BREAST IMPLANT CONTROVERSY: WHAT YOU NEED TO KNOW

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Silicone implants have been around since the sixties. The first case of BIA-ALCL was reported in 1992 [1]. The condition came to the attention of TGA in 2009 and it has been monitoring it since 2011. The number of cases since then has significantly increased. As of December 2018 there were 656 cases worldwide, and as of May 2019 78 cases have been reported in Australian women (including 4 deaths). To put this in perspective, there are an estimated 10 million women with breast implants worldwide. In Australia alone there are 13000 – 17000 women undergoing breast implant related procedures annually [2,3] . These are estimated numbers as no one knows for sure exact numbers, as there are only few registries for breast implants across the world (Australia has one, started relatively recently) and not every surgeon participates in them.

It has been identified that heavily textured implants have a significantly higher risk profile than those that are lightly textured or smooth. The risk estimates currently suggest that heavily textured implants such as those manufactured by Allergan (Biocell) have a risk of somewhere around 1 in 1000, and others that are less heavily textured such as Mentor implants (Siltex) are somewhere around 1 in 80000 [3] . There is a lot less information about smaller companies out there, but polyurethane implants are thought to be similar to heavily textured silicone implants.

As a result of this information, in April 2019 French and Canadian Authorities withdrew Allergan Biocell implants from the market. Australia, USA and the rest of the world is yet to follow and the FDA and TGA have both put out statements that they are gathering more information before a final decision is made. In Australia the stock that's still available in hospitals and on surgeon's shelves and can continue to be used [4].

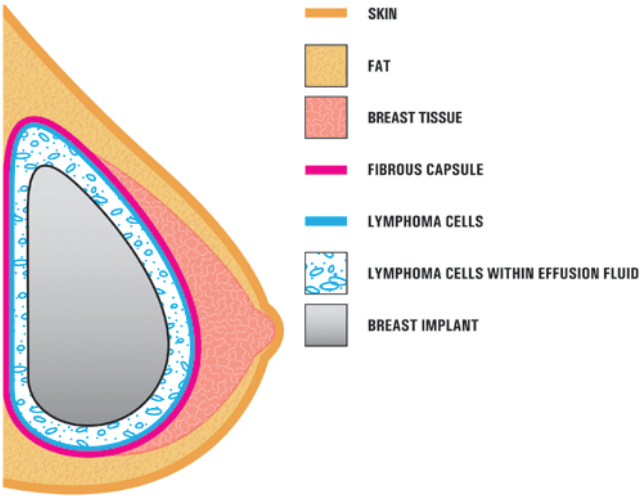
Breast implants are very common in Australia, both in patients who have had a reconstruction post mastectomy for breast cancer and of course in a multitude of patients who have had breast augmentation for cosmetic or developmental reasons. Vast majority of these patients have some form of textured implants in them.

The reason that textured implants are used in preference to smooth implants, is that they offer a range of improvements and a decrease in some of the common complications of breast implants such as contracture, rotation and rippling, which have a much higher incidence than BIA-ALCL. However, as the incidence of this condition rises, particularly in specific types of implant, these paradigms may require review and further justification, as part of the informed consent with patient.

So there are a couple of things you need to know. Firstly, how do you counsel potential patients who may be anxious about the type of implants they have and what to do about it, and secondly what does BIA-ALCL look like and what to look out for and how to manage it.

When speaking to patients, it is important to assure them that the risks are very very low indeed (compare it with the risk of Hodgkin's Lymphoma, which is 1 in 50). What we know now is that the risk is not completely dependent on the implant texture alone, but on the technique with which the implants have been inserted (i.e. likelihood of bacterial contamination) and possibly on some genetic susceptibility as well. So there is no need to rush out and get the implants out based on the science at the moment. It is however, a decision for an individual patient, in terms of how much risk they are comfortable with, and if they do wish to pursue this, their surgeon should be able to help.

If the patient does choose to keep them and monitor them, what are the signs to look out for? The usual timeframe for symptoms to appear is 3 to 14 years post implantation. Typically they present with a unilateral breast swelling and pain, caused by seroma forming around the implant. This seroma typically contains cancerous cells floating in it. The fluid needs to be aspirated with an FNA and sent for cytology, if a mass is present core biopsy should be performed also [3].



Typically if picked up at this stage, the condition is completely curable with explanation and total capsulectomy. In cases where there is invasion into a capsule or a mass, chemotherapy is indicated and the prognosis is less favourable. Luckily, majority of patients that have been diagnosed so far have presented with an early form only and have been cured [3].

At the end of the day this is a complex discussion with the patient and needs to take into account a number of variables, including the initial reason for implant insertion, what would happen if the implant was removed, what kind of implant is in situ and it's risk profile, the amount of risk the patient and their surgeon are willing to accept, and the new developments that are constantly coming to light, particularly over the last 8 years and moving forwards. Be sure to involve their surgeon or someone who has expert knowledge in this area and is able to guide the patient in their decision making.

References:

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3. https://www.tga.gov.au/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl
4. https://www.tga.gov.au/breast-implant-associated-cancer-or-bia-alcl

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