How do Women Feel about Silent Rupture?

• 2017 online randomized survey, independent third party

• 933 women – 45% RNs

• 97% would want to know if their silicone gel implant had silently ruptured

• 95% would want to replace a ruptured silicone gel implant, even if not causing symptoms
Silent Rupture of Silicone Gel Implants

- *Intact* implants are FDA approved as safe
- *Ruptured* implants are NOT approved
  - There was no 10-year clinical trial of ruptured implants
- Surgeons and patients have a dilemma:
  - Reassure and leave it in – “silicone gel implants are safe”
  - Remove it – FDA recommendation / women’s preference
A Ruptured Implant is Defective...... Before Implanted or After Implanted
Extent of Silent Rupture Problem

• >150,000 women have ruptured implants and don’t know
  • Estimate based on 2007-2017 ASPS & ASAPS procedural statistics
  • Assume 1% rupture per year
  • Assume few get MRIs

• Warranty funds available for replacement ($3,500 each)

• Patient dilemma – high cost of MRIs to access warranty funds
Is High Resolution Ultrasound an Option?

- Marc Salzman, MD presentation at ASPS
  - Ruptures confirmed in surgery
- Scanner – inexpensive, hand-held, in office
- Ideal started study - 1,000 women, 9 sites
  - Implanted between 2000-2015
  - No symptoms
  - Survey of feelings about silent rupture
Informed Consent - Optimal Process

• Surgeon *listens* to patient’s concerns
• Presents all 3 implant options / choices
  • Saline, silicone gel, structured
  • Unbiased and objective information
  • Ethical informed consent process
• Women’s implant choices are NOT limited
• Woman chooses implant best for her - with help of surgeon
Informed Consent - Altered by Hospital Bias

• Some hospitals limit number of vendors and implants
  • Disregard technology differences - “structured” is not “saline”
• Some hospitals block companies with physician stockholders
  • HCA, Tenet, Intermountain
  • Response to an HHS policy
• Limits women’s implant choices
Informed Consent - Altered by Surgeon Bias

- Some surgeons dismiss women’s concerns
  - Silent rupture / MRIs / health issues
- Some surgeons will only use silicone gel
  - Resist change – “this implant works best for me”
  - Discourage saline-filled options
- Limits women’s implant choices
“People Don’t Know What They Want Until You Show It To Them”  

Steve Jobs  
CEO, Apple
“Let Me Show You all Your Choices”