

# BREAST IMPLANT ASSOCIATED ALCL

## A REVIEW OF THE JOINT TASK FORCE FINDINGS

PRESIDENT OF THE AUSTRALASIAN SOCIETY OF AESTHETIC PLASTIC SURGEONS AND CHAIRMAN OF THE BIA-ALCL JOINT TASK FORCE DR MARK MAGNUSSON SPEAKS TO AESTHETIC MEDICAL PRACTITIONER ABOUT THE FINDINGS OF THE AUSTRALIAN-LED RESEARCH.



Dr Mark Magnusson

### BEHIND THE TASK FORCE

The breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) Joint Task Force is a collaboration between the Australasian Society of Aesthetic Plastic Surgeons, Australian Society of Plastic Surgeons and New Zealand Association of Plastic Surgeons. We have also important partnerships with Macquarie University, the Australian Breast Device Registry run by Monash University and the Peter MacCallum Cancer Centre. I am also joint clinical lead on the research paper with Prof Anand Deva.

The work commenced initially after the increasing scientific information about the new disease breast implant associated anaplastic large cell lymphoma and a requirement to more completely understand it to ensure the safety of our own patients.

For almost three years we have been canvassing industry to access to sales data and collating clinical data on all cases of this rare disease in Australia and New Zealand. When we evaluated this data we understood its public health significance and shared it with the TGA and Australian Department of Health which in due course led to a new update being released by the TGA on 20 December 2016.

Uniquely what we have been able to achieve is to compare the number of cases with the number of implants sold for the first time. This has allowed us to perform a more accurate assessment of the risk but also for the first time to define the different level of risk associated with different breast implants.

### JUST HOW COMMON IS BIA-ALCL?

BIA-ALCL is rare. The data we collated, which has now been subjected to peer review and accepted for publication in *Plastic and Reconstructive Surgery* online ahead of print later in the year, included cases from both Australia and New Zealand and totalled 55 cases. The TGA update on BIA-ALCL from 20 December 2016 refers only to 46 cases that relate to the Australian patients identified by our research. For the first time, our publication quantifies that BIA-ALCL occurs at different rates with different implant types.

No patient who has had only smooth breast implants has gone on to develop this disease. All patients being diagnosed with BIA-ALCL have had textured breast implants, however not all breast implants have the same type of textured surface. Those with a lower surface area, sometimes called microtextured, have an incidence of about one in 60,000. Those with a higher surface area, sometimes called macrotextured, have an incidence of about 1 in 4,000-8,000.

BIA-ALCL is a rare disease regardless of which implant has been used. The risk of breast cancer for Australian women is one in eight. The risk for an Australian woman developing any form of lymphoma who lives to the age of 84 is one in 50.

### WORLDWIDE INCONSISTENCIES

This is a rare disease and the true number of patients is not known with certainty, however we are

FEATURE

THE 'UNIFYING THEORY' CITES TEXTURE, BACTERIA, GENETICS AND TIME AS THE LIKELY CAUSATIVE FACTORS

confident that this is the best data to date.

Documented cases may exist on a number of databases, have duplicate entries on certain databases, be entered without accurate diagnosis, and for the majority of patients worldwide there is an incomplete clinical history. The original implant is only known in about 50% of patients with this disease worldwide.

The present study, for the first time, presents a complete capture of patients in a defined geographic area (Australia and New Zealand) by searching lymphoma registries, the Australian Breast Device Registry, patients reported to the TGA and patients diagnosed within a cooperative network of specialist plastic surgeons, breast surgeons and other doctors who insert breast implants.

In addition, we have complete clinical histories of these patients including knowledge relating to the various implant procedures these women have undertaken.

**DOES AUSTRALIA HAVE A RELATIVELY HIGH INCIDENCE OF THE DISEASE?**

I am not entirely convinced that Australia has an especially high incidence but that perhaps we have good data.

In Australia we have a health system that supports the investigation of disease in an affordable way (Medicare), a comprehensive network to capture these cases, including mandatory reporting to lymphoma registries and the TGA, and a relatively small network of surgeons who both insert and revise breast implants who have been working cooperatively to tackle this disease. Consequently, we are capturing these patients.

In addition, we have also been able to obtain the most accurate sales figures for different implant types in our population compared with similar studies.

There are other studies from the United States that have similar

incidences of this disease for various implant types. Other countries, notably the Dutch, are also currently performing comprehensive evaluation of the incidence of this disease in their own communities which will give us an interesting perspective about our own data.

Worldwide there are inconsistencies in the understanding of this disease, the diagnostic approach, access to affordable health care and reporting. It is recognised that diagnostic tests may not always be performed because there is a lack of recognition of the disease, because they are expensive or because the diagnosis has not been considered.

**BACTERIA, BIOFILM AND BIA-ALCL**

We know that it is probably impossible to insert an implant into the body without carrying some bacteria from the skin or in this instance potentially also from the breast itself.

Bacteria can grow on the surface of a breast implant and this does relate to its surface area. A smooth implant has the smallest surface area for the size of that implant. A microtextured implant, which has small hills and valleys on its surface, has a larger area for the given size. A macrotextured implant has relatively larger hills and deep valleys and consequently a larger area.

Bacteria adhere to the surface of an implant and cover themselves with what we call a biofilm. The larger the surface area, the larger the number of bacteria that can be supported on the surface of the implant.

When the bacterial number reaches a certain threshold, the body will respond to this. For certain types of bacteria this has been shown to lead to capsular contracture, which is not cancer and does not lead to cancer. What we have found in patients with BIA-ALCL is that bacteria are also present within the tumour and around the implant but the type of bacteria is different.

The hypothesis is that bacteria in sufficient numbers on the surface of the implant is attacked by the body's immune system and many different types of cells are present in this response. In some patients, this response may lead to a single type of cell becoming the dominant type and in genetically susceptible individuals this may transform into lymphoma.

While there are other theories, the theory that is supported by the strongest evidence at present is the "unifying theory" relating to subclinical infection, an inflammatory response from the body which becomes monoclonal and may transform into lymphoma in those who are susceptible. The unifying theory cites texture, bacteria, genetics and time as the likely causative factors.

Australian and New Zealand plastic surgeons are at the forefront

of this research in collaboration with global partners into the cause of this disease and it is a rapidly advancing area.

**SYMPTOMS AND DIAGNOSIS**

The symptoms of BIA-ALCL most commonly are a persistent swelling of the breast due to fluid collecting around the implant. It can present as a lump in the breast or armpit as well and it usually develops 3 to 14 years after the insertion of the implant but most commonly around 7 to 8 years.

A woman with a persistent fluid swelling around an implant should be investigated with ultrasound and if fluid is identified it should be removed and tested. Tests are performed specifically to look for a single abnormal T-cell clone that is CD30-positive and ALK-negative.

Mammogram is not useful. More complex examinations such as MRI or PET/CT are performed once a diagnosis is established.

**CURRENT RECOMMENDED STEPS**

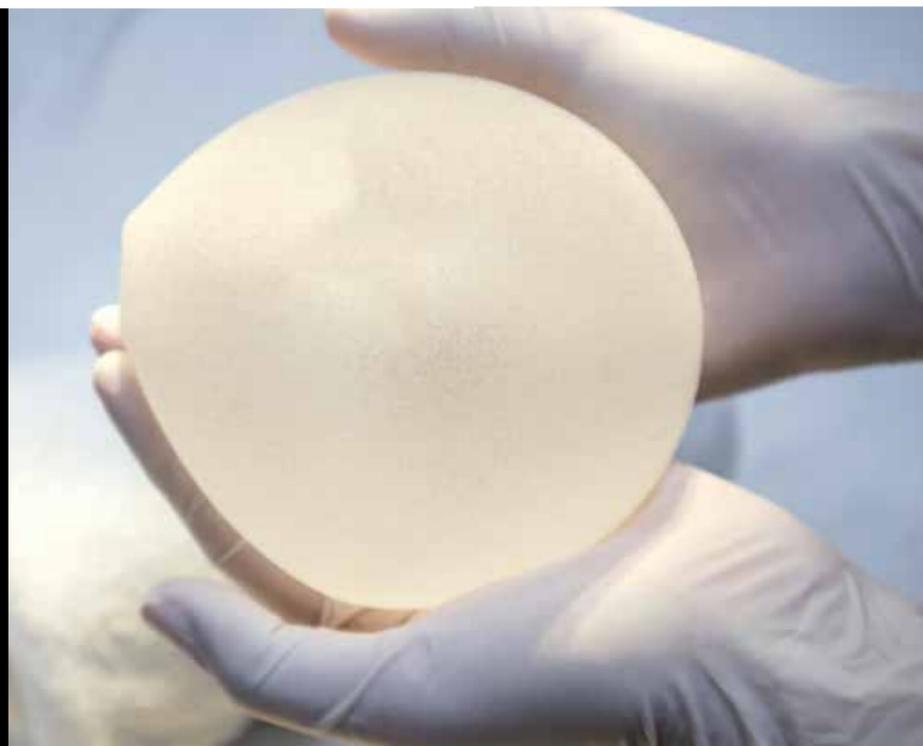
Not all implants have the same risk for BIA-ALCL. Different implants also have different performance capabilities inside the body. It is important to consider individual implant selection for each patient based on relative risk and benefit analysis. This needs to be part of the consent process for patients considering implant surgery.

There is accumulating evidence that bacteria are associated with other complications of breast implant surgery such as the risk of capsular contracture and acute infection, neither of which lead to cancer.

Infection control standards are extremely important in breast implant surgery to ensure best outcomes. A 14-point plan has been developed collating evidence-based

**14 POINT PLAN**

1. Use intravenous antibiotic prophylaxis at the time of anaesthetic induction.
2. Avoid periareolar incisions; these have been shown in both laboratory and clinical studies to lead to a higher rate of contracture as the pocket dissection is contaminated directly by bacteria within the breast tissue.
3. Use nipple shields to prevent spillage of bacteria into the pocket.
4. Perform careful atraumatic dissection to minimise devascularised tissue.
5. Perform careful haemostasis.
6. Avoid dissection into the breast parenchyma. The use of a dual-plane, subfascial pocket has anatomic advantages.
7. Perform pocket irrigation with triple antibiotic solution or betadine.
8. Use an introduction sleeve. Use of a cut-off surgical glove or funnel to minimise skin contact is recommended.
9. Use new instruments and drapes, and change surgical gloves prior to handling the implant.
10. Minimise the time of implant opening.
11. Minimise repositioning and replacement of the implant.
12. Use a layered closure.
13. Avoid using a drainage tube, which can be a potential site of entry for bacteria.
14. Use antibiotic prophylaxis to cover subsequent procedures that breach skin or mucosa.



### KEY POINTS

- BIA-ALCL is a rare form of non-Hodgkin's lymphoma.
- When diagnosed early and managed properly, it is curable. There are only 12 deaths worldwide from this disease in a 50-year history of breast implants.
- Australian and New Zealand plastic surgeons are at the forefront of research into this condition through international collaboration and are working with regulators to maintain public safety. This is a rapidly evolving area with constant updates that are shared with the TGA.
- Without symptoms or signs of BIA-ALCL, routine implant removal is not required unless there are other additional concerns.
- There are different implant types available and implant selection needs to take into account the relative risks and performance benefits of individual implant types for individual patient needs. This needs to be discussed with the patient and should form part of the consent process.
- Breast implants are not lifetime devices and women with breast implants should all consider that they will require revision or replacement of the breast implants at some time. The most likely reasons will be for capsular contracture, implant migration, implant rupture and size change. BIA-ALCL remains a rare disease.

steps that can be undertaken during surgery when appropriate to minimise the bacterial load around the implant. These steps have been demonstrated to significantly reduce the incidence of capsular contracture.

The 14-point plan is a guide and individual steps can be applied subject to specific patient requirements and the experience of the surgeon. All of these steps won't necessarily apply to every situation.

If the unifying theory is proven, steps taken to minimise the rate of bacterial contamination of a breast implant at the time of surgery may be important in reducing its incidence. Regardless of BIA-ALCL, minimising bacterial contamination at the time of implant surgery is associated with a reduction in other risks.

### INTERNATIONAL COLLABORATION

In Australia, we have a BIA-ALCL Joint Task Force that has been responsible for completing this epidemiological study. In addition, our members are associated with Global Advisory and Research Boards collaborating with colleagues around the world to ensure that the development of knowledge is as rapid as possible.

The Australasian Society of Aesthetic Plastic Surgeons, Australian Society of Plastic Surgeons and New Zealand Association of Plastic Surgeons have put out a number of joint updates on this disease which have been shared with our international partner Societies in the United States and the International Society of Aesthetic Plastic Surgery with members from over 100 countries. Additionally, the Australian Breast Device Registry is shared through affiliated societies on the iCOBRA (International Collaboration of Breast Registry Activities) network with still more International Plastic Surgery

Societies. This is yet another source of information sharing.

As new information comes to hand our Joint Task Force has strong links with the Department of Health and TGA and consequently this information is immediately shared with our health regulators.

The goal is to ensure that there is a uniform global standard for diagnosis and treatment to ensure safety for our patients and best outcomes from breast implant surgery.

### WHAT DO WE NEED TO BE TELLING PATIENTS?

Firstly, I think we have confirmed that this is a rare disease and I think we have determined the most accurate incidence data which allows us to talk more realistically with patients.

Different types of implants have different relative risks and different relative performance strengths.

Each woman has a different starting point and therefore a different requirement and it is important to consider all of these points when selecting an implant. This needs to be discussed between surgeon and patient when considering breast implant surgery.

BIA-ALCL is a rare form of non-Hodgkin's lymphoma; it is not breast cancer. When diagnosed early and treated properly, this disease is curable. It usually presents with persistent swelling of one breast and its onset is usually several years after the initial surgery.

Different implants perform differently in the body and have different relative risks for complications, including BIA-ALCL. It is important to choose an implant specific to your requirements and goals. This choice needs to balance the risks and benefits of your selection and should form part of the consent process. **AMP**