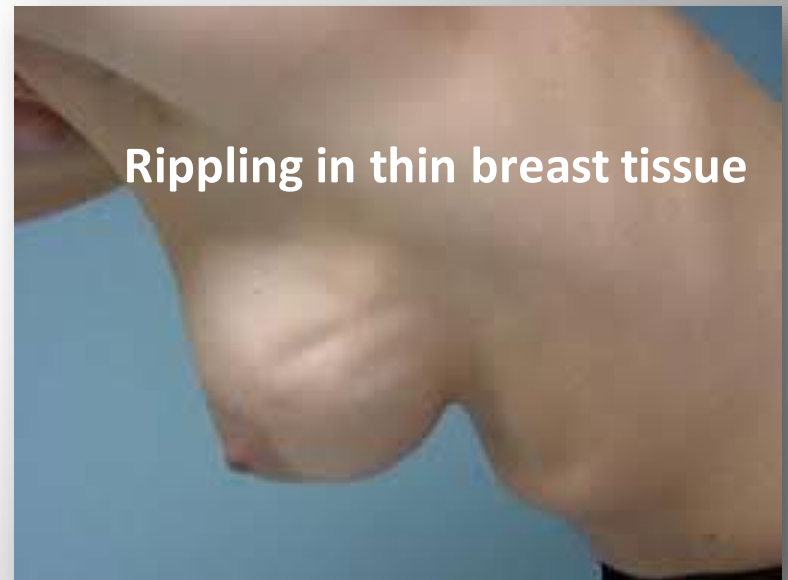
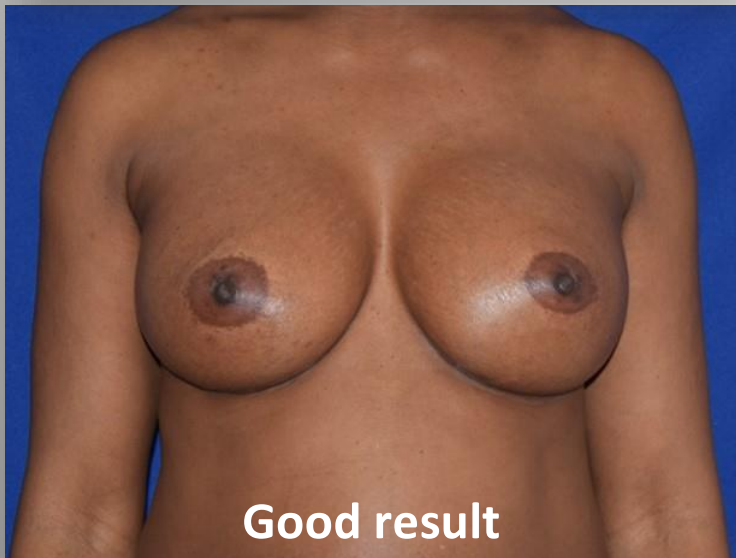
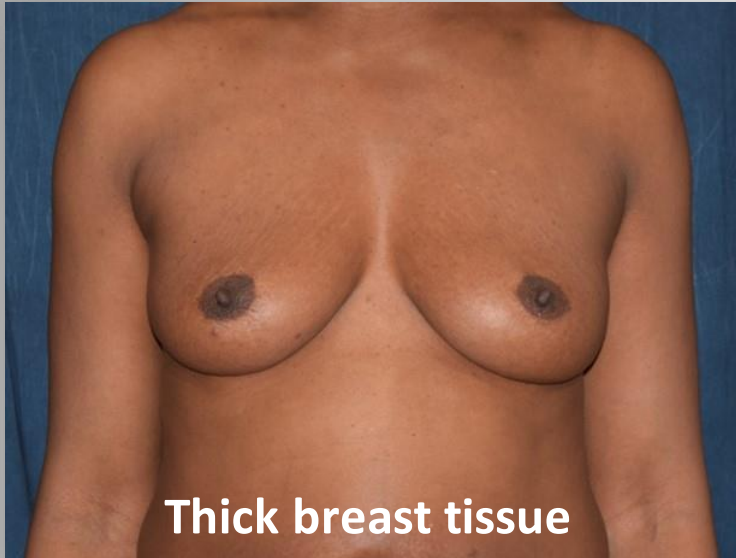


Saline Implants

- Favorable cost
- Smaller incision
- “Safer”
- Adjustable size range
- Deflation known (no surveillance)
- **Rippling, palpability** (in thinner breast tissue)
- **OR time** (few minutes)
- **Not for**
 - Thin patients
 - Small breast

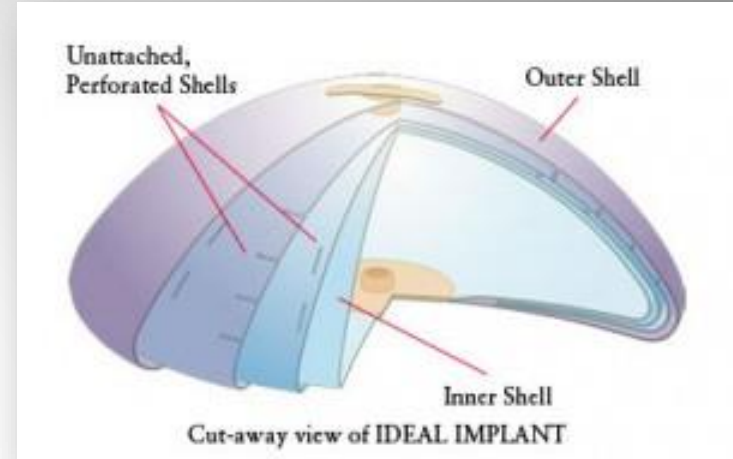


Saline Implants



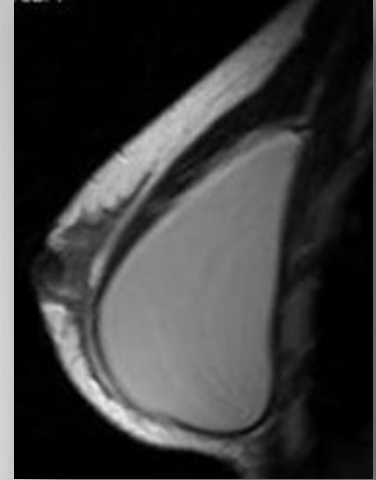
Structured Saline Implants

- Smaller incision
- “Safer”
- Adjustable size range
- Deflation known (no surveillance)
- **Less rippling, palpability?** (in thinner breast tissue)
- **Higher cost**
- **OR time** (few minutes)



Gel Implants

- More natural look & feel
- Shorter OR time
- **Shell integrity not known** (MRI surveillance)
- **Longer incision**
- **Gel concerns**
- **Higher cost**



Implant Profiles

Match breast width to implant width



**Not
commonly
used**

**Commonly
used**

**Common,
more “fake”
appearance**

**Not for
augmentation**

Smooth vs Textured

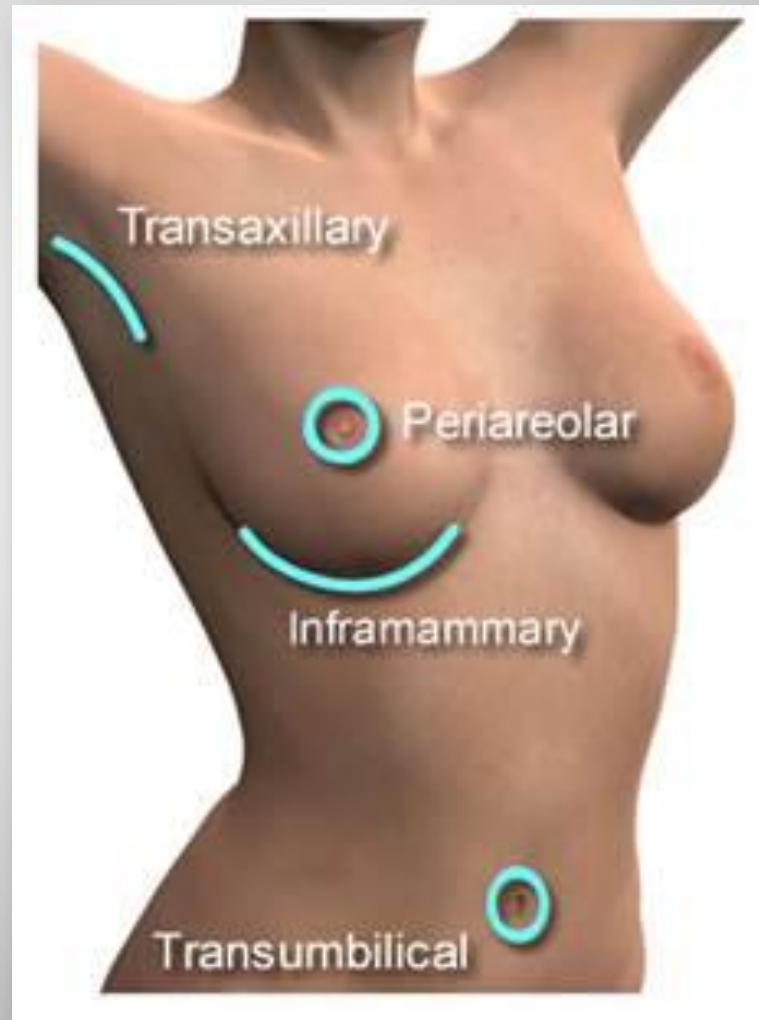
Smooth

- More contracture
 - Subglandular
 - Not when submuscular
- Less palpable

Textured

- Reduced contracture
- Palpability
- Double capsule & seroma
- ALCL?

Incision Choices



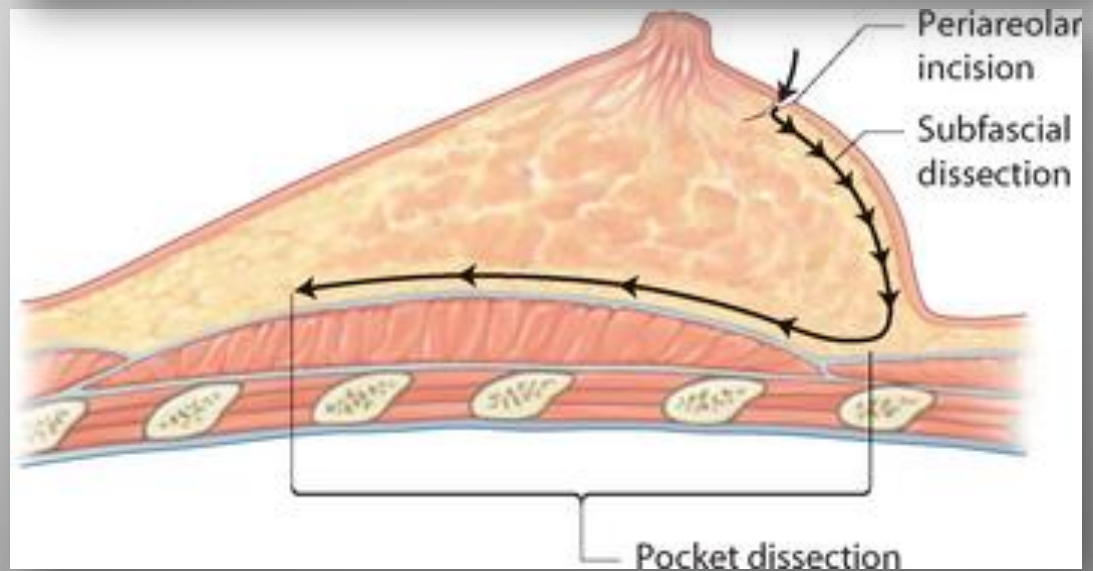
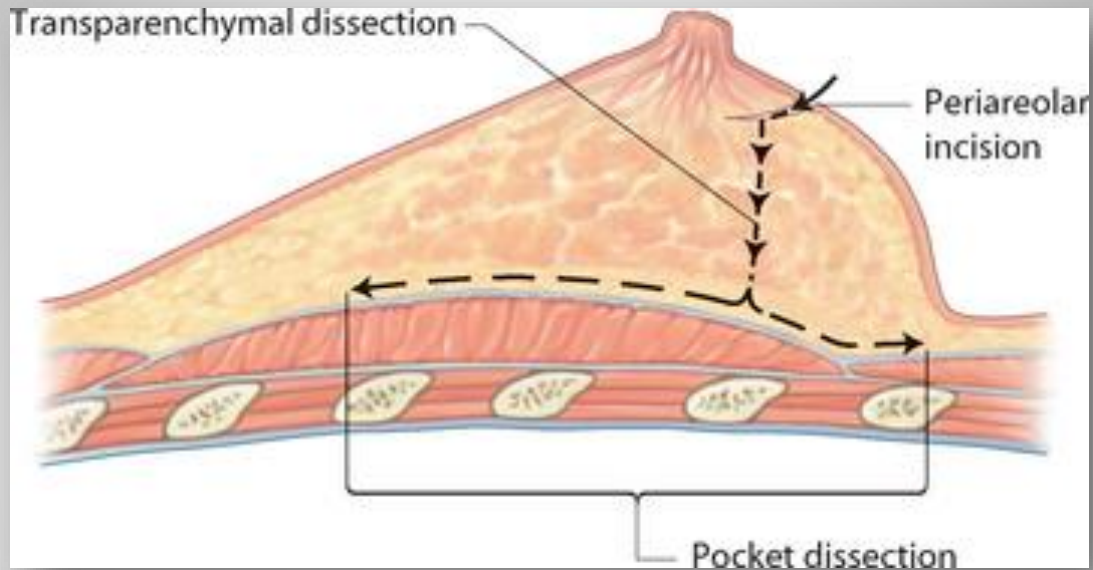
Inframammary Crease Incision

- Suitable for most cases
- No size limitations
- Direct access to pocket
- IMF Adjustments
- Scar superior migration
- Risk of implant extrusion

Periareolar Incision

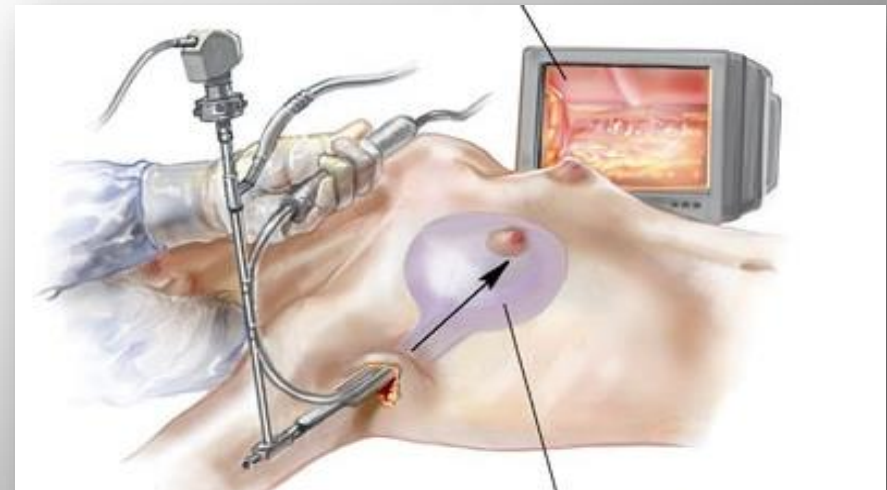
- Scar may be less visible
- Size limitation
- Hyperpigmentation
- Harder with larger breasts
- Nipple sensation & pain
- Capsular contracture?
- Transparenchymal vs subcutaneous

Periareolar Incision Options



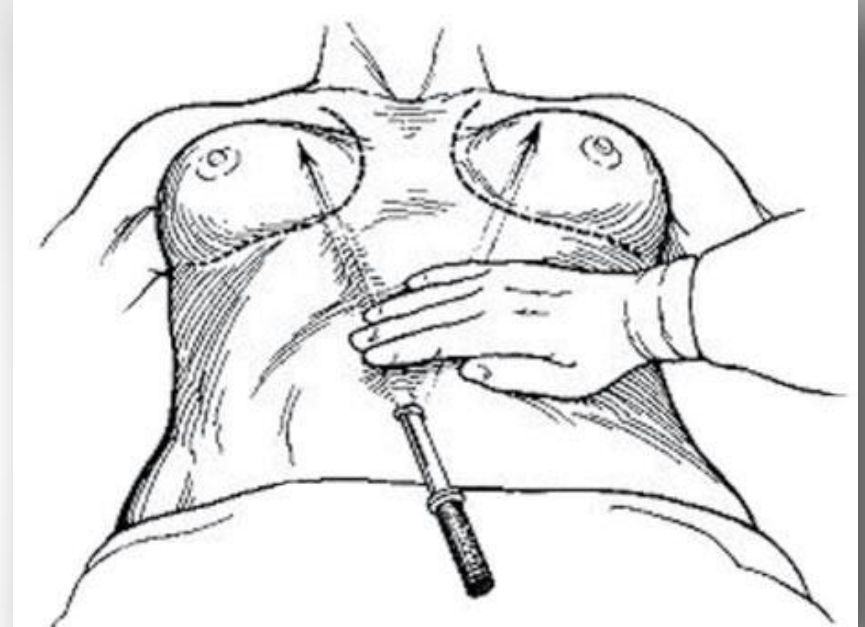
Transaxillary Incision

- Favorable scar
- Size limitation
- Instrumentation
- Less IMF control?
- Capsular contracture?
- Endoscopic
- Retractor
- “Blind”



Transumbilical Incision

- Favorable scar
- Saline implants only
- Instrumentation
- Less IMF control
- Less pocket control
- Less muscle release control



Implant Pocket Options

Sub Muscular



Subglandular



Subfascial



Dual-plane



Subglandular

- Less pain
- Faster recovery
- “Awake” procedure
- Better for ptosis
- More palpability & visibility
- Capsular contracture
- Mammograms



Subfascial

- Less pain
- Faster recovery
- “Awake” procedure
- Better for ptosis
- More palpability & visibility
- Capsular contracture?
- Mammograms

Less data on advantages & disadvantages

Submuscular

- Less palpability & visibility
- Less capsular contracture
- Mammograms
- **Anesthesia required** (usually)
- **More discomfort**
- **Longer recovery**
 - Time to “settle”
- **Animation deformity**
- **Lateral displacement**



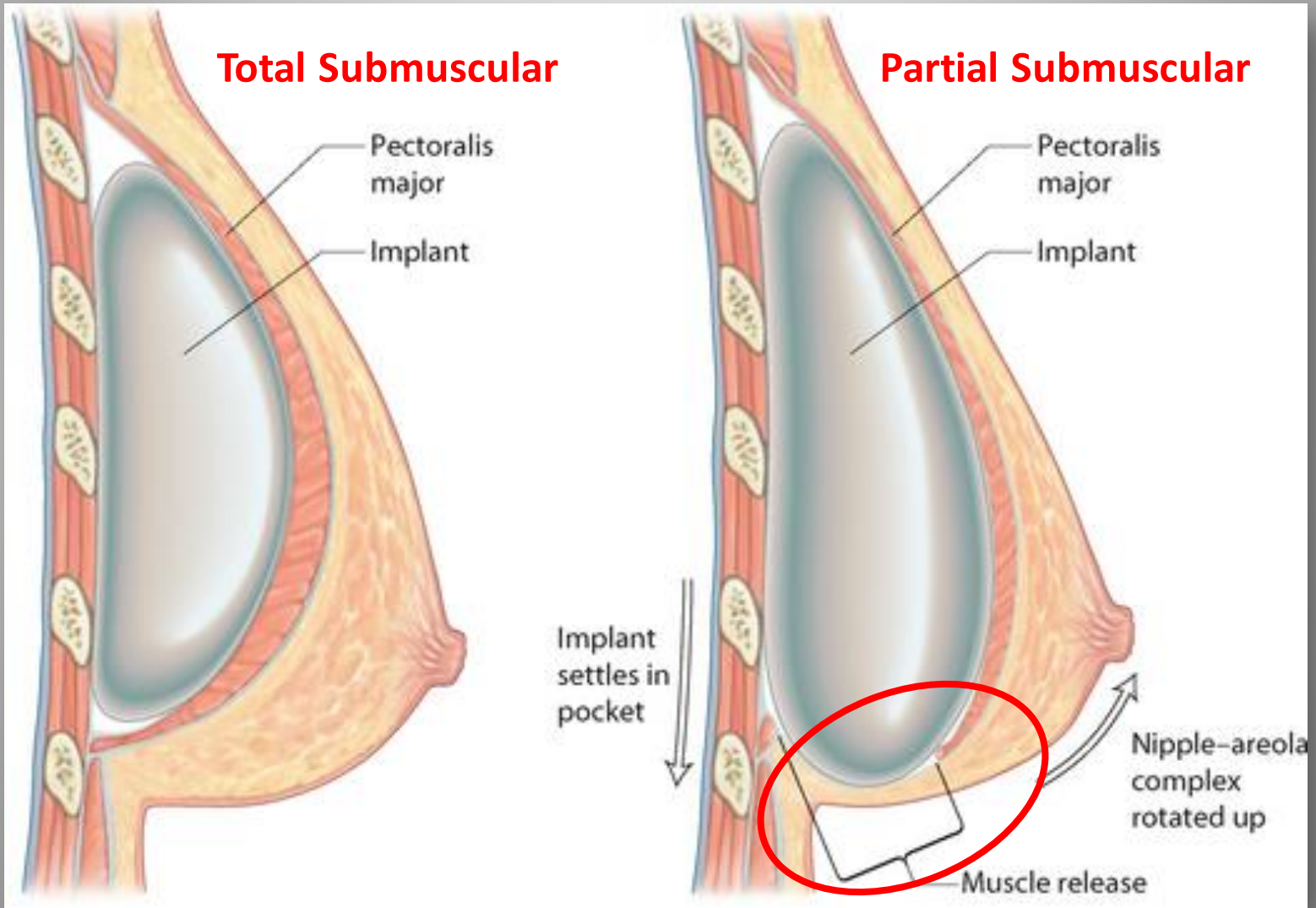
Animation Deformity: Mild



Animation Deformity: Severe



Pectoralis Muscle Release



Dual Plane

COSMETIC

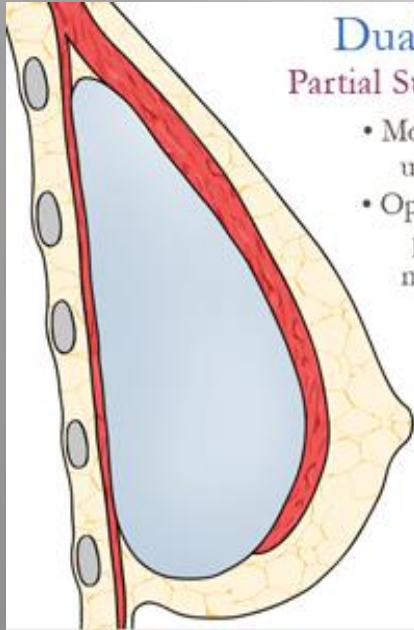
Dual Plane Breast Augmentation: Optimizing Implant-Soft-Tissue Relationships in a Wide Range of Breast Types

John B. Tebbets, M.D.
Dallas, Texas

In breast augmentation, surgeons usually choose a pocket location for the implant behind breast parenchyma (retromammary), partially behind the pectoralis major

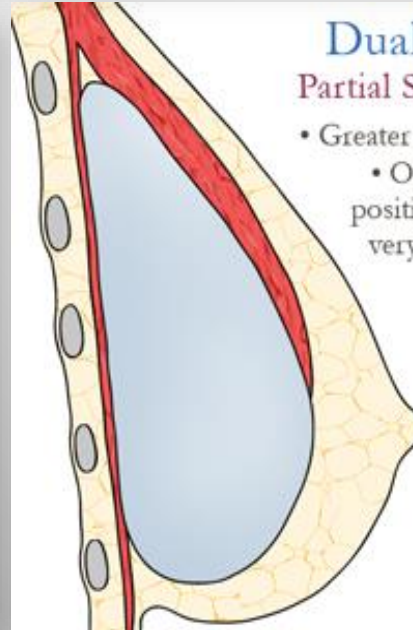
Dual Plane I Partial Submuscular

- Most commonly used technique
- Optimal implant placement for normal breasts



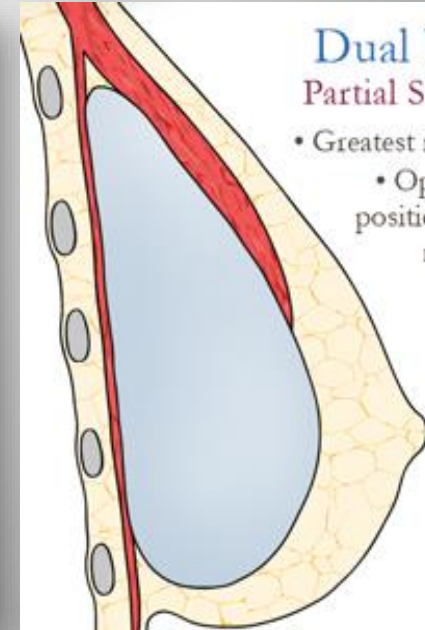
Dual Plane II Partial Submuscular

- Greater muscle release
- Optimal implant position to improve very slight sagging



Dual Plane III Partial Submuscular

- Greatest muscle release
- Optimal implant position to improve minor sagging



For non-ptotic breast

For slightly ptotic breast

For minor ptotic breast

Double Bubble

SPECIAL TOPIC

Rectangular Strip

The Double-Bubble Deformity: Cause, Prevention, and Treatment

Neal Handel, M.D.
Santa Barbara, Calif.

Background: The double-bubble deformity is a widely recognized complication of breast augmentation, but there have been very few articles in the peer-

- Appreciate & respect the IMF
- Risk factors
 - Tuberosus breasts
 - Constricted inframammary fold
 - Short nipple – IMF distance

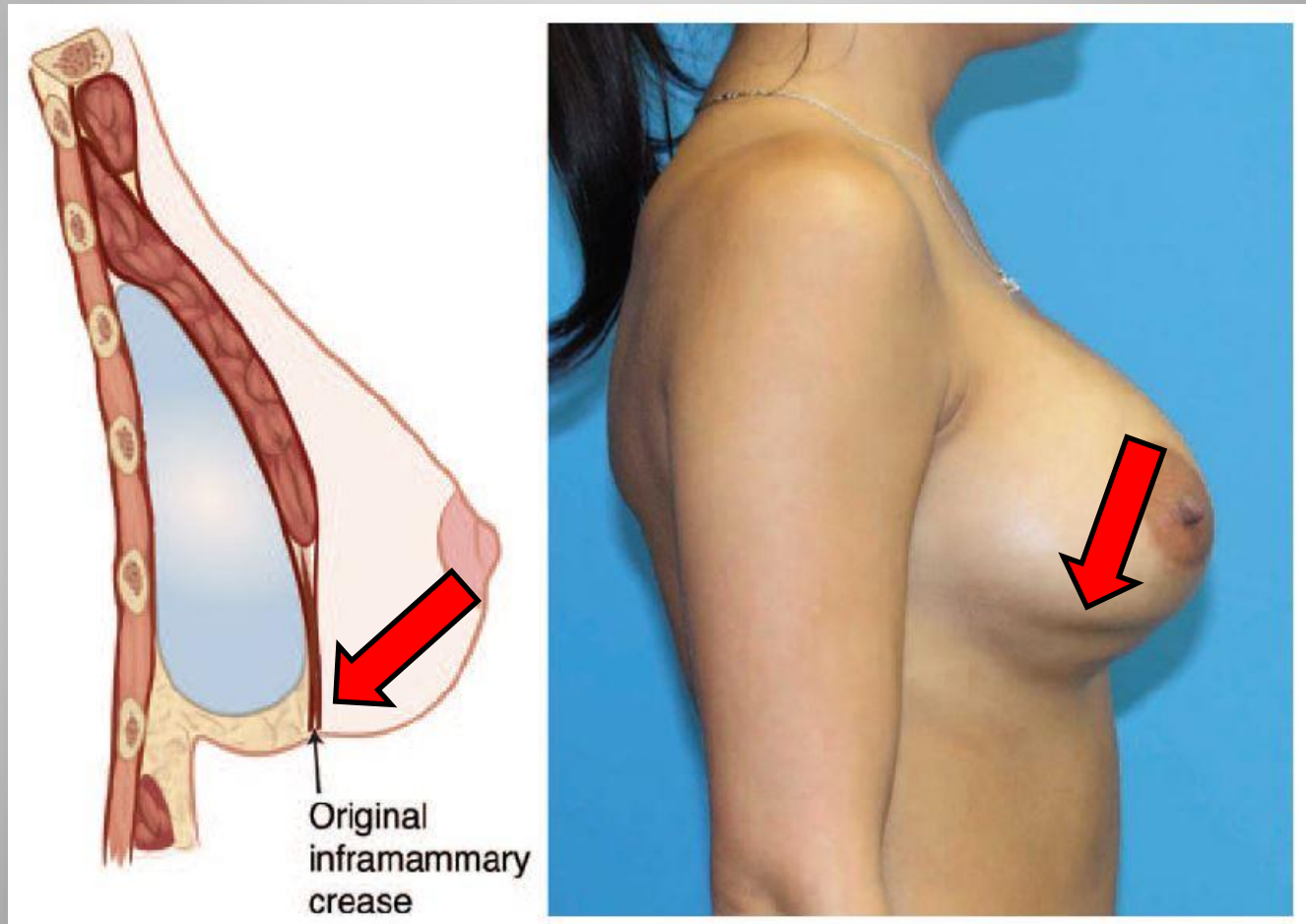


Double Bubble



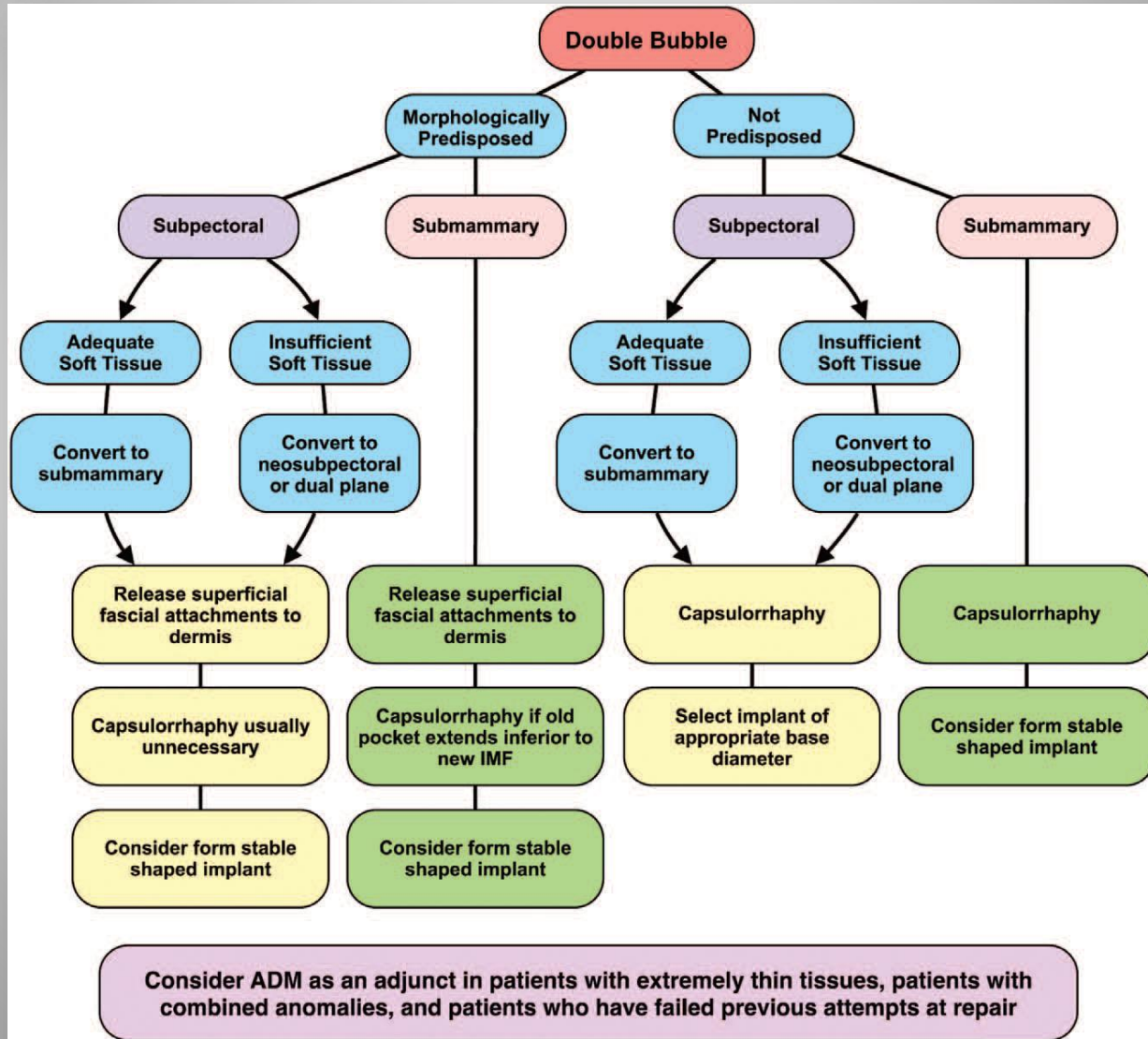
- Original IMF lowered
- Implant too large for Nipple – IMF distance
- Original IMF did not expand

Double Bubble



Need to release fibrous connection from muscle to dermis

Double Bubble Decision Making



Implant Malposition

Implant not in intended position

- Superior
- Inferior
- Lateral
- Medial
- Combination



Combination inferior & lateral malposition

Superior Malposition

Causes

- Failure to release inferior muscle
 - Common in trans-axillary approach
- Too large implant for footprint
- Muscle activity (animation)
- Capsular contracture



Inferior Malposition

Causes

- Release of original IMF
- Large implant
- Muscle hyperactivity
- “Weak” IMF

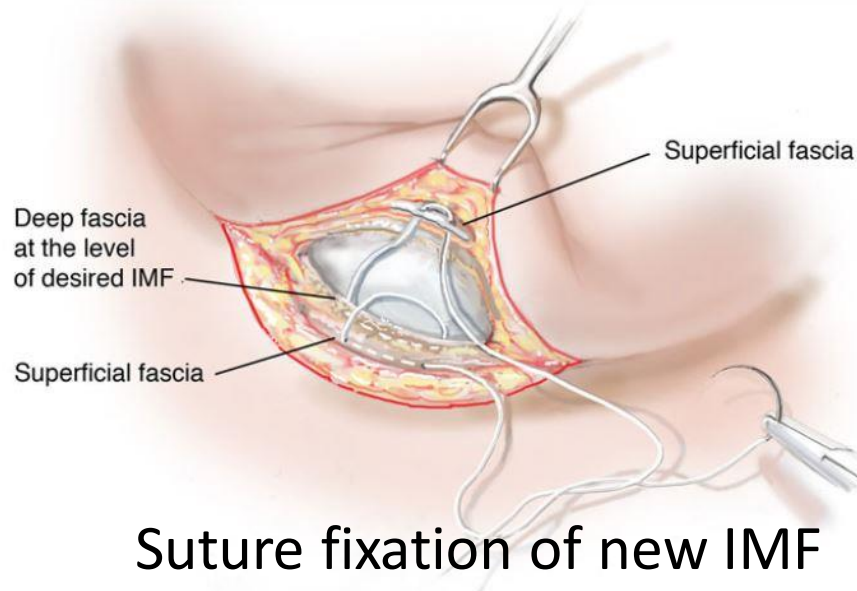


Inferior Malposition

My Way

The Inframammary Fold (IMF) Fixation Suture: Proactive Control of the IMF in Primary Breast Augmentation

Carey F. Campbell, MD; Kevin H. Small, MD;
and William P. Adams Jr, MD



Medial Malposition (Symmastia)

Causes

- Extensive medial dissection
- Large implant
- Attempt to create cleavage



Lateral Malposition

Causes

- Extensive lateral dissection
- Large implant
- Muscle hyperactivity
- Chest wall anatomy
- Obvious when laying down



Patient Experience & Pain Control

- Educate on expectations
- No need for drains
- No need for constrictive wraps
- Surgical bra or breast band OK
- Multimodality analgesia
 - Block pain in differ ways
- Liposomal bupivacaine (Exparel)?
- Pain pump?
- No need for massage or exercises

Choice of Anesthesia

SPECIAL TOPIC

Breast Implant Procedures under Conscious Sedation: A 6-Year Experience in 461 Consecutive Patients

Michael S. Gart, M.D.
Jason H. Ko, M.D.
Kamaldeep S. Heyer, M.D.
Thomas A. Mustoe, M.D.
Chicago, Ill.; and Seattle, Wash.

Background: Breast implant procedures are commonly performed using general anesthesia; however, patient apprehension, the potential for improved safety, lower costs, and faster recovery times have increased interest in the use of conscious sedation in plastic surgery. The authors examined the safety and efficacy of breast implant procedures performed under conscious sedation over a 6-year period using their standardized institutional protocol.



- General anesthesia + intubation or LMA
- Possible with surgeon administered sedation
- Better to do with TIVA by anesthesiologist

Multimodality Analgesia

- Night before
 - **Gabapentin** 600 mg PO
- Perioperative
 - **Lidocaine (1%) +Epi & Marcaine (0.5%)**
 - Incisions (5 cc per side) + medial & lateral field block (20 cc per side)
 - **Acetaminophen** 1000 mg PO (No need for IV)
 - **Celebrex** 200 mg 1 PO
 - or
 - **Ketorolac** 30 mg IV when closing incisions
 - **Marcaine** 0.5% 5 cc in each pocket
- Postoperative
 - **Gabapentin** 300 - 600 mg PO q 6 hrs
 - **Ibuprofen** 400 mg PO q 4 hr or **Naproxen** 220 PO q 6 hr
 - **Acetaminophen** 325 mg PO q 4 hr
 - **Oxycodone** 5 mg PO q 4 hr (if needed)



ALCL

SPECIAL TOPIC

Breast Implant Informed Consent Should Include the Risk of Anaplastic Large Cell Lymphoma

Mark W. Clemens, M.D.
Roberto N. Miranda, M.D.
Charles E. Butler, M.D.

Houston, Texas

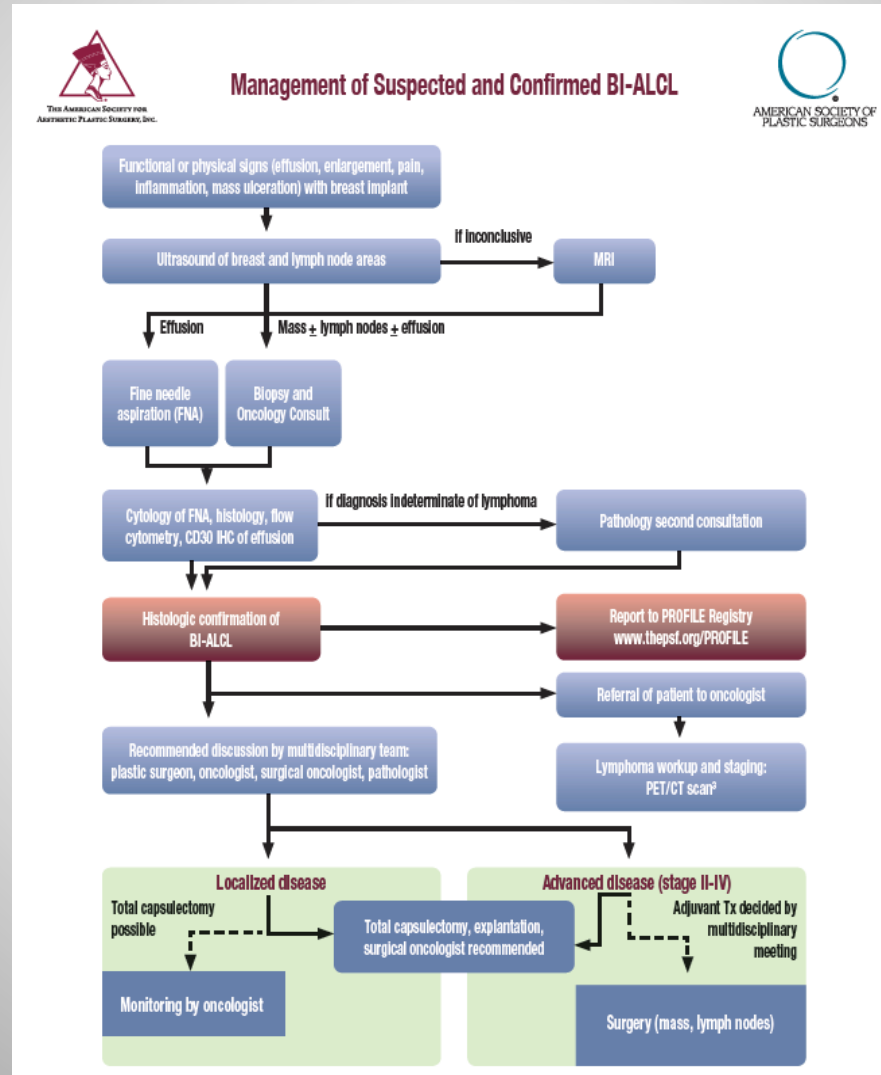
Summary: Breast implant–associated anaplastic large cell lymphoma (ALCL) is a rare T-cell lymphoma arising around breast implants. Public awareness has increased following a safety communication warning of the association of breast implant–associated ALCL by the U.S. Food and Drug Administration in 2011. Difficulty with determining an accurate assessment of risk, including

“Although extremely rare, there have been cases reported of ALCL, a type of lymphoma or, cancer of the immune system, associated with breast implants.”

ALCL

- Analysis of all significant seromas > 1 yr
 - CD30 immunohistochemistry
- Very rare (as of 9/26/16)
 - < 1 to 3 in 1,000,000
 - 1 in 30,000 in textured implants? (1 in 4000 in Biocell)
 - NO documented cases with SMOOTH shells in USA
 - 2 cases with SMOOTH shells in Australia (3.6)
- Guidelines on diagnosis & treatment
- Early stage – good prognosis with surgery
- Late stage – worse prognosis, + immunoTx

Management of Suspected ALCL



Capsular Contracture

Prevention

- Implant choice
 - Smooth vs textured
 - Shaped vs round
- Incision choice
- Implant pocket
- Pocket irrigation
 - Betadine
 - Antibiotics
- Surgical technique
 - No touch methods
 - Keller Funnel
- Pharmacologic



Capsular Contracture Over Time

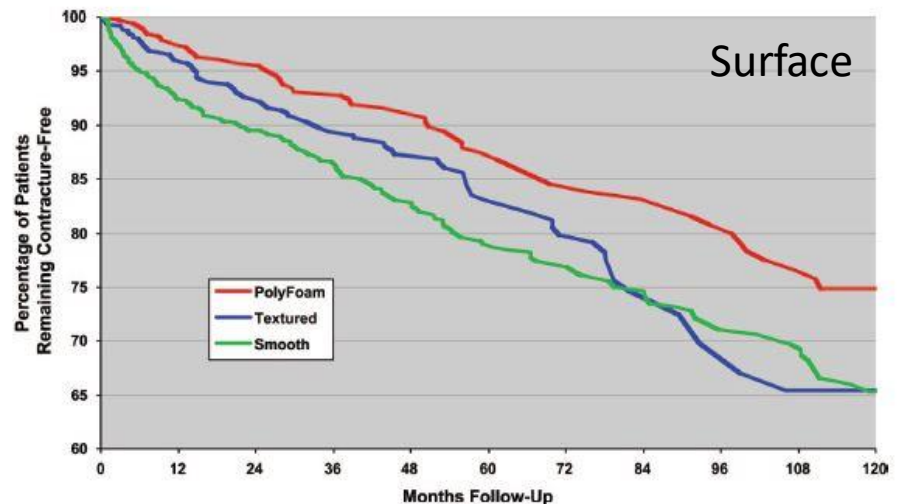
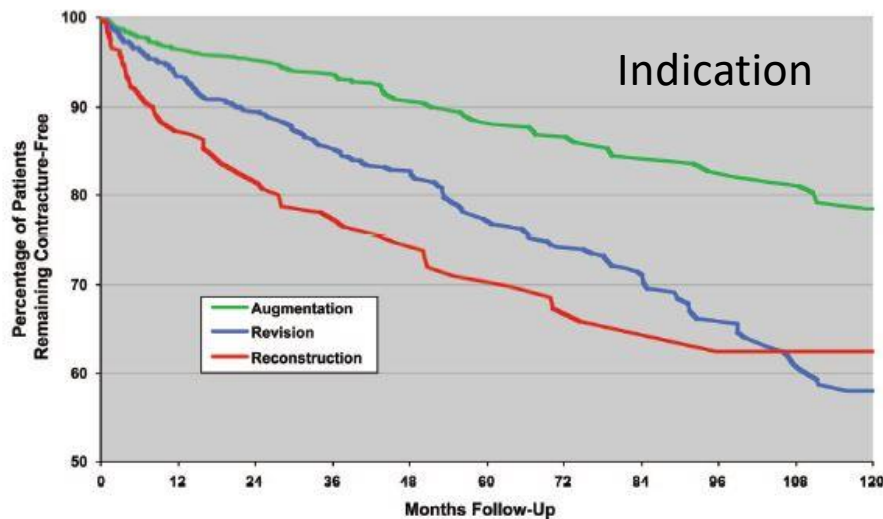
COSMETIC

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



Capsular Contracture Over Time

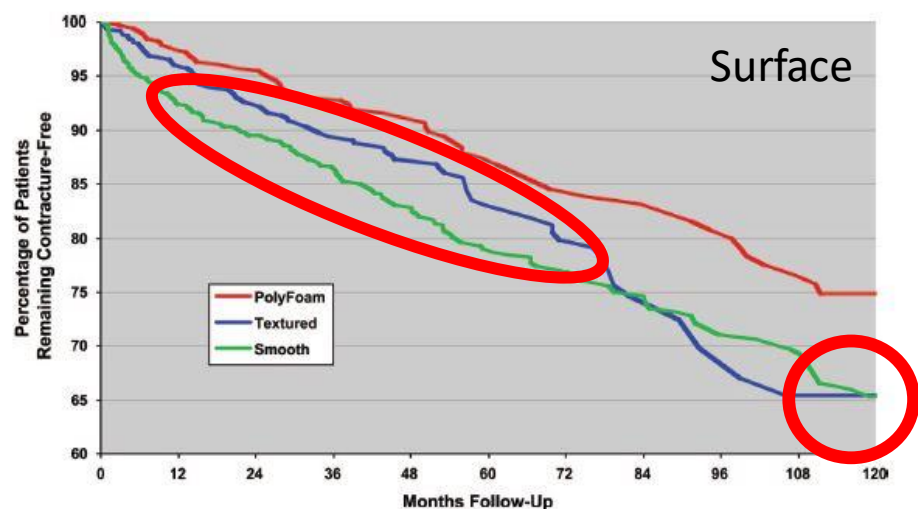
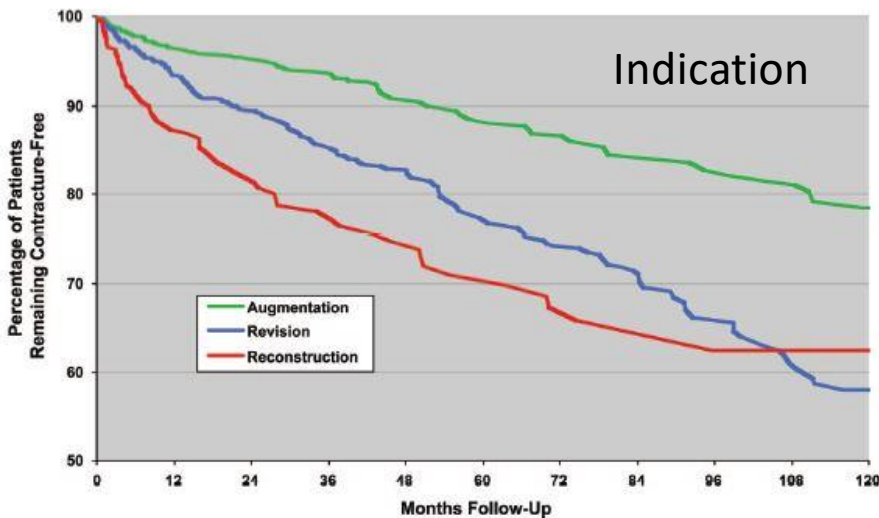
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Is capsular contracture inevitable?



Incidence: Allergan Saline

Allergan Saline Implants

<u>Procedure</u>	<u>1 yr</u>	<u>3 yr</u>	<u>5 yr</u>	<u>7 yr</u>
• 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

<u>Procedure</u>	<u>1 yr</u>	<u>3 yr</u>	<u>5 yr</u>	<u>7 yr</u>	<u>10 yr</u>
• 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

<u>Procedure</u>	<u>7 yr</u>
• 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%**

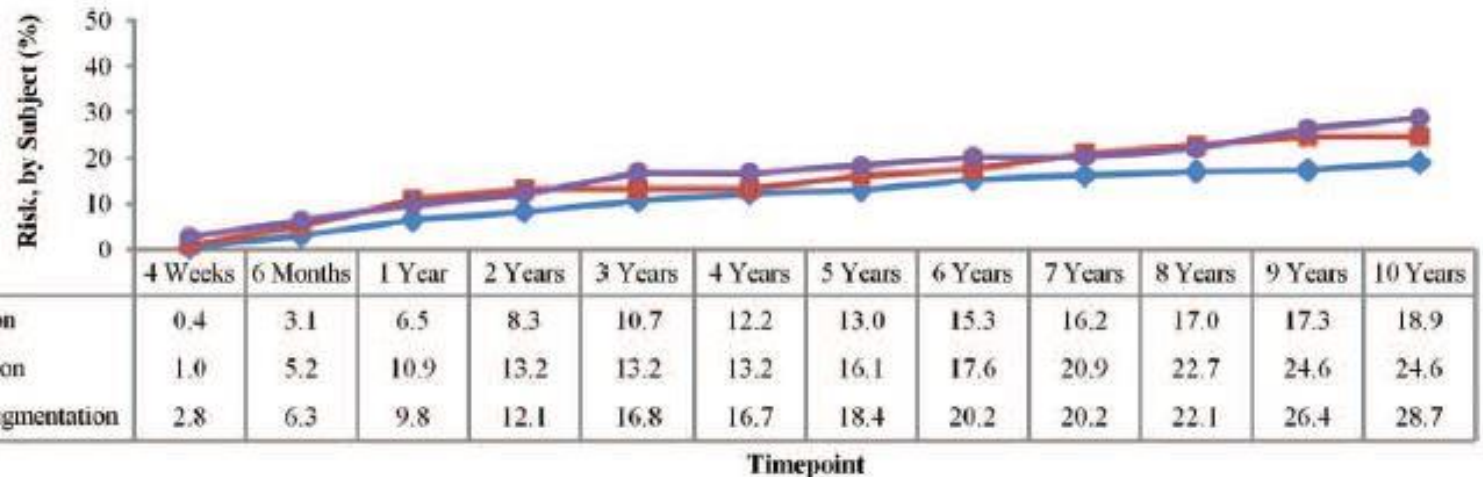
COSMETIC 2014



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.




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%)

COSMETIC 2014

Natrelle Round Silicone Breast Implant
Core Study Results at 10 Years



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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

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

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

- **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

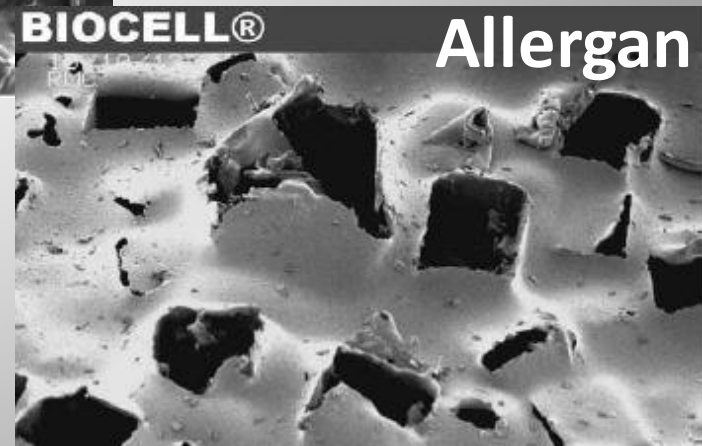
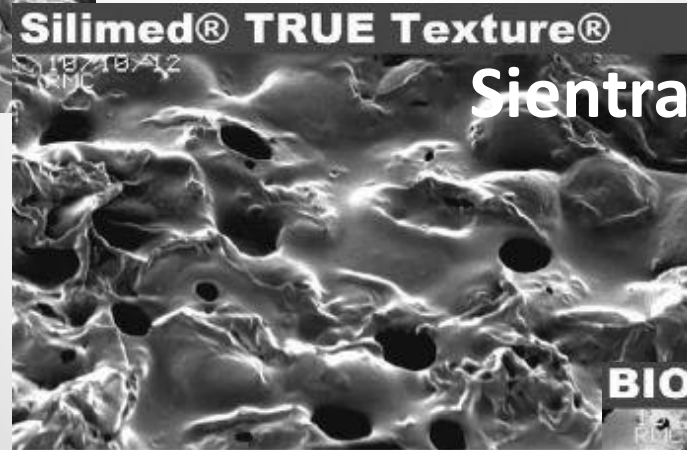
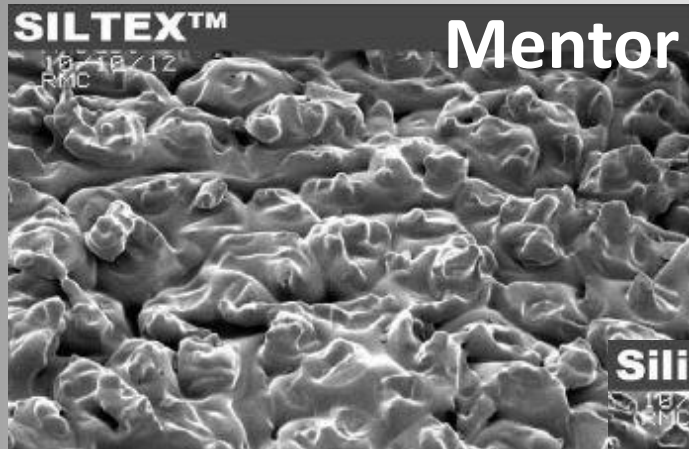
Boyd R. Burkhardt, M.D., and Christopher P. Demas, M.D.
Tucson, Ariz.

1994

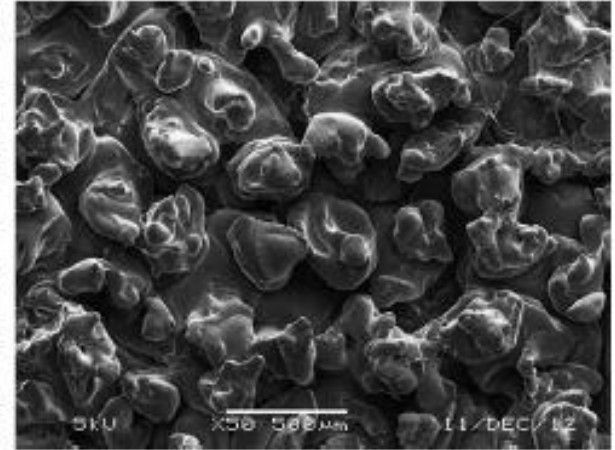
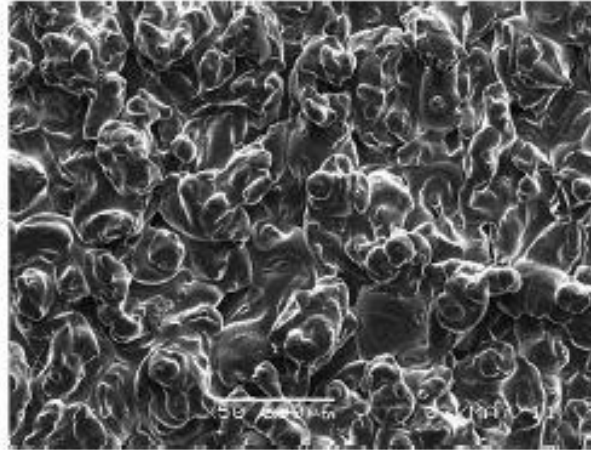
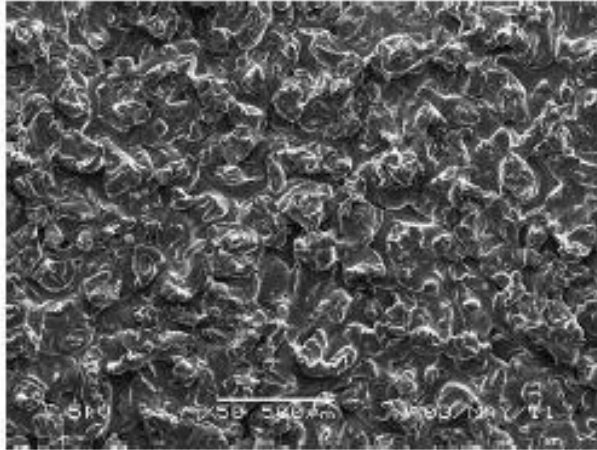
- **Saline Siltex (Mentor)**
- 56 patients
- Smooth + Betadine or saline
- Textured + Betadine or saline
- All periareolar & subglandular
- Most contractures in smooth group
- Betadine had no effect

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

Textured Surfaces NOT the Same



Differences in Same Manufacturer



**Mentor
Round**

**Mentor
Shaped**

**Mentor
CPX**

MemoryGel

MemoryShape

Tissue Expander

100 pores/inch

65 pores/inch

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

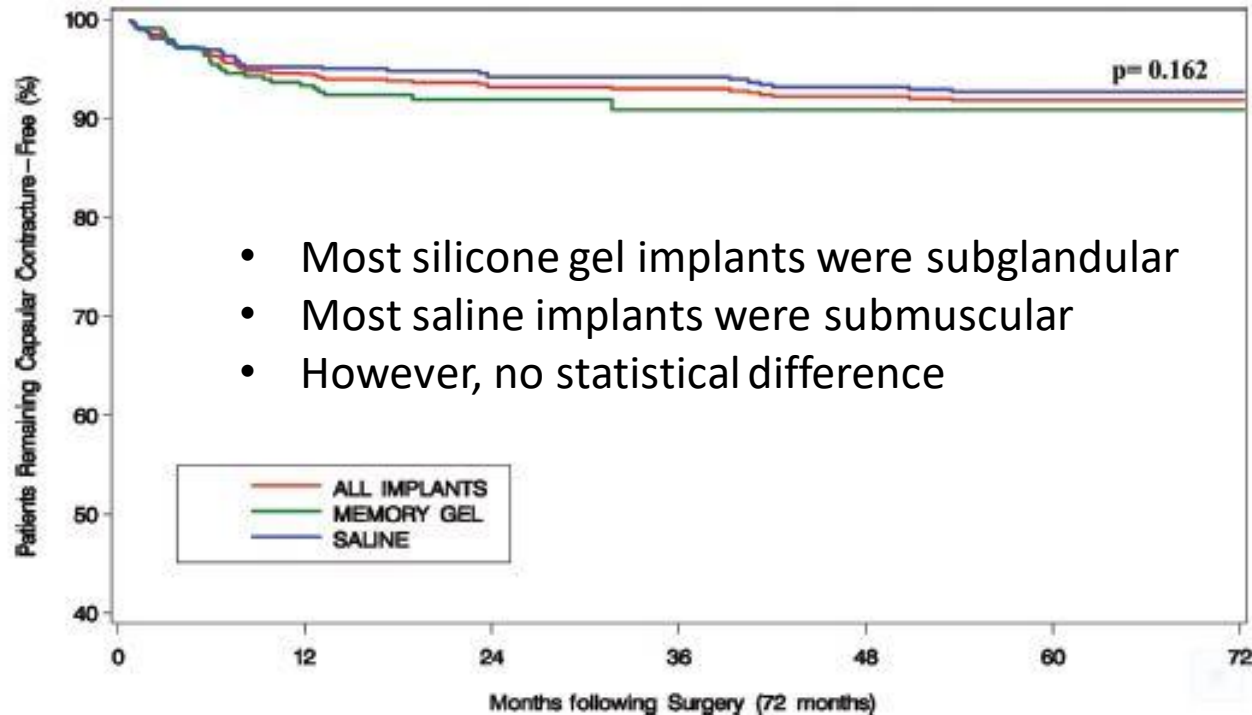
A 15-Year Experience with Primary Breast Augmentation



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 (Subglandular)

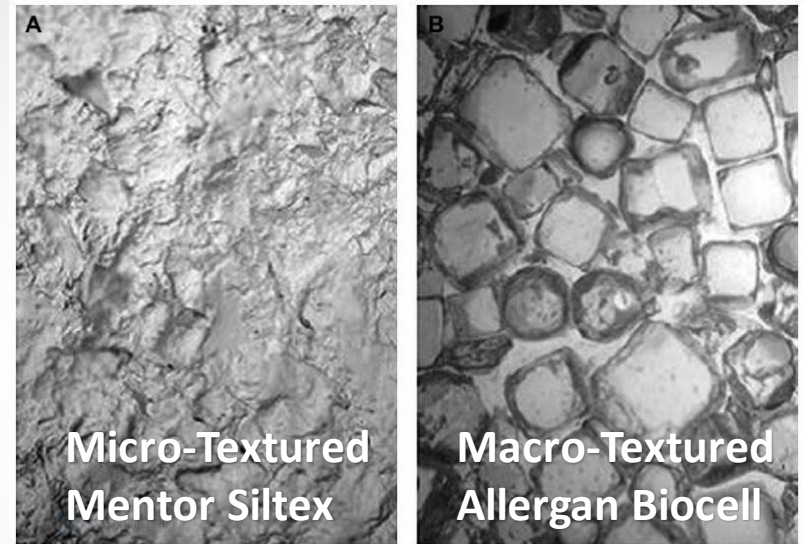
- CC higher with smooth vs textured at:
 - 1 year [RR = 4.16]
 - 3 years [RR = 7.2]
 - 7 years (RR = 2.98)

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-adherence
- Double capsule
- Late seroma



Breast Surgery

Special Topic

Benefits and Limitations of Macrot textured Breast Implants and Consensus Recommendations for Optimizing Their Effectiveness

2012



G. Patrick Maxwell, MD; Michael Schefflan, MD; Scott Spear, MD; Maurizio B. Nava, MD; and Per Hedén, MD, PhD

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 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



Breast Surgery

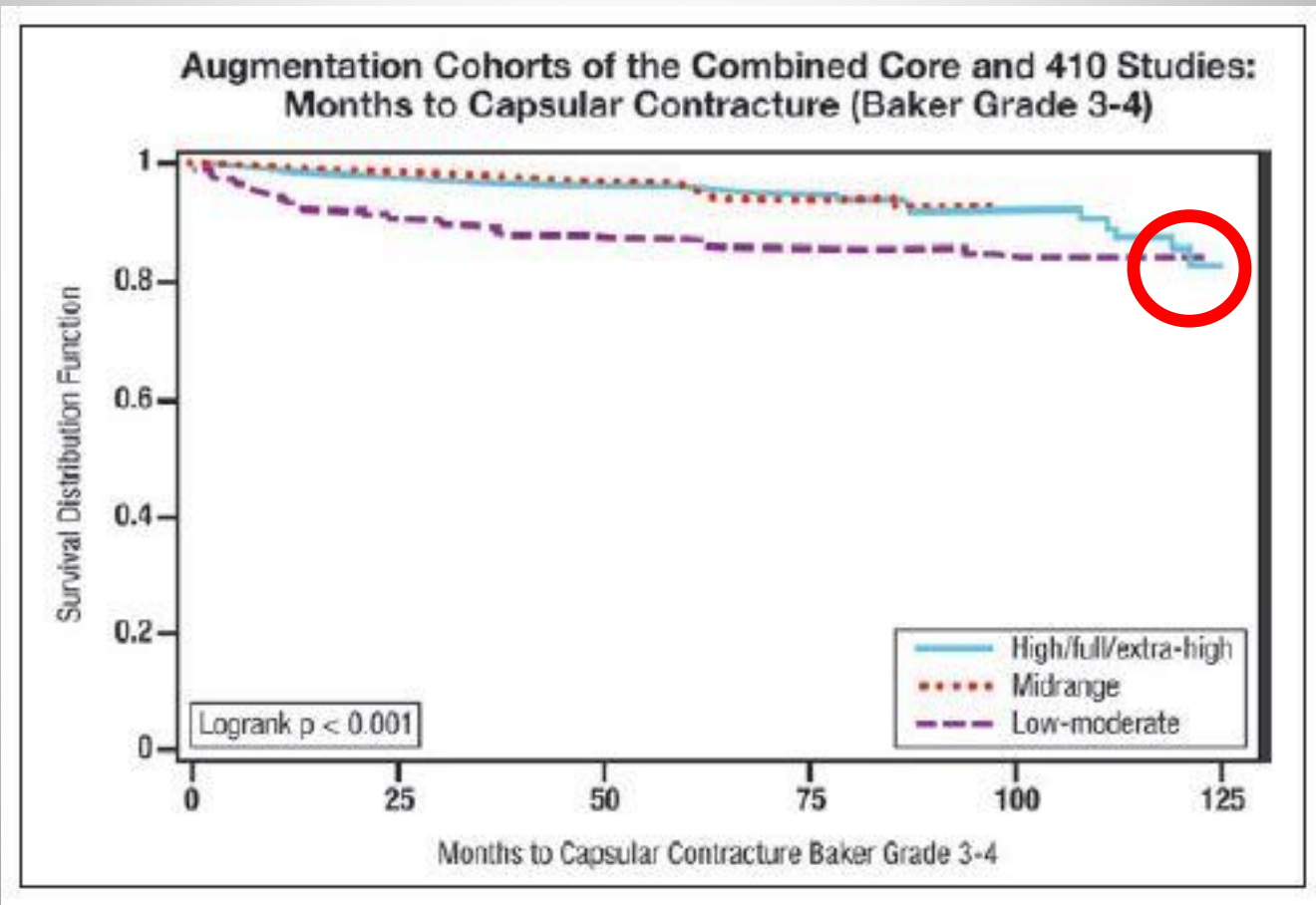
Clinical Trial Outcomes of High- and Extra High–Profile Breast Implants

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

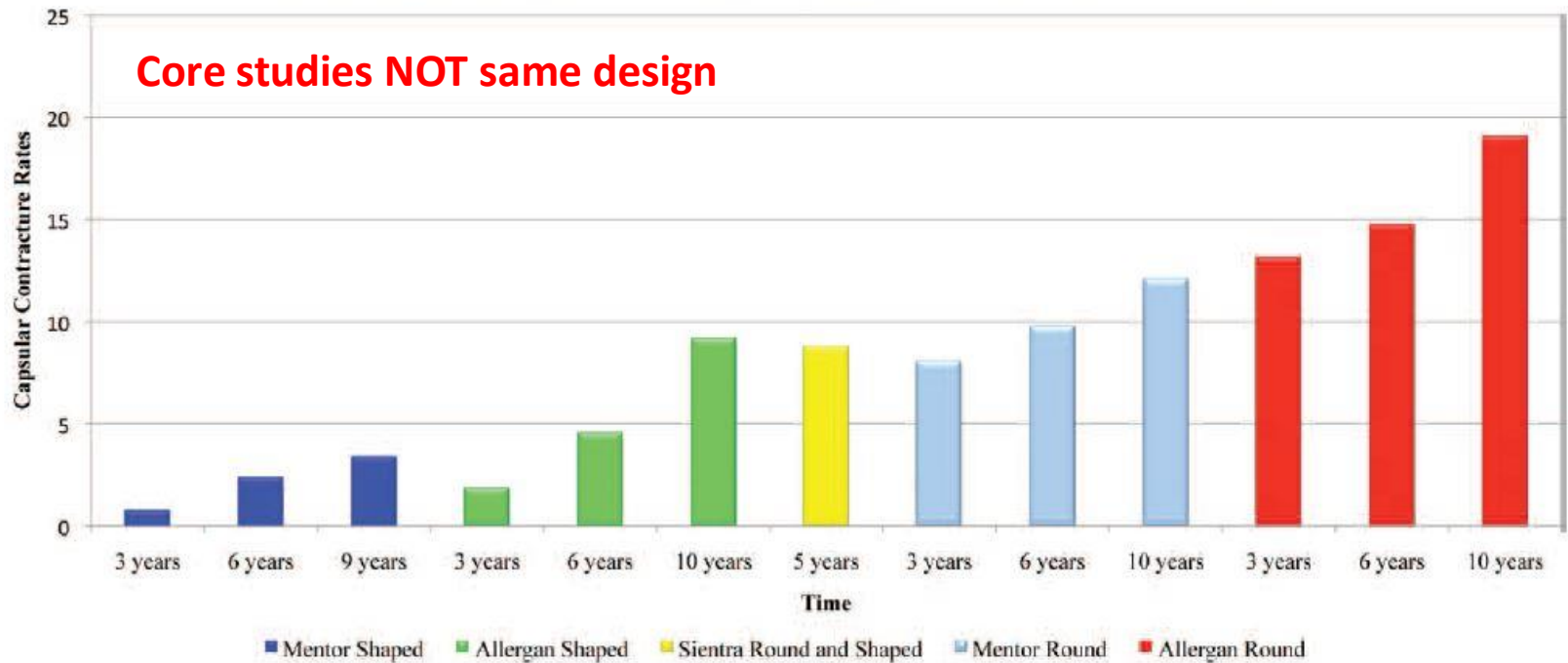
Implant Profile

May not matter after 10 years



Core Studies Summary: CC

Capsular Contracture Rates following Primary Breast Augmentation



2015

SPECIAL TOPIC

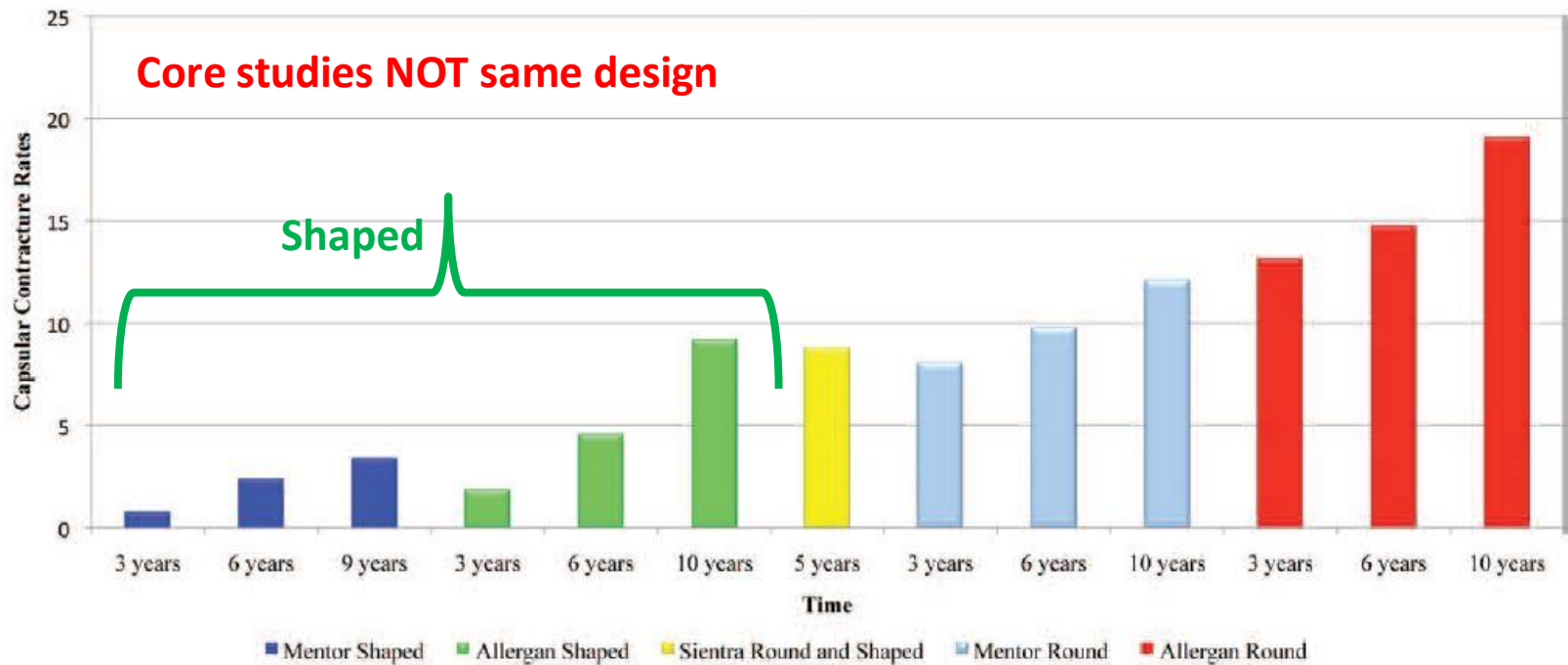
Textured Silicone Breast Implant Use in Primary Augmentation: Core Data Update and Review

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

Capsular Contracture Rates following Primary Breast Augmentation



2015

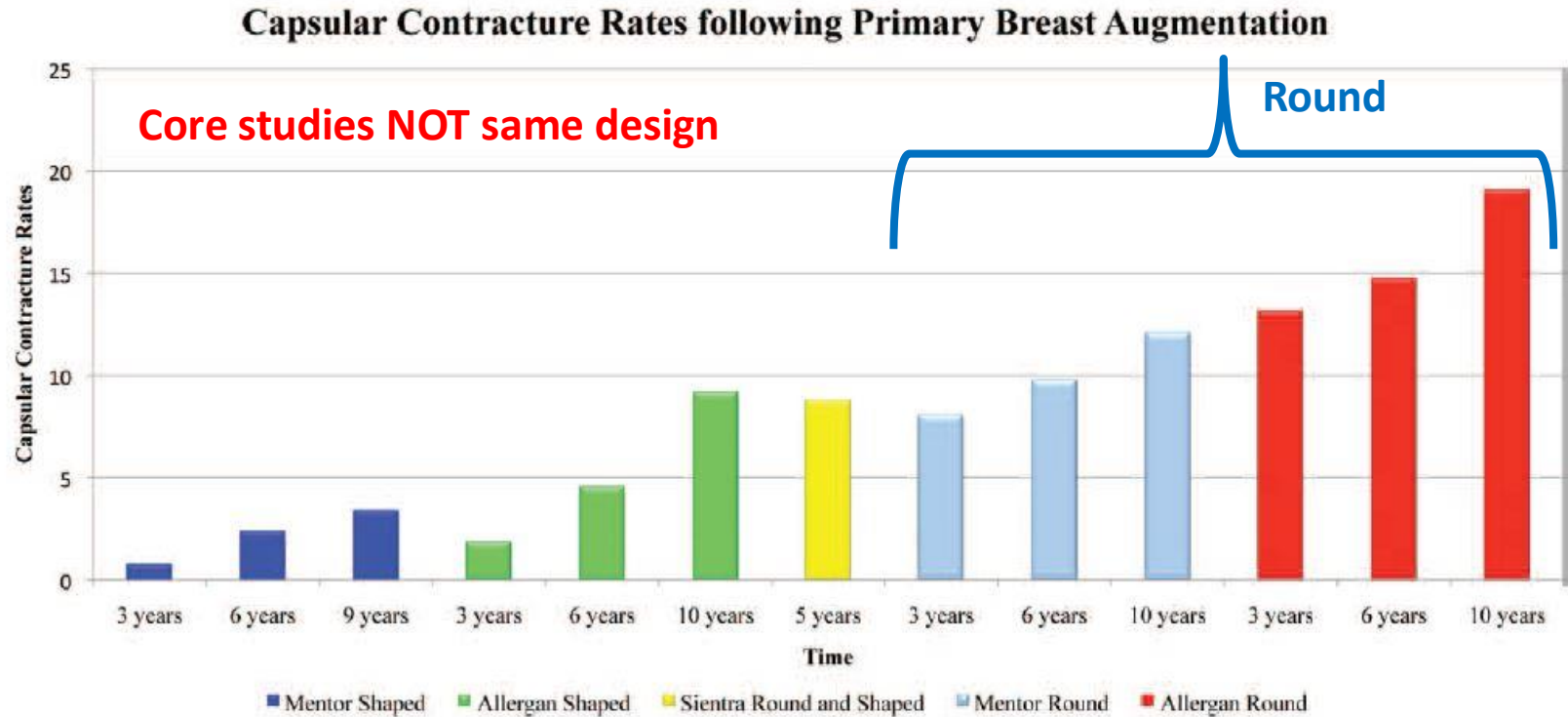
SPECIAL TOPIC

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Core Studies Summary: CC



2015

SPECIAL TOPIC

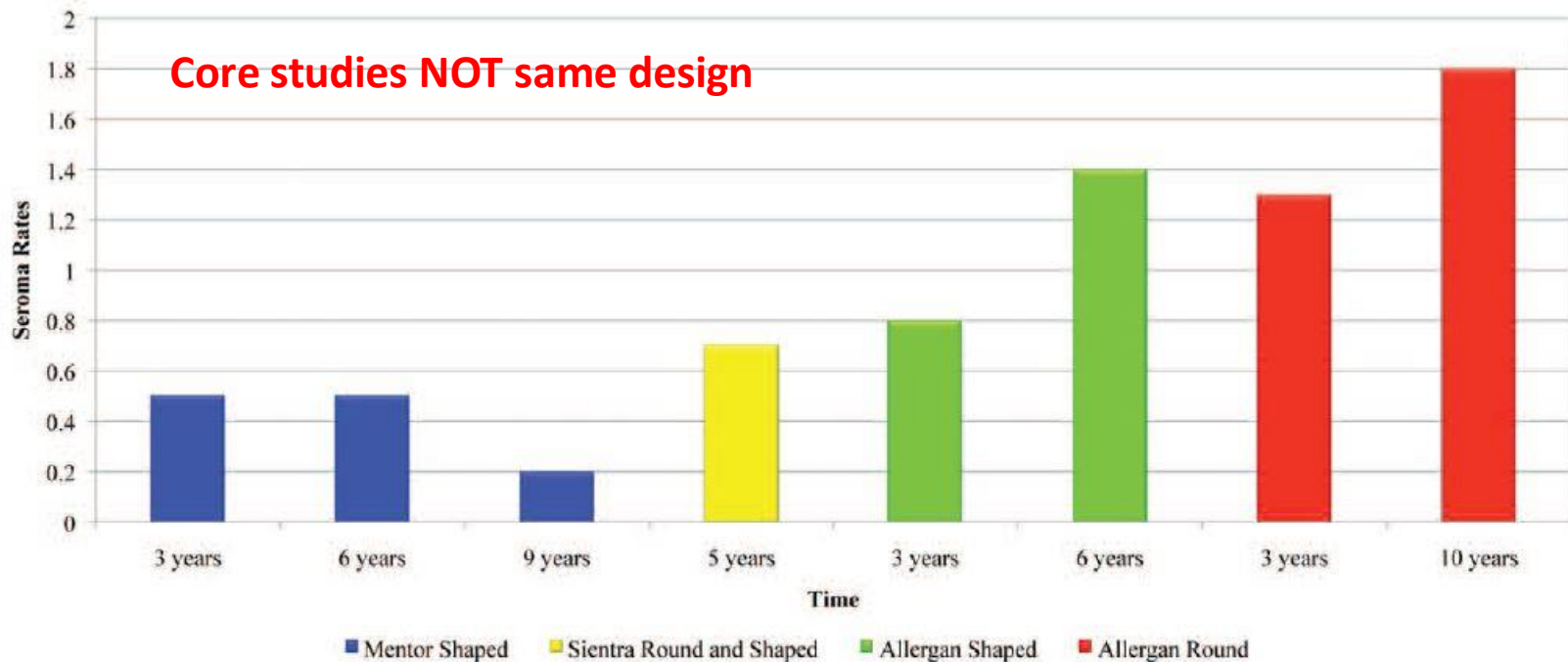
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Core Studies Summary: Seroma

Seroma Rates following Primary Breast Augmentation



2015

SPECIAL TOPIC

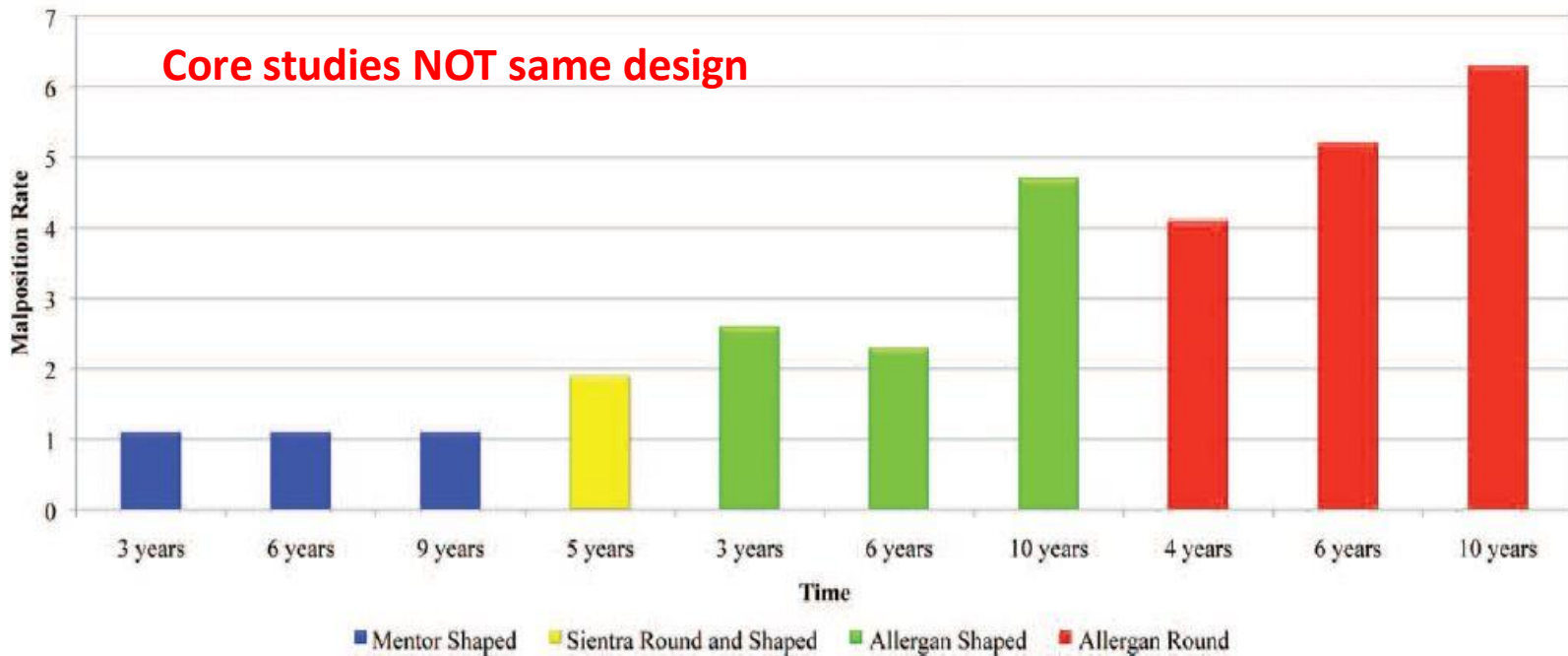
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Core Studies Summary: Malposition

Malposition Rates following Primary Breast Augmentation



2015

SPECIAL TOPIC

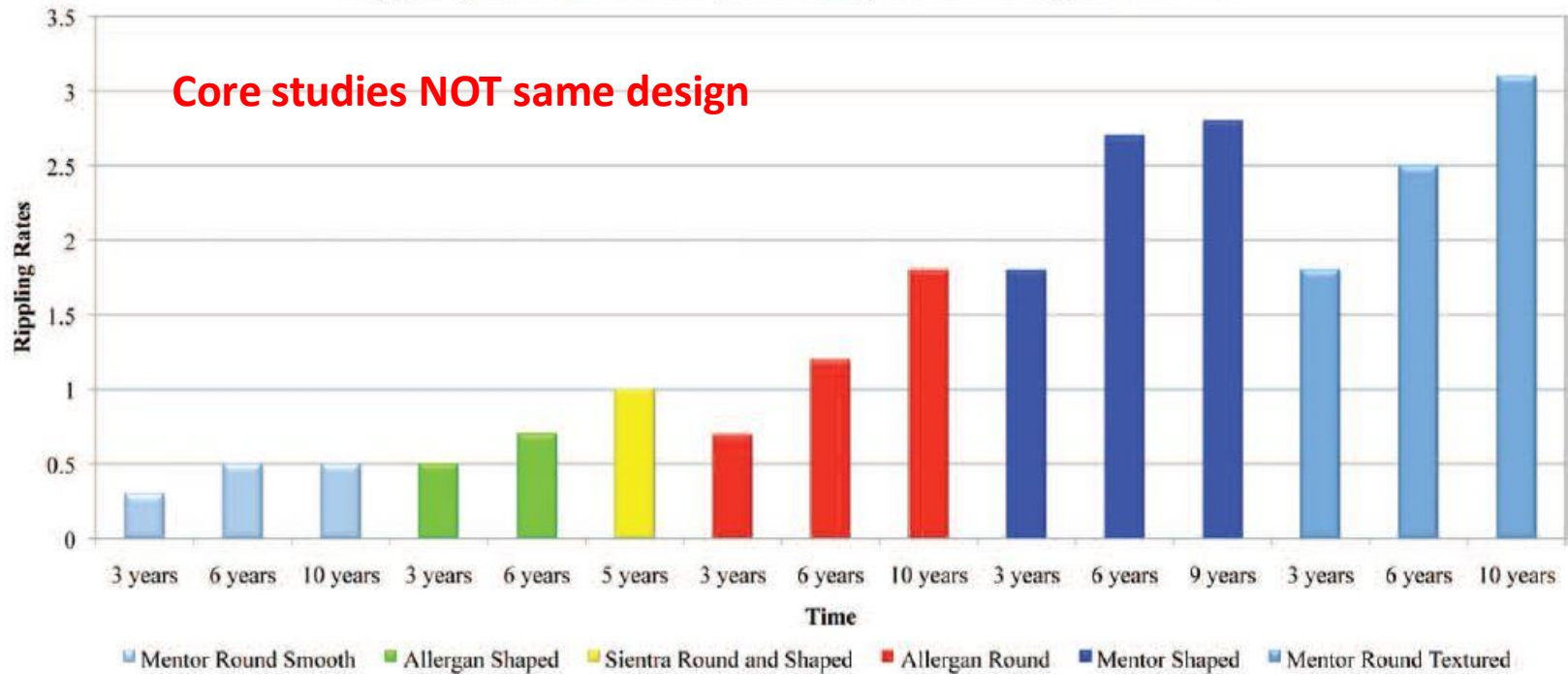
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Atlanta, Ga.

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Core Studies Summary: Rippling

Rippling Rates following Primary Breast Augmentation



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-

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

Breast Surgery

Effect of Incision Choice on Outcomes in Primary Breast Augmentation

2012



Jeffrey M. Jacobson, MD; Margaret E. Gatti, MD, MPH;
Adam D. Schaffner, MD; Lauren M. Hill, MD; and Scott L. Spear, MD

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

Breast Surgery

Capsular Contracture Rate in a Low-Risk Population After Primary Augmentation Mammoplasty

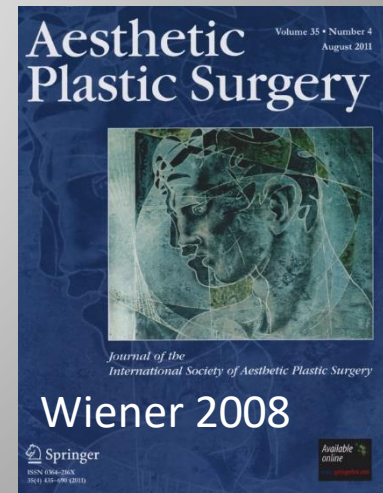
2013



Andrew L. Blount, MD; Matthew D. Martin, MD; Kyle D. Lineberry, BS; Nicolas Kettaneh, BS; and David R. Alfonso, MD


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.”




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



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.

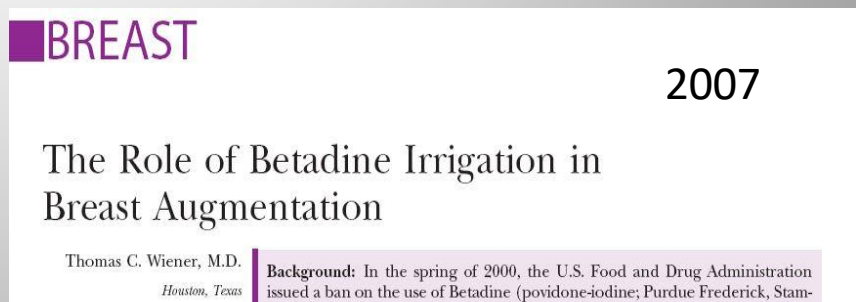
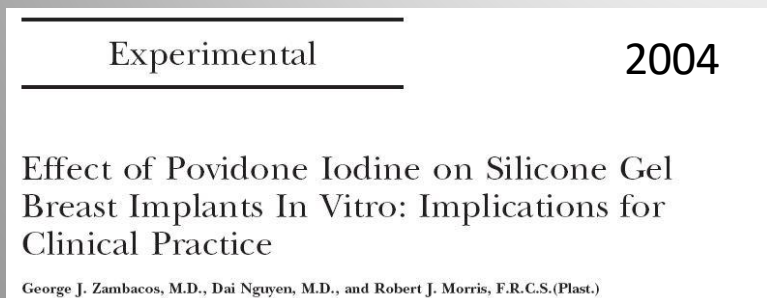
Methods: A retrospective review of a single surgeon's prospectively maintained

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**



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

2013

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



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



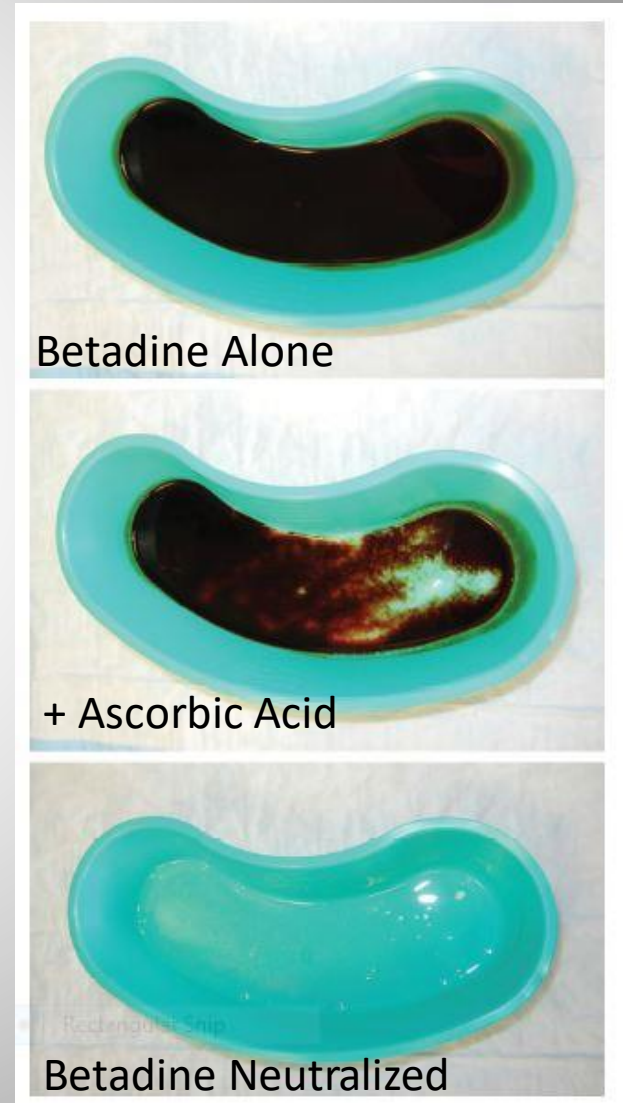
Efficacy and Safety of Povidone-Iodine Irrigation in Reducing the Risk of Capsular Contracture in Aesthetic Breast Augmentation: A Systematic Review and Meta-Analysis

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**





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: 1^o or 2^o 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

Breast Surgery

Evaluating the Role of Postoperative Prophylactic Antibiotics in Primary and Secondary Breast Augmentation: A Retrospective Review

2015



Michael N. Mirzabeigi, MS; Alexander F. Mericli, MD; Timothy Ortlip, MS; Gary A. Tuma, MD; Steven E. Copit, MD; James W. Fox IV, MD; and John H. Moore Jr., MD, FACS

Electrocautery 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

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

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. Giordano¹, A. Salmi¹

¹Turku 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



\$100 to \$130



One case use

Keller Funnel

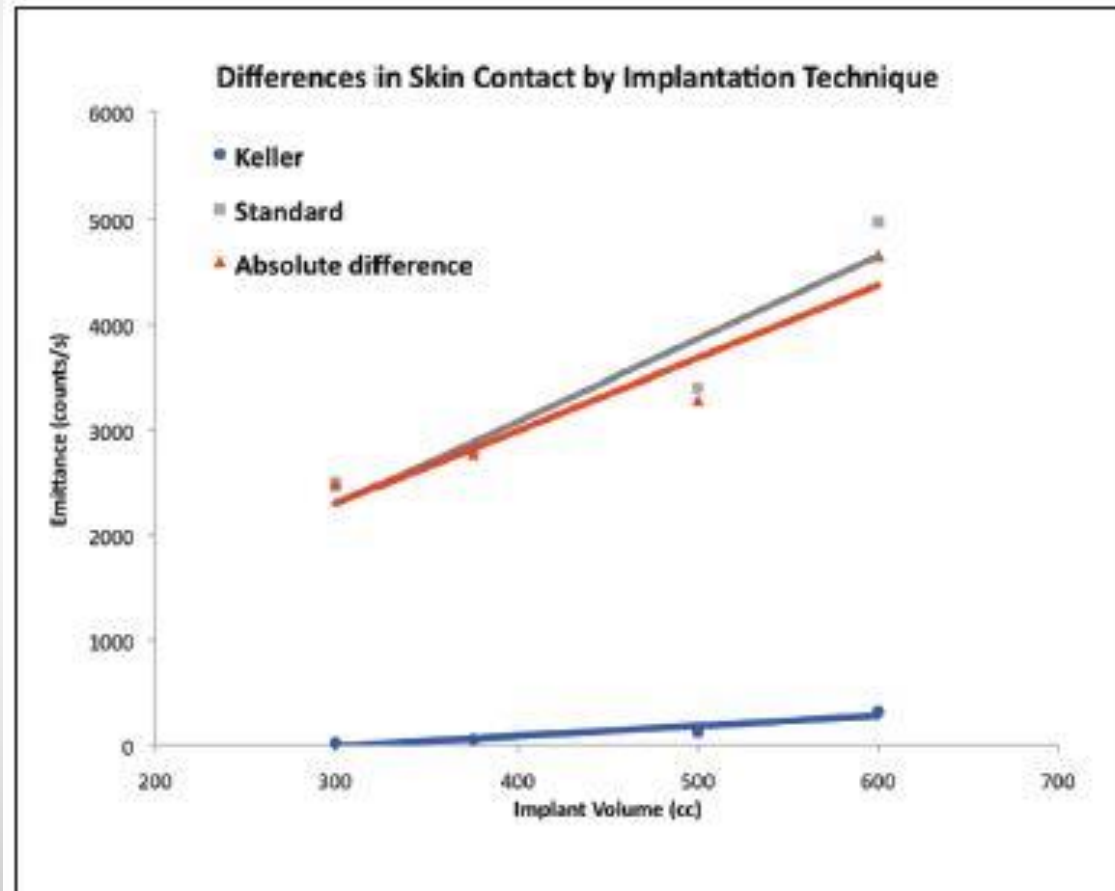
27-fold reduction
in skin contact

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



Keller Funnel

Breast Surgery

Preliminary Report

2015

Does Implant Insertion with a Funnel Decrease Capsular Contracture? A Preliminary Report

Nicholas A. Flugstad, MD; Jason N. Pozner, MD; Richard A. Baxter, MD; Craig Creasman, MD; Sepehr Egrari, MD; Scot Martin, MD; Charles A. Messa III, MD; Alfonso Oliva, MD; S. Larry Schlesinger, MD; and Bill G. Kortesis, MD, FACS

- 7 center retrospective analysis of CC related reoperation
- Reoperation within 1 year
 - 0.68% Keller Funnel (n=1620)
 - 1.49% no Keller Funnel (n= 1177)
- 54% reduction in CC reoperation

Zafirlukast (Accolate) & Montelukast (Singulair)

- Leukotrienes (LTs)
 - Produced by leukocytes
 - Promote inflammation & smooth muscle contraction
- Mechanism of Action
 - Block LTs at final inflammatory pathway

Prophylactic Singulair


COSMETIC

Rectangular Slip

Prevention of Capsular Contracture Using Leukotriene Antagonists

Ruth Graf, Ph.D.
Adriana S. K. Ascenço, M.D.
Renato da S. Freitas, Ph.D.
Priscilla Balbinot, M.Sc.
Carolina Peressutti, M.D.
Diogo F. B. Costa, M.D.
Fábio de H. C. R. dos Santos, M.D.
Marco A. S. Ratti, M.D.
Rodrigo M. Kulchetscki, M.D.

Curitiba, Paraná, Brazil



Background: Capsular contracture is a common occurrence in plastic surgery, with a prevalence varying from 0.5 percent up to 30 percent. Although the standard treatment is capsulectomy, alternative treatments have been studied, such as the use of leukotriene inhibitors. These drugs have recently been evaluated in the prophylaxis of contracture. The authors aimed to assess the efficacy of montelukast (Singulair) in the prevention of capsular contracture in patients undergoing mammoplasty with textured silicone prostheses.

Methods: The authors followed 82 patients (164 breasts) for a minimum of 2 years. Of these, 37 were administered montelukast.

Results: The number of affected patients and the severity were higher among the 45 patients who did not use montelukast.

Conclusion: The prophylactic use of Singulair was, in this sample, shown to be effective in helping to reduce the incidence of capsular contracture. (*Plast. Reconstr. Surg.* 136: 592e, 2015.)

CLINICAL QUESTION / LEVEL OF EVIDENCE: Therapeutic, III.

- 82 patients over 2 years
- Mostly subglandular & subfascial
- Reduction in CC with Singulair
- Not well designed study

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
- Subglandular – Consider textured over smooth
 - Seroma, ALCL, double capsule

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

Breast Augmentation: Surgical Decisions & Complications

Karol A Gutowski, MD, FACS

Instructional Course

plastic
surgery

THE MEETING

Los Angeles

September 23-27, 2016

