Breast Implants and Complications
Practical Advice for GPs
Rod Cooter AM MD FRACS
Adelaide, Australia, May 2019

Disclosures
• No financial association with any biomedical company
• Specifically no financial payment from any implant company

Breast Augmentation - Increased Demand
2000
212,500 Implants
Ref. USASPS National Plastic Surgery Statistics

Breast Implants – Beneficial Evidence
...“breast augmentation significantly improves satisfaction with breast appearance, psychological well-being, and sexual well-being”...
...“overall satisfaction is most strongly correlated with breast appearance satisfaction”...

Common Reasons for Choosing Breast Implants
• Always had small breasts
• Loss of volume (after breast feeding)
• Major weight loss
• Unequal breasts
• After breast cancer surgery
• After risk reducing mastectomy

Evolution of Breast Augmentation
1890s
• Fat
• Paraffin
• Glass balls
• Ivory

1900s
• JPMI Japanese prostitution injected industrial silicone to enlarge breasts

1940s
• Ivalon sponges
• Polyethylene
• Polytetrafluoroethylene
• Teflon

1950s
• Medical grade silicone injections

1960s
• Medical grade silicone injections
Late 19th Century
- Silicone invented as polymer of silicone dioxide

1940s
- Hydrocephalus shunts
- Lubricant used in WWII

1950s
- 1st breast implant

1960s
- Thick walls, fixation patches, capsular contractures

1970s
- Thinner walls, bleed rate, ruptures, extravasation

1980s / 1990s
- More viscous gels
- Textured surfaces

2000s
- More viscous gels
- Textured surfaces

2010
- Nano texture
- Microchips

Evolution of Silicone

Evolution of Silicone Breast Implants

Implant Extraction Video

Ruptured Implant

Variety of Implants

Microchip in Implant
Current Breast Implant Issues

1. Conflict of interest in literature
2. Breast implant associated Anaplastic Large Cell Lymphoma (BIA-ALCL) & Regulation
3. Breast Implant Illness (BII) & Social Media
4. Surgical Tourism & Internet Consultations

Conflict of Interest around Breast Implants

1. 1990 Dow Crisis
2. 2010 PIP Crisis
3. 2012 Senate inquiry
4. 2013 ASERNIP-S review

CURRENT
- BIA-ALCL
- BII
- Surgical tourism

Silicone Implant Controversies

PIP Implant Cavity with Milky Solution

Quorum Flow Chart

JAMA Conflict of Interest Theme Issue: Statements

"There was a higher likelihood of receipt and higher value of reported payments to surgeons than to primary care physicians"

"The greater the financial interest, the greater the likelihood professional judgment will be biased, and the more severe the COI."
- McCoy MS, Emanuel EJ. Why there are no "potential" conflicts of interest. JAMA. 2017 May 2;317(17):1721-2.

"It seems plausible that very large payments warrant greater concern about conflict of interest causing bias and undue influence."
- Le D, Glaad F. Payments to physicians; what about the amount of money makes a difference? JAMA. 2017 May 2;317(17):1719-20.
Plastic Surgeons Receiving Industry Payments

### Plastic Surgery Literature Conundrum

If Conflict of Interest is **not transparent** in our literature, and Literature is **basis** for formulating clinical guidelines, it is problematic because guidelines tell us what we should be doing.

**Question:** How can we generate meaningful data?

**Answer:** Clinical Quality Registries because robust registries tell us what we are doing!

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**Australian Breast Device Registry**

**Current Situation**

Data from 38,343 patients relating to 79,554 breast devices
- 1.1% patient opt out rate
- 269 sites and 491 surgeons contributing nationally
- Completed first rounds of surgeon and site reporting
- Collecting Patient Reported Outcome Measures at 1, 2, 5, 10 years

**Issues Identified – Primary Implants**

<table>
<thead>
<tr>
<th>Year</th>
<th>Nb</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>247</td>
<td>29.3%</td>
</tr>
<tr>
<td>2013</td>
<td>247</td>
<td>29.3%</td>
</tr>
<tr>
<td>2014</td>
<td>247</td>
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</tr>
<tr>
<td>2015</td>
<td>247</td>
<td>29.3%</td>
</tr>
<tr>
<td>2016</td>
<td>247</td>
<td>29.3%</td>
</tr>
</tbody>
</table>

### Table 1. Issues identified at revision of primary implant breast

- Capsule contraction
- Skin sparing problems
- Device rupture
- Deep vascular infection
- Device infection
- Breast asymmetry
- Infection, change of implant position (ACCIP)
Capsular Tissue

The ICOBRA project is designed to pick up low frequency events such as ALCL among patients with breast implants.

North America: United States, Canada
Europe: Austria, France, Germany, Ireland, Italy, Netherlands, United Kingdom, Switzerland
Africa: South Africa, Tunisia
Oceania: Australia, New Zealand
Asia: Brazil

Breast Implant Associated Anaplastic Large Cell Lymphoma

Anaplastic T-cell Lymphoma association with breast implants first reported 1997

Ref: Keech JA & Creech BJ
Anaplastic T-cell Lymphoma in Proximity to a Saline Filled Breast Implant
Plast Reconstr Surg 1997;100(2):554-555

BIA-ALCL Perspective

- This is a rare tumour
- WHO Classification of Lymphomas
  - now recognised as a distinct entity
- ALCL is a rare type of NHL
- Surveillance, Epidemiology, and End Results (SEER) program of the NCI statistics:
  - 3: 100,000,000 ALCLs in breast / year

BIA-ALCL

- Two major variants of ALCL
  - One expresses the protein anaplastic lymphoma kinase (ALK+)
  - One does not express anaplastic lymphoma kinase (ALK-)
- BIA – ALCL are (ALK-)
• BIA – ALCL are CD30 positive
  – CD30 antigen is a transmembrane glycoprotein
    member of the tumour necrosis factor (TNF) receptor superfamily
  – CD30 expression in neoplastic cells is mainly positive in
    lymphoid neoplasms:
    • Hodgkin's lymphoma
    • Anaplastic large cell lymphoma
    • Primary cutaneous T-cell lymphoma

Clinical Results – BIA-ALCL

The Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma in Australia and New Zealand Confirms the Highest Risk for Grade 4 Surface Breast Implants.

BACKGROUND: The epidemiology and implant-specific risk for breast implant-associated (BIA) anaplastic large cell lymphoma (ALCL) has been previously reported for Australia and New Zealand. The authors now present updated data and risk assessment since their last report.

CONCLUSIONS: The number of confirmed cases of BIA-ALCL in Australia and New Zealand continues to rise. The implant-specific risk has now changed to reflect a strong link to implant surface area/roughness as a major association with this cancer.

Textured Surfaces

SPECIAL UPDATE: The epidemiology of Breast Implant-Associated Large Cell Lymphoma in Australia and New Zealand confirms the highest risk for grade 4 surface breast implants

Abstract

BACKGROUND: The epidemiology and implant-specific risk for BIA-ALCL, has been previously reported for Australia and New Zealand. We now present updated data and risk assessment relative to our last report.

METHODS: New cases in Australia and New Zealand were identified and analyzed. Updated data from three leading breast implant manufacturers (i.e., Mentor, Allergan, and Sientra) were reviewed to estimate implant-specific risk.

RESULTS: A total of 36 new cases of ALCL were diagnosed between January 2017 to April 2018 involving the total number of confirmed cases in Australia and New Zealand to 111. This represents a 87% increase in number of reported cases over this time period. The mean age and time to development remained unchanged. The implant-specific risk has increased for Sientra Polyurethane (214 cases higher) as compared with Silastic, which has remained relatively stable (165 times higher) compared with Silikon implants.

CONCLUSIONS: The number of confirmed cases of BIA-ALCL in Australia and New Zealand continues to rise. The implant-specific risk has now changed to reflect a strong link to implant surface area/roughness as a major association with this cancer.

Breast Implant Illness and Social Media
Breast Implant Illness (BII)

Table 1: Systemic Symptoms Associated With Silicone Breast Implants

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Nausea</td>
<td>Nausea</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Fatigue</td>
</tr>
<tr>
<td>Headache</td>
<td>Headache</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>Sleep disturbance</td>
</tr>
<tr>
<td>Mood changes</td>
<td>Mood changes</td>
</tr>
<tr>
<td>Irritability</td>
<td>Irritability</td>
</tr>
<tr>
<td>Photosensitivity</td>
<td>Photosensitivity</td>
</tr>
<tr>
<td>Dermatitis</td>
<td>Dermatitis</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Fatigue</td>
</tr>
<tr>
<td>Night sweats</td>
<td>Night sweats</td>
</tr>
<tr>
<td>Increased sweating</td>
<td>Increased sweating</td>
</tr>
</tbody>
</table>

Table 2: Proposed Stratification of BII Based on Preexisting Disease and Likely Outcome

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
<th>Prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>BII type A</td>
<td>No preexisting disease</td>
<td>Most likely will improve after explanation</td>
</tr>
<tr>
<td>BII type B</td>
<td>Abnormal markers but short duration of disease</td>
<td>Short honeymoon but likely to have return of symptoms</td>
</tr>
<tr>
<td>BII type C</td>
<td>Proven autoimmune disease</td>
<td>Improve after explanation</td>
</tr>
</tbody>
</table>

Breast Implant Illness: A Way Forward

Summary: The link between breast implants and systemic disease has been reported since the 1990s. Although many studies have looked at either specific symptoms or whole breast implant populations, the issue is still prevalent and remains controversial. This review examines the evidence for associations between breast implants and autoimmune disease, with a specific focus on BII and associated conditions. The authors discuss the limitations and potential biases in the current literature and propose future research directions to better understand the relationship between breast implants and health outcomes. 

Authors: Mark R. Magoss, MBBS, FEACR, Paul J. Conlon, MBBS, FACS, and Jessica A. K. Yoo, MD, MPH.

BII: Blogs and Social Media Influence

**Blogger Removes Breast Implants That Caused Weight Gain**

A blogger has had her breast implants removed after she claims they caused her to suffer from body odor, weight gain, and fatigue. Six Cooper, the 29-year-old behind the blog “Healing of My Mummy,” posted a photo of herself to her Instagram followers, showing her removed breast implants. She said years ago:

“I can’t believe it’s been one week,” she said of her explant surgery. “This past week, I’ve been sore, but have felt incredible. More so than the last few years. I went from being practically bedridden to hiking more energy for life.”

**Facebook**

BII Awareness

No Journey Through Chaos, Explor & Healing

Our team

Visit us for the latest research and information on breast implants and their potential health effects.
RESULTS: We identified 17 observational studies. Common destinations included Europe, South America and South East Asia. Infections complications were common. Wound dehiscence and aesthetic dissatisfaction also featured. Catastrophic outcomes such as sepsis, intubation and ventilation, radical bilateral mastectomy, irreversible hypoxic brain injury and death were also reported. There were expectations that home country health systems would treat complications and provide non-medically indicated revision procedures. The burden on home country health systems was evident from a public health perspective.
Game of Implants

The “Game of Implants”: A Perspective on the Crisis-Prone History of Breast Implants

Anand K. Desai, BSc (Med), MBBS (Hons), MS, FRACS; Amanda Corson, BMedSc (Hons), MBBS (Hons); Mark Magrannison, MBBS, FRACS; and Rodney Cussen, MBBS, MD, FRACS

Abstract

Since their introduction into the market, breast implants have been the subject of many controversies. It is briefly examined the factors that have shaped the breast implant industry to make it what it is today. This review will concentrate more on the use of implants in aesthetic surgery rather than use in breast reconstruction, but some of the factors have relevance to both indications.


Practical Advice

Patients seeking breast implants

- Not lifetime devices: 10-15 year exchanges
- Ensure surgeon contributes data to ABDR
- See surgeon twice before procedure with a 7-10 day cooling off period
- Seek fully informed financial consent especially for post-op problems
- If considering surgical tourism, take an ABDR form for surgeon to complete

Patient with breast implants

- Annual check
- BSE and regular MMG with Eklund manoeuvre
- U/S as alternate breast screen +/- MRI
- Ruptured cohesive gel implant cannot be diagnosed on clinical exam
- U/S over calls rupture, MRI is best

Actively swollen breast

- Suspect anaplastic large cell lymphoma
- Examine for lymphadenopathy (axilla, neck) ultrasound guided fluid aspiration and request CD30, ALK status
- Reassure patient can be cured in early stage
- Urgent referral to plastic surgeon
Practical Advice

Lethargy, Joint Pains, Brain Fog

- Exclude other pathology
- Rheumatologist, Immunologist referrals as appropriate
- Caution patient that explanting implants may have no effect on symptoms
- Once implants are removed there may be no rebate from Medicare for re-alignment at a later date

Thank You

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