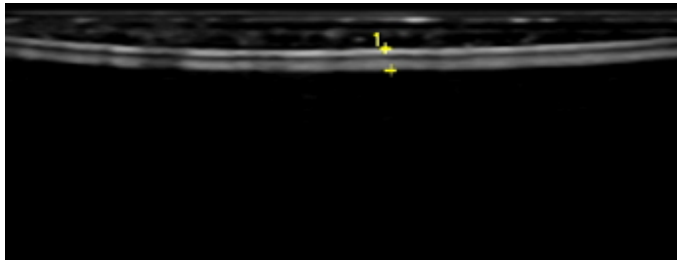
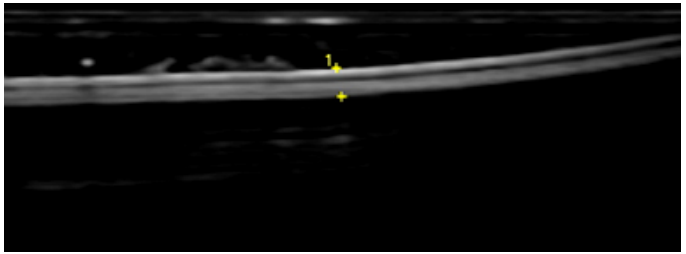
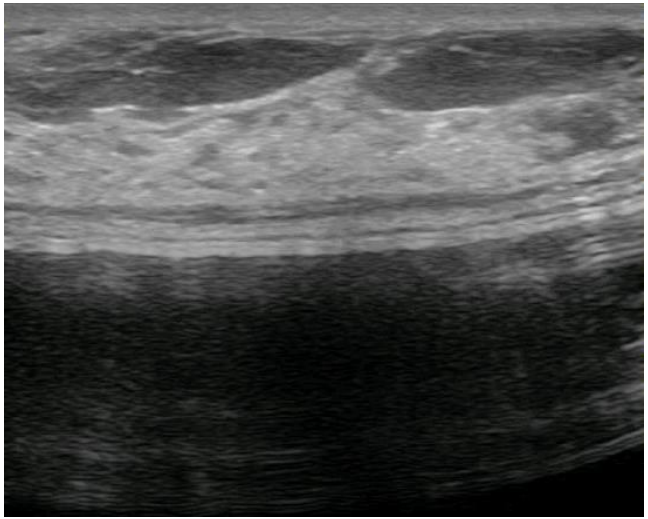
ASAPS Instructional Course – New Orleans 2019





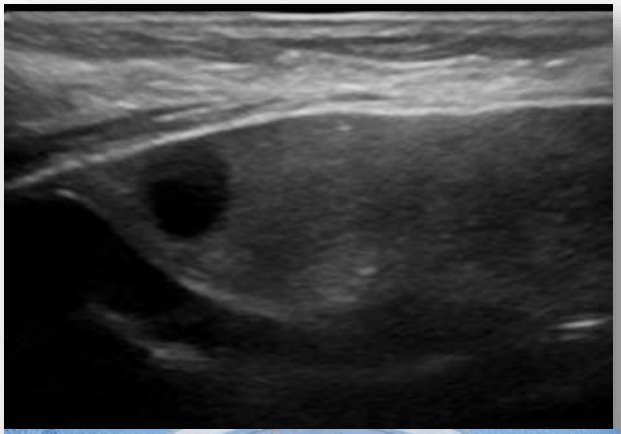
- Everyone needs a good implant screening system:
  - FDA
  - Manufacturers
  - Plastic Surgeons
  - Patients
- Requires a reliable hardware platform, a Hi Res transducer 8-16 MHz, Software platform for plastic surgeons
- Implant & HRUS technologies are converging
  - Implants more cohesive & higher fill
  - Ultrasound technology more accurate

Current State of HRUS



- Ultrasound and Image guided procedures are gaining acceptance

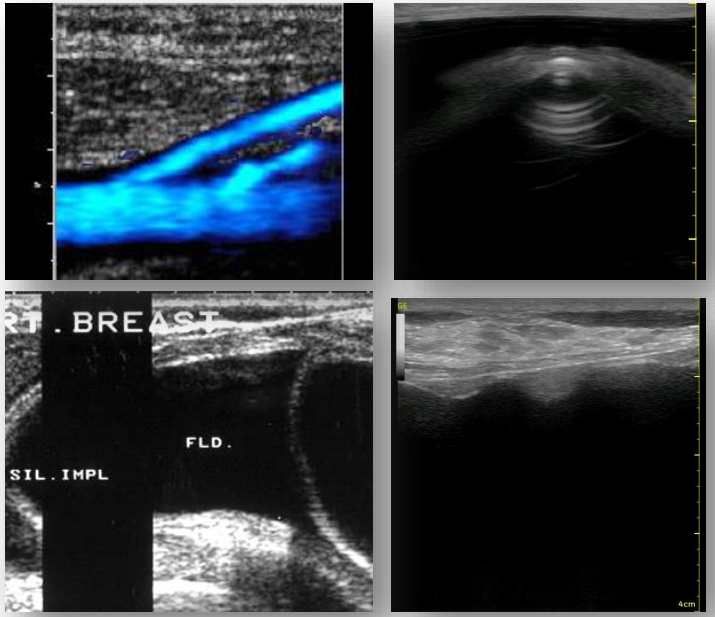
  Ultrasound has been popular as an alternative to MRI. The advantages include decreased cost and time; no pain, dynamic screening options and increased patient compliance for breast implant monitoring



PS Opportunities

- Breast Implant - Shell failure
- Breast Implant – Rotation
- Breast Implant – Gel Fracture
- Seroma vs. Swelling Breast
- Hematoma – Acute Trauma
- Tissue Expander Port ID
- Implant Capsule/ADM evaluation
- Fat Transfer Guidance & Evaluation
- Breast Evaluation – General

Additional Applications

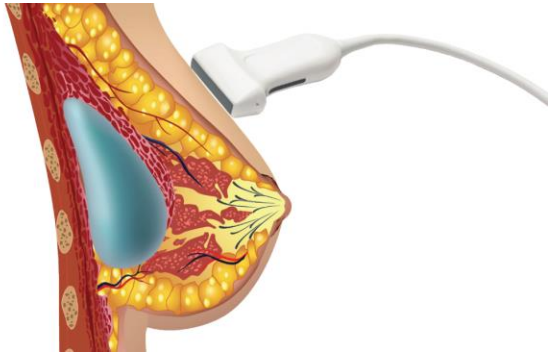


- Seroma ID body vs edema
- Lap-band ports - ID other ports
- Mandible/Facial fractures
- Hand Fractures and management
- Vein identification & ablation
- Muscle ID for Botox – Corrugators
- Future Research

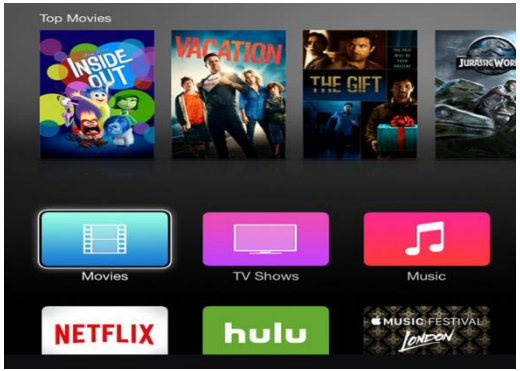
It’s an Entire System

- Ultrasound Hardware

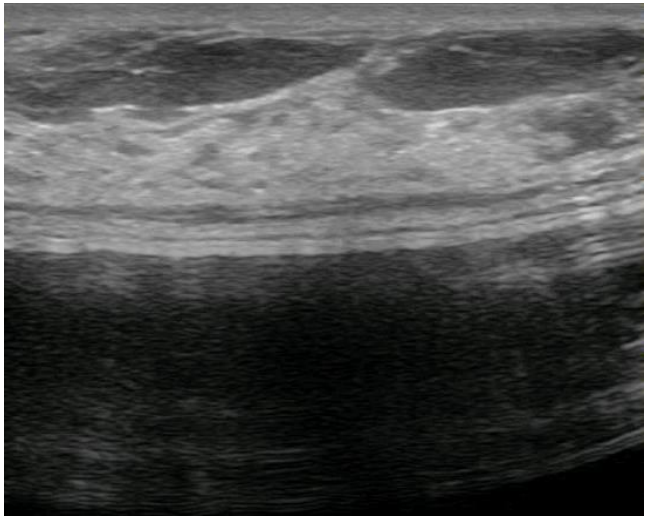
- Hi Frequency Transducer



- Software Platform

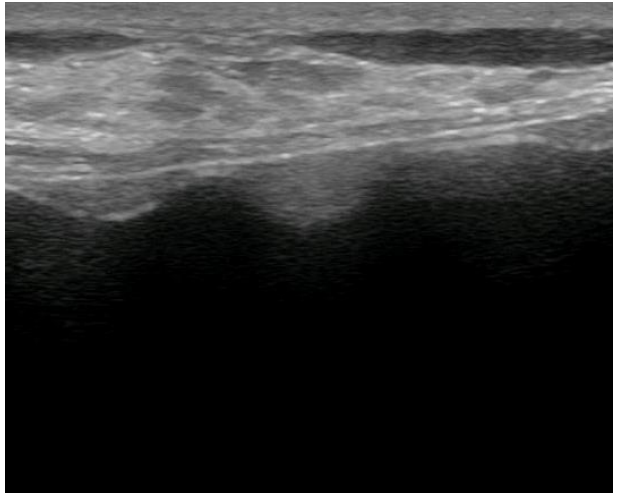


Basic Requirements



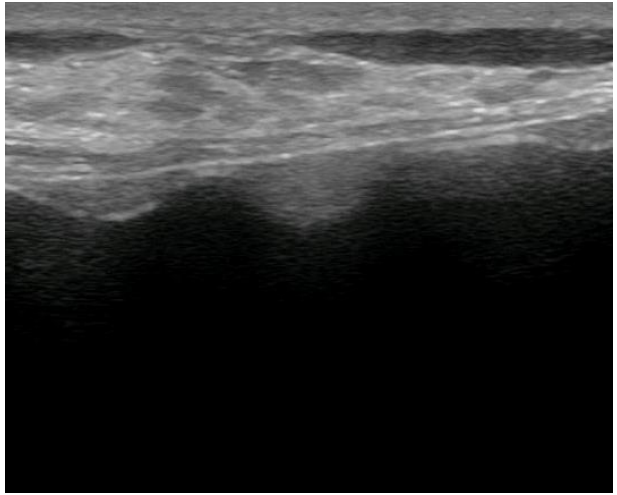
- Reasonable Cost
- Reliable/ minimal downtime
- Straightforward to navigate
- High quality images
- Resource library
- Training and follow-up
- Good support and follow-up
- Continued enhancements
- Eventual Accreditation

Software Suggestions



- Each application will have optimized initial settings
- Have basic adjustments easily accessible: Depth, Brightness, Sharpness…with Toggle bar
- Easy database search
- Save as .jpeg .tiff .mov …
- *Wifi connectivity to send directly to email, patient chart - EMR

Library of Comparisons



- Have smooth-textured-intact images
- Seroma images, etc. that can be brought up to compare to current imaging patient
- Easy transfer of images

PS Applications

- Breast Implant - Shell failure
- Breast Implant – Rotation
- Breast Implant – Gel Fracture
- Seroma vs. Swelling Breast
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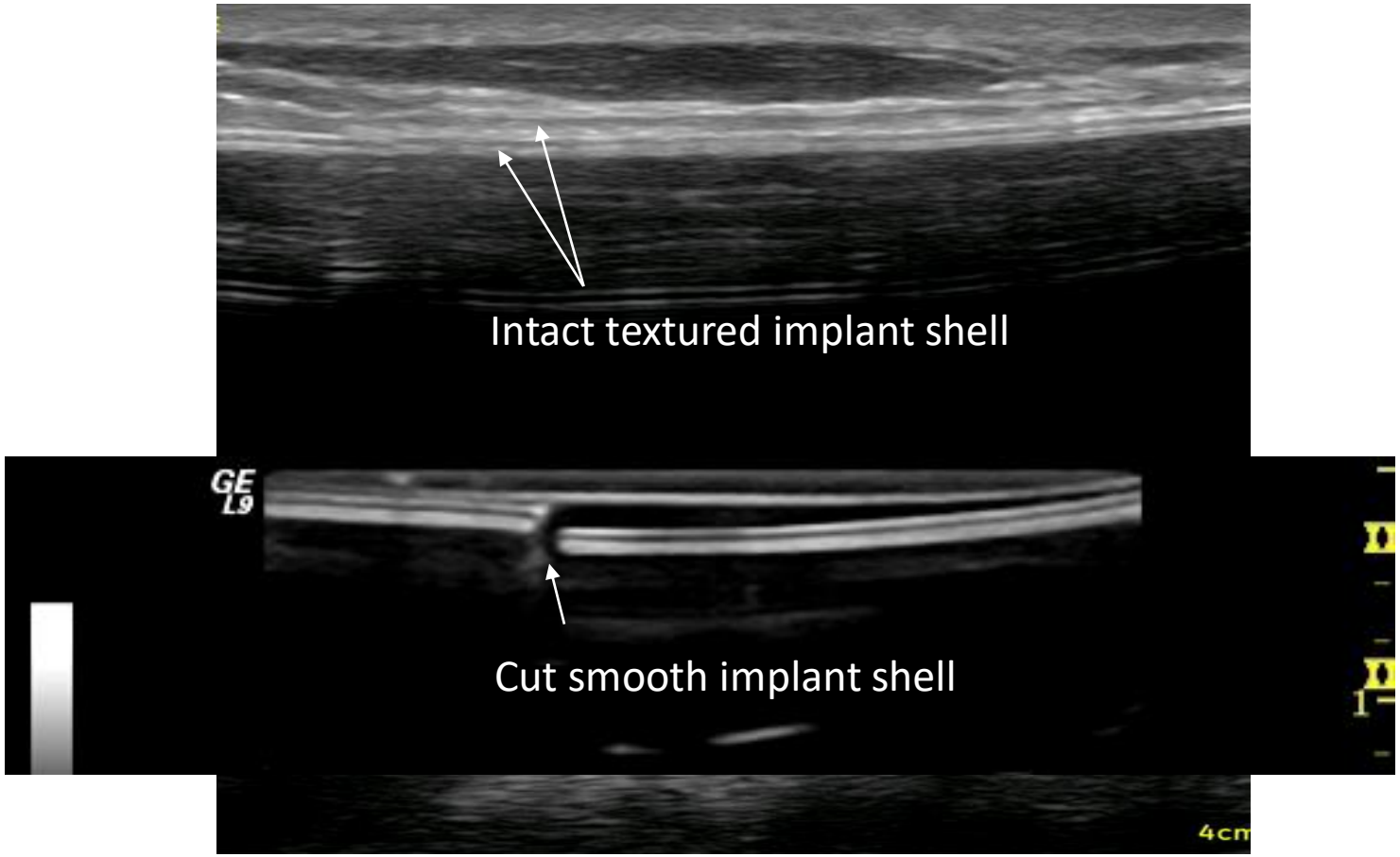
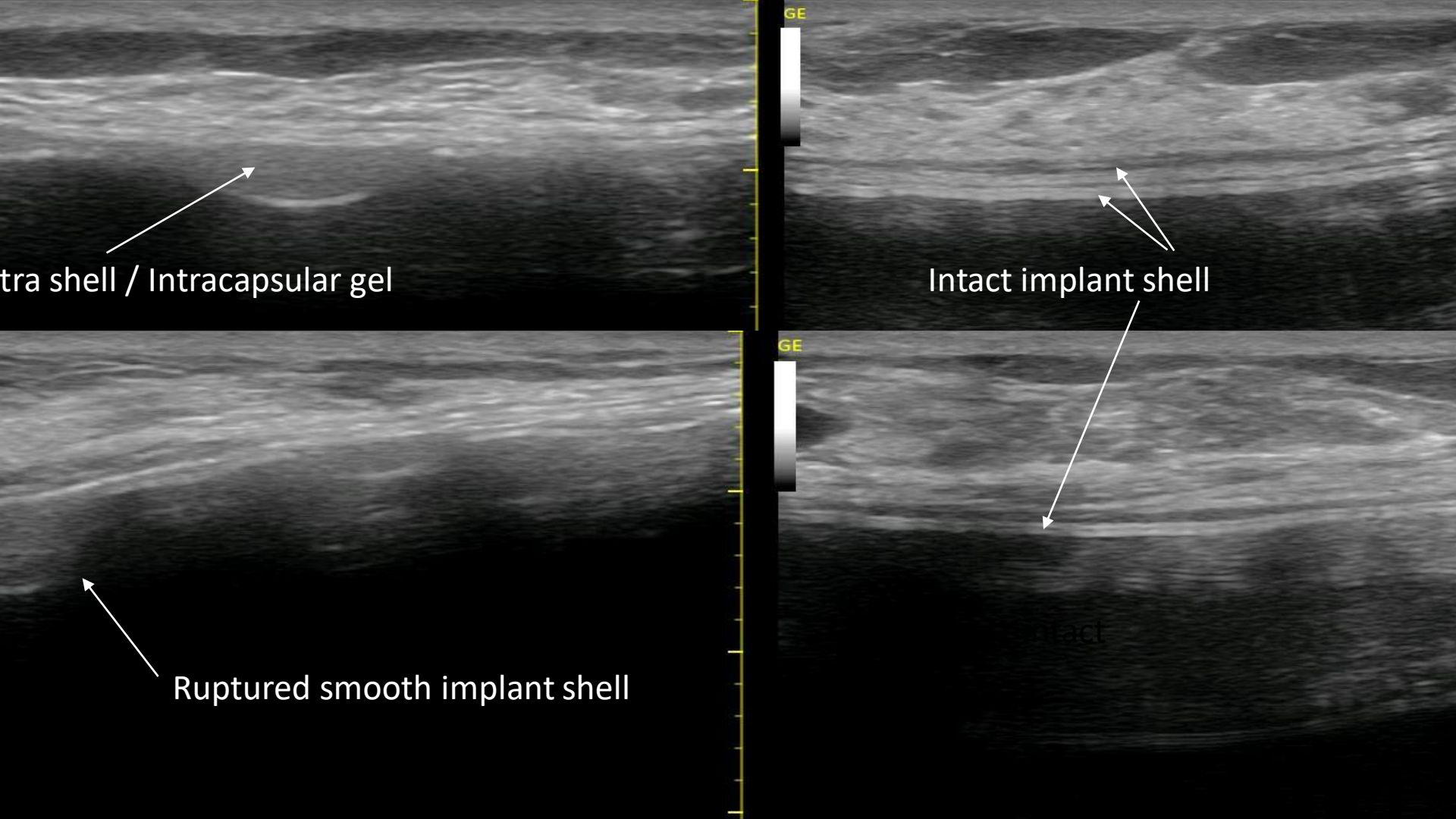
- Tissue Expander Port ID
- Implant Capsule/ADM evaluation
- Fat Transfer Guidance & Evaluation
- Breast Evaluation – General
- Future & Other Applications

ROI Potential

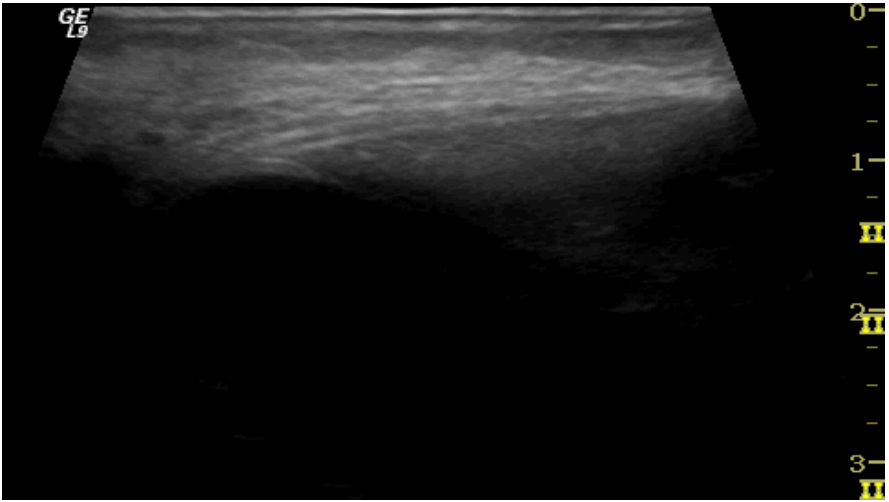
- Whoever dx the rupture does the revision
- Could charge $500-1000 /pt to screen their devices for life or charge per screening
  (I put in $1000 for lifetime screening but then back out to show it has value)
- Get patients back in office yearly to screen purchase products---add surgery-products
- Charge insurance for ultrasound drainage of seromas---looking into charging insurance for implant screening
- Define breast swelling vs Fluid collection
- Patient piece of mind = “Priceless”


Intact textured implant shell
GE
L9
Cut smooth implant shell
4cm

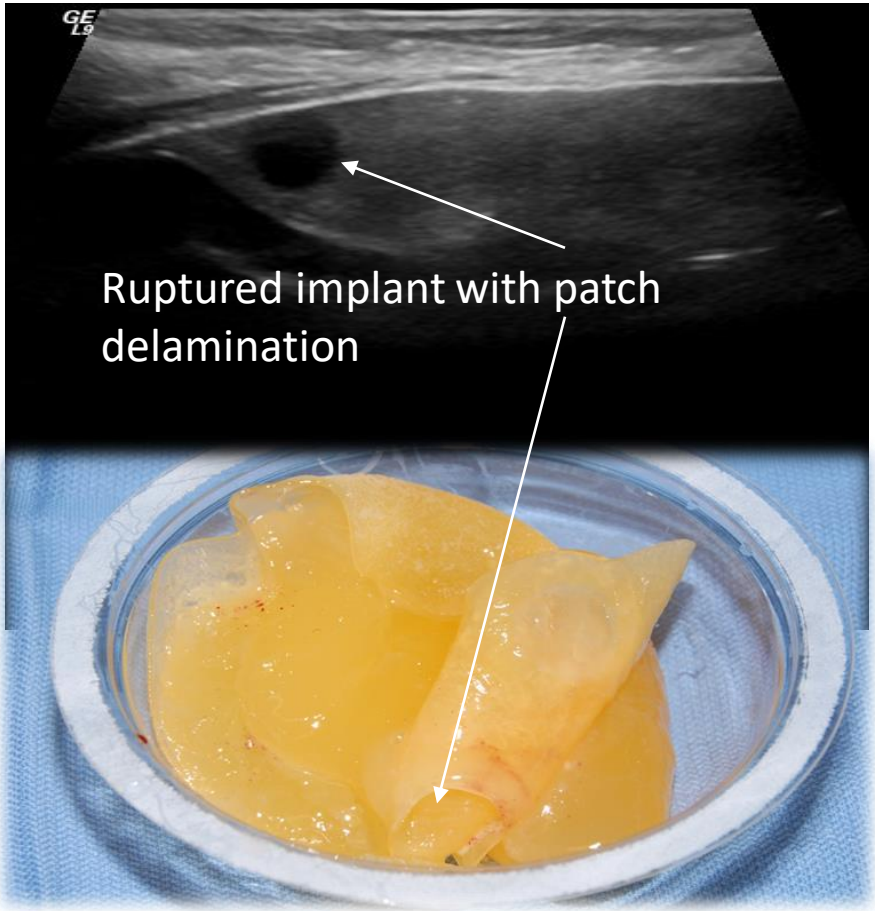

tra shell / Intracapsular gel
Intact implant shell
Ruptured smooth implant shell
Intact

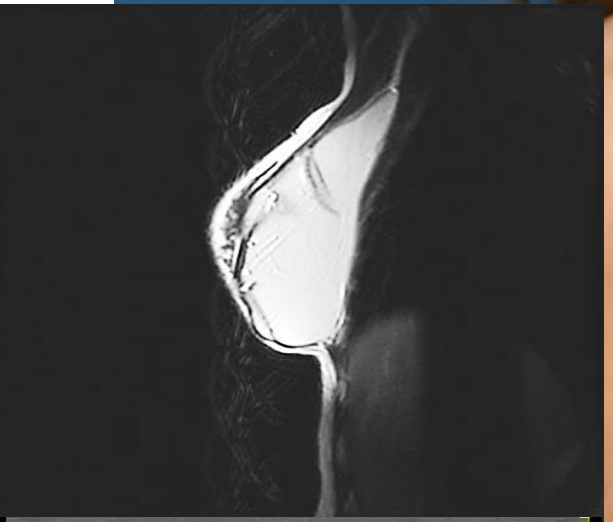

GE
4cm

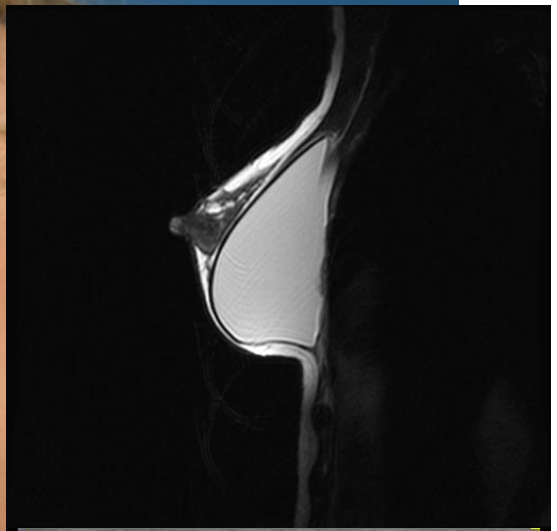

GE
4cm



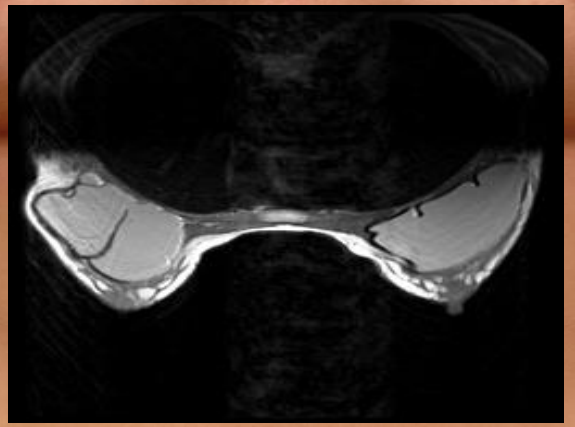
Video showing gel outside of the shell but intracapsular



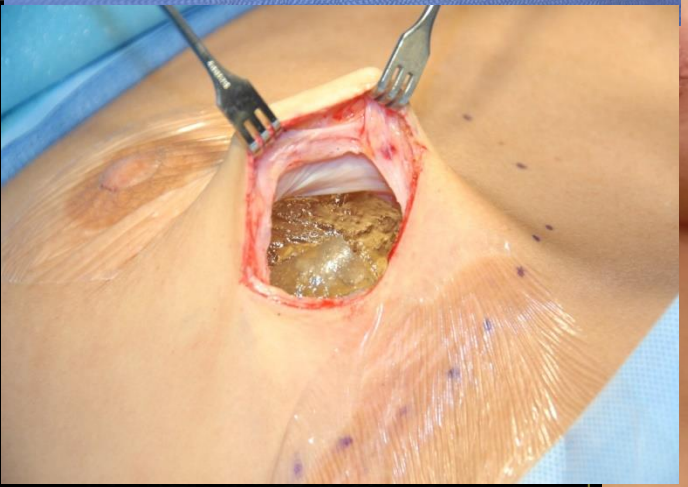


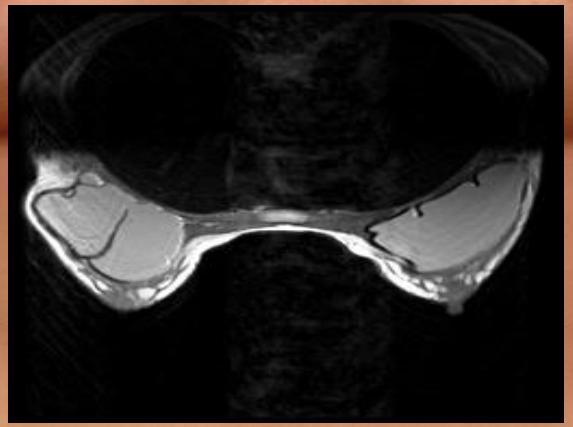


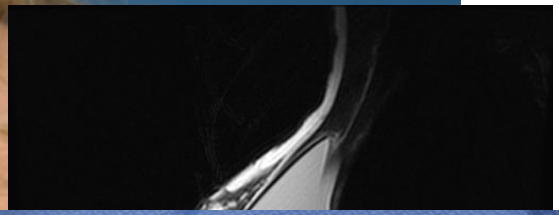

GE
4cm

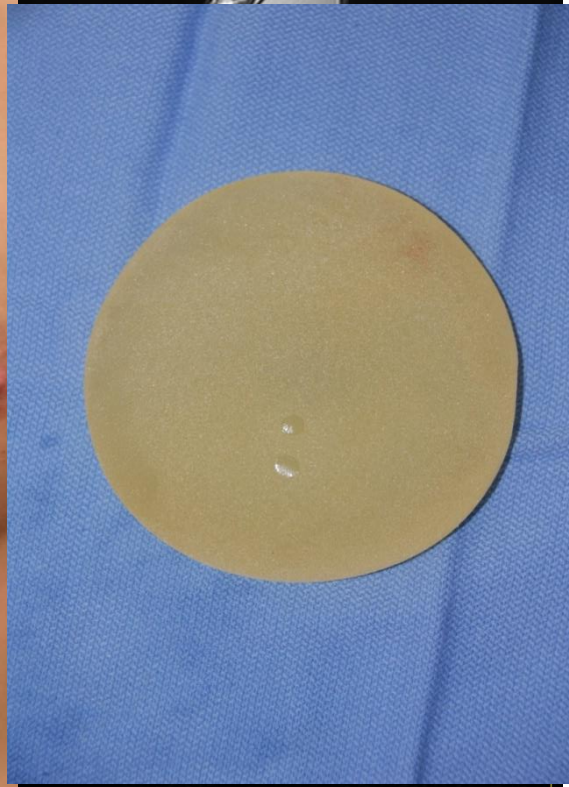


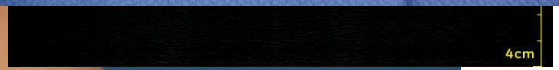

GE
4cm

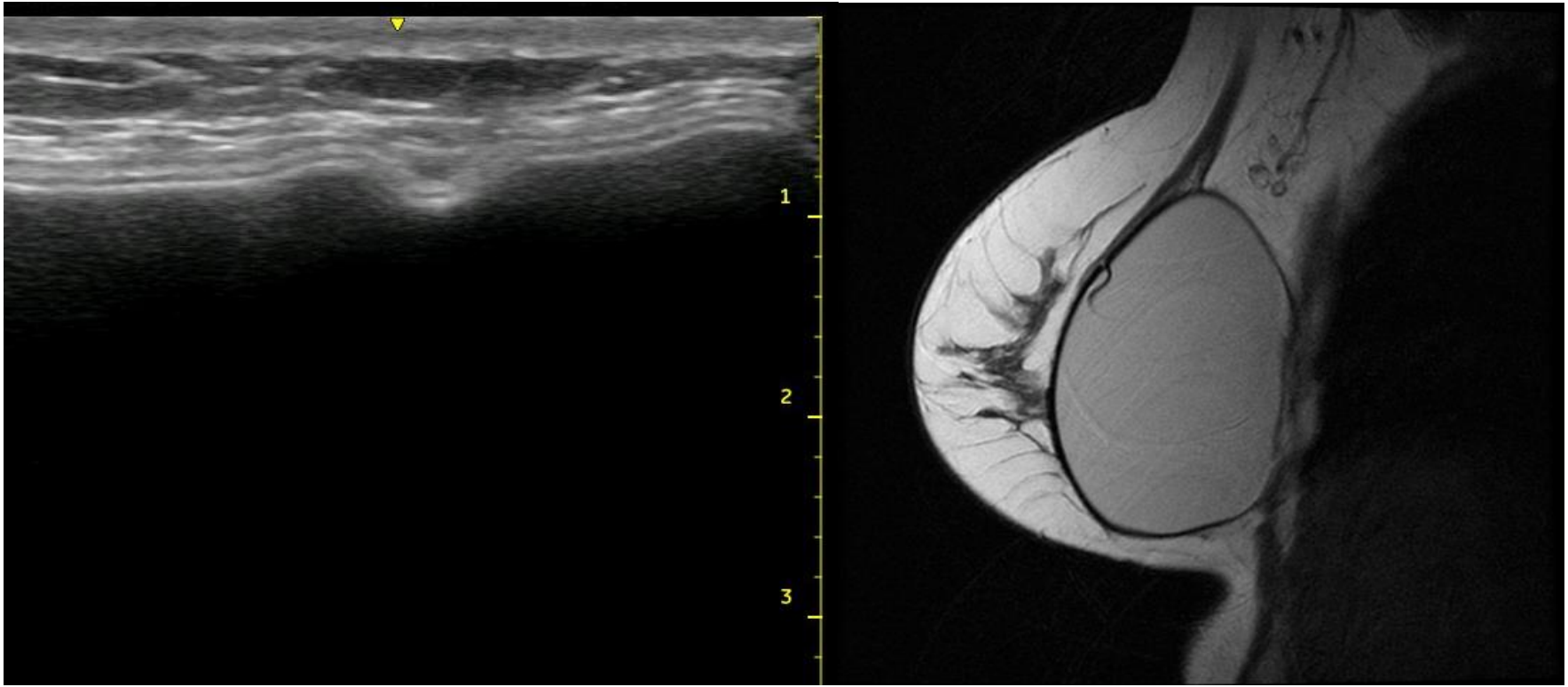

4cm

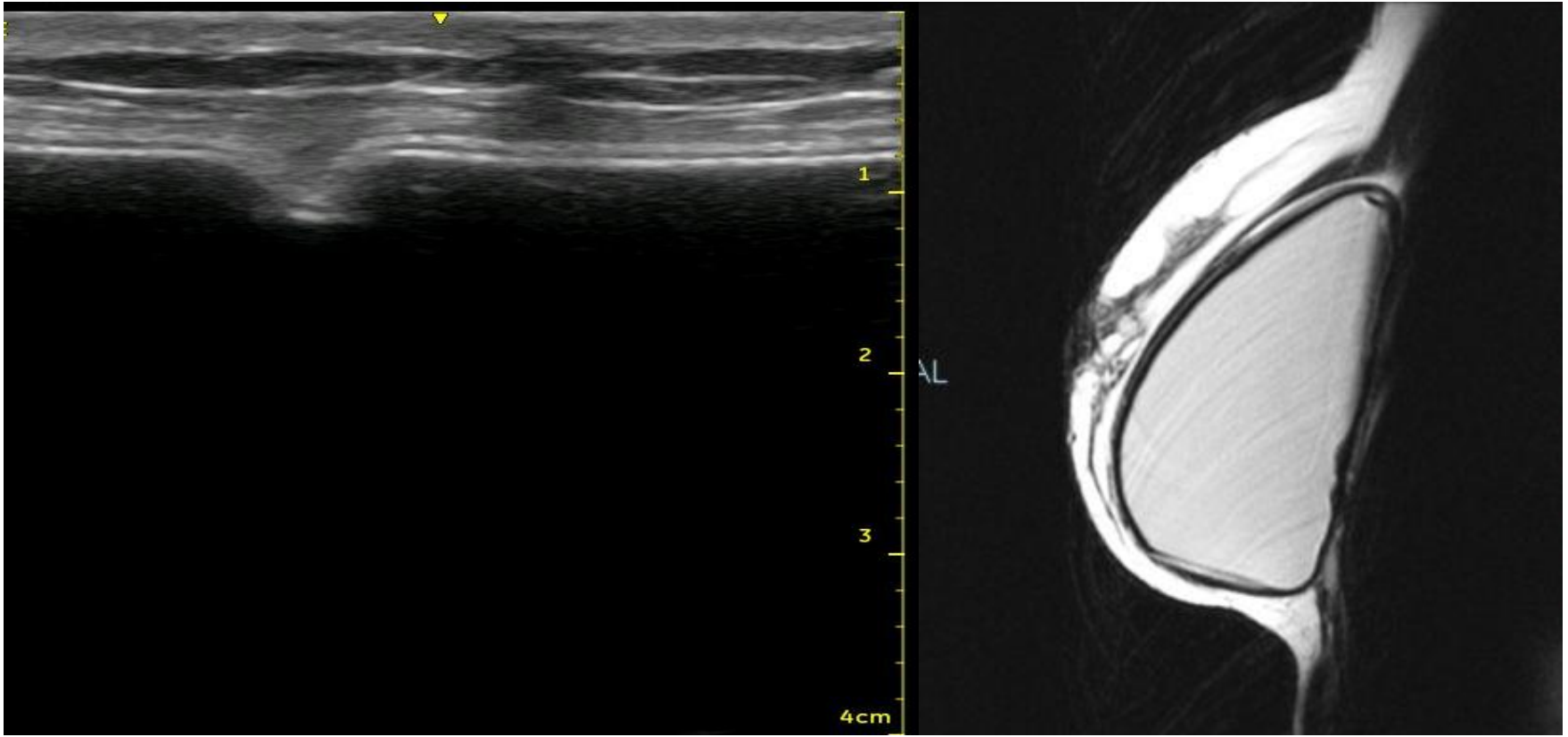






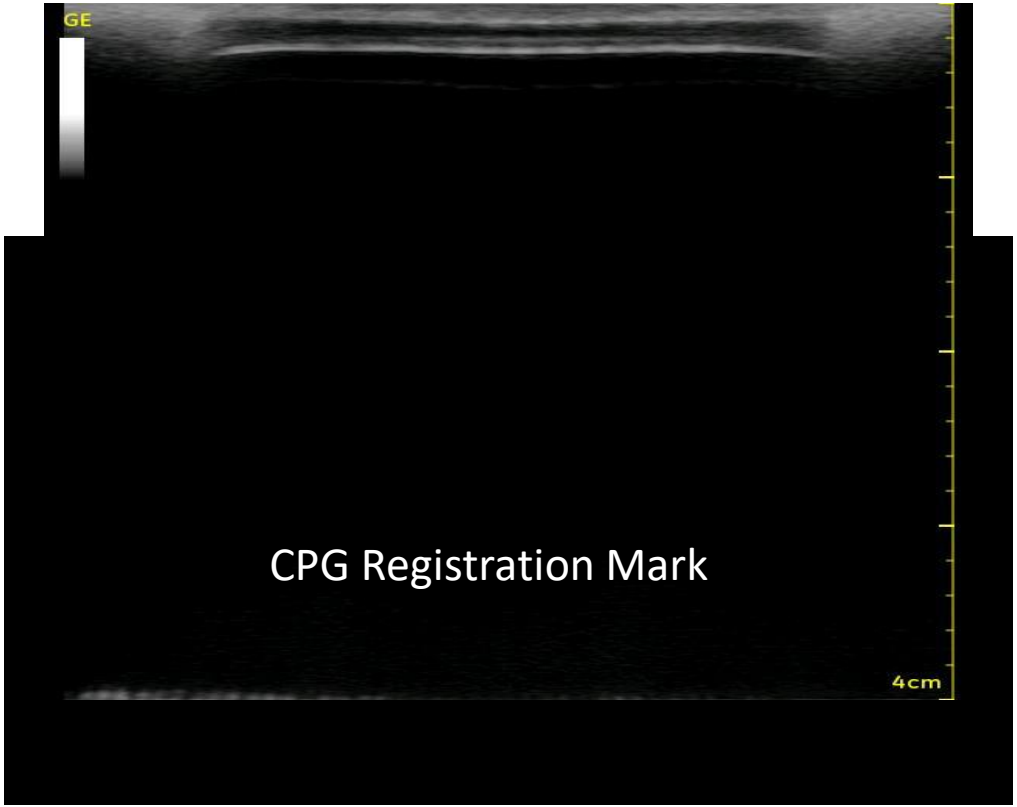

4cm


1
2
3

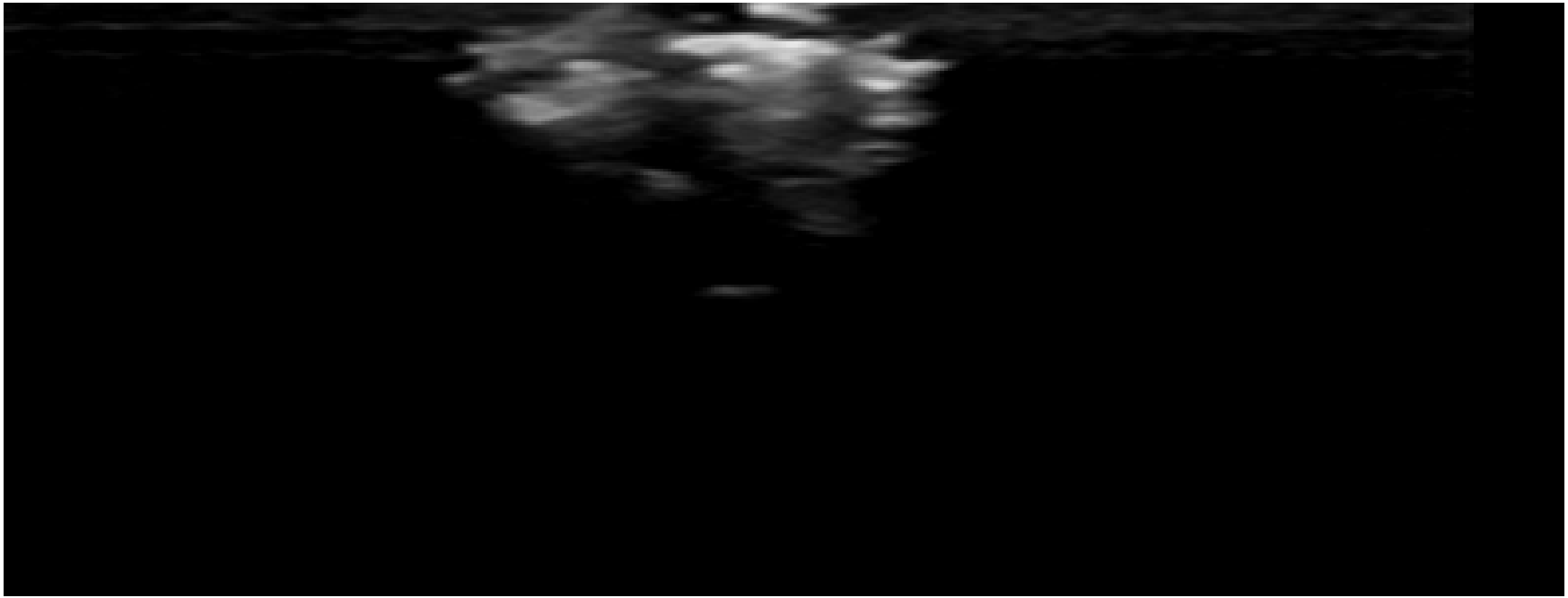

1
2
3
4cm
AL

Rotation – Registration Marks

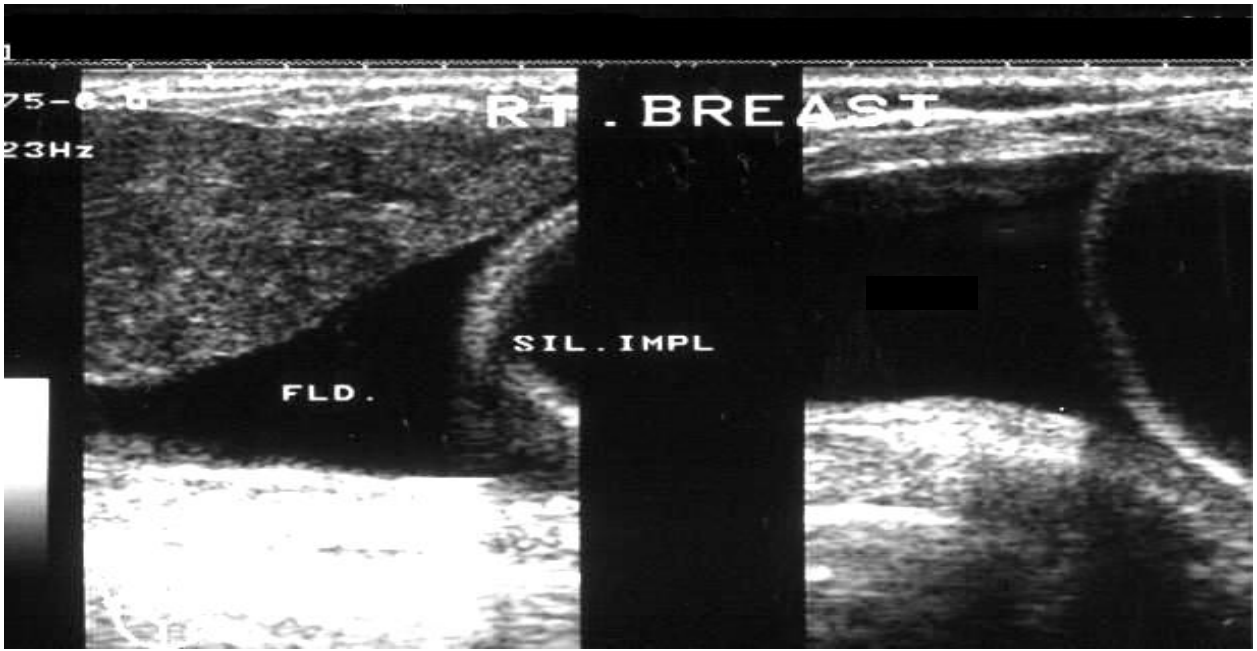
Rotation – Registration Marks



Internal Gel Fracture



Fluid - Seroma



Current Research

Plastic & Reconstructive Surgery:
POST ACCEPTANCE, 25 March 2011
doi: 10.1097/PRS.0b013e318217fdb0

Managing Late Periprosthetic Fluid Collections (Seroma) in Patients With Breast Implants: A Consensus Panel Recommendation and Review of the Literature

Bengtson, Bradley MD; Brody, Garry S. MD; Brown, Mitchell H. MD; Glicksman, Caroline MD; Hammond, Dennis MD; Kaplan, Hilton MD, PhD; Maxwell, G. Patrick MD; Oefelein, Michael G. MD; Reisman, Neal R. MD, JD; Spear, Scott L. MD; Jewell, Mark L. MD; Late Periprosthetic Fluid Collection After Breast Implant Working Group

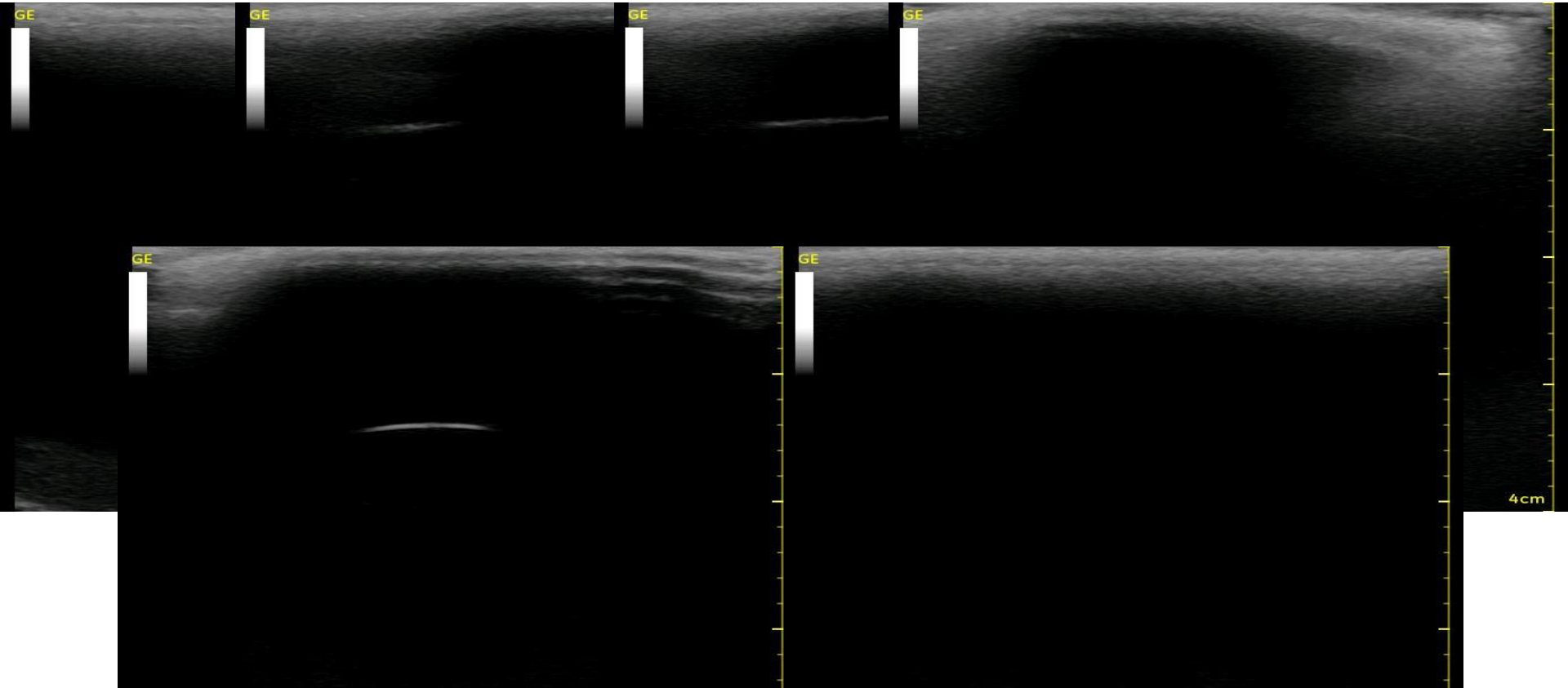
Abstract

Background: The goal of this consensus is to establish an algorithm for the management of patients who develop a late or delayed periprosthetic fluid collection. A work group of practicing plastic surgeons and device industry physicians met periodically by teleconference and discussed issues pertinent to the diagnosis and management of late periprosthetic fluid collections in patients with breast implants. Based on these meetings, treatment recommendations and a treatment algorithm were prepared in association with an editorial assistant.

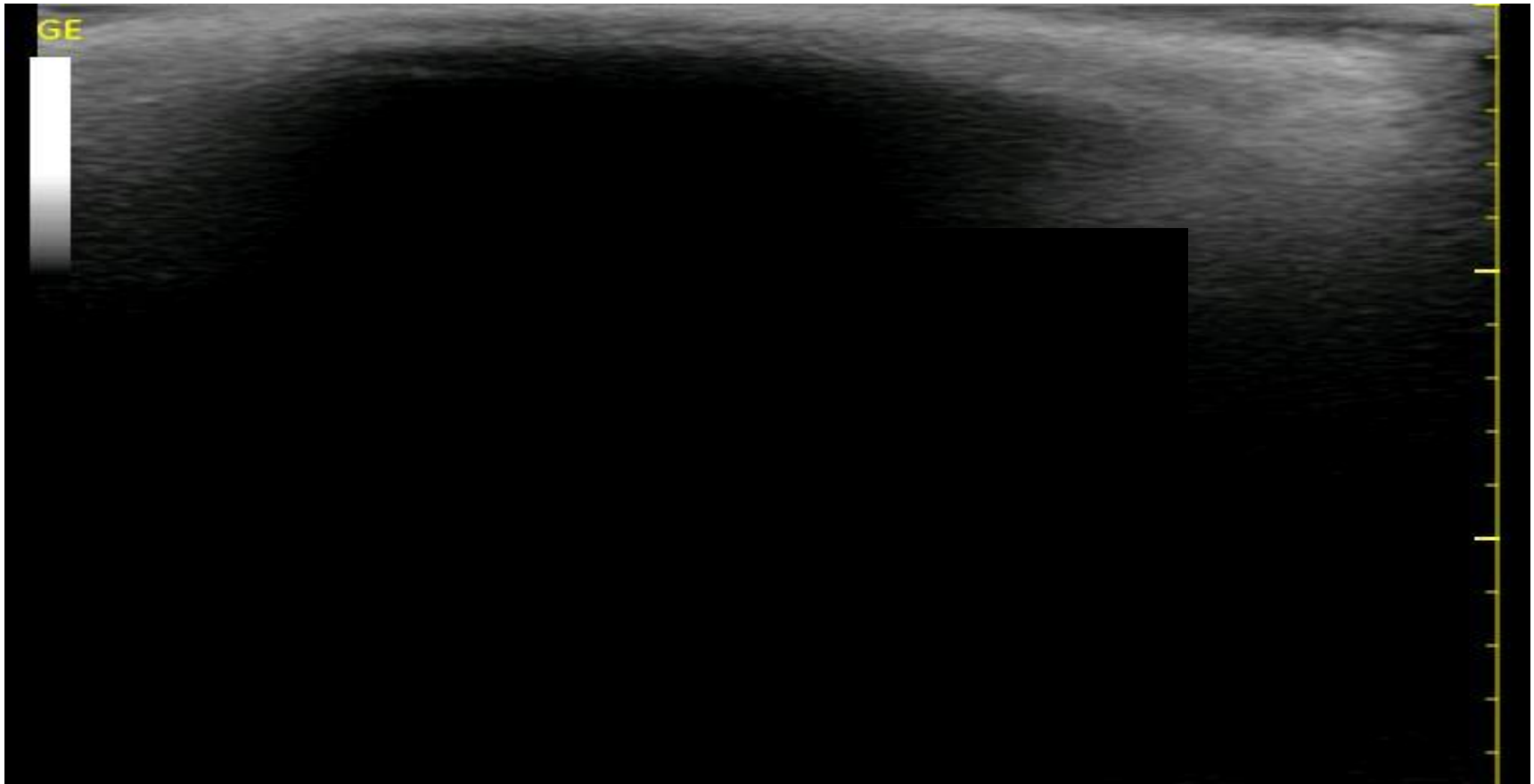
Method: The work group participants discussed optimal care approaches developed in their private practices as well as from evidence in the literature.

- Late Seroma Management
- Ultrasound key in initial evaluation
- Swelling vs. Fluid

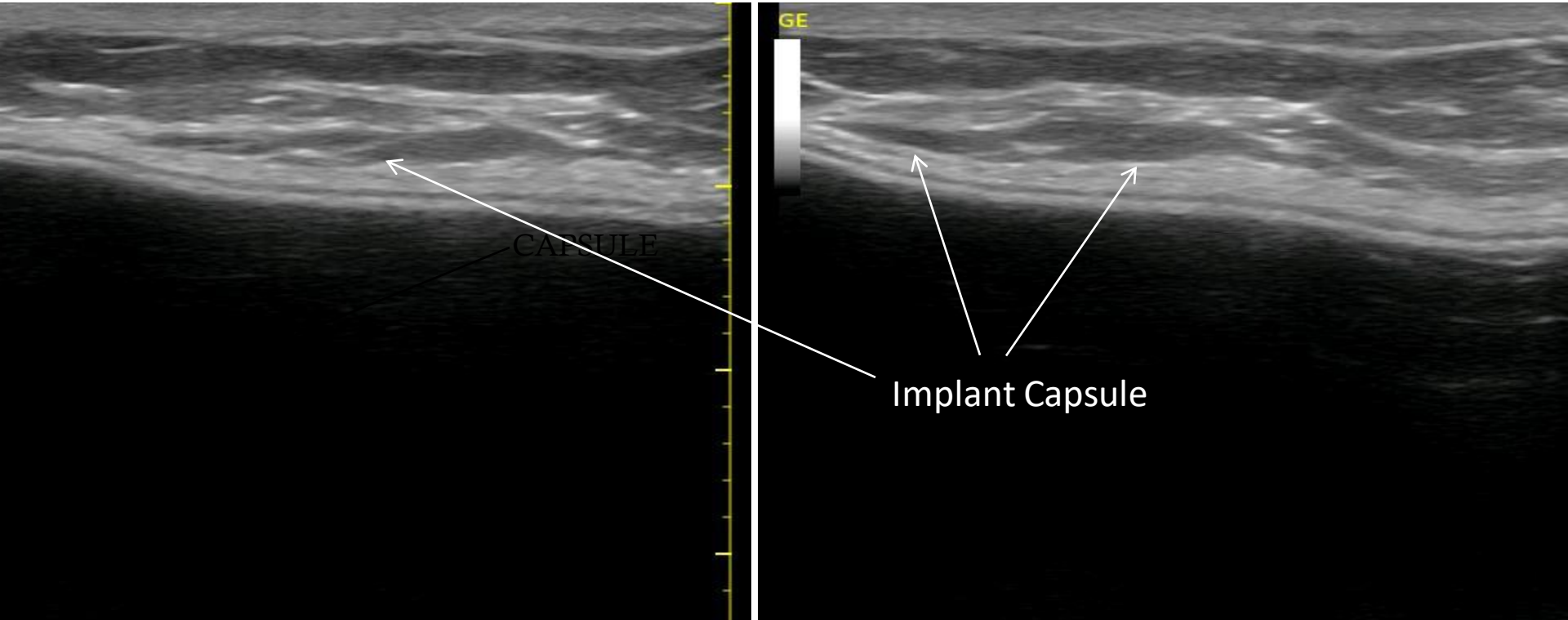
Tissue Expander Port ID



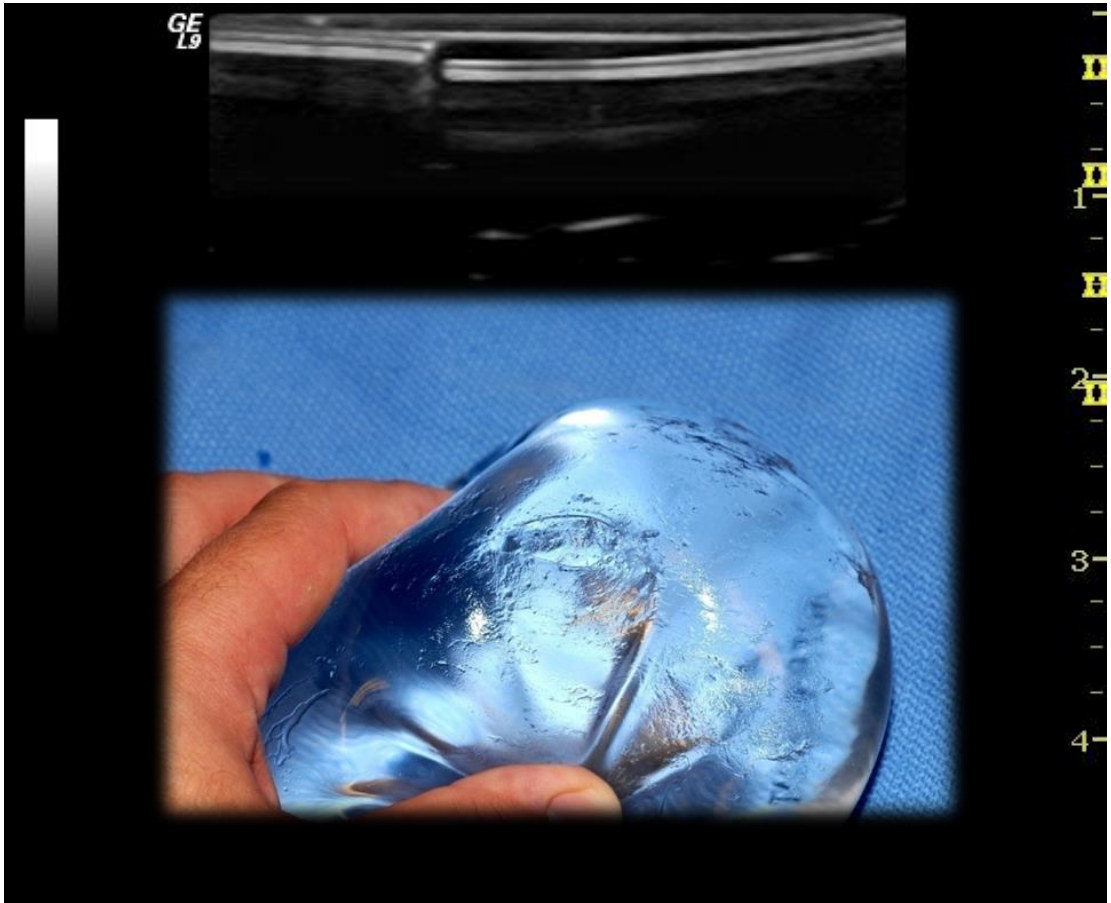
Tissue Expander Port ID



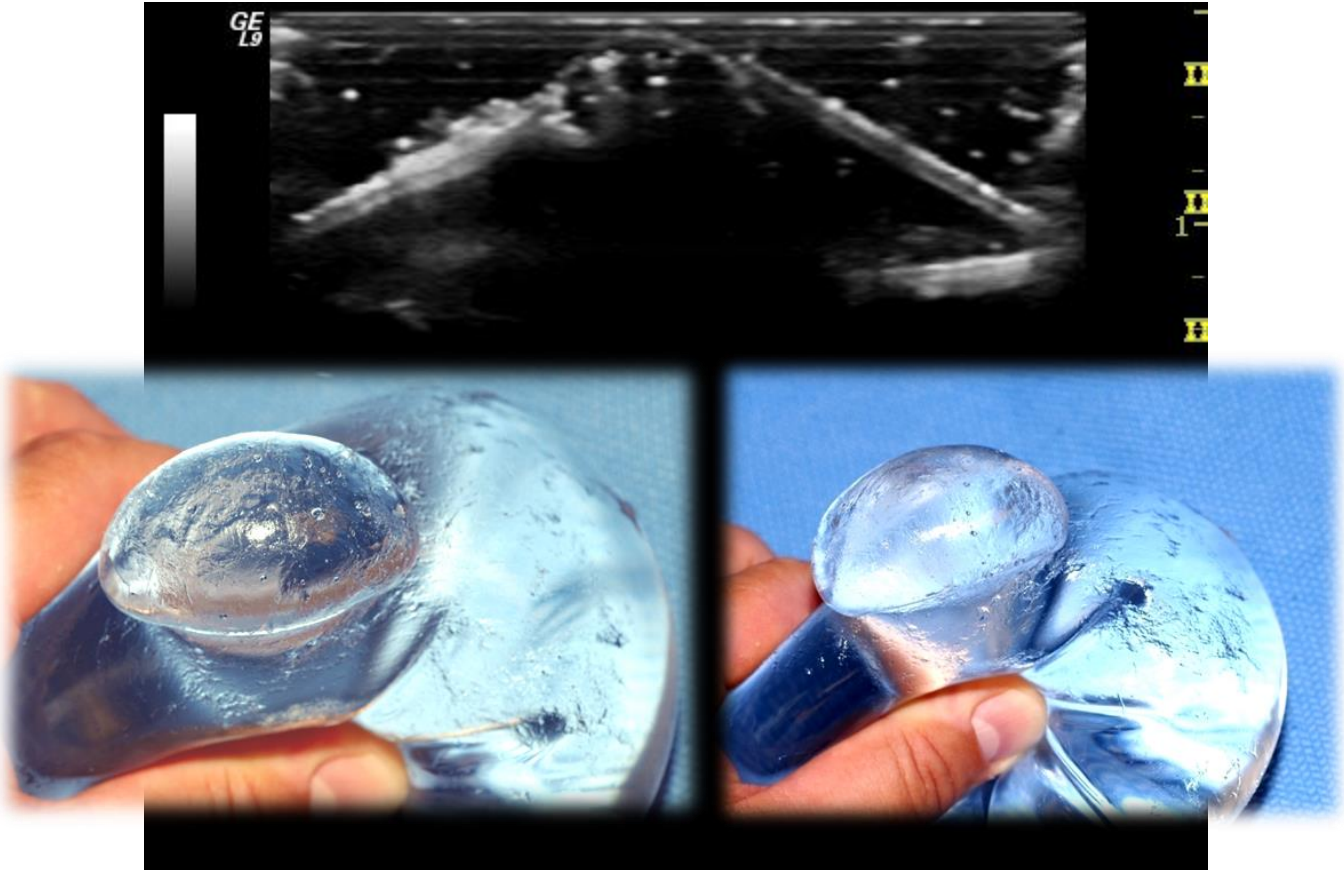
Implant Capsule



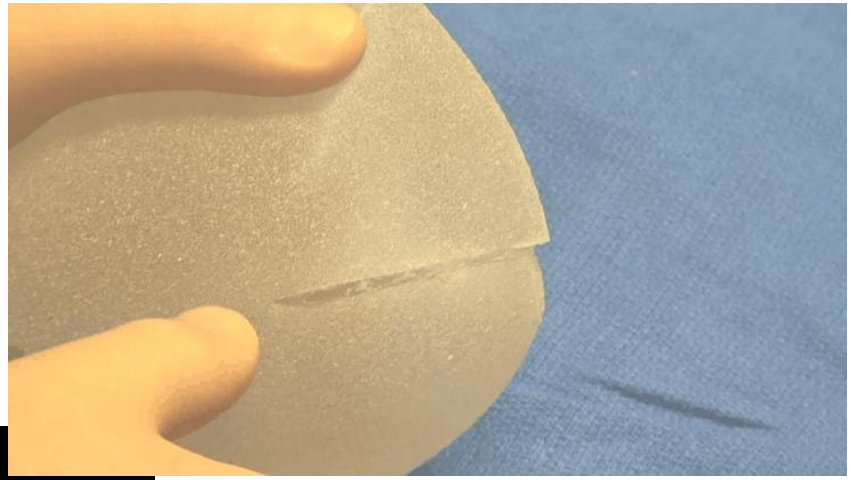
Natrelle smooth implant shell cut

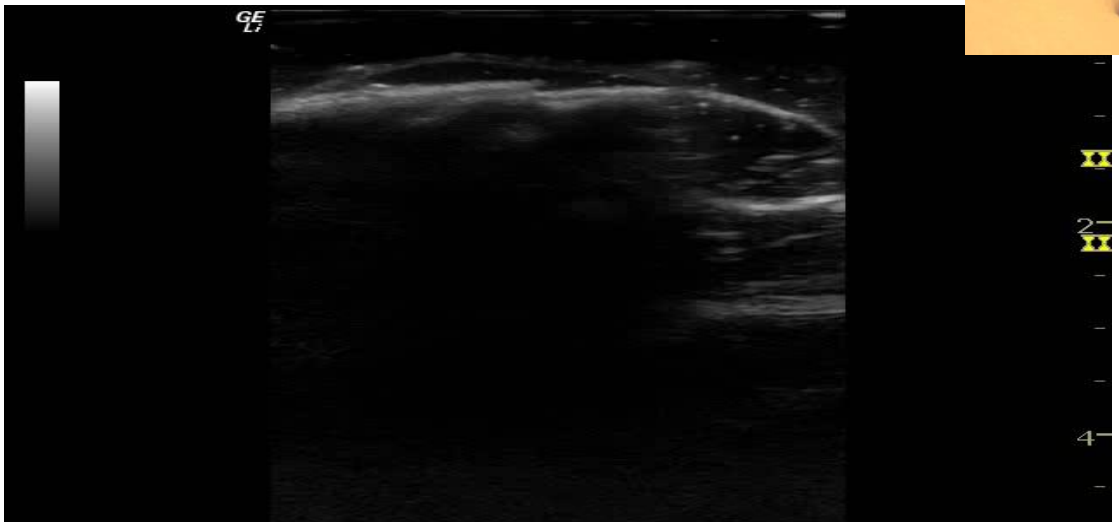


Natrelle Style 15 Bulge



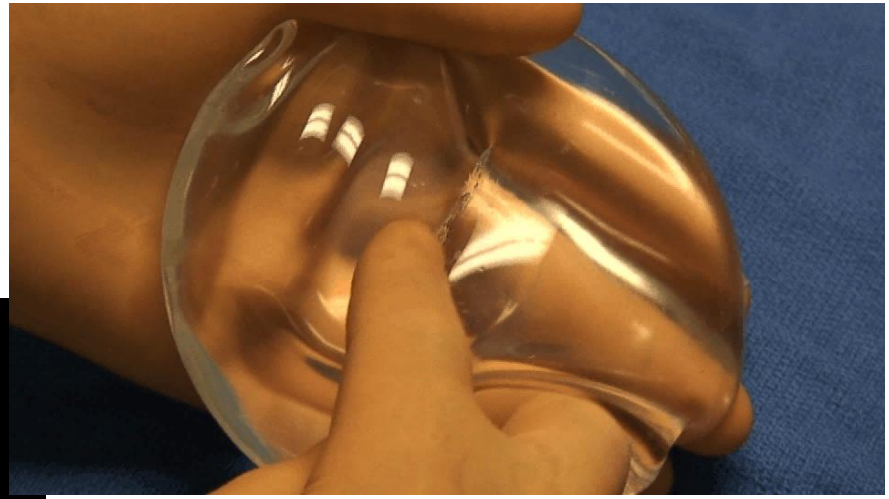
One of the great things about HRUS is that it is dynamic…if suspect rupture it can be accentuated

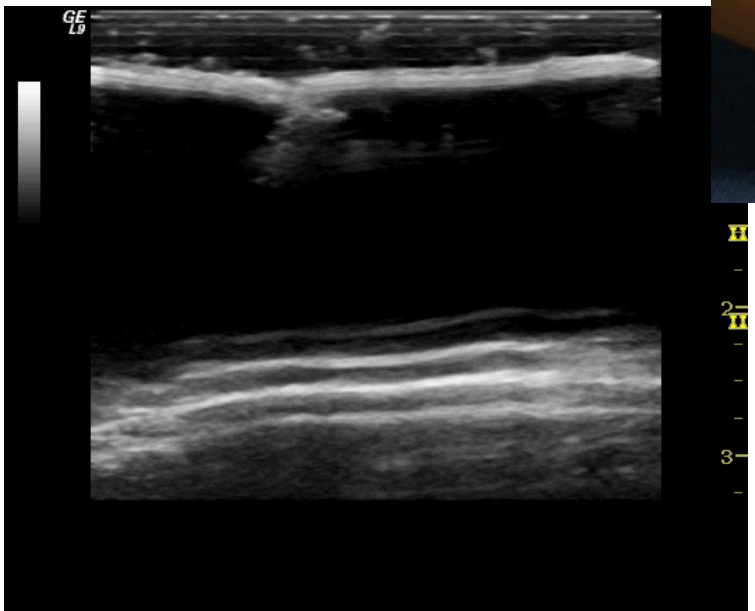




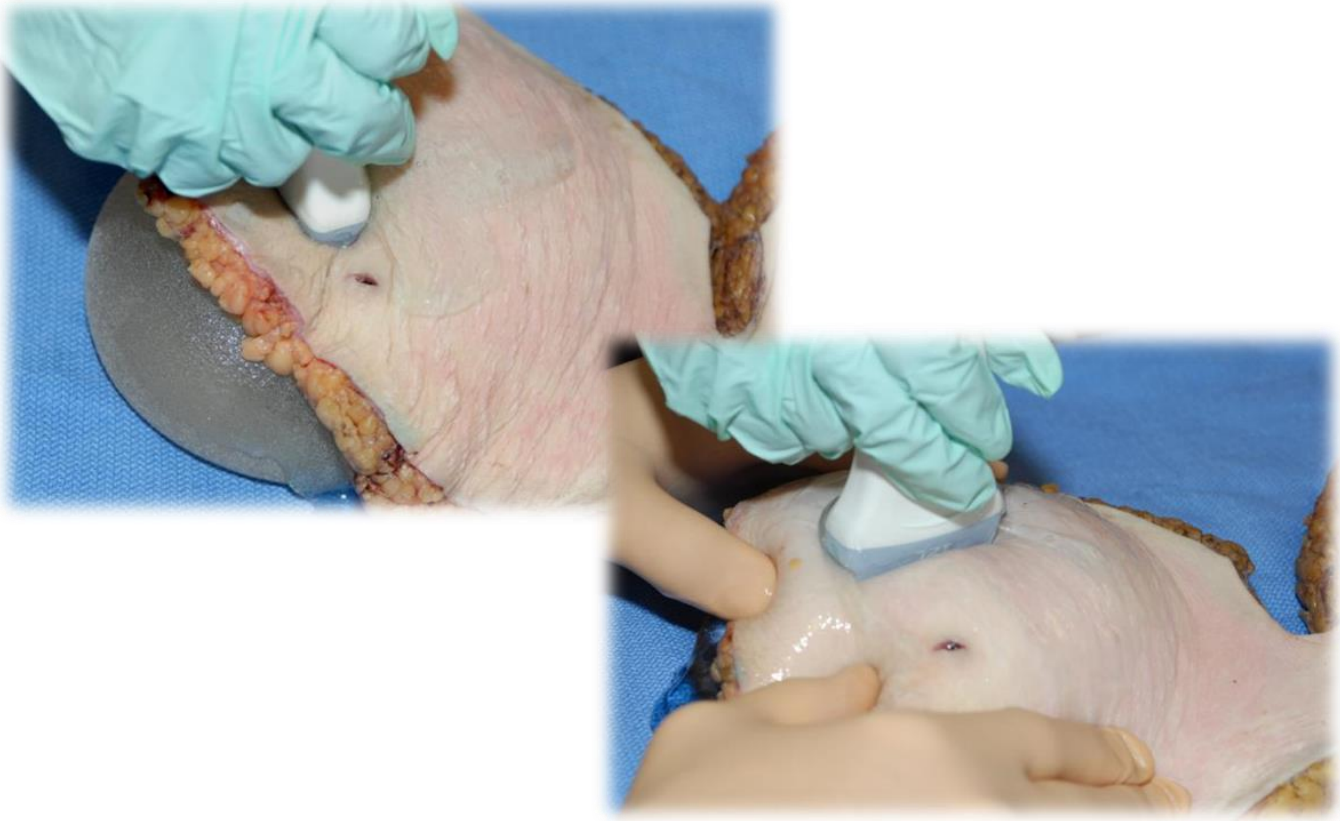
Highly cohesive gel retracts back into the shell

Smooth responsive gel implant

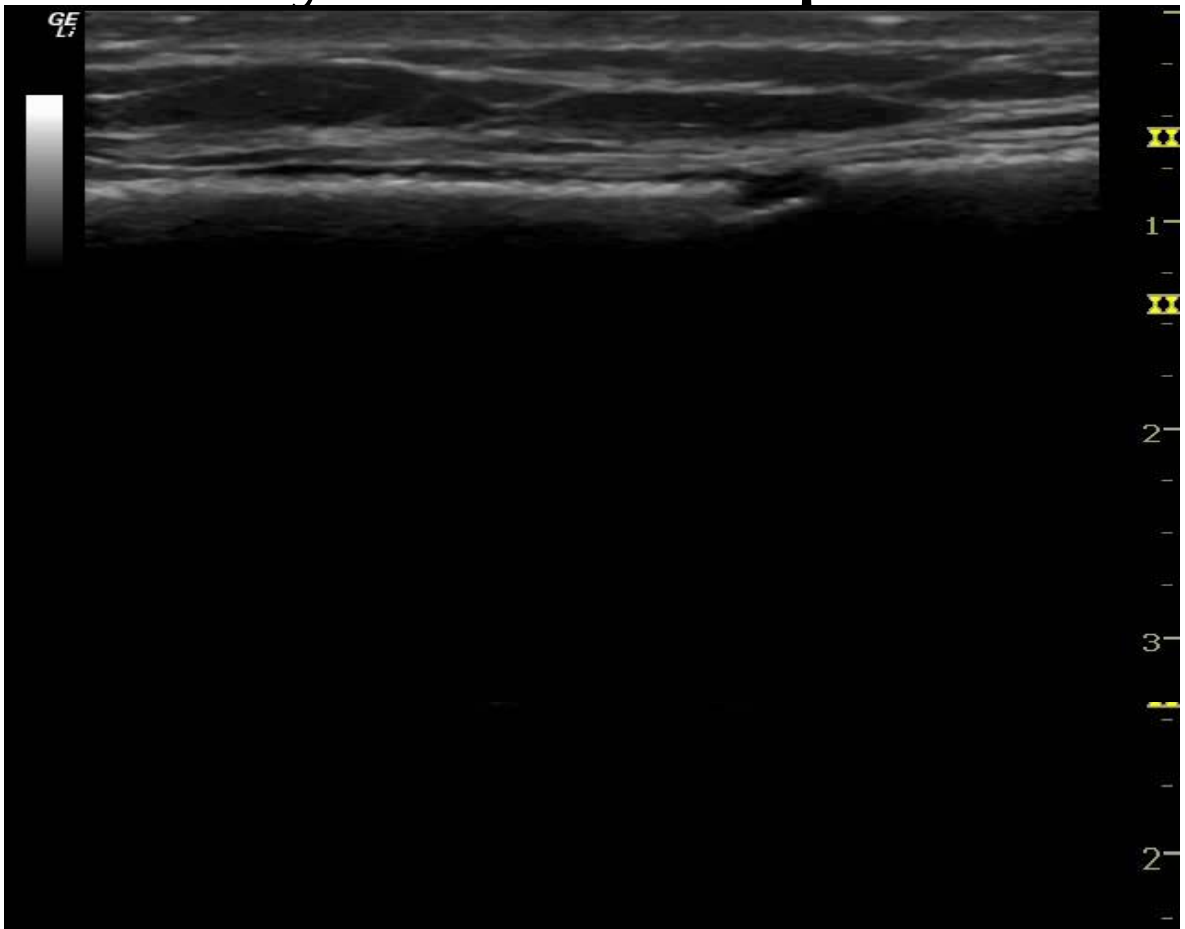




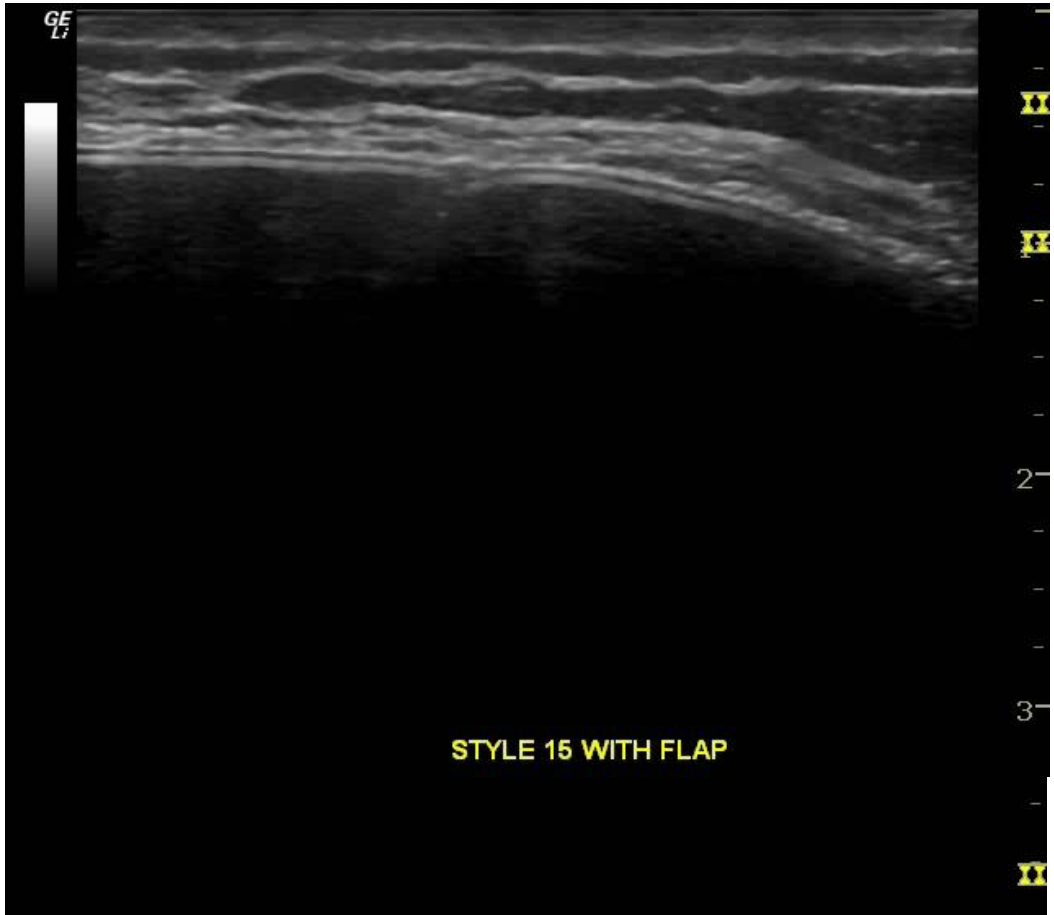
Scanning - Flap Simulation

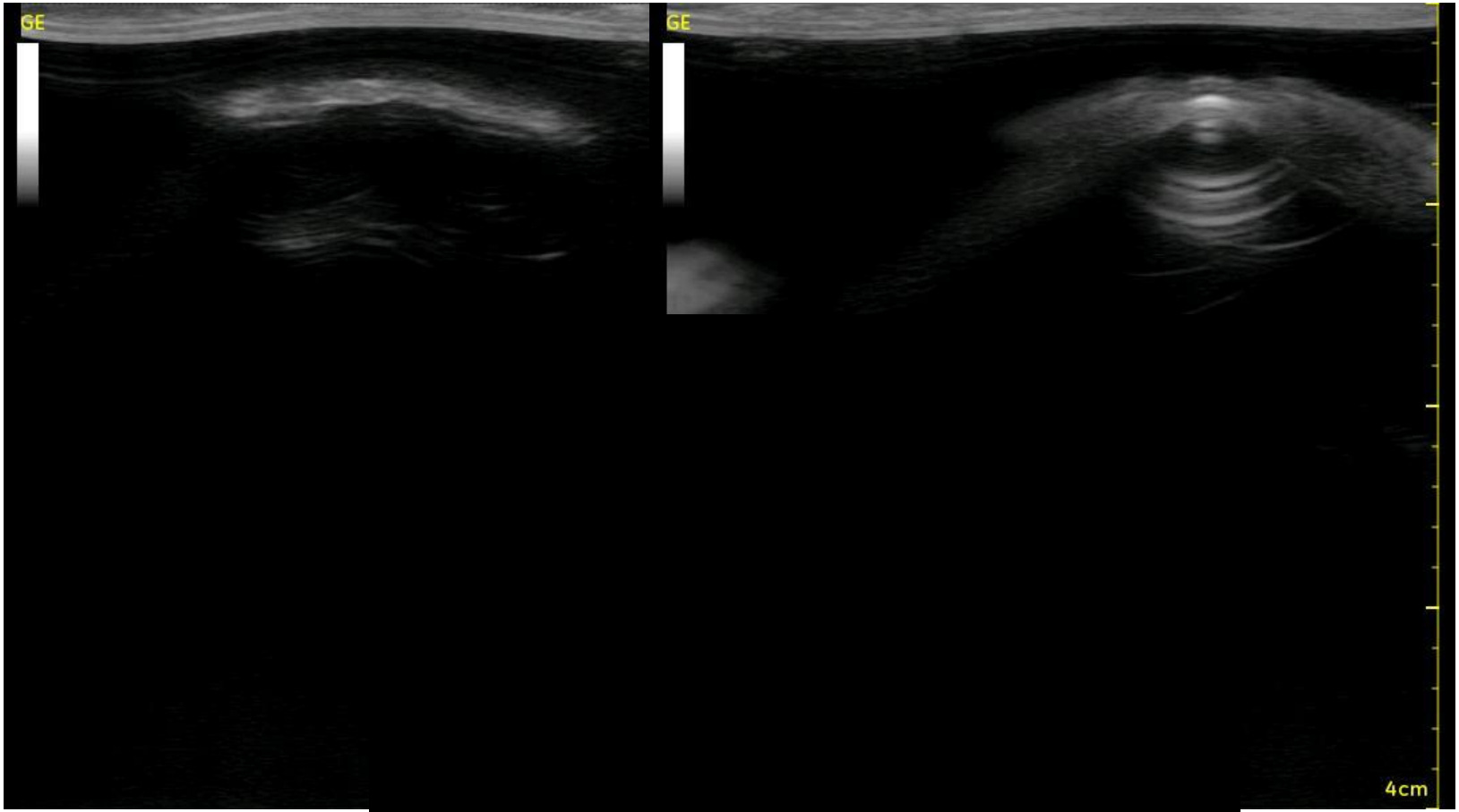


Cut Style 410 Flap Model

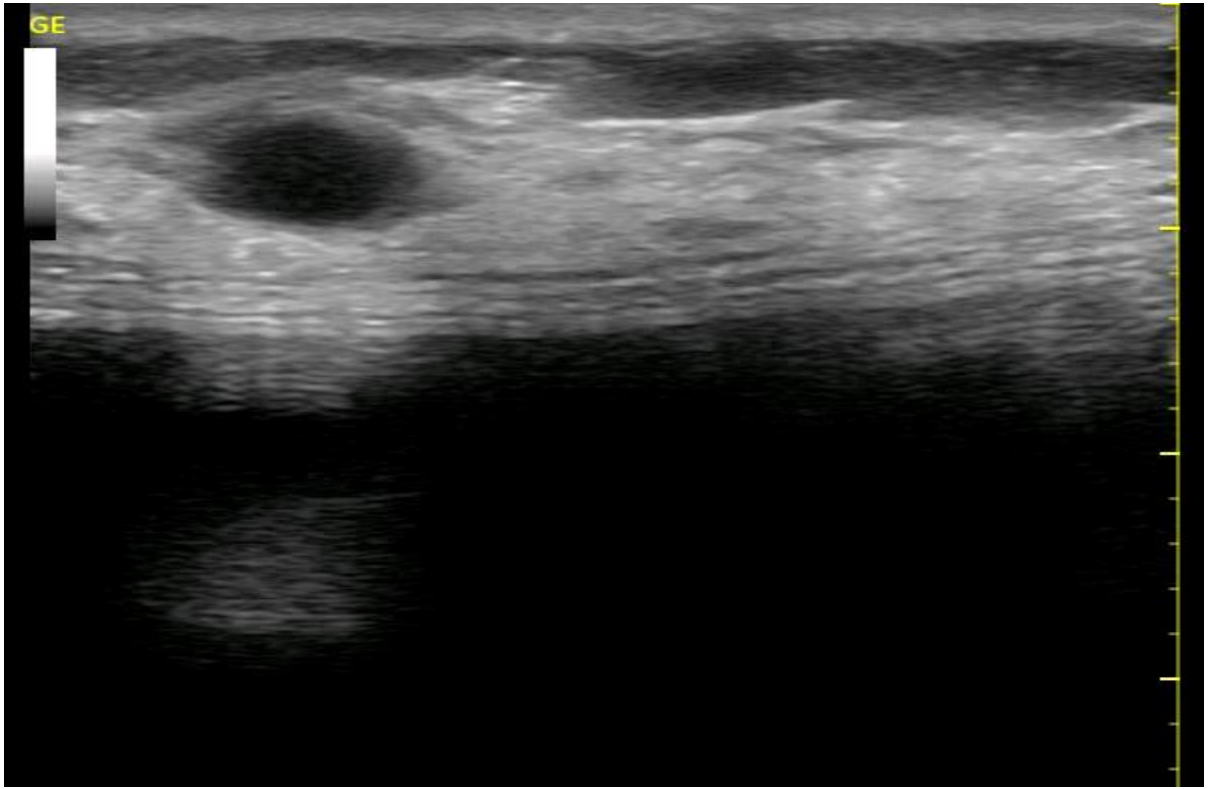


Cut Style 15 Flap Model

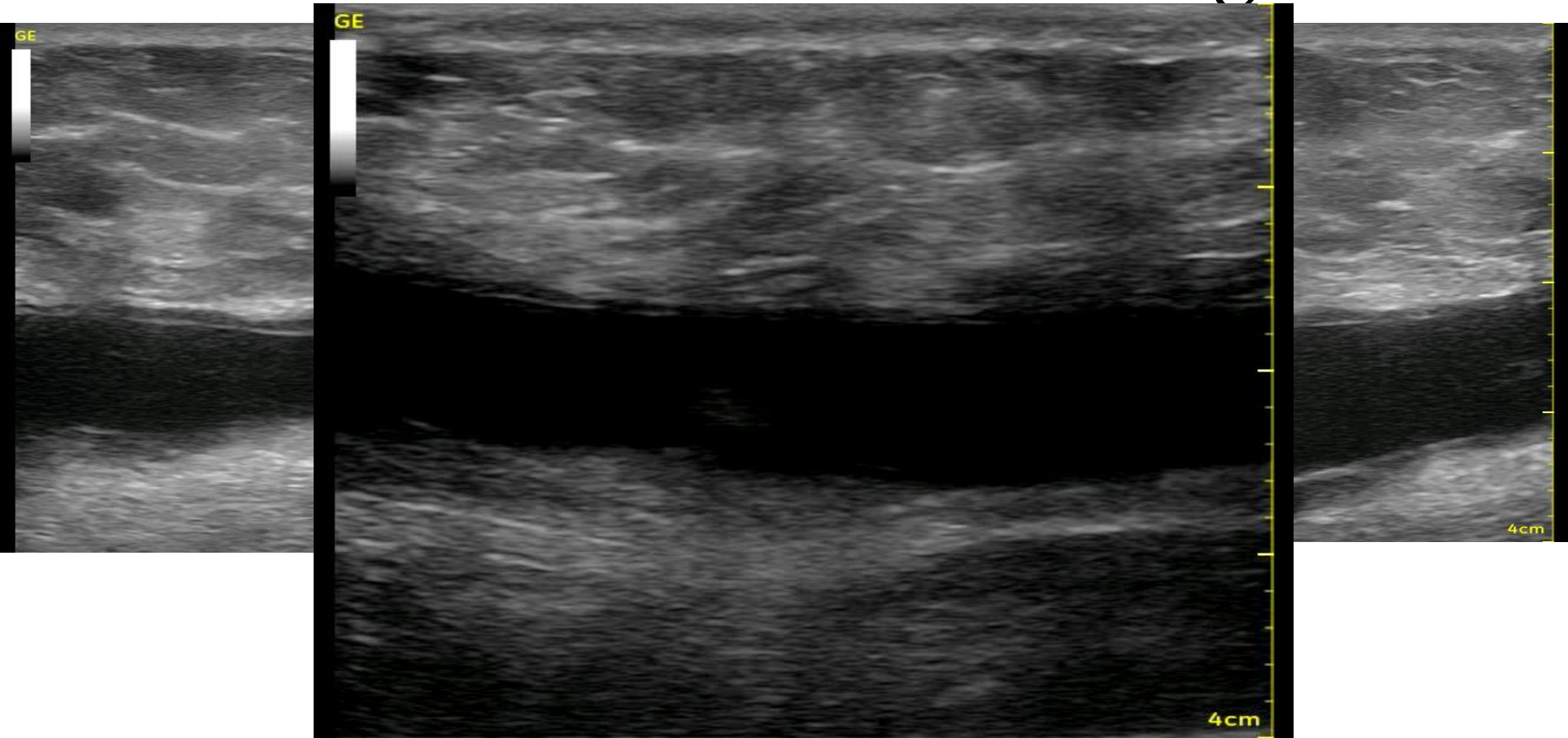


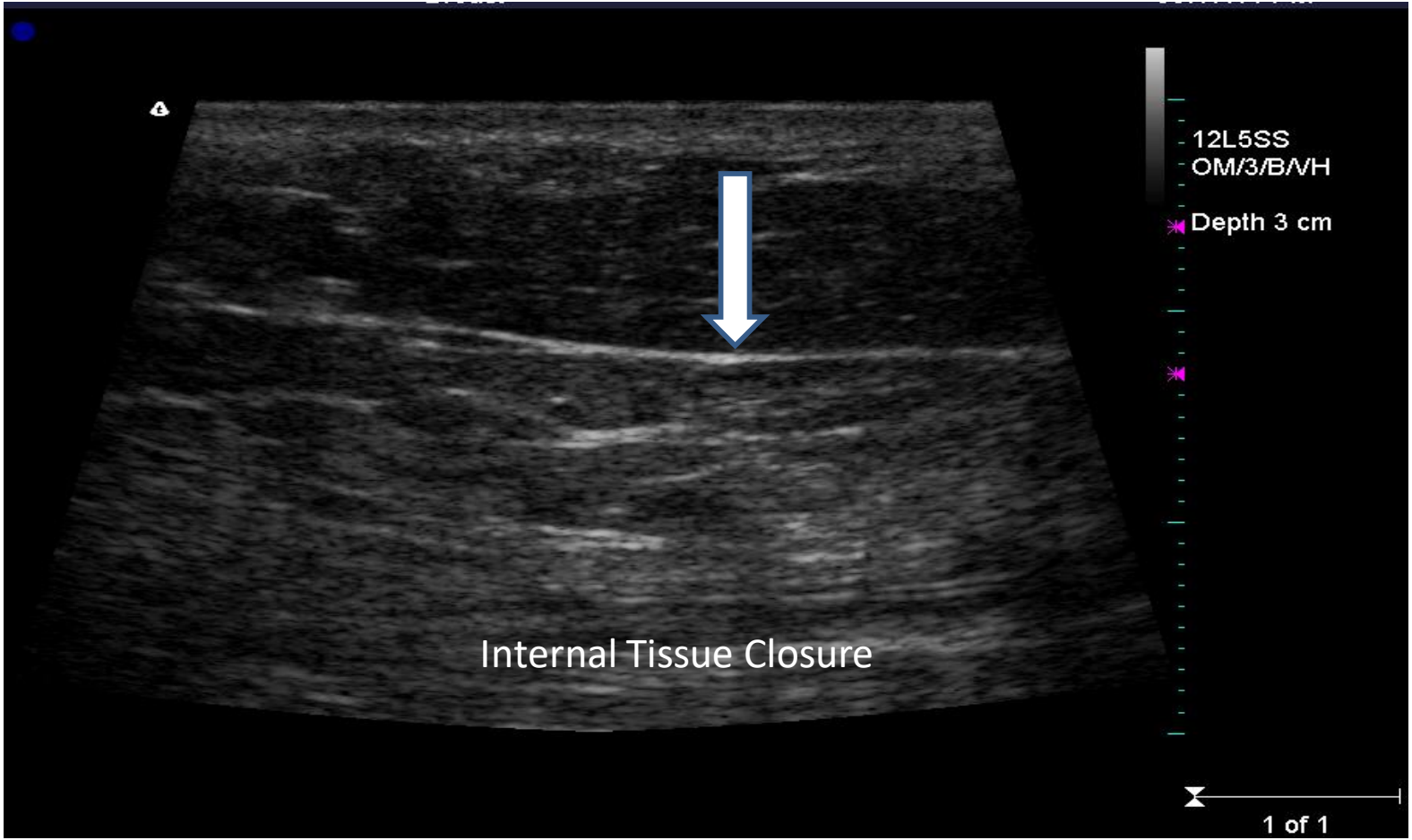

GE
GE
4cm

General - Breast Cysts

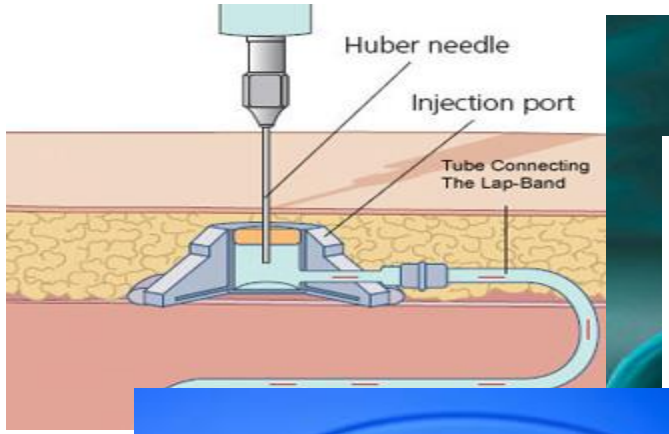


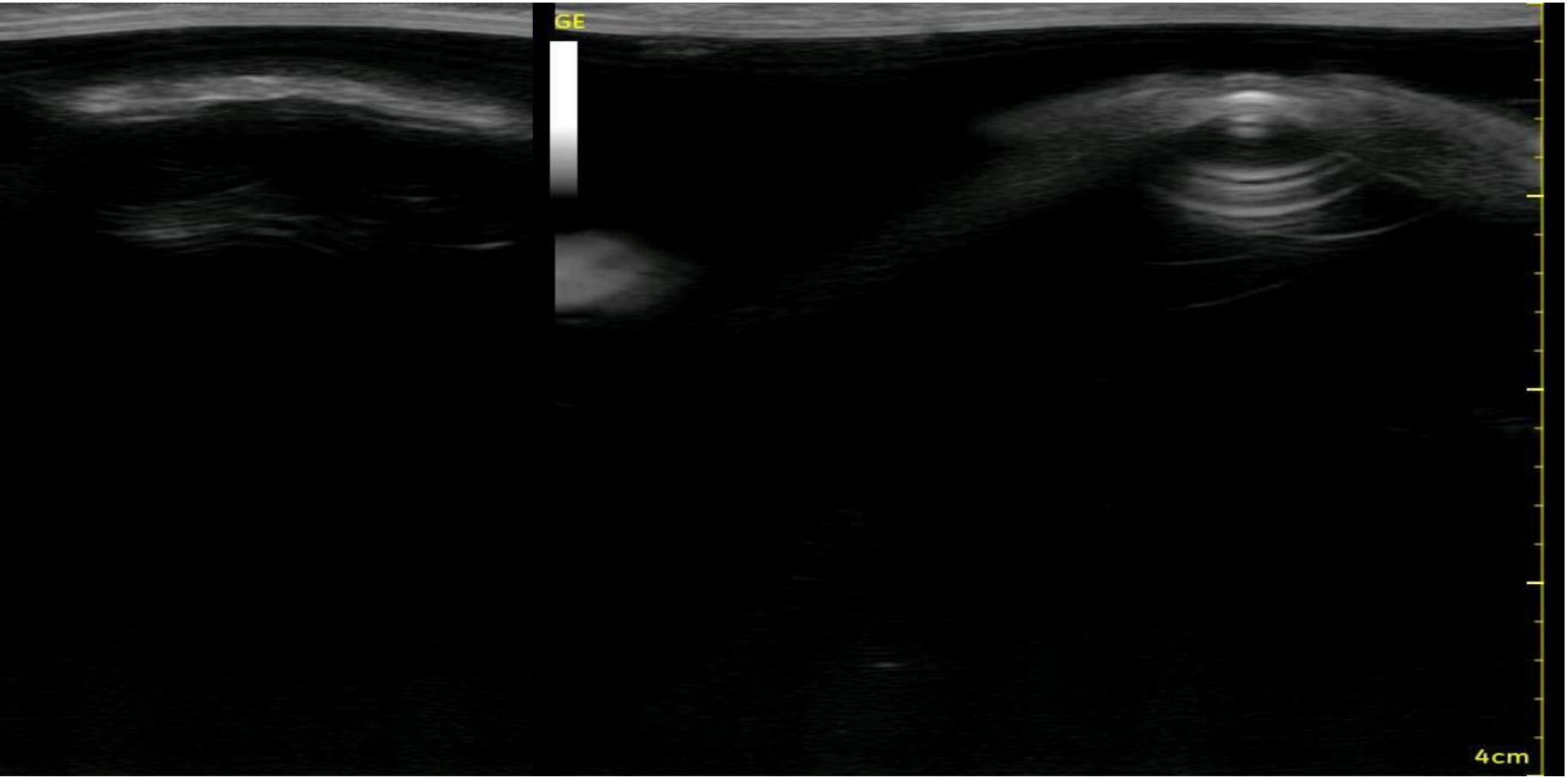
Revolutionized Seroma Management



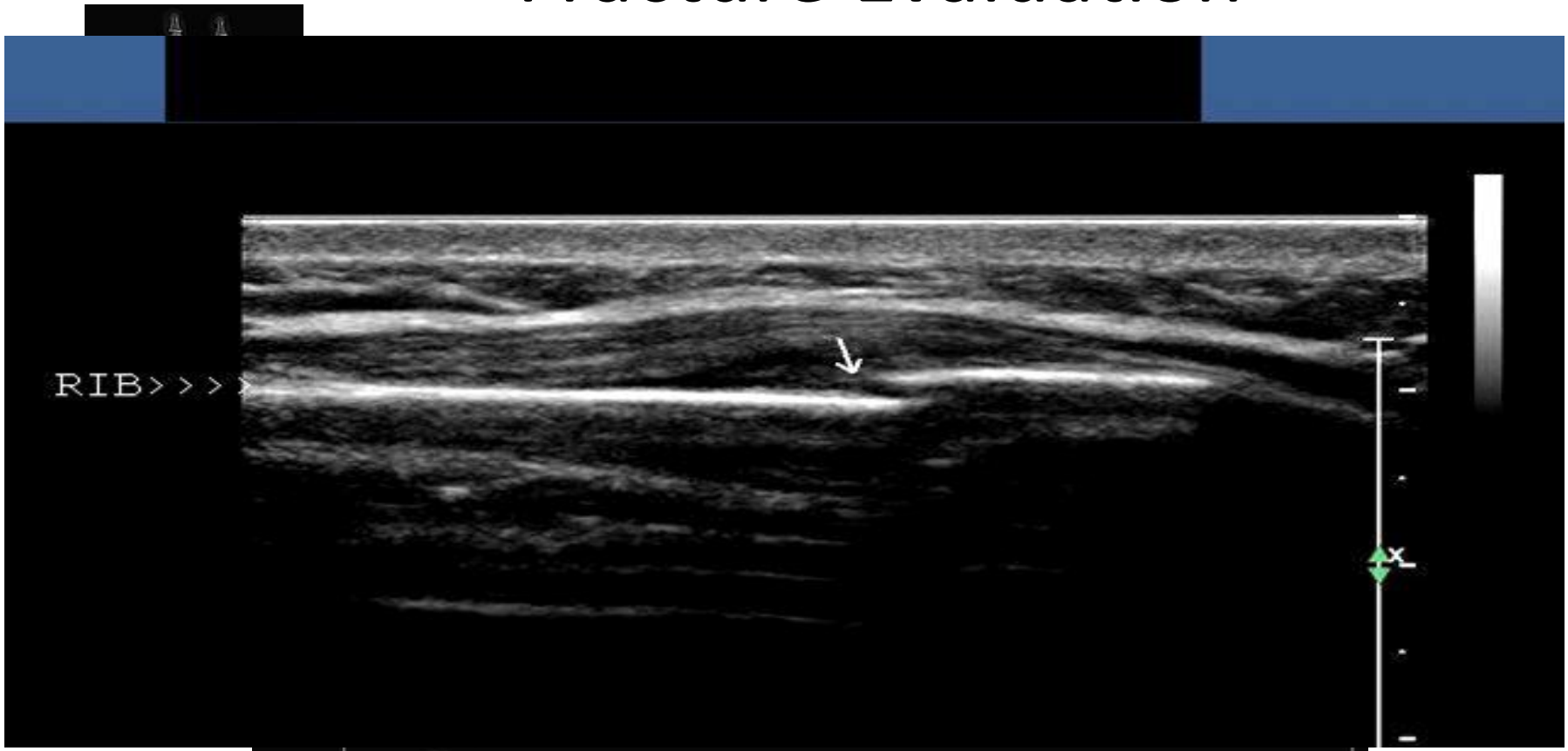

12L5SS
OM/3/B/VH
Depth 3 cm
Internal Tissue Closure
1 of 1

Lap-Band and other Ports

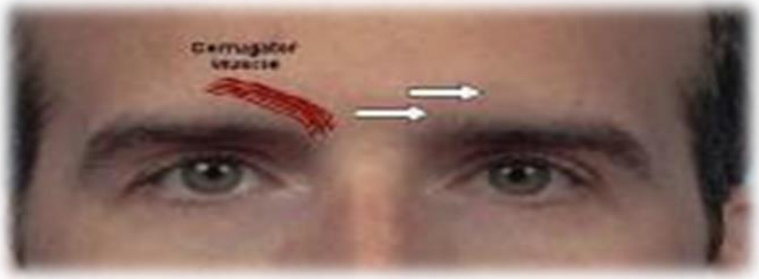


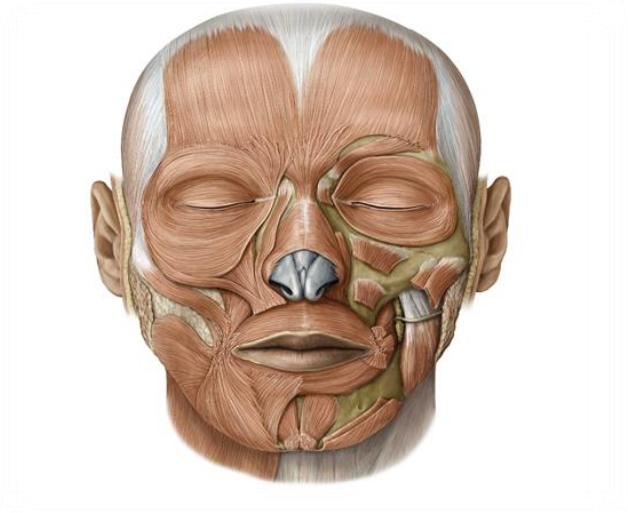

GE
4cm

Fracture Evaluation

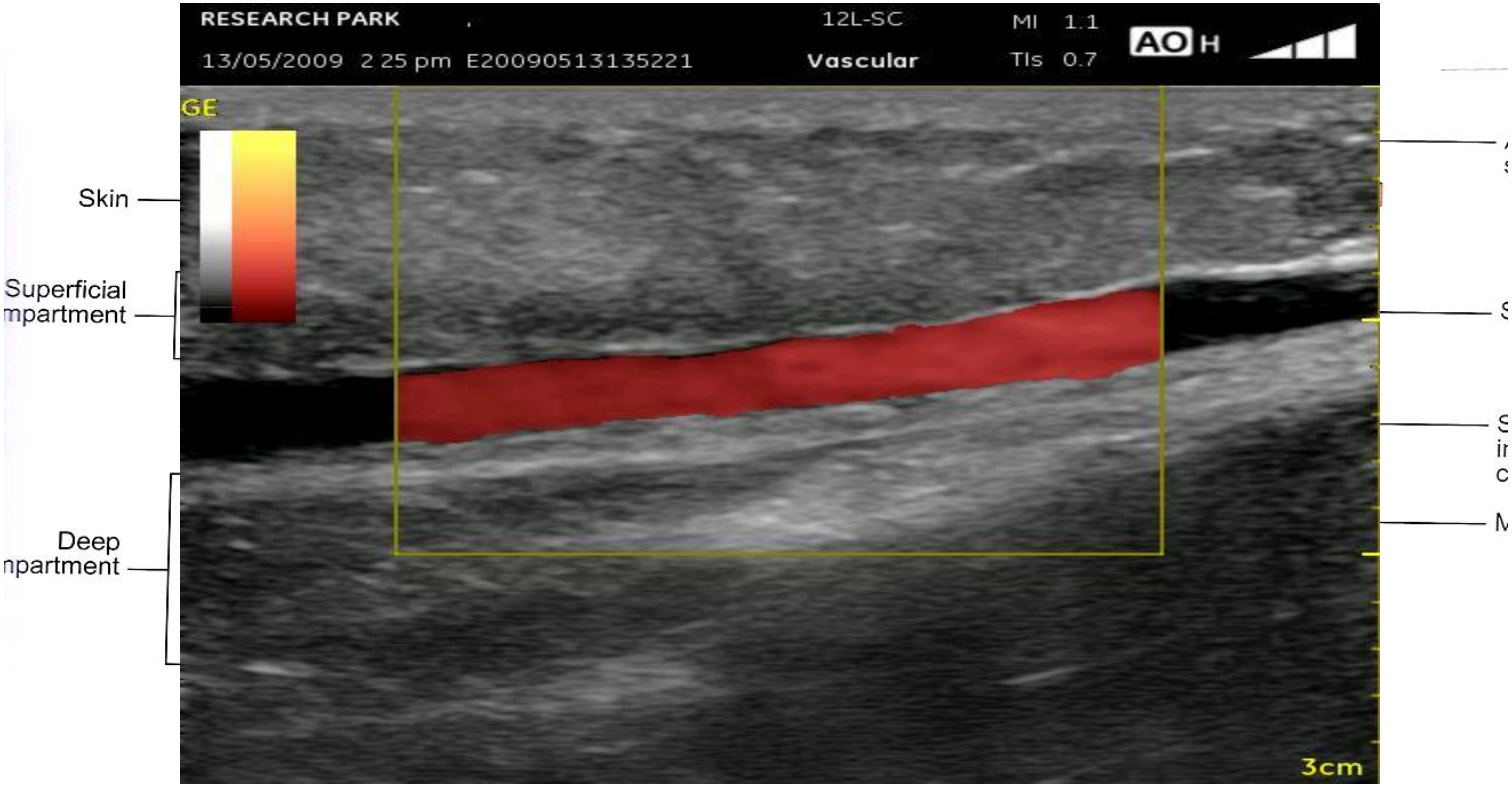


Muscle localization - Botox

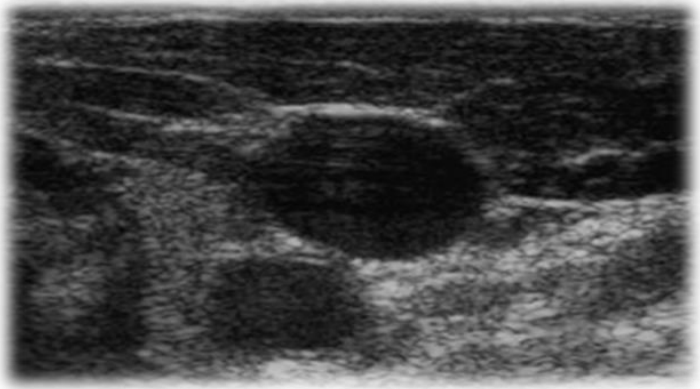


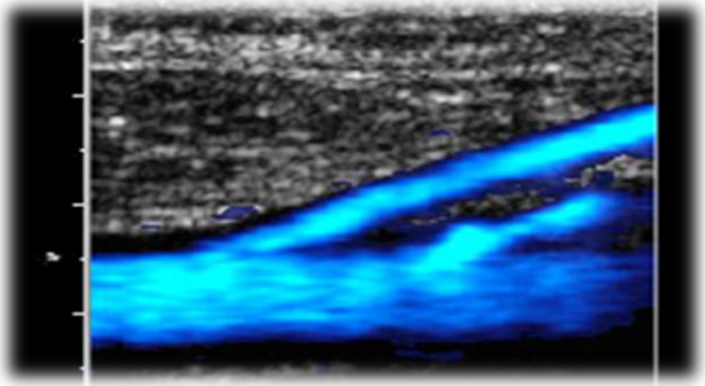


Diagnostic vein & ablation



Diagnostic vein & ablation



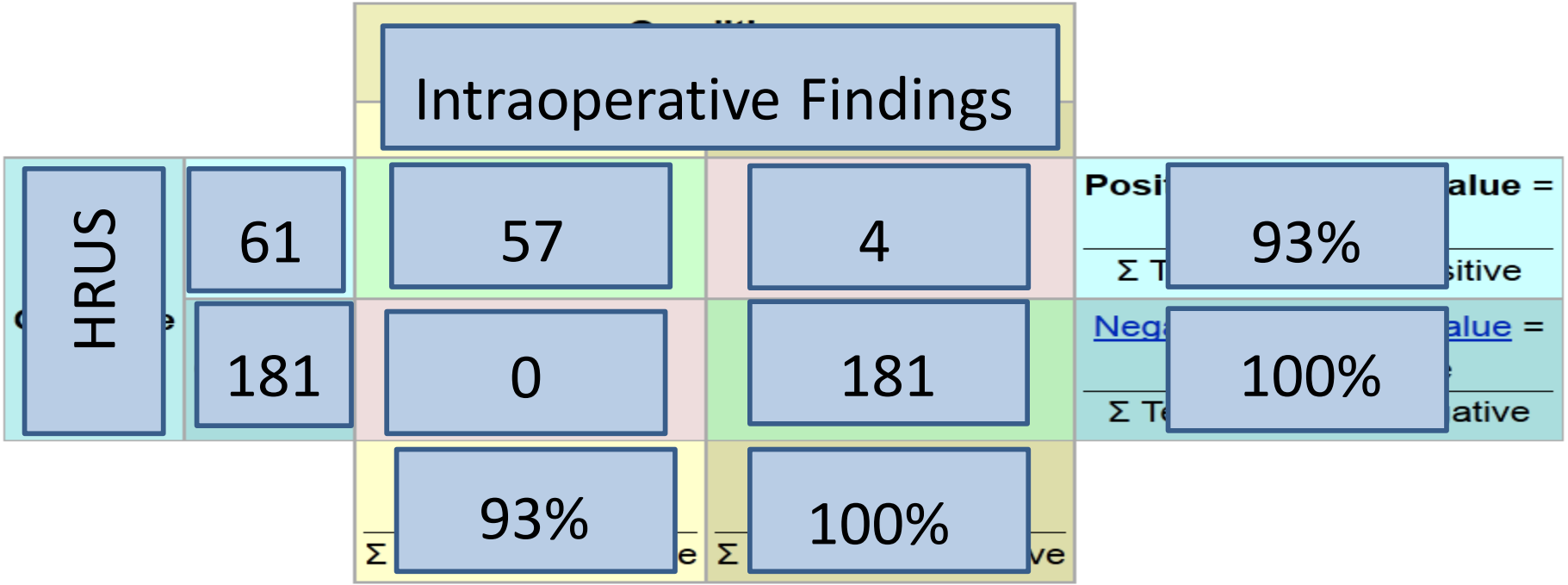


Diagnostic vein & ablation

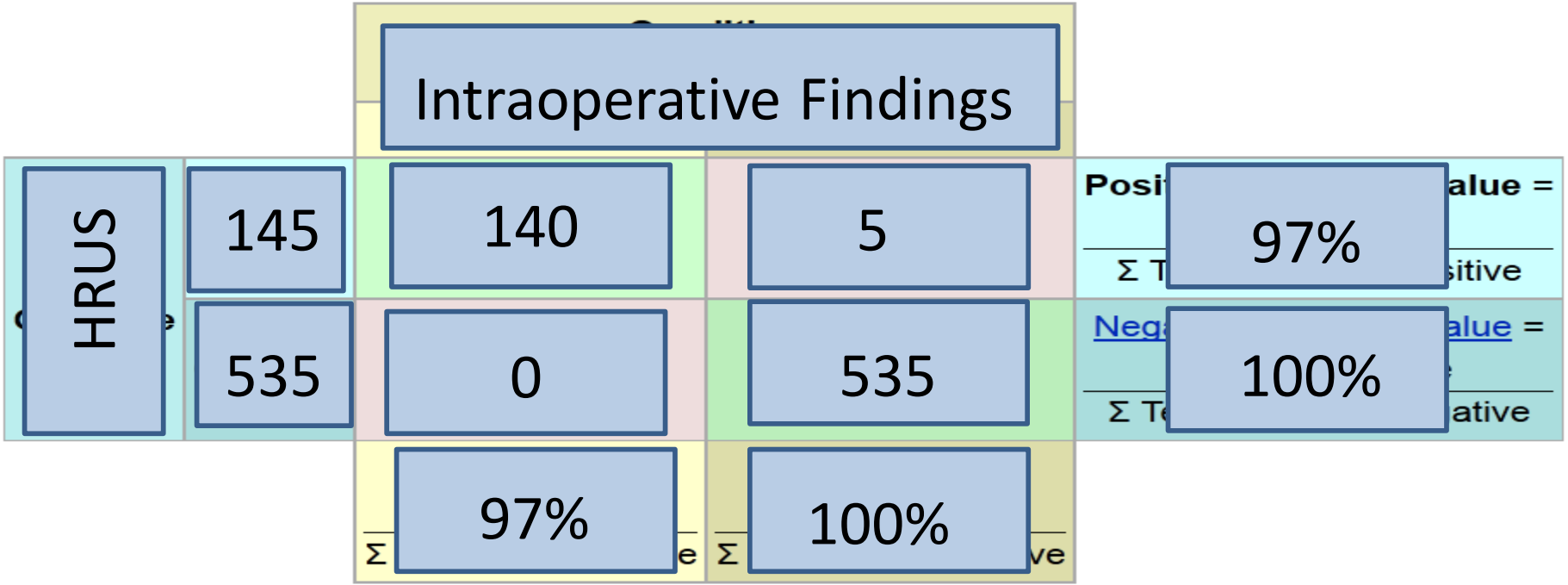
HRUS - Further Study

		Condition (as determined by "Gold standard")		
		Condition Positive	Condition Negative	
Test Outcome	Test Outcome Positive	**True Positive**	**False Positive** (Type I error)	**Positive predictive value** = Σ True Positive / Σ Test Outcome Positive
	Test Outcome Negative	**False Negative** (Type II error)	**True Negative**	Negative predictive value = Σ True Negative / Σ Test Outcome Negative
		Sensitivity = Σ True Positive / Σ Condition Positive	Specificity = Σ True Negative / Σ Condition Negative	

HRUS – First 242 Patients



HRUS – First 680 Patients



Publications

Silicone Breast Implants and Magnetic Imaging Screening for Rupture: Do U and Drug Administration Recommend Reflect an Evidence-Based Practice Ap Patient Care?

Colleen M. McCarthy, M.D., M.S., Andrea L. Pusic, M.D., M.H.S., Carolyn L. Kerrigan, M.D.

Summary: Regular magnetic resonance imaging ha the purpose of screening for silicone implant rupture a screening test is critically examined, it appears that is lacking. For example, there is no conclusive evidenc using magnetic resonance imaging screening of asym a reduction in patient morbidity. Furthermore, has unclear whether the potential benefits of screening t ing tests outweigh the risks and potential costs for the uncertainty, shared medical decision making can be ferent women, underlying beliefs and values will swa ferent directions. By engaging a woman in the proc cision making, however, the plastic surgeon and her a mutually agreeable choice that reflects the patien health preferences. (Plast. Reconstr. Surg. 121: 1127,

The recent decision by the U.S. Food and Drug Administration to approve silicone breast implants in the U.S. market has been applauded, yet its recommendation regarding screening for silicone implant ruptures has sparked much debate.[1] The U.S. Food and Drug Administration stipulates that routine magnetic resonance imaging is necessary to accurately identify silicone implant rupture and recommends that all patients with silicone implants undergo magnetic resonance imaging at 3 years after implantation and every 2 years thereafter.[2] Although it is generally agreed that the detection and treatment of a frank rupture with extracapsular silicone spread may decrease the associated morbidity (silicone granulomas, change in breast appearance), there remains uncertainty about the benefits of mass screening for silent implant ruptures.

The U.S. Food and recommendation appea mass magnetic resonanc asymptomatic women m tient morbidity caused by phenomenon has clearly Critics are concerned th proach exposes patients t of the screening test (inc tially, to the risks of the This ongoing debate wil volved parties on the iss resonance imaging screen to a net benefit or net ha

Those divided will the notion of shared me In this context, the decisi screen an individual pat after thoughtful consider individual places on each and harms.[3,4] Proponents

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Disclosure: The authors h in any of the products me

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Economic Analysis of Screening Strategies f Rupture of Silicone Gel Breast Implants

Kevin C. Chung, M.D., M.S. Sunitha Malay, M.P.H. Melissa J. Shauver, M.P.H. H. Myra Kim, Sc.D.

Background: In 2006, the U.S. Food and Drug Administration recom screening of all women with silicone gel breast implants with magne nance imaging 3 years after implantation and every 2 years thereafter their integrity. The cost for these serial examinations over the lifetim breast implants is an added burden to insurance payers and to wom authors performed an economic analysis to determine optimal screeni egies by considering the diagnostic accuracy of the screening tests, cost tests, and subsequent implant removal.
Methods: The authors determined aggregate/pooled values for sensiti specificity of the screening tests of ultrasound and magnetic resonance in detecting silicone breast implant ruptures from the data obtaine published literature. They compiled costs, based on Medicare reimburs for 2011, for the following elements: imaging modalities, anesthesia, an surgical treatment options for detected ruptures. A decision tree was compare three alternate screening strategies of ultrasound only, magn onance imaging only, and ultrasound followed by magnetic resonance in tomatic and symptomatic women.
Results: The cost per rupture of screening and management of ruptu ultrasound in asymptomatic women was $1090; in symptomatic women $1622. A similar cost for magnetic resonance imaging in asymptomatic was $2067; in symptomatic women it was $2143. A similar cost for ultr followed by imaging in asymptomatic women was $637; in symptomatic w it was $2068.
Conclusion: Screening with ultrasound followed by magnetic resonanc ing was optimal for asymptomatic women, and screening with ultrasou optimal for symptomatic women. (Plast. Reconstr. Surg. 130: 225, 2012

Approximately 0.3 percent of women (250,000 to 340,000) in the United States get breast implants each year. The majority of implantations are done for augmentation purposes; few are done for reconstruction purposes. Breast augmentation was the top cosmetic surgical procedure performed from 2006 to 2010.[1] Breast reconstruction rose to the top five reconstructive procedures in 2010.[1] Among the nearly 300,000 breast augmentations and 93,000 breast reconstructions performed in 2010, 146,000 (51 per cent) and 54,450 (59 percent), respective done with silicone implants.[1] Like any device, silicone breast implants have a product life. This is especially important ering the young age of many implant rec Complications of breast implantation pain, capsular contracture, and rupture. is defined as a disruption in the integrity implant, ranging from focal rupture throu sized holes to large, visible tears[2] and ma from trauma, deterioration of implant sh time, or manufacturing defects. The re leaked silicone gel may remain within t tissue capsule as an intracapsular rupture

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Breast Surgery

Preliminary Report

Diagnosis of Ruptured Breast Implants Through High-Resolution Ultrasound Combined With Real-Time Elastography

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Angrit Stachs, MD; Max Dieterich, MD; Steffi Hartmann, MD; Johannes Stubert, MD; Toralf Reimer, PhD; and Bernd Gerber, PhD

Abstract

Background: Implant rupture is a late complication of breast implant surgery is often a silent phenomenon that is difficult to diagnose. Sonoelastography is a new ultrasound-based technique that allows assessment of tissue elasticity.
Objectives: This study was undertaken to evaluate elastographic findings in normal and ruptured breast implants.
Methods: This prospective study included 28 implants in 16 patients, all of whom underwent high-resolution ultrasound and real-time elastography. The diagnosis of implant rupture was confirmed by surgery.
Results: Implant rupture was diagnosed in 5 out of 28 implants (17.9%). In those patients with ruptured implants, 3 had no symptoms, 1 presented with pain, and 1 complained of ipsilateral axillary lymph node swelling. Implants with a homogenous anechoic interior were considered to be intact. Ultrasound findings indicating implant rupture included multiple parallel echogenic lines in the implant interior in 2 cases and a mix of hyperechoic and hypoechoic masses in 3 cases. The feasibility of real-time elastography of implants was demonstrated in all cases. Elastograms of intact implants revealed a typical blue-green-red pattern familiar from cystic lesions. In all 5 ruptured implants, elastography revealed yellow-green figures without typical layering.
Conclusions: To the authors' knowledge this is the first series to combine high-resolution ultrasound with real-time elastography for the diagnosis of implant rupture. Since there are distinct differences between elastograms of intact and ruptured implants, addition of real-time elastography to conventional ultrasound may improve implant surveillance and obviate the need for magnetic resonance imaging.

Level of Evidence: 3

Therapeutic

Accepted for publication September 5, 2014; online publish-ahead-of-print March 24, 2015.

Over the past 25 years, the number of silicone breast implants for cosmetic or reconstructive surgery has increased substantially.[1] In 2006, the US Food and Drug Administration (FDA) recommended routine magnetic resonance imaging (MRI) evaluations for postoperative implant surveillance.[2] A recent meta-analysis of studies on the diagnostic accuracy of MRI for detecting silicone breast implant rupture revealed sensitivity of 87.0% and specificity of 89.9%.[3] However, because diagnostic accuracy was 14-fold higher in symptomatic compared with asymptomatic patients, it was concluded that most of the studies considered for the meta-analysis were methodologically flawed because only patients with symptoms were included.[4] In terms of expense and specific contraindications (eg, metallic implants, claustrophobia), MRI cannot be generally recommended as a screening method for implant rupture in asymptomatic women.

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- *Milan study and Nahabedians review*
- *2006-2008???*
- *8mhz vs 12-15*
- *Extra capsular gel?*
- *Looking at everything but shell*

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BREAST

Outcomes Article

Appropriate Use of Magnetic Resonance Imaging and Ultrasound to Detect Early Silicone Gel Breast Implant Rupture in Postmastectomy Reconstruction

Mario Rietjens
Gaetano Villa
Antonio Toesca
Stefania Rizzo
Sara Raimondi
Fabio Rossetto
Claudia Sangalli
Francesca De Lorenzi
Andrea Manconi
Angelo Gustavo Zucca Matthes
Badir Chahuan
Fabricio Brenelli
Massimo Bellomi
Jean Yves Petit

Milan, Italy; and Barretos, Brazil

Background: Implant rupture is one of the most important sequelae of breast reconstruction after mastectomy. The primary aim of this study was to compare magnetic resonance imaging and ultrasound evaluation with intraoperative findings and provide a reliable description of the occurrence of each radiological sign.

Methods: The authors prospectively recruited a consecutive series of 102 postmastectomy patients requiring implant change for aesthetic purposes. Magnetic resonance imaging and ultrasound evaluation results were compared with intraoperative findings. Sensitivity, specificity, positive predictive value, negative predictive value, and the overall accuracy of magnetic resonance imaging and ultrasound in detecting ruptured implants were calculated, along with their corresponding 95 percent confidence intervals.

Results: Magnetic resonance imaging performs better than ultrasound for diagnosis of breast implant rupture, with overall accuracies of 94 and 72 percent, respectively. The negative predictive value of ultrasound was 85 percent, meaning that in the case of negative ultrasound findings, magnetic resonance imaging may be avoided. Teardrop sign and water droplets are the most common findings on magnetic resonance imaging.

Conclusions: Magnetic resonance imaging should be considered the method of choice for investigating silicone gel implant rupture in postmastectomy patients, and the standardization of magnetic resonance imaging criteria may improve magnetic resonance imaging accuracy. The authors therefore suggest a strategy of screening asymptomatic women with ultrasound every year and with magnetic resonance imaging every 5 years. (*Plast. Reconstr. Surg.* 134: 13e, 2014.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Diagnostic, II.

DIAGNOSTIC

Implant-based reconstruction is the most popular technique of breast reconstruction after mastectomy. Implant rupture is one of the most important sequelae, resulting in a significant deterioration of aesthetic outcomes and requiring a further surgical procedure. Although extracapsular silicone leakage has been investigated in the past for correlation with autoimmune diseases, a rare form of lymphoma, or other locoregional or systemic events, no increased risk of connective tissue diseases or cancer is evident in women with extracapsular ruptures.[1–6] However, revision procedures after ruptured implants may increase the risk of local adverse events such as capsular contracture, scarring, pain, and aesthetic failure.[2,7,8]

The true prevalence of implant ruptures in asymptomatic patients is unknown.[1,7] Implant rupture can occur in the early period after implantation or following a long interval. Its prevalence increases with implant age. Hölmich et al.[3] found 2 percent of ruptured prostheses at 5 years and

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DISCUSSION

Outcomes Article

Discussion: Appropriate Use of Magnetic Resonance Imaging and Ultrasound to Detect Early Silicone Gel Breast Implant Rupture in Postmastectomy Reconstruction

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Washington, D.C.

Current strategies for assessing breast implant rupture include visual inspection, palpation, mammography, ultrasound, computed tomography, and magnetic resonance imaging. Visual inspection is usually not useful but may provide clues regarding rupture, especially when a contour abnormality is noted with different maneuvers, such as arm raising. Palpation is also limited and has been demonstrated to have a sensitivity of only 30 percent. Mammography has limited benefit and is considered useful for detecting extracapsular rupture but limited for intracapsular rupture. Standard resolution ultrasound is useful for extracapsular but not intracapsular rupture. Computed tomography scanning is associated with ionizing radiation and is not recommended for routine screening. Magnetic resonance imaging is useful for intracapsular and extracapsular rupture and is the current accepted standard.

In 2006, following the approval of the use of silicone gel breast implants in the United States, the Food and Drug Administration recommended that all women with silicone gel breast implants undergo screening with magnetic resonance imaging 3 years after implantation and every 2 years thereafter.[1] To many patients and surgeons, this recommendation was considered excessive and unrealistic, primarily because of the inconvenience imposed on the majority of patients, as most were asymptomatic, but also because of the associated high costs. In order to lessen the inconvenience and reduce the cost associated with routine magnetic resonance imaging, various strategies have been considered and studied. As healthcare costs continue to escalate, there will be a strong emphasis by third-party payers, governments, and hospitals to reduce costs. Cost reduction must be balanced with safety and efficacy standards that have been well established.

In the article "Appropriate Use of Magnetic Resonance Imaging and Ultrasound to Detect Early Silicone Gel Implant Rupture in Postmastectomy Reconstruction," the authors from the European Institute of Oncology have prospectively studied this issue and concluded that magnetic resonance imaging should be considered the method of choice to definitively investigate silicone gel implant rupture in postmastectomy women.[2] This conclusion was based on calculations of sensitivity, specificity, negative predictive value, and positive predictive value for both magnetic resonance imaging and ultrasound. The overall accuracy for magnetic resonance imaging was 94 percent, whereas that for ultrasound was 72 percent. The authors acknowledge that the cost of magnetic resonance imaging is an issue and that ultrasound will continue to have a role. Thus, for symptomatic patients, magnetic resonance imaging was recommended. For asymptomatic patients, yearly ultrasound examinations are sufficient as long as the patient remains asymptomatic, with magnetic resonance imaging examination every 5 years. Although the study has a level 2 evidence rating because all patients were prospectively enrolled, it may be more appropriate to classify this as level 3 evidence because almost all patients had the same diagnostic examination, there was no randomization, and there was no control group.

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