**REPORT ON BREAST IMPLANT ILLNESS**

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There are a growing number of women who believe that they have a condition, which they have called Breast Implant Illness. This condition consists of a very broad range of non-specific symptoms such as hair loss, brain fog, general fatigue, fibromyalgia, ME, irritable bowel syndrome, skin conditions, lupus, rheumatoid, SLE, Reynaud’s.

These symptoms seem to be a very similar collection of symptoms that were seen during the Dow Corning crisis in the early 90s. The difference on this occasion is because of social media the patients are able to find each other and are gathering together in large groups. Mostly they are represented on Facebook pages. The American Facebook page <https://www.facebook.com/groups/Healingbreastimplantillness/> currently has 55,000 members at the last count and these are private Facebook groups to which we have no access. The English Facebook group has over 1000 members.

Many of these patients have tried a range of strategies to overcome their ailments, including nutritional advice, changes in diet and a variety of lifestyle changes. Most of them have reached the conclusion that their breast implants are responsible for their malaise and present requesting explantation. In most cases they request a complete capsulectomy using what they describe as an en-bloc technique, delivering the implant and capsule intact with no breaches. They hope that with this strategy all tissue in contact with the silicone is removed, none of the silicone is spilt, the biofilm is not breached and they feel that only this technique will give them the best chance of recovery. They request to see photos, to show that the implants came out en-bloc and they also request histology on the capsules to exclude ALCL.

In reality this is not always achievable in every patient and depends very much on the state of the capsule and the condition of the underlying implant. This whole treatment strategy goes very much against the general advice that we as plastic surgeons would give them, but as the psychological component of this condition is very important for their recovery, in most cases the surgeons treating these patients have been complying with their requests. Between three surgeons who are currently seeing a lot of these patients, we have treated over 150 such patients in the last year.

Even though there is no evidence linking silicone implants to these conditions, remarkably quite a few of the symptoms do appear to resolve, within about 3 months of surgery. We are currently undertaking a study of the preoperative symptoms and the postoperative recovery to try and establish which of these conditions appear to improve following explantation in the hopes that this will help guide and inform the preoperative discussion with the patient.

This is a vulnerable group of patients who are looking to the plastic surgery community for recognition of this condition. Many surgeons quite reasonably point out to their patients that there is no evidence linking silicone to these symptoms, and this is causing frustration and has led to a movement amongst the patient group for greater recognition.

On 26 November there will be a Panorama documentary, part of which appears to involve breast implants, and is likely to focus on breast implant illness and this group of patients. There is a risk that it will take a very negative view of breast implants and of plastic surgeons using breast implants. It is important therefore that we are prepared with as many of the facts available to handle media and press enquiries.

Please find enclosed a list containing some of the current literature available on this subject with a brief summary produced by my colleague Ben Miranda. There are very few good scientific publications on breast implant illness, this is predominantly a patient driven condition at present that has not gained much traction in the plastic surgery community yet.

**Summary of Literature - Breast Implant Illness**

**Points:**

1. Breast Implant illness-type symptoms increasingly reported over the 1980s–early 90s which resulted in temporary withdrawal from market recommendation by the FDA in early 1992. This was rapidly overturned for Mentor silicone implants during mid 1992.
2. Auto-immune disease was identified as a potentially related factor which in **Shons 1992 study (see ref)** was not supported due to only 28 cases being reported from 1 – 2 000 000 women in the USA who had implants and due to the incidence of AID in the general population, nearer 1000 cases would be expected.
3. Small study of 38 implant cases **(Rohrich 2000 – see ref)**, retrospectively matched for implant removal found temporary improvement in breast implant related illness-type symptoms. BUT STUDY NUMBERS TOO SMALL!
4. **Fryzek 2001 (see ref)** study in 2500 patients randomly selected from Swedish breast implant registry, when compared to 3500 breast reduction patients, found that although breast augmentation patients were more likely to report illness-type symptoms, the lack of specificity and absence of a dose-response relationship suggests no causal association.
5. **Dush 2001 (see ref)** looked at 179 women with silicone implants involved in product liability and litigation for breast implant illness-type symptoms. 86% of cases were performed for cosmetic reasons. 2 validated screening tests were filled-in by patients to look for the presence / absence of functional psychiatric illness. 65% response rate (117 patients replied). These data were compared to 231 female undergraduate students, 161 medical / surgical inpatients and 60 anxious psychiatric patients. Breast augmentation patients were shown to have significantly higher anxiety states (53%) and traits (52%) compared to undergraduate students and medical/surgical inpatients (p<0.001) and statistically similar anxiety reactions as psychiatric patients with anxiety disorders (49%, 48%). As this was an uncontrolled study with a variety of reported symptoms between individuals, only a hypothesis could be concluded which is that these patients are at risk of somatisation and it is unlikely that true rheumatological / connective tissue disorders exist. Also likely that their psychological pre-disposition is what led them to seek implants in the first place. BUT of course their symptoms must still be taken seriously nonetheless.
6. **De Jong 2002 (see ref)** study of 42 silicone breast implant patients who self-reported illness-type symptoms in a questionnaire. They found 12/48 had increased polymer binding Ig and none of these patients were categorised as being ‘severe’ in their symptom and clinical examination reports. Furthermore 17 years average silicone exposure in the ‘minimal symptoms group’ did not result in induction of polymer binding Ig. Only conclusion here is that there is no strong association between silicone exposure and detectable Ig levels in the blood.
7. **Tang 2017 (see ref)** study of 2 BII support groups on facebook with 4200 and 18800 members respectively. Of 345 posts and comments for augmentation and BII, 165 reported BII type symptoms. Looking at reconstruction, 73 posts were reviewed and 66% experienced BII type symptoms – 44% of these pursued implant removal and only 50% of these described improvement after explantation.

Conclusion:

1. Lack of good data (the main issue in drawing any conclusions at all)
2. No causal association demonstrated in literature so far
3. Variety of generalised symptoms reported making it difficult to ascertain possible ‘true’ related illness features
4. No biochemical association demonstrated
5. Likely psychological pre-disposition of patients to develop symptoms.
6. Explantation only works for 50% patients

**FDA BI Postapproval Study Ann of Surg 2018 Comments:**

* Largest breast implant outcome study in the literature = important to precipitate further investigations.
* Only Allergan & Mentor included.
* Highlights the REAL ISSUE of POTENTIAL problems in relation to breast implants
* Highlights the IMPORTANCE of LISTENING to patient-reported symptoms post implants
* Highlights the LOW POTENTIAL OVERALL RISK of developing any of the published illness for multiple reasons:
1. Data shows a COMBINATION of increased illness risk with breast implants BUT also decreased illness risk with BIs (see later).
2. Reported risk rates are extremely low in terms of % when looking at the data ranging from 0.004% - 0.6%
3. Most data relies on SELF-REPORTING by patients and is related to the single manufacturer ‘Mentor’ implants only. BUT Allergan self-reported data are CONFIRMED BY A PHYSICIAN = ‘true’ diagnoses (but has shorter follow up of only 2 years)
* Included BI patients are grouped together BUT cosmetic and reconstructive groups are very different e.g. (Melanoma risk may be significantly more in cosmetic patients who are likely to sunbathe more after their augments!)
* General population figures for comparison are taken from heterogenous papers that include significantly older data with broad spectrum of different cases.
* Significant attrition rate in follow-up, retrospective analysis and no good control group = Unreliable conclusions despite high numbers.

To highlight the ‘combination’ of increased & decreased illness risk:

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|  | **Mentor** | **Allergan** |
| SLE | 0.65% risk = 1.11X increased risk vs. general population | 0.006% risk = 9X protective vs. general population |
| RA | 0.35% risk = 5.96X increased risk vs. general population | 0.008% risk = 7X protective vs. general population |
| Scleroderma | 0.04% risk (but reported as 7X more likely vs. general population) | No reports |
| Sjogren’s  | 0.06% risk (but reported as 8X more likely vs. general population) | No reports |
| Breast Cancer | No difference in general population | No reports |
| Lung Cancer | 9X protective vs. general population | No reports |
| Melanoma | 0.08% risk (but reported as 3.71X more likely vs. general population *? increased in sunbathing young breast augment patients.* | No reports  |

**Conclusion:**

* While this paper agrees with some of the conclusions of **(Balk 2016 – see ref)** systematic review, it also contradicts other aspects and even this systematic review is confounded by included study heterogeneity.
* This study shows illness risk increase BUT ALSO ‘protective’ nature of BIs! AND in ALL CASES the % risk/protection is extremely small.
* However patient reported symptoms are real and must be taken seriously.
* Properly designed, prospectively enrolled, controlled, diagnosis-confirmed, long term follow-up studies are required to present accurate data.