EASAPS response to "implant files"

The European Association of Societies for Aesthetic Plastic Surgery (EASAPS) representing all National Societies of Aesthetic Plastic surgery understands the concerns as expressed by the research journalists in the implant files. Medical devices implanted into a human body can cause harm and suffering for patients which should be avoided at all time.

Having said that, innovation and research has led to development of many devices that have improved the quality of life of many patients and have saved the lives of others.

Without innovation no progress in medicine.

Keeping this in mind EASAPS wants to emphasize that all decisions with respect to implants in general and breast implants in particular must be based on scientific data and not on emotions. As plastic surgeons focused on aesthetic, we know more than any specialty how changes in appearance can impact self-esteem and how a patient feels about them self. Our primary concern is always the patient and his/her safety, while making decisions on evidenced based science.

Looking at all scientific data available EASAPS comes to the following conclusions:

- Textured implants are not known to increase the risk for breast cancer.
- No evidenced- based data suggest removal of any implants prophylactically.
- EASAPS has no convincing data to support banning of any certified breast implants in Europe.
- Patients with breast implants (textured/ smooth) without any symptoms are recommended to follow the recommended program of patient safety and breast cancer screening in their national country as well as yearly check-ups.
- Unexpected swelling of the breast is a sign for follow up by a plastic surgeon
- Specific recommendations on the use of textured/smooth implants may vary across the European countries. Plastic surgeons in charge of implant-based indications should follow national recommendations until international consensus is obtained.

EASAPS comments on BIA-ALCL (Breast Implant Associated Anaplastic Large Cell Lymphoma)

- BIA-ALCL is an extremely rare condition that is detectable and curable
- BIA-ALCL should be considered as being a multifactorial condition involving:
  Genetic factors (JAK1/CD3 signaling pathway); Bacterial involvement; Textured implant surface and Duration of exposure. The etiology and pathogenesis of BIA-ALCL is not fully elucidated and intensive worldwide research is ongoing.
- Information on BIA-ALCL should be included in all informed consents.
- All patients requesting implant-based surgery for reconstructive or cosmetic purposes must be informed on the risk of BIA-ALCL when choosing textured implants.
- To our knowledge, no case of BIA-ALCL has been reported in patients with smooth surface implants alone.

More details on BIA-ALCL (Breast Implant Associated Anaplastic Large Cell Lymphoma)

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a distinct type of T-cell lymphoma, developing around implants, that can occur 2 to 25 years (median 8 years) post-implantation. Most patients present with a swelling of the breast, which is usually associated with pain and fluid collecting around the implant. Less commonly, a lump in the breast and/or in the axilla can be present. A symptomatic periprosthetic fluid collection (> 1-year post implantation) should be investigated with ultrasound and fine needle aspiration. Immunohistochemistry confirms the diagnosis BIA-ALCL with CD30+ and ALK– expression. In most patients with disease localized to the periprosthetic fluid, surgery alone usually is curative. A total capsulectomy and bilateral implant removal should be performed. Before surgical intervention, international recommendations state that a PET-CT scan should be done to exclude disseminated disease. De Jong et al in 2008 were the first to publish a report identifying an increased risk of BIA-ALCL in association with breast implants (odds ratio, 18.2; 95% CI, 2.1-156.8). Several studies have shown that BIA-ALCL is related to textured implant shells having a high surface area.

In 2011, the FDA (US Food and Drug Administration) informed on the clear relationship between textured breast implants and the occurrence of the Anaplastic Large Cell Lymphoma, a rare subtype of Non-Hodgkin Lymphoma.

WHO has considered BIA-ALCL as a specific entity since 2016.

EASAPS recommends reporting all confirmed cases of BIA-ALCL to the international profile registry (www.thepsf.org/profile) collecting all confirmed cases as well to the national breast implant registries.

Collaboration across clinicians, research groups, regulators, and patients are highly important, and a transparent sharing of outcomes and data is mandatory. National Breast Implant Registries are recommended to co-work with ICOBRA for sharing a huge amount of data within a short time thereby improving statistical validity.

EASAPS suggests relying national decisions on high quality, peer reviewed and published scientific evidence.

Intensive research is ongoing on the following questions:

- DO BRCA PATIENTS PRESENT AN INCREASED RISK FOR BIA-ALCL ?
- Does the NUMBER OF SURGERIES IMPACT ON THE INCIDENCE of BIA-ALCL?
- WHICH TYPE OF IMPLANTS ARE PREVALENT?
- IN WHICH WAY HAS THE DURATION OF EXPOSURE IMPACT?
- WHAT IS THE BACKGROUND RISK FOR ALCL WITHOUT BREAST IMPLANTS?
- WHAT IS THE GENETIC DYSREGULATION = MUTATION?

22 European Aesthetic Plastic Surgery Societies of 20 countries that we were able to reach support these conclusions. International collaboration with other Societies and countries continues to stay up to date of the current scientific status of this disease and other diseases that might be related to breast implants. We will keep patients and our colleagues up to date.

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