Patient Safety Advisory - Breast Implant Removal and Capsulectomy

Joint Safety Statement of the International Society of Aesthetic Plastic Surgery (ISAPS), The Aesthetic Society, and The Aesthetic Surgery Education and Research Foundation (ASERF)

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There has been a worldwide increase in the number of patients requesting implant removal for a variety of systemic symptoms that they attribute to their implants. This has been referred to as Silicone Incompatibility Syndrome (SIS), Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA), and Breast Implant Illness (BII).1 In the US, the Food and Drug Administration (FDA) has included systemic symptoms in a box warning that is required for all implants sold in the US which states, "Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases, and others. Individual patient risk for the development of these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement."[2]

Patients with self-described symptoms request removal of the implant and capsule, "en bloc". Their concern is that toxins from the implant, such as heavy metals, including platinum, silicone, and/or bacteria and fungus, could be in the capsules and failure to remove the capsule would leave toxins behind and could preclude symptom improvement. For that reason, they seek out surgeons who guarantee total en bloc capsulectomy and this is perpetuated on some social media sites as well as by surgeons who promote themselves as "explant experts".[3]

What We Know

- Systemic symptoms patients attribute to their breast implants have been reported with all types of implants: saline and gel filled, smooth and textured surfaces, and has been reported with implants from every manufacturer.
- Over 100 symptoms have been reported, in no specific configuration.
- Some patients will experience symptom improvement with implant removal.

What Is the Data?

The Aesthetic Surgery Journal has published four papers from an ASERF-funded study, "Systemic Symptoms in Women – Biospecimen Analysis Study." This study, with Drs. Caroline Glicksman and Patricia McGuire as principal investigators, is the first prospective, blinded study comparing women with self-described BII to two control groups. The study evaluated symptom surveys, NIH-validated patient-reported outcome measures, and biospecimens (peripheral blood and implant capsules) for consistent, objective, measurable differences between the symptomatic cohort and the two control groups (women with implants without systemic symptoms they attribute to their implants, and women undergoing cosmetic mastopexy who have never had any implanted medical device) which could be used to make a diagnosis or point to a cause of symptoms in these patients.[4–7]

1. The self-described BII cohort reported statistically significantly higher symptoms at baseline from the two control cohorts.
2. The BII cohort experienced rapid symptom improvement after implant removal which was sustained through one year of follow-up. The symptom improvement was independent of whether part or all the capsule was removed. There was no statistical difference in reported symptoms between the two control groups at any time point.
3. There was no measurable difference in the biospecimens between the cohorts including heavy metals testing and next generation sequencing (PCR) for bacterial and fungal DNA of the implant surface or capsule.
4. Recently presented data from a parallel study in Australia, with Drs. Anand Deva and Mark Magnusson as principal investigators, has shown similar results with symptom improvement after implant removal, independent of the type of capsulectomy performed.[8]
5. A study by Byrd and Nissen in the Netherlands prospectively followed patients undergoing implant removal and showed that symptom improvement occurred even with no capsule removed in subjects with no other indication for capsulectomy.[9]

Terminology Is Important

- The term en bloc describes a procedure for malignancy where a tumor is removed with a margin of uninvolved tissue. This term should not be used for a capsulectomy performed in the absence of malignancy.[10]
- The often self-reported term BII implies a causation by breast implants when there is currently no direct evidence of causation, only a potential association. A more accurate characterization would be to use the term "Systemic Symptoms Associated with Breast Implants (SSBI)".

What Does This Mean for Plastic Surgeons and for Our Patients?

As board-certified plastic surgeons, we should practice evidence-based medicine. The absolute indication for en bloc capsulectomy is removal of an implant and capsule in the

presence of capsular malignancy. Relative indications for total capsulectomy are capsular contracture, rupture of a gel implant, and possibly with removal and exchange of textured implants. There is currently no good peer-reviewed evidence that capsulectomy is required for symptom improvement in the absence of other indications. Patient preference may be considered with appropriate informed consent. Capsulectomy is a more invasive procedure, may be more expensive, and may carry higher risks.

- Surgeons who state that en bloc capsulectomy is required for symptom improvement should not do so without the scientific data to support their claims and potentially violate ethical standards, as it could lead patients to undergo surgical procedures that may not be indicated.[11]
- Surgeons promoting themselves as "explant experts" who have no additional training or other basis to deem them more of an expert than other board-certified plastic surgeons, should cease marketing themselves as such.
- Surgeons should keep abreast of scientific knowledge (AMA Principles of Medical Ethics).
- Surgeons should not falsely represent a skill set; The Aesthetic Society Code of Ethics Section 3.01, B.14.: Claiming superiority in skills or services, including superiority due to the member's gender or ethnicity, which claims cannot be easily and factually substantiated by patients.

SSBI remain a diagnosis of exclusion so patients should have an appropriate medical evaluation to rule out other causes prior to surgery. Patients should be given educated choices using up-to-date, scientific data including removal of their implants with or without capsulectomy with the risks and benefits fully explained. It is likely patients will see at least partial symptom improvement after implant removal and their improvement may occur with partial capsulectomy, or no capsulectomy. Further prospective research is necessary, and guidance may change as more data becomes available.[12]

Safety Information for Patients

1. Breast implants are not lifetime devices and require regular follow-ups with your plastic surgeon.[2]
2. Implant integrity should be evaluated with high-resolution ultrasound (HRUS) or MRI five years after implant placement and every 2–3 years after.[2]
3. Any persistent symptoms that occur in patients with breast implants should be evaluated for other medical diseases prior to consideration of undergoing implant removal surgery.
4. For patients who develop symptoms that they attribute to their breast implants, if no other cause is found, it is likely that they will see at least partial symptom improvement after implant removal. The symptom improvement may occur with no

or partial capsulectomy which is a procedure that is less invasive, less expensive and may carry lower risk.
5. Patients should seek out board-certified plastic surgeons for any concerns with their breast implants.

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