



ASPS/PSF COMMITMENT TO PATIENT EDUCATION, SAFETY AND RESEARCH

Lynn Jeffers, MD, FACS

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**



AMERICAN SOCIETY OF
PLASTIC SURGEONS®



THE PLASTIC SURGERY
FOUNDATION™

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.



AMERICAN SOCIETY OF
PLASTIC SURGEONS®



THE PLASTIC SURGERY
FOUNDATION™

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

AMERICAN SOCIETY OF PLASTIC SURGEONS®

Committees/ Taskforces

Patient Safety Committee

Quality and Performance
Measurement Committee

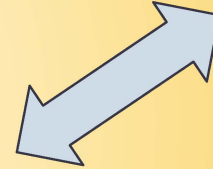
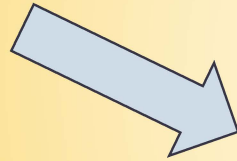
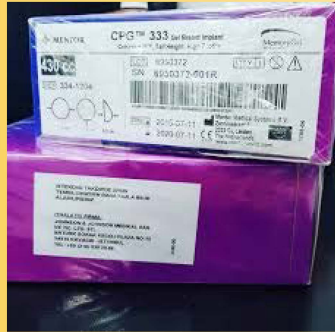
BIA -ALCL Committee

Women's Health and
Devices Task Force (WHDTF)

Research
Funding

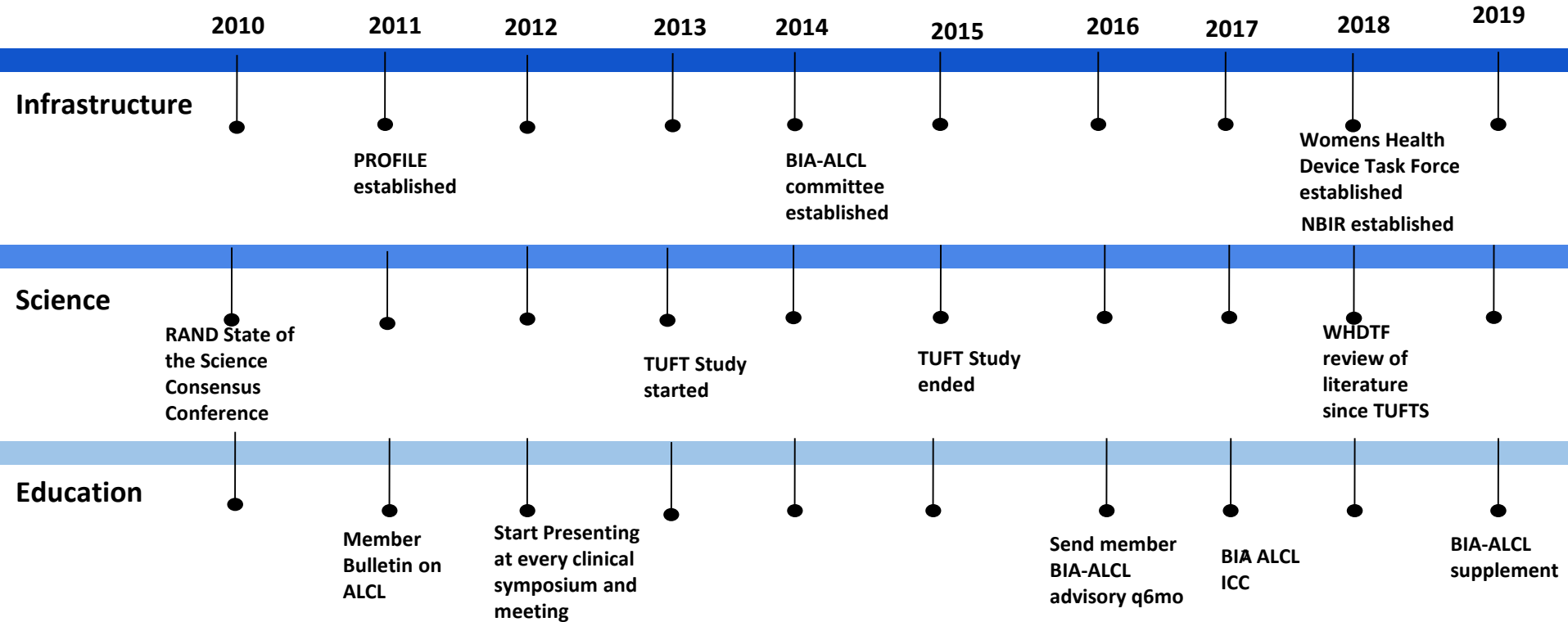
Clinical Trials
Network

Plastic Surgery
Registries
Network
(PSRN)



NATIONAL BREAST IMPLANT REGISTRY

Established History of Implant Science and Education





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



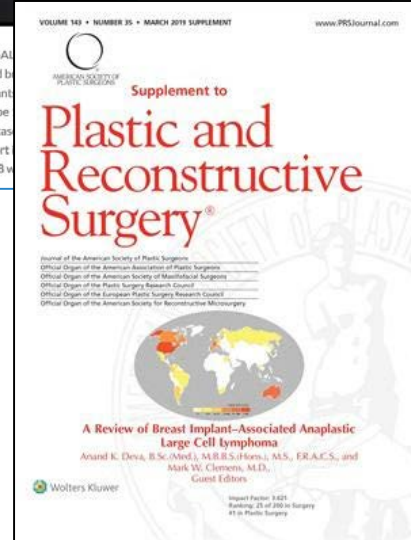
Commitment to Patient Advocacy

- **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

The collage features several digital resources from the ASPS website:

- Reconstructive Breast Reconstruction:** A page titled "Know Your Post-Mastectomy Options" with a circular diagram showing "Find a Plastic Surgeon", "Patient Safety", and "Before & After Photos".
- What is breast reconstruction?:** A page with a video player and a "TABLE OF CONTENTS" including Introduction, Candidates, Cost, Consultation, Questions to Ask, Types of Breast Reconstruction, and Risks and Safety.
- Breast Implant Associated Lymphoma (BIA-ALCL):** A "Disease Summary" page with a diagram of a breast implant and text explaining the condition, its symptoms, and the importance of early detection.
- BIA-ALCL SYMPTOMS:** A page explaining common symptoms like breast enlargement, pain, asymmetry, lumps, skin rash, and fluid collection.
- BIA-ALCL DIAGNOSIS:** A page detailing the diagnostic process, including physical exams, ultrasound, and PET/CT scans.
- Treatment of BIA-ALCL:** A page explaining the treatment options, including surgery and chemotherapy.
- After Treatment:** A page discussing the follow-up care and the importance of long-term monitoring.
- CONTACT US:** A page with contact information for the ASPS, including a phone number and email address.
- What are the risks of breast augmentation?:** A page discussing the risks of breast augmentation and the importance of informed consent.

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. Based on adverse event reports, the United States Food and Drug Administration (FDA) estimates the total number of cases of BIA-ALCL over 450 cases. It has been noted that the majority of BIA-ALCL patients have a history of a textured-surface device. An exact single-number estimate of the risk for both textured and non-textured implants is not possible with currently available data. Lifetime risk of BIA-ALCL has been estimated at 1:1,000 to 1: 30,000 for women with textured breast implants, and BIA-ALCL risk is currently under investigation. BIA-ALCL usually involves swelling of the breast at an average of 3 to 14 years after the initial breast implant operation. Most cases were cured by removal of the implant and the capsule surrounding the implant; however, rare cases have required chemotherapy and/or radiation therapy for treatment.

Patients with breast implants should be followed by a surgeon over time and seek professional care for implant-related symptoms such as pain, lumps, swelling, or asymmetry. Patients should monitor their breast implants with routine breast self-exams and follow standard medical recommendations for imaging (e.g. Mammography, Ultrasound, MRI). Abnormal screening results or implant-related symptoms may result in additional expenses for tests and/or procedures to properly diagnose and treat your condition. Tests and procedures could include but may not be limited to: obtaining breast fluid or tissue for pathology and laboratory evaluation, surgery to remove the scar capsule around the breast implant, implant removal, or implant replacement.

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

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

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

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!



AMERICAN SOCIETY OF
PLASTIC SURGEONS®



THE PLASTIC SURGERY
FOUNDATION™