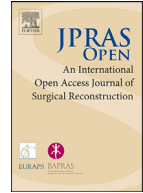




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Breast lymphomas, breast implants and capsules The timeline of BIA-ALCL with respect to surgical consent: the UK perspective

Keith Allison^{a,*}, Adam Gilmour^b

^a *Consultant Plastic Surgeon, South Tees Hospitals NHS Foundation Trust, Middlesbrough*

^b *Consultant Plastic Surgeon, Canniesburn Plastic Surgery Unit, Glasgow*

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ABSTRACT

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare type of T-Cell (non-Hodgkin's) lymphoma associated with the use of silicone breast implants. Recent widespread awareness has focused not only on the management of this condition but also in regards to potential litigation of surgeons, clinics, and breast implant manufacturers. Allegations of causation and inappropriate patient consent are being raised. The purpose of this article is to establish the timeline of relevant discoveries regarding this condition and associated implications with regards to appropriate informed patient consent.

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Background

Silicone breast implants have been used for breast augmentation since 1962; when pioneering Texas-based Plastic Surgeons Cronin and Gerow collaborated with Industrial Silicone Manufacturing Company Dow Corning (USA) to manufacture a sealed “bag” composed of an outer firm silicone shell and liquid silicone filling. Their patented invention was classified as a major success following live patient testing, and the product received widespread market adoption in 1964.¹ Previous attempts

* Corresponding author.

E-mail address: keith.allison@nhs.net (K. Allison).

at breast augmentation through the direct injection/implantation of various materials had ultimately ended in failure, thus the new implant was revolutionary.

Over the past six decades, there have been significant improvements in the design, composition, manufacturing process, and surgical techniques associated with these silicone implantable devices. Silicone-based breast implants are used not only for aesthetic enhancement in terms of improved volumisation or shape of the breast, but they also have become a mainstay in the management of congenital breast anomalies and for breast reconstruction following extirpative surgery for breast disease such as breast cancer.

Although silicone breast implants have been used successfully in millions of patients worldwide, they have recurrently been the subject of major controversy with regards to potential associated health problems.

This “silicone controversy” began in 1990 when CBS talk-show host Connie Chung built a case against the dangers of silicone polymers when she broadcast the stories of three women who believed their “flu-like” symptoms, mouth ulcers, rash, and general fatigue were attributed to their silicone breast implants. Despite there being no scientific evidence to support this and the talk-show medical experts giving their opinion on the subject themselves having no clinical experience with implantable devices, it generated widespread media attention and public interest. This in turn created a nationwide panic and health scare amongst patients who had a history of previous silicone device insertion (not just breast implants). Over the subsequent two years, reports of patients with similar symptoms began to grow on talk shows and news bulletins. Bowing to public opinion, in April 1992, the FDA commissioner Dr. David Kessler chose to issue a moratorium on the use of silicone breast implants in the USA, despite no robust scientific evidence and against the advice of his own advisory panel.² This paved the way for litigation and multiple class action lawsuits were brought against implant manufacturers.

In the United Kingdom (UK), a more evidence-based approach was undertaken, and the use of silicone implants continued pending extensive investigation. This was conducted by the Independent Review Group (IRG); set up by the Department of Health, who published their findings in 1998. This concluded that “no relationship was shown between silicone gel implants and long-term systemic illness (affecting the whole body), nor with specific connective tissue disease or nonspecific systemic illness”.³

More recent problems have been related to the Trilucent implant (2000)⁴ in terms of the constituent filling material within the silicone shell and then the manufacturing quality of the Poly Implant Prothese (PIP) implant (2010).⁵ Both of these implant problems were highlighted by the patients and their surgeons, and this led to license withdrawal, recall / removal of the implants, and prosecutions.

Currently, the discovery and associated implications of BIA-ALCL have led to a new chapter in the controversy and legal implications for practitioners and manufacturers surrounding the use of silicone breast implants. Simultaneously, the symptom profiles that initially attracted attention and investigation in the 1990’s have now been categorized as “Breast Implant Illness,” prompting the need renewed data collection and research.⁶

BIA-ALCL

Anaplastic large cell lymphoma (ALCL) refers to a group of non-Hodgkin’s lymphomas in which aberrant T-cells proliferate uncontrollably. In 2016, the World Health Organization (WHO) separated ALCL into 4 types: Anaplastic Lymphoma Kinase Positive, ALK-negative ALCL, primary cutaneous ALCL, and BIA-ALCL.⁷

BIA-ALCL is a rare CD30-positive ALK negative lymphoma, classified as a notifiable disease within the UK. The exact pathogenesis has not been established⁸ but is believed to be caused by a reaction to surface texturization of silicone breast implants. There are 2 distinct disease phenotypes: the most common involves presentation with a painless collection of fluid (seroma) with in-situ capsular disease, and the second is a more aggressive, mass-forming subtype. The average time to presentation is 7-10 years after implantation.⁹ It has occurred in both cosmetic and reconstructive patients receiving breast implants, in various implant insertion planes, and across a range of implant manufac-

turers. Treatment should involve multidisciplinary discussion at both Breast and Hematology MDTs, then subsequent total / en-bloc capsulectomy; which in most cases is curative. For more advanced cases chemotherapy, radiotherapy, and even stem cell transplant may be considered.

Cumulative data from the first case recorded in the UK in 2012 until December 2020 confirms 83 cases complying with the WHO diagnostic criteria.⁷ There has been 1 death directly attributable to BIA-ALCL. The current incidence of the condition within the UK, given by the Medicines Healthcare Regulatory Authority (MHRA) in November 2021, is suggested at 1 in 15,000 implants sold.¹⁰ However, this is a crude estimate and is regularly revised following consultation with the PRASEAG (Plastic Reconstructive Aesthetic Surgery Advisory Group) as the incidence of this condition becomes more established.

Chronology for BIA-ALCL

There have already been reviews of the literature associated with each BIA-ALCL publication, and so the initial publication listings are mostly duplicated. The data relating to BIA-ALCL has increased exponentially since 2016. In 2019, Miranda et al. described the process of recognition of BIA-ALCL from the Keech patient in 1997.¹¹ In their paper, they tabulate “Seminal Events” in understanding BIA-ALCL and a “Timeline” in scientific papers. This paper, whilst informative, acts as a showcase for those authors’ experiences but does not reflect those of surgeons in the UK at that stage.

The following establishes the important chronological timeline of BIA-ALCL.

1972 – Wiseman et al. reported a series of primary breast non-Hodgkin’s lymphomas.¹² No reference is made to breast implants use in this cohort of patients.

1985 – ALCL first described as a neoplastic proliferation of lymphoid cells that are anaplastic in appearance.¹³

1994 – ALCL is included in the Revised European and American Lymphoma (REAL) classification as a rare type of lymphoma that involves a variety of tissues, including the breast, and falls within a broad category of lymphoproliferative disorders with a wide spectrum of clinical behavior.¹⁴

1996 – Duvic et al. reported 3 cases of cutaneous T-cell lymphoma associated with breast implants.¹⁵

1997 – Keech and Creech published the case of a 41-year-old patient, presented with a mass in proximity to a saline-filled breast implant (McGhann Style 168) inserted in 1991 for elective augmentation. This mass is confirmed to be an anaplastic T-cell lymphoma.¹⁶

2001 – ALCL is included in WHO classification of lymphoid neoplasms.

2002 – Gaudet et al. reported 2 cases of primary breast lymphoma.¹⁷ The first case is a CD30-positive ALCL of T-cell phenotype, which is ALK negative occurring 7 years after implant-based breast cancer reconstruction. The second case is a similar CD30-positive ALK negative ALCL in a patient presented with nodules overlying her right breast implant. She had a history of mantle radiotherapy for Hodgkin’s lymphoma, then bilateral breast implant insertion 20 years later.

2003 – Sahoo reported a single case of ALCL presented in the capsule of a silicone breast implant.¹⁸

2006 – Fritzsche et al. reported a single case of ALCL occurring around a breast implant 32 years after a patient had underwent implant-based breast reconstruction for primary breast cancer.¹⁹

2007 – Olack et al. reported a case of ALCL with a T-cell phenotype arising within the capsule of a saline tissue expander breast implant used for breast reconstruction after primary breast cancer.²⁰

2007 – Newman et al. described a patient who developed ALCL within her breast adjacent to a silicone breast implant that had been inserted 14 years previously for elective aesthetic augmentation surgery.²¹ They conclude that it is unlikely that any cause-effect relationship exists between breast implants and primary breast lymphoma since chance alone could account for the low incidence of primary breast lymphoma in patients with breast implants. They perform a literature review, referencing 5 other cases, including Gaudet et al.¹⁵

2008 – WHO classification revised to divide ALCL into 2 separate types based upon ALK protein expression in tumor samples.²²

2008 – Roden et al. reported 4 patients from the Mayo Clinic, Rochester, USA, between 1995 and 2007, with confirmed primary ALCL occurring with a seroma and breast implants. They reference 5 of the previously reported cases.²³

2008 – Wong et al. published a case report of a patient presented with primary ALCL within a breast implant capsule and contributed another review of the literature.²⁴

2009 – Lipworth et al. aimed to determine whether there was an epidemiological increased lymphoma risk in breast implant patients. They reviewed 5 long-term studies comprising 43000 women, followed up over a long period. They concluded no credible evidence of an increase in primary non-Hodgkin's lymphoma of the breast.²⁵

2009 – Bishara et al., from Canada, reported an “interesting case” of a patient developing primary ALCL within the capsule of a saline-filled breast implant used for reconstruction after a radical mastectomy for breast cancer.²⁶

2010 – Thompson et al. described the incidence of 23 CD30-positive cases of ALCL associated with breast implants, and they explained that the scientific literature showed support for the association of this kind of lymphoma with breast implanted women, but also other cohort studies which did not.²⁷ “The lack of strong epidemiological evidence makes a firm conclusion regarding the causative role of breast implants in this disease more difficult.”

2010 – Li et al. concluded that “silicone implants may have a role in the development of primary breast ALK negative ALCL. The underlying mechanism of this possible link remains unknown.”²⁸

2011 (Jan) – The US Food and Drug Administration (FDA) published a document “ALCL in Women with Breast Implants: Preliminary FDA Findings and Analyses”. This document concluded that at that stage “Because the risk of ALCL appears very small, FDA believes that the totality of evidence continues to support a reasonable assurance that FDA-approved breast implants are safe and effective when used as labeled.”²⁹ As a background to this, at that stage, the total number of reports of cases of ALCL in patients with breast implants worldwide was approximately 60, against a background of 5-10 million implants.³⁰

2011 (Feb) – The MHRA released a medical device alert on Breast Implants with the following statement: “There is uncertain evidence that women with breast implants may have a very small but increased risk of ALCL of the breast. The MHRA has not received any adverse incident reports identifying ALCL in association with breast implants in the UK. Discussions with the relevant UK professional bodies have not identified any cases.” The actions recommended to plastic surgeons are: “No change to current best practice is needed; If you are contacted by concerned women about this issue, reassure them that ALCL is a very rare form of cancer; During the initial consultation and subsequent follow-up examinations, encourage women to self-examine for changes in their breasts and seek medical advice if they are concerned.” They also requested that healthcare professionals report cases of ALCL occurring in patients with breast implants.³⁰

2011 (Feb) – The implant manufacturer Allergan produced a document (principally for the US market) describing the Natrelle 410 implant and providing advice upon its use and recommendations for the physician or surgeon. Several statements within this document do not apply to the UK market, for example, the certification scheme for surgeons. The document provides “important factors to convey to patients,” but ALCL is not one of these factors in this section. In a section on “other reported conditions” ALCL is mentioned within a background statement of “there have been reports in the literature of other conditions in women with silicone gel-filled breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. No cause and effect relationship has been established between breast implants, and the conditions listed in table 4. Furthermore, there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants”.³¹

This document was not routinely available to UK surgeons at that time. A slightly later instructions for use information leaflet available in the UK in 2013 had no mention or reference to ALCL.³² Experience from that time period was that this document would normally be placed in the implant box / packaging and would be available to the surgeon only at the time of surgery. Most surgeons did not look at this, and this document was usually discarded with the implant packaging. It was also not shared with patients as the decision making about the implant was made in the clinic without the sterile implant packaging having been opened.

2011 (Apr) – Lechner et al. published a report titled “Breast Implant-Associated, ALK-Negative, T-Cell, Anaplastic, Large-Cell Lymphoma: Establishment and Characterization of a Model Cell Line (TLBR-

1) for This Newly Emerging Clinical Entity".³³ They referenced Brody et al.'s suggestion that textured implants using the low salt method may pose an increased risk for this malignancy within a background 900 primary breast T-cell ALCL.³⁴

2011 (Aug) – Popplewell et al. published a review of 7 patients within their institution diagnosed with primary ALK negative ALCL associated with breast implants and perform a wider literature review reporting 24 other cases.³⁵

2012 – Aladily et al. reported 13 cases of ALCL associated with breast implant.³⁶

2012 – Taylor et al. published a series of 5 patients in Australia with ALCL and breast implants to illustrate the spectrum of presentation of the disease in textured surface implanted patients. In their article, they refer to 42 cases of non-Hodgkin's lymphoma of the breast in association with breast implants, 35 of which were ALCL and make the statement. "We, and others, feel that ALK-1-negative ALCL in association with implants may well represent a new, distinct form of this lymphoma, but we believe that it should be left up to the experts at the World Health Organization to define further. This lymphoma clinically behaves more like primary cutaneous ALK-1-negative ALCL rather than the systemic form."³⁷

The Taylor paper has been referenced as a time point at which surgeons should have been informing their patients about ALCL. The paper has relevance to the general knowledge of this condition, and similar to other papers, it mentioned the chronology of discoveries up until that point. It was published in a plastic surgery journal and was the fourth such plastic surgery publication over this period. This was the first such paper to suggest that ALCL should be considered in patients presented with late onset seroma after breast implant use, and it also made the suggestion: "We suggest that, despite the overall low number of cases of this condition and the limited scientific knowledge about it to date, patients considering breast implant surgery for any reason should be advised of the remote possibility of implants being associated with the development of breast lymphoma".

2013 – Sorensen et al. presented the first UK case report of a primary ALCL occurring in a patient with previous implant-based breast reconstruction at the BAPRAS annual scientific meeting. This was subsequently published in 2014.³⁸

2014 – Hart et al. reported 2 cases of Breast Implant-Associated ALCL and perform a systematic review of the literature. They note that both of these patients had periprosthetic implant fluid and were successfully treated via implant removal and capsulectomy. They find 63 cases of implant-associated ALCL during their systematic review.³⁹

2014 (Dec) – In response to 3 reported cases of ALCL occurring in association with breast implants, the MHRA/MDA released a further statement supporting their previous recommendation. "No change to current best practice is needed. There is no indication for any routine action in the form of explanation or regular radiological or MRI examination."⁴⁰

2015 – The British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS) released a statement advising patients on the risks of ALCL. This was in response to a study by the French National Cancer Institute reporting a small risk between ALCL and textured breast implants. At that time the President of the association, Nigel Mercer, specifically mentioned "It is the responsibility of the operating surgeon to ensure that the patient is told verbally and in writing of the risk of ALCL before the procedure so they can make a fully informed decision before going ahead."⁴¹

2016 – Clemens paper published declaring "polls in the UK and the USA in 2015 showed that a majority of breast / plastic surgeons did not routinely warn patients of the risk of BIA-ALCL".⁴²

2016 (May) – BIA-ALCL is recognized by the WHO as a new distinct entity.

2017 – The Scientific Committee on Health Environmental and Emerging Risks (SCHEER) published scientific advice on the state of scientific knowledge regarding a possible connection between breast implants and ALCL. They conclude that based on scientific information retrieved from the literature that "there is currently insufficient scientific information available to establish a methodologically robust risk assessment to investigate a possible association of breast implants with ALCL development" and that the SCHEER "recommends a more in-depth evaluation on the possible association between breast implants and ALCL."⁴³

2017 – Johnson et al. published “Breast Implant-Associated ALCL: The UK experience. Recommendations on its management and implications for informed consent” in the European Journal of Surgical Oncology (EJSO).⁴⁴ This paper refers to “A recent, informal conference poll of plastic surgeons in the UK suggested that 75% of respondents did not routinely discuss BIA-ALCL with their patients prior to implant surgery”. This poll was taken from Clemens et al. work in 2016.⁴²

2018 – MHRA placed a medical device alert / UK update on BIA-ALCL comprising of Joint Statement between ABS, BAAPS, BAPRAS, & MHRA on BIA-ALCL, the professional organizations representing many surgical professionals explaining their involvement in the research and information sharing regarding BIA-ALCL.⁴⁵

2018 (Dec) – Allergan fail to have CE mark renewal of their BIOCELL® textured breast implant and expander range within the European Union.⁴⁶

2019 (Feb) – A UK perspective on BIA-ALCL was described by Mercer.⁴⁷

2019 (Mar) – The newly set up European Taskforce on BIA-ALCL produced a summary of the position at that time, quoting approximately 800 confirmed and unconfirmed reports of BIA-ALCL worldwide, viewed in the context of an estimated 10-35 million breast implants that have been implanted, as approximated in the scientific literature.⁴⁸

2019 (April) – Statement made by Mercer, Chair of the PRASEAG committed based at the MHRA explaining “Based on analysis of the latest scientific evidence and expert clinical opinion, the MHRA advises that there is no need for people with breast implants in the UK to have them removed because there is no new evidence that the risk has changed. The situation will be reviewed regularly by the MHRA.”⁴⁹

2019 (Jul) – Allergan has announced a voluntary worldwide recall of their BIOCELL® textured breast implant and expander range.⁵⁰

2019 (Nov) – Further joint statement on behalf of BAAPS, ABS, and BAPRAS is produced stating that the current state of play as regards to BIA-ALCL is that there are several theories regarding the role that implant surface texture plays in the development of BIA-ALCL. However, there is currently no conclusive evidence of differences in the risk of developing BIA-ALCL between the different types of textured implants used in the UK.⁵¹

2019 (Sep) – Estimated risk of developing BIA-ALCL in the UK is 1 in 24000 implants sold.

2020 (Sep) – Estimated risk of developing BIA-ALCL in the UK is 1 in 20000 implants sold.

2021 (Jan) – UK specific guidelines on the diagnosis and treatment of BIA-ALCL published.⁵²

2021 (Oct) – The US FDA changed their advice about sharing information regarding BIA-ALCL with patients, making it mandatory with a patient decision checklist and required as part of the patient consent process.⁵³

2021 (Nov) – Estimated risk of developing BIA-ALCL in the UK is 1 in 15000 implants sold.

Discussion: Surgeon responsibility as regards consent

Informed consent should be a process by which a patient voluntarily confirms their willingness to undergo treatment. This should involve an in-person discussion between the surgeon and the patient covering all aspects of the proposed treatment, including any other potential options. Information (either verbal or documented) should be provided to the patient in language that they can understand. The patient must have the capacity to be able to weigh up the factors regarding the treatment and come to a decision about whether or not to proceed. Prior to proceeding to surgical treatment, a consent form should be completed. If the treatment is staged, then the informed consent process should be revisited before each stage, with re-discussing options and further documentation signed.

The standards for the treatment and the consent to that treatment process that surgeons are currently required to meet are “Bolam”, “Bolitho”, and “Montgomery”:

In *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, [1957] 2 WLUK 94

The doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art. Putting it the other way

round, a man is not negligent if he is acting in accordance with such a practice merely because there is a body of opinion that would take a contrary view.

In *Bolitho v City & Hackney Health Authority* [1998] AC 232, [1997] 11 WLUK 222

The court has to be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a logical basis.

The key parts of the *Montgomery* ruling were that (*Montgomery v Lanarkshire Health Board* [2015] AC 1430)

Lords Kerr and Reid:

87. An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

90. ...the doctor's advisory role involves dialogue, with the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information that she cannot reasonably be expected to grasp, let alone routinely demanding her signature on a consent form.

85. "A person can of course decide that she does not wish to be informed of risks of injury (just as a person may choose to ignore the information leaflet enclosed with her medicine); and a doctor is not obliged to discuss the risks inherent in treatment with a person who makes it clear that she would prefer not to discuss the matter.

For the period of time from 1997 to 2011, most surgeons performing breast implant surgery would not have been aware of the potential association of breast implants and ALCL. Early case reports were in separate, unconnected, and mostly nonsurgical journal publications that would not have necessarily been part of a plastic surgeons reading list, **even the Johnson paper in the EJSO**.⁴⁴ It should also be recognized that there is always a gap in the translation of scientific data and knowledge from the laboratory/specific research groups to the general scientific (or in this case) medical and surgical audiences. This time lag is variable and depends on a host of different modalities or communications.⁵⁴

From 2011 to 2014, a "reasonable body of plastic/breast surgeons" may have been aware of the ALCL diagnosis, but not have discussed nor consented patients based upon it being a very rare tumor with an equivocal association at that time, according to the scientific literature and advice from regulatory bodies such as the MHRA and FDA. Although the alerts had been made in 2011 by the FDA and MHRA, the penetrance of these alerts was low. At that time, whilst these alerts were accessible if one searched for them specifically, they were not distributed individually to surgeons or associations. Whilst some hospital governance departments may have been alerted, this process was patchy, and the mechanisms to further disseminate this information was poor and probably depended on individual hospitals, departments, surgeon circumstances, and experiences.

As mentioned in the chronology, the Taylor et al. paper article in 2012 introduced the idea of consent for patients undergoing breast implant surgery. However, the journal specifically highlighted that: "The views, opinions, and techniques set forth in this article addressing ALCL in women with breast implants are those of the individual author(s) and do not reflect the views, opinions, or recommendations of the American Society of Plastic Surgeons, the *Journal*, or the *Journal* editors. Any treatment recommendations contained in the article are those of the individual author(s) and are not to be considered or construed as practice guidelines, practice standards, or practice parameters. The use of any treatment technique described in the article is at the sole discretion of the physician in the exercise of his or her independent medical judgment taking into account the patient's individual circumstances."

Consequently, this suggested change in practice over consent did not reach enough of a threshold in circulation to surgical world professionals, groups, or proof of association to mandate change at that point.

The UK position began to change with the 2015 BAPRAS press alert. The scientific literature even at that stage was sparse and not widely dispersed in plastic surgery journals. Even considering Montgomery, many surgeons would not have introduced the discussion of ALCL into their patient consultation/consent process on the basis of a lack of understanding about it and therefore the attachment of materiality to that risk. Our experience at that time (and subsequently) has been that, despite informed discussion of BIA-ALCL during the consultation/consenting process, it has neither influenced or deterred our patients' choices in having breast implant surgery either for reconstruction or cosmetic purposes.

Johnson et al. in 2017⁴⁴ discussed the 2015 Montgomery ruling and the General Medical Councils' Guide to Good Medical Practice⁵⁵, explaining that this “guidance” should be regarded as a mandatory requirement to inform the patient about BIA-ALCL as a distinct entity

It was in 2018 that UK-based surgeons, hospitals, and health care providers were acutely and widely informed of BIA-ALCL and their responsibilities as part of the consenting process secondary to the joint statements, released by the MHRA, ABS, BAAPS, and BAPRAS. This was closely followed by the failure of Allergan to achieve CE mark approval for their BIOCELL® textured implant/expander range and subsequent recall of the product. It is this time point that it became inexcusable to not discuss with patients about the diagnosis of BIA-ALCL and its association with textured surface breast implants.

Several attempted medical negligence actions regarding BIA-ALCL have been pursued in the UK. Until now, action against implant manufacturers and causation of the disease process of BIA-ALCL has been avoided in favor of pursuit of allegations against individual Breast and Plastic Surgeons who have carried out breast implant insertion in patients who have subsequently developed BIA-ALCL. The direction of travel with these cases has been to find fault due to a lack of information provided by the surgeon to the patient as part of the consent process.

Conclusions

The authors believe that the key time point with regards to the duty of care for UK surgeons to consent their patients to the risk of this condition was from the release of the joint statement made by the associations and the MHRA in 2018.⁴⁵ It was from this stage, we believe that the association of BIA-ALCL and breast implants should have been widely known about.

Prior to this time point, it can be argued that there was a relative paucity of information about a very rare associated disease, which had been noted in oncology and pathology journals but few surgery publications. As a result, many UK-based surgeons would not have been aware, let alone have received advice or mandates to share this knowledge with their patients, consequently Montgomery “materiality” could not be assigned. Undoubtedly, there were some surgeons discussing BIA-ALCL with their patients between 2015 and 2018, but there were a significant number of surgeons who did not as part of their standard practice. Although this has not to our knowledge been tested in the UK courts, we believe that the judicial application of both “Bolam” and or “Bolitho” may render allegations of lack of satisfactory consent by surgeons during this time period unsuccessful.

The average time from implantation until onset of symptoms of BIA-ALCL is 7-10 years, and it is a likely that that there will be a legacy of further attempted medicolegal cases based on a failure of consent.

Conflict of Interest statement

KA is a member of PRASEAG (Plastic Reconstructive and Aesthetic Surgery Advisory Group) and an independent medical expert witness.

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Ethical Approval statement

Not required.

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