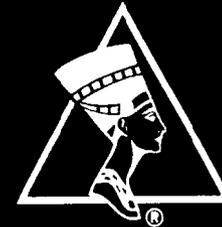




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The Silicone Breast Implant *Education Symposium*

Leaking vs. Ruptured Silicone, Capsulectomy vs. Capsulotomy – How to Decide

ASPS/PSEF – ASAPS

Laurie A. Casas, M.D

Silicone Gel Implants

Local Complications

- Capsular contracture, gel bleed, rupture, wrinkling, rippling, infection, calcifications
 - Some rates increase over time
 - Can require reoperation
 - Incidence can vary depending on
 - Surgical technique (SG vs. Sp)
 - Implant characteristics (shell, filler, age of implant)
 - Patient anatomy (tissue thickness, skin envelop)

FDA Guidance Document Draft 1/2004

- Most significant clinical concern
 - Rupture rate of silicone gel implants
 - Early detection
 - Clinical significance of intra or extra capsular rupture



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Data On Local Complications With Silicone Gel Implants

- Many reports (see bibliography)
- Large cohorts reported by Mentor and Inamed



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Data On Local Complications With Silicone Gel Augmentation

- Most common
 - Need for Reoperation (>20%)
 - Capsular contracture (SP<SG; baker III-IV ~7% early)
 - Implant leakage/rupture (~1% per year early)
 - Infection (1.5%)
 - Wrinkling (depends on site SG, SP, tissue thickness)

Literature References?



Relevant Definitions

- Baker Classification Capsular Contracture
 - I Soft, natural breast
 - II Little firm/no distortion/looks natural
 - III Breast feels firm/ looks distorted
 - IV Pain and Distortion



Relevant Definitions

- Capsule
 - Normal foreign body (breast implant) reaction
 - Thin vascular capsules
 - May be associated with baker III-IV capsular contracture
 - Thick, fibrous, avascular capsule +/- calcifications
 - Usually associated with baker III-IV capsular contracture



Characteristics Of Silicone Gel Implants 1960-2004

- Shell characteristics
 - Thick (early), thin (early), thicker with barrier internal layer to decrease gel bleed (since 1979)
- Silicone gel characteristics
 - Varying degrees higher molecular weight silicone gel (more “cohesive”) and low molecular weight silicone “oil” (liquid, greasy)



Relevant Definitions

- Silicone gel bleed or diffusion
 - Gel (low molecular weight “oil”) moves through the INTACT elastomer shell
 - 1960-1979 implants: varying degrees of bleed and shell thickness to improve “feel” and cap.contr.rate
 - Since 1993 only available silicone gel implants in US through controlled studies
 - Less gel bleed-more” cohesive” gel (i.e. Less low molecular weight silicone “oil”)
 - Thicker shell with 2nd interior barrier layer

Silicone Gel Bleed Or Diffusion Clinical Significance

- Local problem, not a systemic problem*
 - Increase in gel bleed associated with increase rate of baker III-I capsular contracture**
 - Increase rupture rate**

*E Bar-Meir(2003), S Gabriel(1994), J Sanchez-Guerro (1995),
P Tugwell(2002)

**JOM(2000), JS Marotta(2002)



Relevant Definitions

- Silicone Gel Implant Rupture
 - Silent Rupture
 - Shell disruption with gel outside of implant
 - Patient asymptomatic (no change in shape, no pain, or change in capsular contracture)
 - True incidence unknown



Relevant Definitions

- Silicone gel implant rupture
 - Shell disruption
 - Diagnosed by
 - Patient – following trauma
 - Physical exam – change in implant shape, sudden change in baker grade with or without pain, palpable mass
 - Imaging – suspected on mammogram, MRI



Relevant Definitions

- Silicone gel implant rupture
 - Intracapsular
 - Gel outside implant shell but within fibrous capsule
 - ? Clinical significance – local complication requiring reoperation
 - Extracapsular
 - Gel outside implant shell and fibrous capsule
 - Local complication requiring reoperation

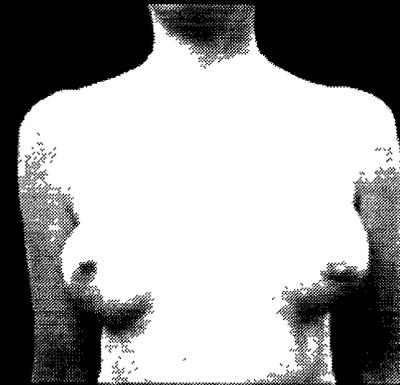


Calcified Fibrous Capsule

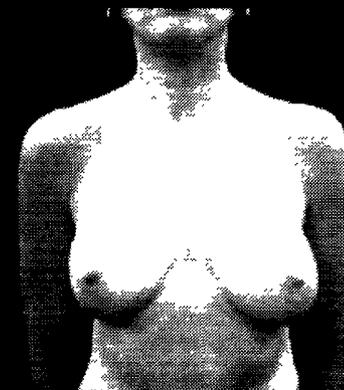


- Made of calcium pyrophosphate
- Related to AGE of implant not shell or gel*
- Associated with baker IV, palpable lumpiness
- Mammogram-breast obscured, calcifications benign
- Treatment
 - Total Capsulectomy and removal of visible/palpable gel

*Destouet(1992)



- 25 y/o SB silicone implant



- Total Capsulectomy, removal calcified capsule and intra-capsular intact R and ruptured L replace SB silicone

Relevant Definitions

- Silicone Granuloma
 - Local complication with NO systemic significance*
 - Rare complication
 - Represents Extracapsular silicone
 - Treatment: surgical resection

*ED Austad (2002)



Relevant Definitions

- Gel migration – extracapsular silicone that travels outside and migrates into chest cavity
 - RARE case reports
 - Diagnosis – palpable, visible radio opacities outside
 - Treatment – remove migrated gel



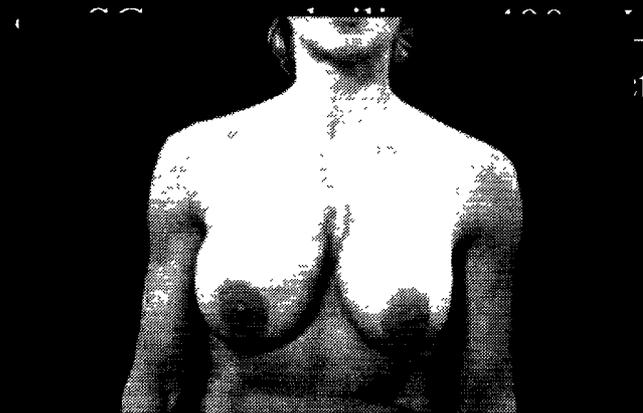
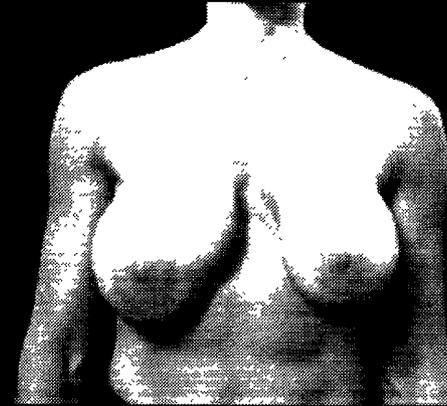
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Capsular Contracture – Baker III/IV

- Clinically significant
 - Distortion
 - Unnatural appearance and feel
 - Pain
- Treatment
 - Total Capsulectomy (if safe), change site, use appropriate implant for tissue characteristics



• Total capsulectomy, SP 375cc

Laurie Casas, MD - DRAF350 P. silicone smooth



Successful Treatment Of Baker III/IV Capsular Contracture And Lowering Recurrence Rate

- Guided by teachings, “data” and personal outcomes
 - 1992 (R Hester, P Maxwell, J Tebbets)
 - Total Capsulectomy and implant site change (as it related to polyurethane coated silicone implants)
 - 1998,2000 (VL young) total Capsulectomy when safe and re-implantation with a “change” of at least one variable; 1) implant position (SG/SP), 2) filler material (saline/silicone), or 3) surface type (smooth/textured)”
 - 2004 (P Maxwell)
 - Capsulectomy for capsules that distort breast shape
 - Implant site change (“virgin” pocket)

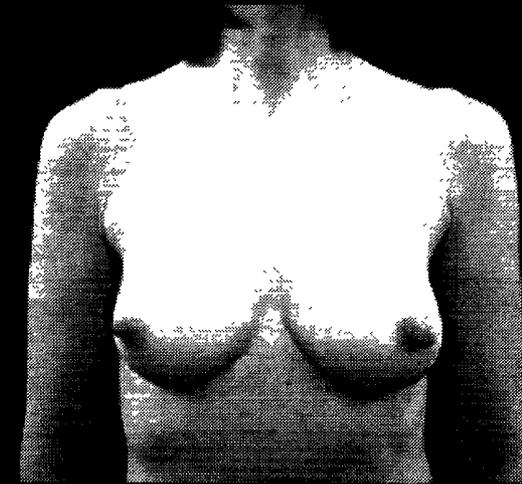


Indications For Capsulotomy

- Closed Capsulotomy for Baker III/IV Contracture
(Manually squeezing the breast to tear the fibrous scar capsule)
 - Not recommended
 - Product warranty issues
 - Implant related risks
 - » Shell rupture
 - » Silicone extracapsular leakage
 - Soft tissue related risks
 - » Bleeding
 - » Uneven capsular release – distortion, unnatural appearance
 - » High recurrence rate (R Moufarrege, AnnPlastSurg 19:62,1987)

Indications For Open Capsulotomy

- Implant Malposition without Baker III/IV*
 - T.E. Conversion to permanent implant
 - Pocket adjustment to better shape breast mound (manufacturers package insert: single use only)
 - KEY: prevention with meticulous intraop. Pocket creation/assessment.



*VL young PRS 102:884,1998

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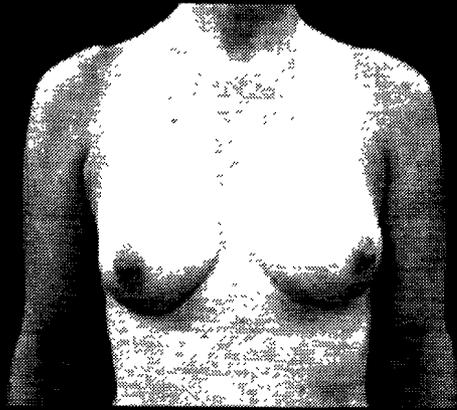
Indications For Total Capsulectomy +/- Implant Replacement*

- Treatment of silicone ruptured implant +/- silicone Granuloma (obscures breast tissue on mammogram)
- Treatment of calcified, thick capsules (palpable mass, obscures breast tissue on mammogram)
- Treatment of Baker III/IV (pain/distortion)
- Treatment of chronic Seroma or infection around an implant (chronic infection)

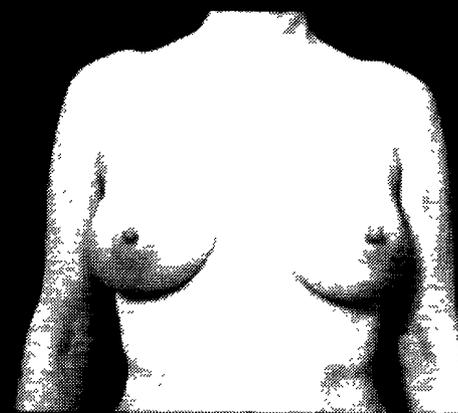
*VL young (1998)

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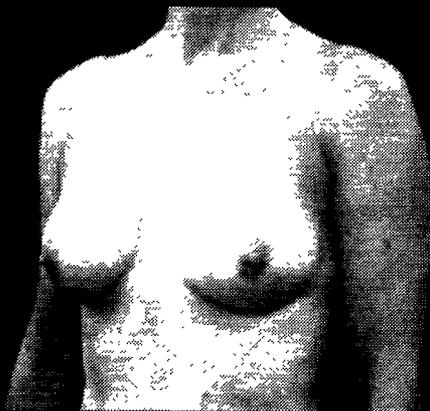
Rationale For Total Capsulectomy Must Outweigh Risks: (SG Usually Straightforward)



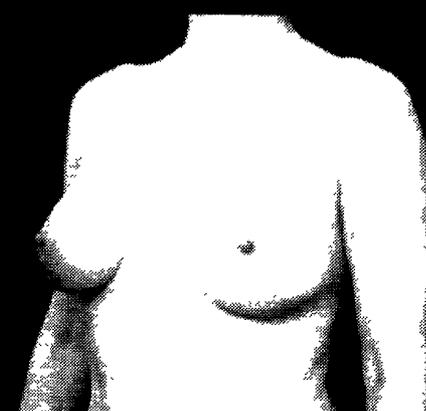
- SG 200cc silicone baker IV, intact



- Total Capsulectomy, SP 325cc



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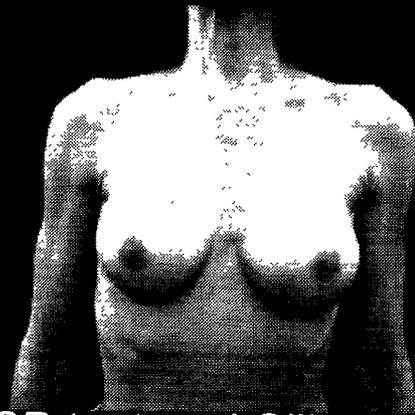
Indications Partial Capsulectomy For Treatment Baker III/IV

- When risks* of total Capsulectomy outweigh the benefits**
 - SP Baker III/IV without calcifications
 - SP Baker III/IV without rupture
 - SP Baker III/IV that extends into axillary contents

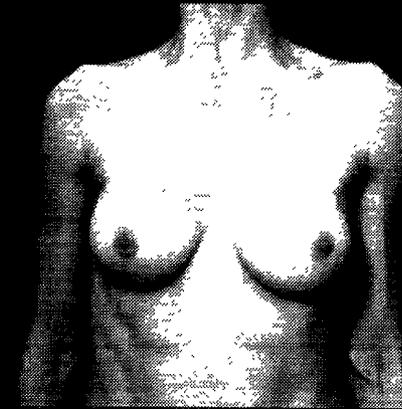
*Risks of bleeding and pneumothorax

**VL young(1998)-"change one variable"

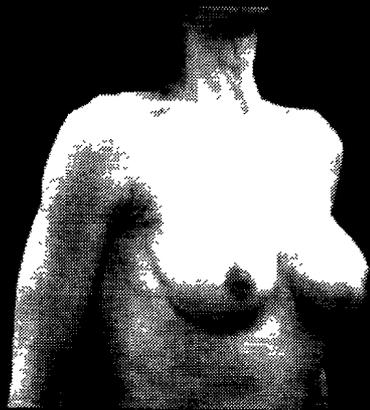
Indication For Partial Capsulectomy (Implant Shell And Size Change)



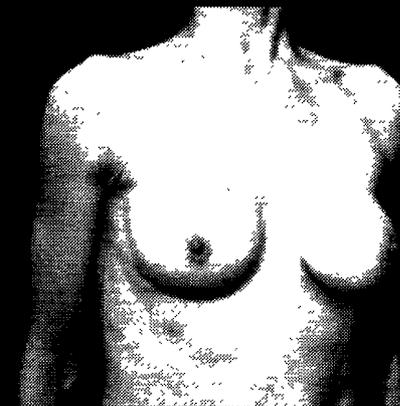
- SP textured Silicone 250cc, Baker III, L medial rippling, R contracted pocket
- Distorted appearance



- L-Superior Capsulectomy
- R-Lateral Capsulectomy
- SP 175cc smooth silicone



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Prevention Visible Wrinkling And Rippling

- Assess tissue quality and thickness
 - Inadequate tissue coverage
 - Dictates SP placement
 - Smooth surface in SP position will have least risk for wrinkling
 - Rate for Baker III/IV capsular contracture similar in SP position for textured and smooth
 - Adequate tissue coverage
 - SG position good option however increase in CC III/IV for smooth vs. Textured
 - SG textured silicone less chance for wrinkling, however not available, SG textured saline has increase rate of wrinkling

Conclusions

- Long term-ONGOING-research needed to establish*
 - Rupture Rates by implant type (shell and filler) and position (SG vs. SP)
 - Longevity of Implant by Type and Position

*Combine Randomized Prospective Trials with Ongoing “Registry” Data



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Conclusions

“Prevention is better than a cure as far
as capsular contracture is concerned”.

Collis (2000)



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Thank You

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Evolution and Advances in Breast Surgery – 2004: How to Decide