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Correspondence

About the French prohibition of textured breast implants: is it justified or over-cautious? The EUSOMA, ESSO/BRESSO position

Dear Editor:

After the publication of the EUSOMA position regarding breast implant associated anaplastic large cell lymphoma (BIA-ALCL) and the use of textured implants in January 2019 [1], the medical devices regulatory authority in France, the ANSM (National Agency of Medicine and Health Products), has recently banned all use of textured surface breast implants. This decision was based on concerns about the risk of BIA ALCL which may be more likely in women with textured versus smooth surfaced implants [2].

BIA-ALCL is a rare disease, estimated to affect one woman in 20–30 000 with breast implants. This incidence may be an underestimate because widespread awareness of the condition is relatively recent. Cases of idiopathic late implant-related seroma may have been treated unknowingly by capsulectomy without histological assessment and hence never diagnosed as such [1].

Early detection of BIA-ALCL leads to cure in more than 95% of cases following removal of the implant and full capsulectomy, without the use of adjuvant systemic treatment [3].

In view of the extreme rarity of this condition and the excellent prognosis of BIA-ALCL the decision of the French regulators (possibly soon to be followed by Canadian Regulators) to advise mandatory withdrawal of textured implants may be overly cautious [2,4]. The scientific community is currently undertaking research and collecting data globally to allow a better understanding of the epidemiology and aetiology of this rare disease. These data are unlikely to provide firm conclusions for several more years. The decision of the French Regulator has the potential to do harm to women, leaving surgeons unable to use a product which has a valuable role in breast reconstruction. Textured implants have a lower rate of capsule formation and their textured surface allows them to retain orientation, permitting use of anatomically shaped implants which are preferred for post mastectomy reconstruction. This role cannot be easily fulfilled by smooth implants.

In Europe Breast Reconstruction is mainly undertaken using textured implants (macro-textured) for the above reasons. In contrast, in the US and Canada, the use of smooth implants is the norm.

There is a new generation of microtextured implants being made available but outcome data from long term follow up is presently limited. Following the logic of the French Regulator, these should not be recommended because their history is too short to allow for any firm conclusions to be drawn about their safety in relation to BIA-ALCL risks, which was the reason underpinning the decision to ban macrotextured implants in the first place [5].

Several other EU Government Health Bodies issued statements of their positions regarding the safety of these devices in April 2019. In the majority of countries it is now mandatory to report cases of BIA-ALCL to National cancer registries and the information on the risk of BIA-ALCL should be clearly written/described in the informed consent before the procedure [6–10].

EUSOMA and ESSO/BRESO clearly endorse this position as the only that can be scientifically supported at the moment and will strive along with other scientific and governmental bodies to help in the discovery of the causality between breast implants and ALCL and also into finding a safer alternative. Research into implant texturing is urgently needed to clarify the optimal solution.

Conflict of interest statement

The authors have not a financial interest to declare in relation to the content of this letter to the editor.

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