Breast Implants and BIA-ALCL: An Overview of a Developing Litigation Surrounding Another Breast Implant Controversy

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Nathan Tavares QC explores the potential for future litigation stemming from a rare form of cancer caused by breast augmentation surgery.

Introduction

Controversy rarely leaves the sphere of breast surgery. The consequences of the PIP scandal, where implants had been fraudulently manufactured with unapproved silicone gel, have been far reaching. The report of the independent inquiry into the actions of rogue breast surgeon Ian Paterson was recently published and the litigation surrounding his misdemeanours and the associated institutional failings will go on for many years. One of the latest issues surrounding breast augmentation surgery is the development of a rare cancer known as Breast Implant Associated Anaplastic Large Cell Lymphoma, or BIA-ALCL as the rather clunky acronym has it.

What is BIA-ALCL?

The specific diagnostic criteria of the disease was defined by the World Health Organisation [WHO] in 2016, but it was identified in medical literature as far back as 1997. Prior to the WHO classification, BIA-ALCL was under-diagnosed, under-reported and not widely known about.

Contrary to misconception in the media it is not a form of breast cancer as it is not found in the breast tissue itself, but is a type of non-Hodgkin's lymphoma (cancer of the immune system). The habitat of BIA-ALCL is usually the scar tissue and fluid (seroma) in fibrous scar tissue in the capsule around the breast implant. It can, however, spread throughout the body. The main symptoms are persistent swelling and the presence of a mass or pain in the area of the breast implant. In most cases the disease develops years after the implant was inserted, and when treated promptly after symptoms first develop the prognosis is usually good and a full recovery can be made. Like all cancers, it can be fatal especially if not caught early. Treatment normally involves surgery to remove the implant and the surrounding tissue. Some patients also require chemotherapy and radiation therapy.

How Common is BIA-ALCL?

There is no doubt that BIA-ALCL is a rare cancer, but its prevalence is not fully known due to significant limitations in world-wide reporting and lack of global breast implant sales data. In 2018 Mintsje de Boer and others[1] published an epidemiological study which demonstrated a 10-20 fold relative risk of BIA-ALCL for women with breast implants, with a prevalence of 1/12,000 with textured implants. As of July 2019, the FDA[2] had a total of 573 US and global medical device reports of BIA-ALCL. Meanwhile the MHRA[3] advises that as of September 2019 it had received 61 reports of BIA-ALCL in patients with breast implants which meet the WHO diagnostic criteria for the disease. There had been three reported deaths in the UK in cases of BIA-ALCL, but only one of these was confirmed to meet the WHO diagnostic criteria for BIA-ALCL. The MHRA suggests that based on these reported cases the estimated incidence of BIA-ALCL in the UK is 1 per 24,000 implants sold. That is for all types of breast implants. Current data shows, however, that the type of silicone implant matters, and textured implants have a significantly higher correlation with BIA-ALCL. The American Society of Plastic Surgeons puts the lifetime risk of BIA-ALCL in a range of 1:2,207 - 1:86,029 for women with textured breast implants.

Textured Implants

There are a variety of different types of silicone breast implant and manufacturer. The type of implant used is very much down to surgeon choice in the context of the particular clinical requirement. The surface of the implant can be smooth or textured with the latter having a rougher finish akin to a sand-paper which reduces the rotational movement of the implant within the capsule. For reasons which are not fully understood the textured implants, particularly the macro-textured implants (akin to coarse sand-paper), have a greater tendency to cause the lymphoma in the fibrous tissue around the implant. The FDA believes tissue expanders with a textured surface are also of concern.

The growing body of data led to Allergan, a US manufacturer of breast implants, withdrawing its textured implants and tissue expanders from worldwide sale. This followed loss of the CE safety certificate in Europe in December 2018 after French regulator, Agence Nationale de Sécurité du Médicament [ANSM] came to the conclusion that only smooth-shell implants should be used due to the increased risk of BIA-ALCL from textured implants[4]. In July 2019 Allergan conducted a worldwide recall of its Biocell textured implants and tissue expanders. The FDA also announced that of the 573 cases of BIA-ALCL known by to them, 481 of the patients were reported to have Allergan breast implants. In addition, 12 of 13 deaths occurring in patients with BIA-ALCL where the manufacturer was known, occurred in

[1] Breast Implants and the Risk of Anaplastic Large-Cell Lymphoma in the Breast JAMA Oncol. 2018 Mar; 4(3): 335–341

[2] The US Food and Drug Administration

[3] The UK Medicines and Healthcare products Regulatory Agency

[4] CE marks for Allergan's Microcell and Biocell textured surfaces were, until December 2018, issued by a French notified body called LNE G-MED

patients implanted with an Allergan breast implant. There were 20 deaths from BIA-ALCL where the manufacturer was not known.

The MHRA issued Medical Device Alerts [MDAs] in 2011, 2014 and 2018 regarding the BIA-ALCL risk from silicone implants[5]. Also in 2018 there was a joint statement issued by the MHRA and the Association of Breast Surgeons [ABS], British Association of Aesthetic Plastic Surgeons [BAAPS] and the British Association of Plastic, Reconstructive and Aesthetic Surgeons [BAPRAS], indicating that an advisory group[6] had been set up to monitor the BIA-ALCL situation. The group advises that clinicians should discuss the potential risk of BIA-ALCL when consenting new patients. In response to Allergan's recall of textured implants, the MHRA issued a statement on Allergan which advised: "*There is currently no evidence of an increased risk to patients and there is no need for people who have Allergan breast implants to get them removed or have any additional clinical follow-up*"[7]. Meanwhile the MHRA hosts a webpage advising on BIA-ALCL[8]. The Breast and Cosmetic Implant Registry [BCIR] was launched by NHS Digital in October 2016 to capture the details of all breast implant procedures undertaken in England by both the NHS and independent healthcare providers.

The Cause of BIA-ALCL

Suffice it to say that the precise causal relationship between silicone breast implants and ALCL remains uncertain. There are a number of theories as yet unproven to scientific standards. Some plastic surgeons believe that the disease originates from bacterial infection and that textured implants provide greater surface area and more crevasses in which bacteria can lodge themselves. The coarser the surface the more hiding places for the bacteria. However in 2017 the European Scientific Committee on Health Environmental and Emerging Risks [SCHEER] published a report which concluded that there is currently insufficient scientific information available to perform a methodologically robust risk assessment on a possible association of breast implants with the development of ALCL.
It is a sad fact that a number of women who have the infamous PIP breast implants have also diagnosed with BIA-ALCL. In 2013 The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks [SCENHIR] issued a preliminary opinion that the link between BIA-ALCL and PIP implants appears to be coincidental and there is no statistically significant correlation between PIP implants and ALCL[9].

BIA-ALCL Litigation

[5] MDA/2011/017; MDA/2014/027; and MDA/2018/027.
[6] The Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group [PRASEAG]
[7] https://www.gov.uk/government/news/mhra-statement-on-allergan
[8] https://www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-alcl
[9] Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR, Opinion on The safety of Poly Implant Prothèse (PIP) Silicone Breast Implants - Update of the Opinion of February 2012

Unsurprisingly, those diagnosed with BIA-ALCL and their families are pursuing the legal remedies they may have. Given the growing media coverage of BIA-ALCL[10], many more women with silicone implants - but without any diagnosis of the cancer- are also taking the legal route potentially for the costs of removal of the implants and associated pain and distress[11]. Needless to say, the Allergan implant recall resulted in prompt commencement (December 2018!) of a class action in the US. The plaintiffs allege that the implants caused them to develop BIA-ALCL, and that Allergan Inc. failed to adequately warn against this risk and failed to promptly and properly report the results of the post-marketing studies relating to these products. Allergan is defending on the basis of the benefit/risk profile of the implants, and the very small overall level of risk.

Defective Product?

The problem for claimants contemplating claims in England and Wales under the Consumer Protection Act 1987/Product Liability Directive85/374/EEC, or in negligence, is the uncertainty surrounding the precise cause of BIA-ALCL. Establishing a design defective may be challenging. Mere association between silicone implants and BIA-ALCL is not enough. As has been set out in the judgment of Andrews J. In the metal-on-metal hip litigation[12] claimants must first identify "*what it is about the state of behaviour of the product or the risks that it posed that led it to fall below the level of safety that persons generally were entitled to expect at the time the product entered the market*"[13]. The fact that implant manufacturers may have placed information regarding a correlation between implants and BIA-ALCL in product literature is clearly insufficient to establish causation. Manufacturers readily publish warnings that a drug or device may cause an adverse complication largely to ensure they maintain market authorisation, but such statements do not admit of a causal relationship. Will pure epidemiology suffice? The problem with BIA-ALCL is that the occurrence rate is very small, hence the absolute risk is small. And questions arise as to what risk is posed by other silicone implant comparators? Is there a materially increased risk sufficient to satisfy the test of defect?

I do not propose to address the epidemiology in detail in this article. Suffice it to say that claimants may be on stronger footing relying on the failure to warn about the risks of BIA-ALCL if known correlations are absent from product literature. The CPA 1987 specifically refers to the nature of warnings about the product as being one of the specific circumstances taken into account in determining what a person was entitled to expect[14]. It is a subset of design defect and potentially less burdensome for claimants. So a product may

[10] See for example Channel 4's Dispatches investigation: "Britain's Breast Implant Scandal", 24th June 2019.
[11] Potentially applying principles derived from *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt and Others*, CJEU cases C-503/13 and C-504/13.
[12] *Gee and others v Depuy International Limited* [2018] EWHC 1208
[13] Paragraph [99]
[14] CPA 1987, s.3(2)(a)

be deemed defective if the warnings regarding the product's association with BIA-ALCL are considered insufficient. The adequacy of warnings in respect of any individual breast implant will, of course, have to be carefully scrutinised by reference to what was or ought to have been known by the manufacturer at the time the product was put into circulation, and what advice was being given by regulatory bodies[15]. Of course, the standard of warning required will depend upon the nature of the person expected to read the warning.

Directions for use provided to surgeons implanting breast prostheses may not need to carry the same information as a patient information leaflet produced by the manufacturer. Circumstances can also be envisaged where a surgeon may be liable in negligence for failing to pass on a patient information leaflet containing relevant information about risks he has not himself drawn to the patient's attention.

Claims under the CPA will be subject to the 10 year longstop under section 11A Limitation Act 1980, and the longstop does add an extra potential hurdle over and above the normal 3 year limitation from date of implant or date of knowledge. Of course, claims in pure negligence are not affected by any longstop.

Informed Consent

The standards by which the sufficiency of warnings are judged under the CPA 1987 will no doubt be determined by the risks of illness or injury that members of the public would expect to be warned about (or expect their medical intermediaries to be warned about). Similar considerations will apply to the information surgeons should provide to patients when obtaining informed consent in accordance with *Montgomery*[16]. Surgeons who implant breast prosthetics ought to be aware of the known and reported risks associated with the product including its association with BIA-ALCL even if precise causation has not been established. Their professional bodies such as the ABS provide regular updates, and ought to be fully aware of medical device alerts put out in Europe or the US. In the circumstances there may well be potential claims where a surgeon has failed to inform a breast surgery patient of the risk of BIA-ALCL. Clearly a surgeon is under a duty to take reasonable care to ensure the patient is aware of material risks involved in the proposed treatment.
It is now well established that a risk will be *material* if a reasonable person in the patient's position, if warned of it, would be likely to attach significance to it, or if the surgeon ought to be aware that this particular patient if warned of the risk would attach significance to it (there is a subjective element to the test). In *Montgomery* the court said:
"*the assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for*

[15] For example, the FDA advises that all patients who have breast implants or are thinking about getting them should be aware of the risk of BIA-ALCL.
[16] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11

example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient."[17]

Doctors will continue to filter the information that they give to patients, so it is likely that expert evidence will be permitted on the issue of what risks would be material to include in the normal case.

Contractual claims may be brought against surgeons where they have been engaged on a private basis, but it seems questionable whether any affected recipients of silicone implants would have a contractual claim against the manufacturers. It would be rare for a person to have purchased the implants themselves or to have a collateral contract between them and the manufacturer[18]. Other potential defendants include any private hospital at which the surgeon worked, either under the non-delegable duty owed by healthcare providers or vicarious liability in the event they were no in the employment or quasi-employment of the hospital.

Factual Causation

If a breach of duty is established in relation to lack of warnings/informed consent, claimants may still face a considerable hurdle in proving that properly advised they would not have had the implants. Risks of various serious conditions with an apparent correlation to silicone implants have been cited for many years, including brain cancer, lung cancer, cervical cancer, even an association with increased suicide. However, it is clear that such admittedly small risks appear not to have dissuaded a vast number of patients from accepting silicone implants. The risks were no doubt considered small enough to justify surgery in their own subjective risk/benefit analysis. There will also be a body of data out there indicating the proportion of patients who accept silicone implants even when expressly warned about the risks of BIA-ALCL.

As the epidemiology evolves, however, the greater correlation that textured implants has with BIA-ALCL will be an important factor. It may be argued that properly informed, patients would have declined the option of textured implants in favour of smooth-surfaced alternatives. If there are alternatives with different risk factors, it is strongly arguable that

[17] At [89]

[18] A collateral contract would probably only arise if a specific assurance about a product had been given by the manufacturer to the individual patient – see for example *Wells (Mertham) Ltd v Buckland Sand and Silica Co Ltd* [1965] 2 QB 170

surgeons should have advised patients of this, particularly as most surgery has been purely for cosmetic purposes.

Damage

Where there has been a diagnosis of BIA-ALCL there will clearly be actionable damage for pain, suffering and loss of amenity (including any psychological damage) as well as the costs of revision surgery and any consequential losses such as earnings loss or travel expenses. Where no diagnosis of BIA-ALCL has been made, however, there will be no actionable damage in common law negligence. It is therefore possible that a complete cause of action will not exist even if the implant would not have been accepted but for a breach of duty. Risk of damage is not treated as actual damage[19]. Anxiety caused to a patient by knowing that they have received an implant with an associated risk of BIA-ALCL will similarly not be considered damage as fear is not classed as personal injury[20]; psychiatric injury would need to be proved instead. Claims for anticipatory removal of breast implants therefore appear to have some major obstacles in tort. Different principles may apply if a successful claim is brought under the CPA 1987[21], however, or in contract. The situation may change if professional or regulatory bodies advise re-augmentation surgery, or if it is recommended for particular patient because of their individual circumstances. Thus far, the BIA-ALCL risk posed by silicone implants whether textured or smooth appear to be of a much more circumscribed magnitude than occurred in relation to PIP implants where the implanted material was not only prone to rupture but was not even fit for human application.

Concluding remarks

Fortunately the number of individuals who have developed BIA-ALCL has remained small. If those individuals, or the families of those who have sadly died from the condition, were the only potential litigants, then the associated litigation would be modest and not profound for the manufacturers, the NHS or the insurers of private breast surgeons. The floodgates may open to some extent, however, if asymptomatic patients are successful in securing compensation for the psychological stress of knowing that have implants which might cause cancer, or if they can recover the costs of anticipatory removal/exchange of implants. Such claims appear to be much more challenging for claimants. BIA-ALCL Litigation in the UK is at a relatively early stage. It throws up some interesting issues for product liability and clinical negligence lawyers, so its progress will be watched with interest.

[19] *Gregg v Scott* [2005] 2 A.C. 176

[20] *Hicks v Chief Constable of the South Yorkshire Police* [1992] 2 All E.R. 65, HL

[21] See the Boston Scientific case referred to above (fn 11).

Find out more

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