Statement re: UK use of biologic or synthetic mesh in Breast surgery

Prepared on behalf of the joint Association of breast Surgery (ABS) & British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) Mesh assisted breast reconstruction guideline writing group.

This statement follows the Safety communication released by the FDA on 31st March 2021 [1].

Breast cancer and breast reconstruction experts from across the UK have been working together to review the literature and provide updated joint ABS & BAPRAS guidelines for biological or synthetic mesh assisted breast reconstruction procedures, which will be released shortly [2,3].

Background: Biologic and synthetic meshes vary significantly in their source, biomechanical properties and processing before use in surgery. Mesh assisted single-stage implant based breast reconstruction is the most frequently performed implant based breast reconstruction in the UK [4].

Commentary: The FDA communication is based predominantly on the MROC study [5]. This study has many limitations; highlighted in the FDA communication[1.] Of note to UK surgeons:

- the FDA analysis is based around 2-stage sub-muscular procedures which does not represent the majority of UK practice[4].
- the FDA highlighted variation between brands of mesh, some of which are no longer in use or have never been used in the UK to our knowledge.

Multiple studies have reported variable complication rates associated with mastectomy and mesh assisted implant based breast reconstruction. The 2017 systematic review concludes that there remains a need for well-designed studies to evaluate the impact of mesh use on the clinical and patient-reported outcomes. [6]

Based on analysis of the latest scientific evidence and on expert clinical opinion, the members of the joint ABS & BAPRAS ADM guidelines writing group has made the following recommendations.

Recommendations for Clinicians:

- Discuss the potential benefits and risks of all relevant treatment options with your patients as part of a shared decision-making process [2,3].
- Be aware that data in the published literature suggest that some biological or synthetic meshes may have higher risk profiles than others. However, the published data is conflicting, predominantly lower quality evidence (case series) with multiple confounders.
- Be aware that the FDA statement predominantly relates to short term post-surgical complications and there is no recommendation for re-operation or removal of biological or synthetic mesh used in breast reconstruction[1].
- Include all cases of mesh assisted breast implant surgery in the BCIR.
- Contribute to research studies in this field to establish high quality evidence.
- Be aware that, in line with the FDA statement, the UK joint ABS & BAPRAS group are not aware of any information that shows an association between ADM use and development of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) [1].

Recommendations for Patients:

- If people are worried following their breast implant surgery, they should contact their surgical breast care team. This is particularly important if they notice swelling around their implant, discharge from the wound, redness of the skin, a fever, discoloured skin or new lumps.

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References

1 Acellular Dermal Matrix (ADM) Products Used in Implant-Based Breast Reconstruction Differ in Complication Rates: FDA Safety Communication https://www.fda.gov/medical-devices/safety-communications/acellular-dermal-matrix-adm-products-used-implant-based-breast-reconstruction-differ-complication

2 Joint guidelines from the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons: Biological and synthetic mesh assisted breast reconstruction procedures. Guidance Platform. at https://associationofbreastsurgery.org.uk/professionals/clinical/guidance-platform

3 Joint guidelines from the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons: Biological and synthetic mesh assisted breast reconstruction procedures. Clinical Guidance and Regulations. at https://www.bapras.org.uk/professionals/clinical-guidance

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6 H, Rafnsdottir S, Selvaggi G, et al. Benefits and risks with acellular dermal matrix (ADM) and mesh support in immediate breast reconstruction: a systematic review and meta-analysis. *J Plast Surg Hand Surg* 2018; **52:** 130–47meta-analysis