ASPS/PSF COMMITMENT TO PATIENT EDUCATION, SAFETY AND RESEARCH

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Past Vice President Health Policy and Advocacy, ASPS
CDRH FDA General and Plastic Surgery Devices Advisory Committee Meeting
General and Plastic Surgery Devices Panel
March 25-26, 2019
ASPS and The PSF

- Largest plastic surgery specialty organization in the world
- ASPS represents 93 percent of all board-certified plastic surgeons in the U.S.
- International members from more than 100 countries
Mission of ASPS and The PSF

American Society of Plastic Surgeons (ASPS)
The mission of ASPS is to advance quality care to plastic surgery patients by encouraging high standards of training, ethics, physician practice and research in plastic surgery. To support its members in the provision of excellent patient care, ASPS will provide: education, advocacy, practice support and enhanced public awareness of the value of plastic surgery, while fostering the highest professional, ethical and quality standards.

The Plastic Surgery Foundation (PSF)
The Plastic Surgery Foundation is the research arm of ASPS. The mission of The PSF is to foster innovation in plastic surgery and to improve the quality of life of plastic surgery patients through research and development, charity care and enhanced public awareness of the value of plastic surgery.
Trusted Partner in Patient Safety

Collaboration with FDA and others:

- National Breast Implant Registry
- PROFILE Registry
- MDEpiNet
- FDA’s Network of Experts
- International Collaboration of Breast Registry Activities (ICOBRA)
- FDA Medwatch Partner
Established Infrastructure for Patient Safety, Quality, Research

Committees/Taskforces
- Patient Safety Committee
- Quality and Performance Measurement Committee
- BIA-ALCL Committee
- Women’s Health and Devices Task Force (WHDTF)

Research Funding

Clinical Trials Network

Plastic Surgery Registries Network (PSRN)
Established History of Implant Science and Education

Infrastructure
- 2010: PROFILE established
- 2011: BIA-ALCL committee established
- 2012: Womens Health Device Task Force established
- 2013: NBIR established

Science
- 2010: RAND State of the Science Consensus Conference
- 2011: TUFT Study started
- 2012: TUFT Study ended
- 2013: WHDTF review of literature since T U F T S

Education
- 2010: Member Bulletin on ALCL
- 2011: Start Presenting at every clinical symposium and meeting
- 2012: Send member BIA-ALCL advisory q6mo
- 2013: BIA ALCL ICC
- 2014: BIA-ALCL supplement
Commitment to Patient Perspective

Patient Perspective
• ASPS/PSF Board of Directors
• Women’s Health and Devices Task Force
• National Breast Implant Registry
• Measures and Guidelines Workgroups
• Breast Reconstruction Awareness Fund Committee

Patient Reported Outcomes in Surgery Conference
• AHRQ 2015 and PCORI 2016 Funding
• Breast-Q, FACE-Q, Wound-Q
• PROS in Registries
Commitment to Patient Advocacy

- WHCRA
- BCPEA
- BIA ALCL Coverage
- Partner with State Societies
- Alliances
- Robust advocacy activities
Commitment to Physician Education

- In-Person Clinical Symposia and Plastic Surgery The Meeting
- PRS and PRS Global Open journals
- ASPS Education Network online learning modules
- Digital communications
- Clinical Practice Guidelines
- BIA-ALCL advisories
- BI Safety Resources on ASPS website
Commitment to Patient Education

Patient Education
- Digital communications
- BI safety resources for patients on the ASPS website
- Patient brochures for plastic surgeons to share with patients
- Informed Consent resources
- Public Education Committee
- Breast Reconstruction Awareness grants
Anaplastic Large Cell Lymphoma (ALCL)
Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is an uncommon type of lymphoma that can develop in the scar capsule near saline or silicone breast implants. This disease is currently being investigated as to its relationship with breast implants. The family of ALCL is a rare cancer of the immune system, which can occur anywhere in the body causing pain and firmness. These deposits must be identified as distinct from the calcium deposits that signify breast cancer.

Calcification:
Calcium deposits can form in the scar tissue surrounding the implant and be visible on mammography, as well as causing pain and firmness. These deposits must be estimated with the LCL to be identified as distinct from the calcium deposits that signify breast cancer.

Silicone Gel Bleed:
The evidence regarding the likelihood of clinical consequences associated with silicone gel bleed is mixed. Over time, extremely small amounts of silicone gel may pass through the shell of the implant and coat the outside of the implant.

Additional Necessary Surgery (Re-Operations)
Many variable conditions may influence the long-term results of surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of the implant.

Capsular Contracture:
Scar tissue, which forms routinely around the breast implant internally, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after surgery or years later. The occurrence of symptomatic capsular contracture is not predictable.
Continued Commitment to...

• Safety
• Quality
• Research
• Engagement
• Education

...Surgeons and Patients
Thank you!