

Information Sheet for Patients Undergoing Bilateral Breast Augmentation (BBA)

Introduction

The breast has been the symbol of femininity since the earliest time. Often, to a woman, in her perception of her body and her concept of self, the size and shape of her breasts plays a dominant role. Whilst padded bras do give the illusion of increased breast size and they help superficially they can paradoxically cause increased problems for a woman once they are removed and the breasts assume their natural appearance. Augmentation mammoplasty or breast enlargement is an established surgical technique that is proven to improve a woman's body image and perception of self with usually positive psychological effects.

Who chooses to have breast augmentation?

There are two main groups of women who request this operation. The commonest group of women are represented by those who have recently completed their family, who were happy with firmer larger breasts during pregnancy, but have found that subsequent to pregnancy and childbirth the breasts have decreased in size and are seemingly deflated. This is often with emptiness in the upper half, causing a more scalloped appearance and sometimes combined with loose skin. The lower pole of the breast may overhang the crease under the breast. The second group is represented by young or middle aged women who are yet to start a family or have decided not to have children, who wish to have breast enlargement as they consider their breasts to be of insufficient size, often disproportionately small to their frame. This often affects their feeling of femininity and overall confidence.

How do I go about finding more information on breast augmentation?

Unfortunately unless there is a significant underlying medical condition which has led to a deformity of the breast or a post-operative deformity that requires correction it is not possible to obtain augmentation mammoplasty on the NHS except in exceptional circumstances. There are numerous sources of information on augmentation from books, magazines, to articles posted on the internet, and these should be complemented by a good quality in-depth consultation with a **specialist** surgeon who will perform the augmentation.

It is possible for women to approach their surgeon directly through the local private hospitals. Please note that it is considered good medical practice for the surgeon to keep the patient's general practitioner informed of any medical interventions that subsequently occur, and we will routinely write to your GP after each consultation. Mr Turton has produced this information to supplement your reading and provide a basis to enhance your understanding and for informed consent. It should be read in conjunction with the related information on his website.

How do I select a surgeon?

Breast augmentation should only be performed by a Specialist Surgeon trained in the technique, whether their background is in the specialty of plastic surgery or a Specialist Oncoplastic Breast Surgeon who comes from the parent specialty of General Surgery - whose usual clinical workload relates *entirely to breast surgery and women with breast disorders*. It is worth checking that the surgeon is a member of the relevant specialty organisation. This includes the Association of Breast Surgery, (ABS) or otherwise BAPRAS. The Specialist Information website lists more details about the surgeon's 'usual' practice, and further details might be found from reviewing their NHS practice too. The National Care Standards Commission is a new agency set-up by the government to ensure the regulation of cosmetic surgery in private hospitals and if you approach a surgeon offering augmentation mammoplasty in the private hospitals of the Nuffield or Spire in Leeds they will have had to fulfil the requirements to be allowed to provide this surgery. It is obviously our opinion that any surgical intervention is better carried out by local experts rather than travelling far and wide. Mr Turton is a Specialist Breast Surgeon and performs Cosmetic Breast Surgery including breast augmentation, reductions, mastopexy, correction of nipple inversion, tuberous breast deformity, breast asymmetry, breast reconstruction, and breast liposuction. He trained in the specialty of general surgery before specialising in Breast, Oncoplastic Breast and Aesthetic Breast Surgery. In private practice his special area of interest is Cosmetic Breast Surgery. He is a Full member of the Association of Breast Surgery (ABS) and has served as a full member of the ABS Clinical Practice and Standards Committee. Mr Turton is also a member of the Aesthetic sub-committee of the ABS and was the first UK Breast Surgeon to be fully Certified in Cosmetic Breast Surgery by the Royal College of Surgeons of England. In addition Mr Turton's NHS Consultant work is exclusively as a Specialist Breast Reconstructive and Oncoplastic Breast Surgeon and he carries out breast augmentation, breast reduction and mastopexy as part of his NHS work where required for congenital and developmental problems or in relation to reconstruction or to obtain symmetry with the other breast. Mr Turton has been in continuous full time employment as a Consultant Specialist Breast Surgeon at Leeds Teaching Hospitals Trust and also in private practice carrying out all aspects of Cosmetic Breast Surgery since 2004 and has performed many thousands of breast operations.

Pre-operative evaluation

You will be seen by your consultant and various questions asked concerning your approach to breast augmentation. You will be asked why you wish your breasts to be enlarged, how long you have thought about this for and what your

expectations are from the surgery. We ask questions to explore this such as what size you would like them to be, and if you had been pregnant previously, the breast size that was attained. The most common answer given to the first question is that women wish to look better in their clothes and be in better proportion to the rest of their body, or be returned to the size they were prior to pregnancy. As far as the second question is concerned it is unrealistic to give an exact estimation of cup size following the procedure but a general opinion can be given.

It is important to achieve a balance between what a woman might desire and what is possible surgically given the limitations of the woman's chest size and tissues etc. Finally, if a woman did not enjoy having larger breasts during pregnancy it is unlikely that a breast augmentation will be a positive experience.

Please tell us about your medical and any previous surgical history. We need to know any medications that you currently use. Pre-existing illnesses, in particular any autoimmune disorders that have affected you or other family members (rheumatoid arthritis, thyroid problems, type-1 diabetes, coeliac disease, vitiligo, Sjogren's syndrome, fibromyalgia, chronic fatigue syndrome, polymyalgia, inflammatory bowel disease) including any skin conditions should be fully disclosed as these may need to be evaluated in more depth. Any smoking history (past or current) including use of e-cigarettes or nicotine products must be disclosed. Please also detail any close family history of cancers, especially breast or ovarian cancer, which relatives were affected, and the approximate age that any of these occurred.

You must detail all medications, herbal preparations and any allergies as adjustment is often needed at the time of surgery. Please also let us know about skin or food allergies. Please also let us know about any un-diagnosed medical symptoms, any personal history of autoimmune disorders, or whether any autoimmune disorders run in your family.

After discussing the woman's motivation for surgery and desire for their final appearance, a full breast examination will be performed. This will include a clinical check for any pre-existing breast lumps. The cosmetic assessment requires a trained eye and the experience of Mr Turton is invaluable here. The measurements taken will be recorded and kept in the notes. In particular any asymmetry of the breasts, chest or back is noted as this it is almost universal in women, although often it has not specifically been recognised by the patient herself. Breasts are rarely exact replicas of each other, but it is important to accept that it is normal for there to be some element of asymmetry of the breasts prior to the procedure. This is due to combinations of physiological differences, developmental differences, or sometimes some underlying skeletal differences from one side to the other. These will obviously need to be recognised as it will always have some impact on the final results. Discrepancies cannot usually be greatly altered by conventional simple breast augmentation surgery and if you are concerned about asymmetry you may need additional surgery or further surgery at a later date. A balance is usually made by patients to accept their starting asymmetry to avoid additional costs, but if it is something that you feel would be difficult to cope with psychologically you should make this clear so that Mr Turton's opinion can be explored as to any potential solutions and what they might entail. Asymmetries will therefore be demonstrated to avoid any dissatisfaction post-operatively. It is worth remembering that augmentation will not produce a perfect type cleavage with nipples pointing straight ahead unless that is what the woman started with.

Specific considerations

Ptois – ptosis (sagging) is the medical term for nipples that have dropped below their original position. There are various grades and in the worst cases they can actually be pointing directly at the floor. **Breast augmentation cannot correct anything other than the mildest case of ptosis.** If a ptosis correction is requested then an alternative procedure known as a **mastopexy** would be required. This can occasionally be combined at the same time as an augmentation, albeit with increased costs and certain increased risks. This however leads to additional incisions and hence scarring around the nipple and often lower breast (see photos of mastopexy or reduction on Mr Turton's website), dependant on which technique is required. Care should be taken to discuss this with your surgeon should you wish the nipple position to be altered. Some women are happy to live with a degree of looseness and ptosis so long as the volume of the breast can be returned with the augmentation. So long as they understand that in a bra they will have good volume and projection but once the bra is removed they will have a more downward deflection of the nipples as before. At all times it should be emphasised that we are aiming to achieve what the woman wants and not some pre conceived idea of perfection. If you do not have ptosis then you will not have to worry about this. Please do remember that breast ptosis can develop later after augmentation and sometimes it can occur just in one breast causing asymmetry. Future weight changes, pregnancies, hormonal changes and simple ageing can all contribute unpredictably to the way the breast behaves as you get older. This can also affect women who do not have implants but is generally more obvious after augmentation.

Implant size

Consideration is always taken regarding the patient's desires. Reviewing pre-and post-op pictures from Mr Turton's web site and printing off the post-op pictures that you feel are most in line with your desires can assist the discussion.

Between 125 and 150 mls of volume will very approximately increase the bra size by about 1 cup. However, this is really too vague a relationship to serve as any useful judgment when choosing implant size. A bio-dimensional assessment will be performed by Mr Turton, to provide you with an implant size that fits your frame and therefore is more natural and in proportion, as is desired by the majority of patients these days. It is far better to base the planned implant on your tissue characteristics and more specifically your breast and chest dimensions. There are many considerations eg: the way previous pregnancies (if applicable) have stretched the tissues, your current breast size and overall current 'starting point'. We do this by assessing the shape of your chest wall, measuring the thickness of your current breast tissue, the skin and breast tissue elasticity, the looseness of the breast skin envelope and the quality of the underlying tissues. We use this information to help decide on the optimal shape and size of the implant and whether it is placed behind or over the muscle. All of this should be carefully considered by your surgeon and taken into account before discussing implant size with the patient. A higher profile round implant will give a fuller appearance in the upper part of the breast (the extra high profile type can give a more artificial look where desired, but the moderate and full profiles can also look very natural in the context of the right starting point, and the optimal profile and size of implant chosen by your Specialist). There are also anatomically designed implants that give a less pronounced fullness in the upper part of the breast, although these don't suit everyone, they can work very well with patients who are very thin and flat chested. You should ask your surgeon to discuss the various merits of each of these with you prior to selecting an implant. CrisaliX 3D imaging is one of the most advanced ways to help guide you as to how you might look after the bi-dimensional assessment has allowed Mr Turton to determine the optimal implant type. This 3D image is able to show a simulation of your potential outcome.

Implant type

Your surgeon will discuss things with you in more depth and answer any questions that you have. The implants all have an outer silicone elastomer shell. Virtually all UK cosmetic breast implants have silicone gel inside- they can be saline-filled but these do not look or feel as natural as silicone, and the high cohesive silicone gels are preferred.

Mr Turton prefers to use high cohesive silicone gel implants. Mr Turton has an extensive experience with different implant manufacturer's implants. He has particular experience and expertise with the full spectrum of anatomically shaped (tear drop) and round implants and their correct placement (see pre- and post-op photos). Mr Turton has extensive knowledge about the safety of breast implants and in particular can help select the best device for your circumstance and will talk through the pros and cons of the varieties available in as much depth as you want.

Positioning of the implant

Textured implants, particularly the heavy textures (macrotextured) had previously been the preferred choice for over 20-years in the UK. This was because this texture allowed tissue to adhere to the implant, and this stopped implant movement. But as the rare link between the most textured devices and the rare breast lymphoma (ALCL) was made since 2011, more and more surgeries are performed now with the lesser textured devices (often referred to as micro textured) or smooth implants (no texture), as these are thought from some studies to have a much lower risk compared to the heavily textured (macro textured) devices.

The implant can be placed either directly under the breast in a "sub-glandular" position (this also includes sub-facial), or partially under the muscle of chest wall known as the "subpectoral" position or "dual plane". Generally for women with very little existing breast tissue a sub-muscular approach is recommended to soften the transition between upper chest and the upper breast with implant. Sub-muscular also reduces the visibility and palpability of the upper edge of the implant where the tissue thickness is very low. It can also mask visible rippling, which might only appear when you sit forwards. Every woman obviously represents an individual case and you should discuss the various advantages and disadvantages of each approach with your surgeon. The sub-muscular position affords a better ability for mammograms to visualise your breast tissue later, although they are still less sensitive than when performed without implants. The breast tissue is partly obscured by cosmetic implants on mammograms. Sub-pectoral positioning is not for everyone thought and it can sometimes look less natural especially if the implant is wrong for your frame. During forced pectoral muscle contraction the upper pole of the breast and the cleavage area will flatten when the implant has been positioned behind the muscle (sometimes referred to as animation of the breast as it makes the breast move). Sometimes the sub-pectoral position can stop the implant filling the overlying envelope of the breast as well, if the envelope is quite loose to start with. Although it is not uncommon for the breast to look and move unnaturally when contracting the pectoral muscles, giving a distorted appearance, this is only really visible if you do this deliberately or when wearing just a bra or are undressed!

On the plus side, sub-pectoral positioning may help lower capsular contraction rates and sub-pectoral positioning is preferred if placing smooth (texture-free) shell implants (which are thought to have the lowest risk of the very rare ALCL). Some patients who have good soft tissue thickness prefer sub-glandular positioning, as it is less painful and the recovery is quicker; they then "reserve" the sub-pectoral position for later in life when they will need their revisions.

However, we recommend the use of the micro-textured implants when using sub-glandular positioning otherwise the capsular contraction risks would be higher.

The Operation

You must not smoke either before or after surgery ideally from 6-weeks before to 6-weeks after. All nicotine products must be completely avoided. Smokers have higher rates of all complications both in the short and long term. The operation is performed under a general anaesthetic and in Mr Turton's practice is always conducted by an experienced Consultant Anaesthetist as safety is his priority. Various approaches are available for the placement of the implant. The commonest approach is by placing the scars underneath the breast in what is called the inframammary position. This is generally considered the one required for the placement of silicone implants as they do not compress enough to be squeezed through holes in either the armpit or around the nipple. It is associated with the lowest complication rate. Your surgeon should discuss the surgical approach with you prior to the operation. Mr Turton has a very careful and skilled technique for breast augmentation that has been refined from years of experience and will help optimise the best cosmetic result for you and reduce the risk of subsequent complications. The stitches used are dissolvable. Mr Turton uses three layers of sutures, with the deepest strength layer designed to be reabsorbed slowly by the body. The top layer is a fine cosmetic suture just under the skin surface to optimise your scar.

Following the procedure the wounds will be dressed with white adhesive strips called steristrips and over this a semi-waterproof dressing will be placed. This will protect your wound, but Mr Turton prefers that you just take shallow baths for the post-operative 1-2 weeks to keep the dressings dry. A tubigrip support is pulled up over the breasts at the end of the operation so that no sports bra is needed at this time, as this is generally preferred to prevent possible implant malposition from an ill-fitting bra. The tubigrip (and any "stabilising band" if this is also applied) should not be removed, but left on even when having a shallow bath (and kept dry!). They should be comfortable and not excessively tight. The tubigrip is often placed as a double layer for the first post-operative night, and then pulled out to a single layer and the bottom trimmed the following morning so that it isn't as tight. An overnight stay is generally always recommended as Mr Turton believes this to be the safest way to look after you and for your reassurance. Antibiotics are given to cover the procedure and for a period of 3 days afterwards.

Returning Home

You normally need regular combination analgesia with sub-muscular augmentation for the first four days (eg a common combination is: Paracetamol and Ibuprofen (sometimes also Tramadol) all taken every day for four days before decreasing a little). The patient is advised that she should restrict her arm movements for the first 7 days trying to keep her elbows close to her sides. On the eighth day you can resume routine non-strenuous activities but should still restrict arm movement; You can usually drive a car again a little earlier than this if it is not uncomfortable to do so. However, you must avoid lifting your arms above shoulder height.

You will be reviewed at around one week after surgery in the dressing clinic and then at around two weeks after surgery in the out patients department. At the end of 2-3 weeks, you will be advised when you can start to wear a sports bra. Usually by 6-weeks you can start to wear an under-wired bra, though you may consider continuing to wear the sports bra at night (which may help reduce breast sag in the long term if you keep it up regularly). If all is well you can resume most normal activities including light exercise at 6-weeks, except when a shaped (anatomical) implant has been used when the period of restriction is far longer to reduce the risk of implant rotation. Swelling usually resolves by 3 weeks but can take 6-8 weeks with sub-pectoral placement and for implant settling to occur. It is worth remembering that exposure of the scars to ultraviolet light will produce permanent pigmentation in the scar. It is therefore advised to avoid tanning booths and exposure of the scars to sun until the scar has gone a white colour, which can take 6-12 months or occasionally two years.

It is very important not to poke around the scar area with your fingers and under no circumstances scratch the area. Doing so can initiate inflammation, protrusion of the suture ends and cause a deep infection leading to implant removal.

Routine massage of the implants (as used to be described for smooth shell saline implants) is not recommended or required and may encourage capsulation. Please do not do this under any circumstance. Please also ensure any sexual breast contact is gentle.

Keeping the scars taped with a thin strip of low allergy tape such as Micropore™, for 3 months can help reduce stretching of the scar whilst it matures, and hence help to keep it as imperceptible as possible. If you have a tendency to form thickened or raised scars there are silicone gels that can be used which might be beneficial. Otherwise Dermatrix gel can be used from 2-weeks and applied twice daily for 12-months for the reassurance to get the best maturation possible. Some patients just use "bio-oil" for around 3-months.

Special consideration/side effects/complications

Pregnancy should preferably be avoided for 6-months after the procedure. It is normally possible to lactate and sometimes breast feed after a subsequent pregnancy after breast augmentation but a small number of women will find that they are unable to do so or that the volume of milk has reduced. It should be remembered that some of these women may not have been able to breast feed even without an augmentation. The antibiotics given during the procedure may make the oral contraceptive pill ineffective. Barrier contraception should therefore be used until an uninterrupted pill cycle is restarted.

Haematoma

In the first few hours after surgery, Haematoma or bruising is the most common complication. This is the same after most surgical procedures and occurs in less than 1% of patients undergoing augmentation mammoplasty under Mr Turton's care. It normally appears within the first 24-hours and is associated with a sudden obvious increase in breast volume with a tight feeling and discomfort. Very small haematomas can be treated conservatively and will settle. However larger haematomas are usually treated by evacuation under anaesthetic on the same day. Avoiding moving around excessively as you come round from the anaesthetic is important to reduce the risk of this occurring.

Infection

The nationally reported deep infection rate leading to implant removal is reported at 2%, which means 2 in every 100 patients. In over 1000 breast implants placed for primary augmentation Mr Turton has never had an infection leading to implant loss.

Minor wound healing problems may occur more frequently and minor infection with redness at the suture line would be treated as infection even if there are no other signs, and this would still be extremely uncommon at less than 2%.

If an implant becomes infected the breast would swell and you would likely feel shivery, unwell, and have a temperature. That would require urgent medical care to treat and remove the implant to prevent serious sepsis forming which could be dangerous. If an implant had to be removed for infection it would be left out for a period of months. This would produce a marked asymmetry if only one breast is affected. It is possible to place an implant subsequently, but there is an increased risk of infection with the second procedure. Not smoking is of particular importance.

ALCL

ALCL stands for Anaplastic Large Cell Lymphoma. In 2011, the American regulatory Agency (the FDA) identified a possible association between breast implants and the development of ALCL, a rare type of non-Hodgkin's lymphoma. It was estimated in 2011 that the FDA was aware of approximately 60 cases of ALCL in women with breast implants, out of approximately 5-10 million women who had received breast implants worldwide. The incidence is likely to rise with time but is still considered exceptionally rare and less than 1000 cases have ever been recognised worldwide as of April 2019.

In the UK our regulatory agency (the MHRA) have asked that all surgeons report cases since 2011. As of 2016, only 12 such cases have ever been recorded in the UK, and even as of April 2019 the total number of cases ever reported remains under 50. This confirms that ALCL is a very rare problem. Nonetheless, it is of ongoing patient and media interest and will be discussed more and more in the future. In the cases reported to date there are cases that have occurred in the commonest used implants such as Allergan Natrelle and even Mentor. It is too early to say for certain whether it can affect all implant types but there is data to suggest different rates with the texturing variations used by different manufacturers. For example, smooth round implants seem to be extremely rarely associated with it. However, there can be some other complications from smooth round implants such as a higher rate of capsular contraction or malposition, and this can lead to more revisional surgery. One theory about the development of ALCL is that minute traces of bacteria get trapped on the textured implant surface (a biofilm) and cause a chronic inflammation that stimulates the adjacent white blood cells in the tissue (the T-cells) and that triggers it is a subset of susceptible patients. But no one knows for sure and it may be a rare type of bacteria that has not yet been discovered, or even a type of rare autoimmunity. The frequency of occurrence does seem different in regions of the World, and overall, as of April 2019, under 1000 cases have ever been recorded World Wide!

The reason to inform you about something so rare (remember a woman's lifetime risk of breast cancer is 1 in 8; in contrast the MHRA report the rate of ALCL to be 1 in 24,000), is that Mr Turton feels that patients should be given as full information as possible, and it would likely be more worrisome if you had not heard of it before and then to learn about it through the media. From the cases that have been reported it is treated by removing the capsule from around the implant, and at this early stage it is entirely curable. Late cases where it has been diagnosed late leads to spread, which can be fatal like any cancer. The key thing is understanding it is rare, but to be aware of it, how it presents, what you would look for and what to do if you had a concern. Late problems with implants are more usually caused by capsular contraction, minor trauma or rarely infection seromas. All of these can present with symptoms that may have overlap with this rare condition of ALCL, and it will be more common in the future to take fluid sample from around the implant if

a sudden effusion occurs to look for the very rare case of ALCL that might be the cause. Updated information is available from the MHRA: <https://www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-alcl>

There is no link with conventional breast cancer, and we know from extensive research that the frequency of breast cancer is no different in patients with cosmetic breast implants compared to the general population. Please feel free to ask more about this if desired.

The Safety of Breast Implants

There are many hundreds of medical devices that are implanted in to patients in this day and age, from hip and knee joints, types of surgical mesh, pacemakers, artificial heart valves, biologic materials as well as breast implants to name just a few. The vast majority of patients implanted with these medical devices have no adverse reactions. The device works and performs as expected to treat medical conditions or help patients better manage their health. However, a growing body of evidence suggests that a small number of patients may have biological responses to certain types of materials in implantable or insertable devices. For example, they develop inflammatory reactions and tissue changes causing pain and other symptoms that may interfere with their quality of life.

Silicone implants have been used in tens of millions of women across the World since the first breast enlargement in 1962. Breast implants are some of the most regulated and investigated devices in the world. There have been large independent reviews that have looked at the safety of silicone implants. In particular the UK Independent Review Group (published in 1998) and the USA Institute of Medicine (IOM) Committee on the Safety of Silicone Breast Implants (published in 1999). Both reports found no link to autoimmune problems or breast cancer. They concluded that local complications were "the primary safety issue with silicone breast implants." These local complications, which included rupture, pain, capsular contracture, disfigurement, and serious infection, lead to medical interventions and repeat surgeries. Importantly, the IOM report concluded that there was no evidence that silicone breast implants caused systemic health effects such as cancer or autoimmune disease. The National Science Panel concluded that silicone is of low toxicity and that the local reaction to silicone is similar to other foreign-body reactions.

In November 2006, the FDA approved Allergan's Natrelle Silicone Gel-Filled Breast Implants and Mentor's MemoryGel Silicone Gel-Filled Breast Implants. The FDA based its approvals on the manufacturers' clinical studies, called Core Studies, which followed hundreds of women with silicone gel-filled breast implants for 3 (Mentor) or 4 (Allergan) years. The last FDA Update on the Safety of Silicone Gel-Filled Breast Implants was published in 2011. They identified that most infections develop in the immediate post-operative period, although infections can develop long after implant and may be underreported. The current body of literature did not support an association between connective tissue disorders and silicone gel-filled breast implants, but most of the available studies have limitations. Based on the totality of the evidence, the FDA believes that silicone gel-filled breast implants have a reasonable assurance of safety and effectiveness when used as labelled. Despite frequent local complications and adverse outcomes, the benefits and risks of breast implants are sufficiently well understood for women to make informed decisions about their use. Most women report high levels of satisfaction with their body image and the shape, feel and size of their implants.

Although existing data do not allow the definite exclusion of systemic or local immune responses associated with silicone breast implants, no valid scientific evidence currently establishes any such association. In fact, the nature of science is such that no scientific data can ever allow the definite and unexceptional exclusion of this possibility. Based on the evaluation of the FDA and discussions with experts elsewhere in the government and academia, we believe the current evidence, although limited, suggests some individuals may be predisposed to develop an immune/inflammatory reaction when exposed to select materials in implants in general (not just breast). The symptoms some patients experience may be limited to the region where the device is implanted or may be more generalized. Symptoms include but are not limited to fatigue, rash, joint and muscle pain or weakness. Although uncommon and varied, these symptoms may share common underlying immune/inflammatory pathways and mimic more well-established inflammatory conditions. In the small subsets of patients who have reported these symptoms, the symptoms may not develop for several years following implantation. As a result, they may not be detected even in larger and longer clinical studies. To date, these symptoms have not been reported with most materials used in medical devices, including most metals. Moreover, when reported, they have tended to be limited to small subsets of patients. As an example, some patients, mostly with a history of pre-existing allergies, may develop allergic skin lesions with certain device use. This risk is usually identified by patch testing for potential device material-related allergens. However, not all device-related reactions are allergic in nature.

Some patients have reported to the FDA concerns that their breast implants may be connected to other health conditions that could be associated with their immune system's response to these devices, resulting in symptoms like chronic fatigue, cognitive issues and muscle pain (like a breast implant illness). While the FDA doesn't have definitive evidence suggesting breast implants are associated with these conditions, they are looking to gain a fuller understanding of this issue to communicate risk, minimize harm and help in the treatment of affected patients. My own view is that we can't 100% exclude the possibility that implants make some patients ill or might set off an autoimmune disorder, and even

**Mr EPL Turton MBChB FRCSed FRCS (Gen Surg) MD (Hons)
Specialist Consultant Breast Surgeon with special interests in Cosmetic Breast Surgery and Reconstructive Breast Surgery
Patient Information Sheet: BBA**

though I have never personally seen this in any of my augmented or reconstructed patients in over 15 years, if a patient was to get such symptoms they may have to accept that implants are simply not for them and have them removed as a precaution. Mentor explore safety data further on their web page on implant safety:
<http://www.mentorwllc.com/global-us/SafetyInformation.aspx>

Nipple Stimulation

Approximately 15% of all patients undergoing primary augmentation will have permanent alteration in sensation on one or both sides. This can involve the nipple, the areola (the brown skin surrounding the nipple), or more commonly some of the skin on the breast itself usually across the lower pole. It may be less sensitive or totally numb. It would be considered permanent if it has still not returned after a year and even removing the implant will not bring it back. Women should therefore be honest about the importance they place on nipple simulation on their sex life. If it is important to the woman then she should consider whether this operation would be advisable given the risk of nipple sensation loss.

Rippling

If the soft tissue coverage of your skin, fat and breast tissue is insufficient to mask the implant properly, unsightly ripples may appear in the skin on the front upper part of the breast, or on the outside and inside of the breast particularly when the breast is in a dependent position (eg when sat upright and bending forwards or bending down). This is usually due to the wavy surface of the outside of the implant and across its upper half, when someone is sat upright (implants are not solid plastic structures, and the surface adjusts according to pressure and support on the shell). It can also be due to adherence to the underlying implant when very textured implants are used, but usually it simply relates to the patient having such thin tissue coverage. In essence it is because implants aren't 100% taut or solid like a rubber ball. Submuscular (under the muscle) rather than subglandular (under the breast) positioning reduces this complication and is recommended if there is little natural breast tissue to cover the implant. It is not always possible to prevent this, but Mr Turton will look at your soft tissue thickness with tissue callipers during the assessment.

Palpable Implants (edges, knuckling, folds, kinks)

Occasionally the top or edge of the implant can be felt as a definite step or fold under the tissue. Submuscular placement reduces this problem but in athletic individuals can lead to cosmetic problems when the chest muscles (pectorals) are tensed. In addition to alternative implant positions the newer biodimensional implants (also called "anatomical" or "shaped") have a less pronounced "take off" than the round prosthesis and have a stiffer gel. Whilst they give less fullness in the upper and inner cleavage they can give a more natural shape to your augmentation if you are incredibly thin or flat chested. These may be particularly appropriate for women with little breast tissue in the upper part of their breasts, where the tissue thickness as measured with callipers on a pinch test is 10mm or less. You should ensure your surgeon discusses these points with you. Folds can appear over time, with capsulation.

Capsular Contracture and Removal of Implants

A contracture is a tight fibrous capsule that the body forms around the breast implant causing it to become less natural looking. Approximately 1:4 women will develop some form of contracture around the implant. Whilst some women will not realise there is a tightened capsule that has formed, occasionally the contracture becomes so tight that the implant becomes rock hard, making the breast look distorted and causing discomfort. In this situation it does of course require removal. The incidence of contracture is falling with only 10-20% of women developing it over a 10 year period, but follow-up data in this group remains imprecise. Pregnancy and breast feeding after augmentation can cause capsular contraction. This may be because of bacteria from sub-acute infections. Prophylactic antibiotics should be considered for invasive procedures such as deep root canal dentistry if you have implants.

Various conservative treatments have been suggested including the use of antioxidants such as vitamin E, however nothing is fool-proof and a certain percentage of patients will develop contracture no matter what they do or how many times they undergo revision procedures. Women should be aware of this before undergoing breast augmentation. However a small amount of capsular contracture is very common and often accepted by other women undergoing this procedure. If a capsular contraction occurs you should have it removed as fully as possible if having replacement implants. My advice is also that if you develop capsular contraction a second time, you should consider removing and not replacing the implants, and simply accepting that implants are not for you. When implants are replaced after a capsulectomy procedure has been performed, the breast shape will change noticeably. It will be less full and you will notice that the breasts and implants have dropped, as there will be more looseness. If you ever have the implants permanently removed in the future after any previous augmentation then the breasts will usually look drooped and flat, and quite commonly worse than if you had never had them in the first place. The weight and compression of tissue from the implants contributes to the droop and emptiness.

Micropolyurethane covered silicone implants are thought to have the lowest capsular contraction rates. But they are harder to place, and usually a longer incision is required to get them in. Silimed manufactured these but they had their licence withdrawn a few years ago as there was some powdery silicone residue found on the implant surface, presumably due to their manufacturing technique. The polyurethane implants are available from a German manufacturer called Polytech. These implants can provide a useful resource for complex revisions as they do not rotate or move around in the implant pocket. However, the link to breast implant lymphoma may be highest with this variety so caution and detailed discussion must be used if they are to be used. In other words their use must be clearly justified. The Australian data on ALCL showed that the risk of BIA-ALCL was still very low, but more common than other implants at around 1 in 2400

implants. There is also a theoretical excess risk of breast cancer of 1 in a million with these implants, which is of negligible significance compared to the normal rates of breast cancer of 1 in 8 in a woman's life span.

One modern theory on capsular contracture is that some occurrences are caused by microscopic contamination of your implant by bacteria from the environment or from your skin or the nipple ducts at the time it is placed in the operating theatre. Mr Turton therefore uses an intricate 14-point protocol to reduce this risk, comprising items such as nipple shields, glove changes, alcohol-chlohexidine skin preparation, no-contact implant placement, use of the Keller funnel, betadine, gentamicin, cefuroxime triple antibiotic/antiseptic rinse. Mr Turton has recorded a very low capsular contraction rate in his patients and has never had a case of BIA-ALCL.

Rupture / Deflation / Replacement

With saline implants (rarely used by Mr Turton except as part of initial stages of some breast reconstructions where these are called tissue expanders) there is the risk of sudden deflation and even with silicone implants no women should regard her initial augmentation as being life long. It is possible that at some stage the silicone implants will have to be adjusted, replaced, or permanently removed. If you have not had any earlier problems, Mr Turton advises patients to strongly consider renewal at the 10-year mark. Some patient might change them earlier, for a size changes, or for problems of rupture or gel "bleed" (the name given to the slow diffusion of silicone out of its covering), or capsular contraction or malposition. Given the continued development of new implant designs it is difficult to predict the expected lifespan but it is certainly longer than with the older designs, but safety concerns have increased. Replacement surgery is far simpler with a non-ruptured implant without complications.

With saline implants deflation can occur slowly or the prosthesis may rupture causing a dramatic deflation. With silicone implants any loss of integrity in the outer shell is generally compensated for by the fact that the body forms a capsule around the silicone - this is referred to as "intra-capsular" rupture. This was not uncommon with the older implant designs and is normally asymptomatic and silent. With the more modern high cohesive gels it is extremely unlikely that any silicone would travel any distance from this capsule unless the rupture was left for a considerable time. The inside of the high cohesive type is more like a set jelly, rather than runny silicone. But with a more prolonged period of rupture some more liquid type silicone can come from the surface and be adsorbed into the surrounding capsule scar. This might incite a stronger inflammation and set of capsular contraction, or it might trigger watery fluid to form crating an effusion that then requires testing. You might get a burning feeling too. But if there are no symptoms, it might only be discovered incidentally when the implants are renewed. A neglected rupture can lead to silicone passing through the capsule and permanently into surrounding tissues, lymph nodes and elsewhere in the body. I specifically recommend the use of high cohesive implants and also strongly reinforce the advice that even if you have had no problems with the implants you have them replaced after 10-years. One of many reasons that I recommend this is that the rupture rate is thought to be around 10% within the first 10-years after augmentation, based on MRI studies, and dealing with any earlier problems is usually much more straightforward.

It should be remembered that having breast implants does not stop the usual involution (shrinkage of breast glandular tissue with thinning) that occurs following pregnancy or with advancing age. Indeed correcting the aesthetic problems caused by these processes is often the reason women request implants in the first place. Ultrasound scans can be used to look for rupture but MRI is more accurate. Both investigations are expensive (US\$ around £300, MRI around £900). In the USA, they recommend MRI after 3-years and then repeated every 2-years thereafter. This has never been the position in the UK, though if patients want to pay for these tests they are available. However no test is 100% accurate- Mr Turton has operated on patients where the test has suggested a rupture but there hasn't been one and vice versa. Patients with breast symptoms should always be referred to the breast clinic by their GP for prompt assessment by a specialist.

Scarring and Pain

Obviously there is always the risk of overgrowth of the scar known as over granulation. This is called a hypertrophic scar and it is a little raised and a little thicker and more noticeable than normal. In extremely rare cases Keloid scarring can occur, although Mr Turton has never seen this in over 15-years of carrying out breast enlargement surgery. If the scar is hidden under the breast this becomes less of a problem but it can be quite dramatic. In over 99% of cases the scar is usually very fine and fades beautifully over the course of a year. Very occasionally women can get an uncomfortable chronic ache on one side or another after augmentation, and is almost certainly related to deep scar tissue or trauma to sensory nerves. Most patients report that the breast implants feel part of them by 6-weeks after augmentation and that they are not aware of them. If you were to get chronic pain, it is sensible to have them removed and accept they are not for you..

Double bubble

An unexpected visual cosmetic result of a double bubble near the crease under the breast can very occasionally occur leaving a less than optimal cosmetic result. This double bubble appearance is slightly more common with pre-existing ptosis (sagging), or with a pre-existing constricted (tuberous) breast. I also think the shaped implants placed under the

muscle can make it more likely to occur when the predisposing starting points are seen. It is also more common where the crease under the breast is very well defined as the condensed tissue (fascia) fails to expand naturally over the lower part of the implant. Although it may improve spontaneously over a number of months you may need to pay for revisional surgery.

Granulomas

It is rare but possible that small lumps may appear over the implant due to the reaction of the body to foreign materials such as silicone. However any lump occurring in the breast whether it has been augmented or not should be appropriately investigated urgently through the NHS breast clinic. Your GP would normally refer you using the "2-week rule".

Malposition

If an implant moves too far to the side or becomes too low falling beyond the crease under the breast, it is referred to as lateral or inferior malposition. It means the implant no longer in the ideal position. It can occur due to problems your breast tissue simply being too loose to hold the implant securely. Also as we are now not tending to use the type of implants with heavily textured surfaces, implants do not adhere to the tissue and are more like a wet bar of soap and quite slippery under the surface of your breast tissue. Malposition can also occur with technical error during surgery- eg when the incision was placed in the armpit it was much more common to find the implant was malpositioned as the surgeon couldn't check the placement as accurately. However, as gravity affects breast tissue and implants weigh more heavily in the pocket causing tissue stretch, malposition can gradually occur over time. This may lead to a bottoming out appearance. Corrective surgery will not always work effectively as it can occur again and is also associated with the costs of revisional surgery. Choosing implants that are too big will encourage malposition. There is some evidence that the micropolyurethane coated anatomical implants are associated with a lower rate of rotational malposition (personal communication) but there are some difficulties with initial insertion through small incisions and the trade-off if using these is the association with breast implant lymphoma is around 23 times higher than with microtextured implants, with an overall rate in the Australian series of around 1 in every 2400 cases. The BLite lighter weight implants are around 30% lighter than standard silicone implants and although they are more expensive being a premium product, patients can consider them for their breast enlargement.

Subsequent Breast Investigations

It is easier to investigate an augmented breast that has had a subpectoral implant (rather than subglandular) placed as obviously the breast tissue is pushed forward by the muscle. Even with sub-glandular implants it is usually possible to perform breast examination and breast biopsy so long as the investigating clinician is aware of the presence of implants. However implants do interfere with mammography and specialist views are required. The detection rate of small non-palpable breast cancers on screening mammography is probably lower when implants are present. A woman should inform her mammographer that she has implants in place so that the proper studies can be done. It is slightly easier to perform mammographic views on a subpectoral implant than on a subglandular implant. Prior to augmentation if the woman is of a more mature age or there are any significant risk factors for breast cancer such as the family history, then mammography may be performed as a screening investigation. Mr Turton can usually arrange a private screening mammogram in women over 40 who have not got any breast symptoms or lumps for approximately £250.00

In Conclusion

Any woman considering augmentation mammoplasty should consider the following points as regards the recent negative publicity over silicone breast implants.

1. There is strong evidence that implants do not cause breast cancer.
2. Implants are not lifetime devices. The rupture rates are around 10% and capsular contraction rates are around 10-20% within 10 years.
3. ALCL is a rare type of lymphoma that is definitely associated with textured implants. Data as of 2019 suggests it occurs between approximately 1 in 1000 and 1 in 30,000 women. There may be a rare link to smooth implants but this is far less common.
4. There is weak evidence that silicone implants may cause autoimmune disease or in rare cases a vague set of illness type symptoms. You should have them removed if that occurs.
5. A general change in the cosmetic appearance is likely to occur with time and you should assume that revisional surgery will be needed at some point in the future. A degree of breast sag can occur early after an implant has been placed and initial fullness can therefore decrease- tissue stretching is more common in women whose breasts had become much bigger during a pregnancy. Tightening the skin again is called a 'mastopexy' and is an option but involves scars around the nipple, down the front of the breast and across the crease, so as to remove the loose skin.

6. The longer a woman has silicone gel-filled breast implants, the more likely she is to experience local complications or adverse outcomes. As many as 1 in 5 primary augmentation patients and 1 in 2 primary reconstruction patients require implant removal within 10 years of implantation.
7. Limitations in the post-approval studies to date preclude the detection of very rare rates of complications. However, post-approval studies to date do not show any definite evidence that silicone gel-filled breast implants cause connective tissue disease or reproductive problems.

Breast augmentation remains a viable surgical intervention for women who appropriately select this procedure and are counselled concerning its possible effects. If there is any doubt we recommend that you discuss the options with your specialist.

Additional Information

Remember:

- 1) If you can feel your ribs in front, underneath or beside your breast you will be able to feel the edge of your implant.
- 2) If feeling the edge of an implant shell could be a problem, do not have an augmentation.
- 3) If you are thin or have very little natural breast tissue you will be more likely to feel your implant, or to get rippling. Sub-muscular placement is more likely to reduce this unwanted problem.
- 4) The larger your implant the worse your breast will look over time. A larger implant will stretch your tissues over time and cause more tissue thinning and sagging than a smaller implant. Visible "rippling" may also occur if you chose a large implant relative to your current breast size.
- 5) No augmentation will provide a totally natural breast. Patients often have asymmetry and this persists or can look more noticeable after augmentation. This is particularly the case with respect to nipple position.
- 6) It is vital that you arrive at a realistic expectation of what can be achieved with the various breast implants.
- 7) Two weeks before surgery we encourage consumption of pineapple (mainly the core part). This is because there is evidence of an anti-inflammatory effect due to Bromelain contained in pineapple. Always disclose all gels, tablets and medication that you are taking including herbal remedies-some increase the risk of haematoma (bleeding) and must be avoided prior to surgery.
- 8) Please avoid these in the week before surgery:
 - a. anti-inflammatory drugs: like Ibuprofen, Neurofen, Diclofenac and aspirin.
 - b. Herbal remedies and vitamins: St John's Wort , Vitamin E, Vitamin C, Gingko Biloba, Echinacea, Garlic, Willow Bark Products.
 - c. Others: antidepressants, warfarin, steroids, viox, or pain killers
 - d. Please also avoid: Avocado, Ginger, Broccoli, Garlic, Vegetable oils, Nuts & seeds (high concentrations of vitamin E)
- 9) Please ensure that any issues have been discussed with your surgeon to your satisfaction prior to undergoing breast augmentation.
- 10) Please do not have breast implants if you are known to have or think you might have body dysmorphic syndrome.

Note: This information is for general guidance only and represents the views and opinions of Mr Turton, Consultant Breast Surgeon. It should in no way be regarded as either definitive or representing the views of any other surgeon, doctor or institution.

Further useful information is available on the internet from the Dept Of Health detailing safety issues and complications relating to breast augmentation and implants: <https://www.gov.uk/drug-device-alerts/medical-device-alert-breast-implants-report-cases-of-anaplastic-large-cell-lymphoma-alc>
<https://www.gov.uk/government/publications/breast-screening-breast-implant-guidelines>
<https://www.gov.uk/government/news/recommendations-to-protect-people-who-choose-cosmetic-surgery>