Breast implants and anaplastic large cell lymphoma
An emerging safety concern for textured implants

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Anaplastic large cell lymphoma (ALCL) has been reported in association with a tibial implant, dental implant, chest injection port, gluteal implant, shoulder repair, and a gastric band placement.1 It is, however, most commonly associated with textured surface breast prostheses used for breast augmentation or reconstruction.2 Breast implant associated ALCL is a type of T cell lymphoma that is mainly indolent. So far, 626 cases and 17 deaths have been reported worldwide.1,2 Early recognition, prompt diagnosis, and appropriate treatment are the cornerstones of current care.

There are two main types of breast implants: smooth surfaced and textured. Texturing is required for anatomically shaped implants to stop them rotating. No confirmed cases of ALCL have been reported with round, smooth surface prostheses. The lymphoma seems exclusively associated with textured prostheses, and the risk is highest for more robustly textured or polyurethane covered implants (range 1:1000 to 1:10 000 implants).3,4

In a prospective study of 17 656 patients with 31 985 anatomical textured prostheses, there were eight cases of ALCL, an incidence of 1 in 4424 prostheses or 1 in 2207 patients (95% confidence interval 1:1120 to 1:5112).5 The risk seems lower in implants with less texturing—around 1:50 000 to 1:80 000.6,7 There may also be geographical variation, with the rate of ALCL being 1 in 11 765 (255 cases) in the US,8 1:6920 (40 cases) in the Netherlands,9 and 1:3345 (81 cases) in Australia.10 This could reflect variation in the use of textured implants or in the collection and reporting of cases within countries.

The pathogenesis of ALCL is probably multifactorial. Leading theories include Gram negative bacteria infiltrating the biofilm on the surface of textured implants resulting in lymphocyte stimulation.9 Some patients show an allergic profile of cytokines mediated by IgE. Shedding of silicone particles from textured implants has been reported and could lead to inflammatory cytokine release and lymphocyte stimulation. Finally, some patients with breast implant ALCL have JAK1/STAT3 gene mutations, suggesting a genetic predisposition.9,11

Symptoms include swelling around the breast implant (related to a delayed seroma), affecting almost 80% of women with ALCL; a mass (40%); capsular contracture (8%); and a rash (2%).11 Women who develop these symptoms should be referred for specialist investigation. If ultrasonography shows fluid around the implant then this should be aspirated and sent for cytology. Large anaplastic cells that stain positive for CD30 are present in ALCL.1-3 Up to 10% of delayed seromas around implants are related to ALCL.1 Subsequent investigation should include positron emission computed tomography to assess the extent of local disease and the presence of metastases.2 Timely investigation of patients presenting with seromas will ensure early detection, when the ALCL is limited to the implant capsule. Treatment in such patients is complete capsulectomy and removal of the implant. A new round, smooth surface implant or autologous reconstruction is an option for women with early stage disease. Lymph node biopsy is not required unless enlarged or suspicious lymph nodes are present.

Some patients develop metastatic disease, and in this case chemotherapy, alone or combined with the monoclonal antibody brentuximab, can be effective.2 Although deaths from breast implant associated ALCL have been reported, for women who have early diagnosis and complete excision of disease the outlook seems excellent based on the data currently available.11 Staging and treatment guidelines are available from the National Comprehensive Cancer Network.1,11

For all women offered breast prostheses, informed consent must include a discussion of the risk of developing ALCL.2 They should be advised that the main symptom of ALCL is swelling around the implant, often years after insertion (median 8-10 years)11,12 and that they should notify their primary care team immediately if this or any of the other symptoms listed above develop. To date, there has been no regulatory guidance from either the US FDA or the UK MHRA on whether women who already have textured breast implants should be contacted. Informing all women with textured implants about ALCL risk would help ensure prompt investigation and treatment should symptoms develop.

Textured breast prostheses will continue to be offered to women who need anatomically shaped prostheses. The current strategy is to discuss the risk of ALCL without causing unnecessary anxiety. Absolute risks remain low. No professional body or regulator has recommended that textured implants need to be
removed prophylactically. There are no clinical or imaging features before a seroma develops, so screening asymptomatic women would be ineffective.

Confirmed cases of ALCL should be reported to government authorities, and national prospective registries of women with breast implants are urgently required to quantify the true incidence of this condition in all types of implant. Full partnership with patients and the public will be particularly important in these endeavours.

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Editors’ note: We judged that The BMJ’s zero tolerance policy for relevant financial competing interests should be over-ridden in this case, in the interests of patient safety.

4 Clemens MW, Nava MB, Ricco N, Miranda RN. Understanding rare adverse sequelae of breast implants: anaplastic large cell lymphoma, late seromas, and double capsules. Gland Surg 2017;6:169-84. 10.21037/gs.2016.11.03 28497021
5 Clemens MW, McGuire P. Commentary: a prospective approach to inform and treat 1,340 patients at risk for BIA-ALCL. Plast Reconstr Surg (forthcoming) 27627558

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