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
- Hematoma – Acute Trauma
- Tissue Expander Port ID
- Implant Capsule/ADM evaluation
- Fat Transfer Guidance & Evaluation
- Breast Evaluation – General
- Future & Other Applications
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

Cut smooth implant shell
Ruptured smooth implant shell

Extra shell / Intracapsular gel

Intact implant shell

Intact
Video showing gel outside of the shell but intracapsular

Ruptured implant with patch delamination
All 29 devices ruptured or intact were identified on MRI and also HRU and confirmed at surgery. 100% Accuracy with independent readers thus far in study.
All 29 devices ruptured or intact were identified on MRI and also HRU and confirmed at surgery. 100% Accuracy with independent readers thus far in study.
Extra capsular gel
Intact
Rotation – Registration Marks

410 Registration Marks
Rotation – Registration Marks

CPG Registration Mark
Internal Gel Fracture
Fluid - Seroma
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.
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
General - Breast Cysts
Revolutionized Seroma Management
Internal Tissue Closure
Lap-Band and other Ports
Fracture Evaluation
Muscle localization - Botox
Diagnostic vein & ablation
Diagnostic vein & ablation
Diagnostic vein & ablation

Before

After
Further Study

- On own over 400 patients scanned
- 245 taken to surgery past 6 years and 460 implants taken to surgery
- One false positive double lumen implant
- One false positive Baker 4 capsule
- No false negatives

### HRUS - Further Study

<table>
<thead>
<tr>
<th>Test Outcome</th>
<th>Condition Positive</th>
<th>Condition Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>True Positive</td>
<td>False Positive</td>
<td>Positive predictive value = [\frac{\Sigma \text{True Positive}}{\Sigma \text{Test Outcome Positive}}]</td>
</tr>
<tr>
<td>False Negative</td>
<td>True Negative</td>
<td>Negative predictive value = [\frac{\Sigma \text{True Negative}}{\Sigma \text{Test Outcome Negative}}]</td>
</tr>
</tbody>
</table>

- **Sensitivity** = \[\frac{\Sigma \text{True Positive}}{\Sigma \text{Condition Positive}}\]
- **Specificity** = \[\frac{\Sigma \text{True Negative}}{\Sigma \text{Condition Negative}}\]
HRUS – First 242 Patients

Intraoperative Findings

<table>
<thead>
<tr>
<th></th>
<th>HRUS</th>
<th>Non-HRUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>61</td>
<td>181</td>
</tr>
<tr>
<td>Negative</td>
<td>181</td>
<td>0</td>
</tr>
</tbody>
</table>

93% (Positive) 100% (Negative)
HRUS – First 680 Patients

Intraoperative Findings

<table>
<thead>
<tr>
<th></th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRUS</td>
<td>145</td>
<td>535</td>
</tr>
<tr>
<td>Intraoperative Findings</td>
<td>140</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>535</td>
</tr>
</tbody>
</table>

Positive Predictive Value = \( \frac{140}{140+5} \) = 96.15%

Negative Predictive Value = \( \frac{535}{535+0} \) = 100%
Publications

Silicone Breast Implants and Magnetic Imaging Screening for Rupture: Do U.S. Food and Drug Administration Recommendations Reflect an Evidence-Based Practice Approach in Patient Care?

Colleen M. McCullough, M.D.
Nerida L. Pow, M.D., M.H.S.
Catherine J. Korga, M.D.
Yan Tang, M.S.

Abstract: In this review, we assess the evidence for magnetic resonance imaging screening for silicone breast implant rupture. The U.S. Food and Drug Administration (FDA) and the American Society for Aesthetic Plastic Surgery (ASAPS) recommend magnetic resonance imaging screening for silicone breast implant rupture. The literature, however, does not provide clear evidence that magnetic resonance imaging screening for silicone breast implant rupture is effective. The purpose of this review is to summarize the current literature on magnetic resonance imaging screening for silicone breast implant rupture and to evaluate the evidence for its effectiveness.

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

Nancy L. Jones, MD
Monica S. Maloney, M.D.
H. Mohsin A. Khan, F.R.C.S.
H. H. M. Khan, M.D.

Abstract: The purpose of this study was to evaluate the cost-effectiveness of different screening strategies for detecting silicone gel breast implant rupture. The study compared three screening strategies: magnetic resonance imaging, ultrasonography, and physical examination. The study found that magnetic resonance imaging was the most cost-effective screening strategy, followed by ultrasonography and then physical examination.

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

Anna Stasik, MD
Mas Otsuka, MD
Steffi Littmann, MD
Volker Stieber, MD
Toddi Reimer, PhD
Bernd Gerber, PhD

Abstract: The purpose of this study was to evaluate the effectiveness of combining high-resolution ultrasound with real-time elastography for diagnosing ruptured breast implants. The study found that the combination of high-resolution ultrasound with real-time elastography was more effective than either technique alone in diagnosing ruptured breast implants.

Level of Evidence: 5

Accepted for publication on September 29, 2016, online edition available on March 1, 2017.
Recent Publications

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

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

Background: Implant rupture is the most important sequelae of breast reconstruction. In this paper, we provide a concise review of the magnetic resonance imaging and ultrasound evaluation results. An appropriate diagnostic evaluation should be performed with a combination of magnetic resonance imaging and ultrasound. The presence of silicone gel, polyurethane, and foreign material within the implant should be detected.

Method: The authors prospectively evaluated the images of 102 post-mastectomy patients presenting with an abnormal magnetic resonance imaging result. Magnetic resonance imaging and ultrasound evaluation results were compared with the results of histopathological analysis and the results of surgical intervention.

Results: Magnetic resonance imaging is more sensitive than ultrasound for the diagnosis of breast implant rupture, with an accuracy of 96% and 79%, respectively. The sensitivity and specificity of magnetic resonance imaging were 96% and 92%, respectively. The combination of magnetic resonance imaging and ultrasound is recommended for the detection of breast implant rupture.

Conclusions: Magnetic resonance imaging should be used as the method of choice for evaluating silicone gel breast implants. Magnetic resonance imaging reveals the presence of silicone gel, polyurethane, and foreign material within the implant. The combination of magnetic resonance imaging and ultrasound is recommended for the detection of breast implant rupture.

Disclosure: The authors have no financial disclosure to any of the products or devices mentioned in this article.

Current strategies for assessing breast implant rupture include visual inspection, palpation, mammography, ultrasound, and magnetic resonance imaging. Visual inspection is usually not helpful in providing a reliable diagnosis of rupture. Magnetic resonance imaging and ultrasound are the gold standards for the diagnosis of breast implant rupture, with an accuracy of 96% and 79%, respectively. Magnetic resonance imaging is more sensitive than ultrasound for the diagnosis of breast implant rupture.

Disclosure: Dr. Nahabedian is a paid consultant for LifeCell Corporation and Bortec. Dr. Nahabedian receives research support from the National Institutes of Health for developing a biomarker for breast cancer.

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