PAUL HARRIS

Breast Implant Exchange

Implants are not lifelong devices, and so need removal or exchange at some point. Factors affecting your recovery and the long-term result, include your general health, your skin type, previous breast surgery, any bleeding tendencies that you have, and your healing capabilities; some of which will be affected by smoking, alcohol and medications. Such issues that are specific to you need to be discussed with Mr Harris directly and are not covered here. Please feel free to ask him any questions you might have before you sign the consent form.

Why do I need an implant exchange?

Although they can last twenty years or more, your implants are not lifelong devices and revisional surgery, removal or replacement may be indicated at any time due to issues with the implants or personal preference. Old implants deteriorate, and may rupture, in which case patients notice their breast becoming misshapen, hard or swollen. If the capsule around your breast is soft, then it does not need removal. If it is thick/hard and painful, then removal becomes necessary, making the surgery far more complex, with a higher complication rate than most other aesthetic breast surgery.

What is Capsular Contracture?

Wherever a cut is made, the body heals by making a scar, and when you have a breast implant, you will produce a scar that will completely surround the breast implant. If you make a thin scar, the implant will feel soft and you will not be able to differentiate it from the normal breast. Sometimes, for reasons not fully understood, the scar can thicken and squeeze the implant, making it feel harder and rounder. This process is called 'encapsulation' and the thick scar is sometimes referred to as capsular contracture.

If severe, it can cause visible distortion of the breast and significant pain. The chances of experiencing a capsular contracture are approximately 10% in the first five years. It can however happen at any stage, even 20 years after the initial operation.

How can this be addressed?

Capsular contracture is treated by removal of the capsule (scar tissue) and exchange or removal of the implant. The procedure, a capsulectomy, is a relatively complex procedure with greater risk than a breast augmentation. During the operation, Mr. Harris will remove the implant and as much of the scar tissue as possible. This is safer than en bloc removal, which endeavours to remove both together, with complete removal of the capsule, the aim being to reduce silicone or infection leaking into the breast. However, sometimes the capsule is stuck fast to the rib cage, and removal may damage to the underlying lung. If this is the case, Mr Harris will leave that small amount of capsule behind. Mr Harris often uses a drain for 24-48 hours following this procedure to drain fluid from the surgical site.

Is there any way to reduce the risk of encapsulation?

The current understanding of encapsulation is that it is your body's reaction to a problem with the implant, and in most cases, we think this is due to a low-grade infection. This can happen at the time of the implant insertion, or at a later date from a blood-borne source. The causative infection can live on the surface of the implant in an indolent (idle or non-active) state. This is known as a 'biofilm'. Recurrence rates are high. The fact that it has happened once, means it is more likely to happen again.

Current concepts to reduce encapsulation focus on reducing the chances of the implant becoming infected. Hence, Mr Harris will cover the nipples at the time of surgery with 'nipple shields' (a sterile clear plastic dressing) to reduce contamination from the normal flora that exist in the nipple ducts. He will also use a delivery device (Keller Funnel[®]) for the implant to reduce contact with the skin, and coat the implant with an antiseptic solution.

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Trading as Paul A Harris Ltd. Registered Office: c/o Attwoods, Chartered Certified Accountants, 6th floor, 2 Kingdom St, London, W2 6BD (Registered in England and Wales – Company No. 08062018 – GMC No. 3476419) Placing the implant under the muscle, rather than under the breast tissue, appears to reduce encapsulation. This may be due to the increased soft tissue coverage making mild encapsulation less obvious rather than a true reduction. Polyurethane texturing also reduces the ability of the tissue to tighten around the implant. There is no evidence to suggest whether saline or silicone-filled implants have a lower rate of this complication. Another option is to remove the implants and capsule, and then re-insert implants after an 'implant holiday' of three or more months.

Where will the incisions be?

Mr. Harris will endeavour to use the incision site from your previous surgery (i.e. the old scar) if possible, and will discuss this with you during your appointment. The most common incision is close to the infra-mammary fold (crease of skin beneath the breast). This allows good access to correctly position the implant whilst placing the scar in an area that usually heals well and is not easy to see. This incision is normally about 5cm long but may be extended if required.

Will the scars be the same as before?

All incisions produce scars, which usually settle down over several months. However, some scars can be troublesome. Hypertrophic scars are red, raised and itchy for several months following the operation. These can be treated but often result in a wide stretched scar. Keloid scars are larger and more difficult to treat but these are extremely rare following breast augmentation.

Even if your scars faded well from the previous surgery, it is important to note that each scar's recovery is different and even if Mr Harris is planning on operating through the old incision site, the scarring may change.

What type of implant will I have?

Breast implants come in different shapes and sizes and whilst almost all consist of an outer casing of silicone, different materials or fluids fill them. The various implants can also have different surfaces and many different implant manufactures are available in the UK. As Mr Harris specialises in plastic surgery of the breast, he will recommend a particular implant to you based on your initial consultation and any subsequent discussions. Each patient is treated as an individual, and one single type of implant is not appropriate for all patients.

Nevertheless, for most breast augmentation operations, Mr Harris will recommend round, silicone gel filled prostheses, because they have a natural feel, produce a fuller more desirable look to the breast, do not suffer the problem of distortion from implant rotation and have very good long-term durability. The silicone filling is usually a cohesive gel (known as 'gummy bear' implants in the USA) rather than a liquid.

Most implants described as 'round' only have a round outline from front view. They have a flat back to fit against the chest wall and offer different amounts of projection forward. Hence, there are a number of possible implants to fit a particular chest wall dimension. The internal gels can be very soft, like a liquid, or much firmer (to help maintain shape). Some implants are shaped like a tear-drop and these are more frequently used in thinner patients or for breast reconstruction. Implants can also be filled with saline rather than silicone and for breast reconstruction, 'tissue expanders' which are a combination of part silicone filling and part saline, are also used. The saline can be added to a t a later date using a needle to a pre-positioned port under the skin, usually below the breast or in the axilla (arm pit). There is also a newer implant called B Lite, which weighs and ripples less than standard silicone implants.

How is the size of my implant chosen?

Patient preferences will help determine implant shape and size. Cup sizes are discussed, but these vary between bra manufacturers. However, cup size is useful as a guide to how much change is desired, although no guarantee can be given to achieve an exact size.

Mr Harris will measure your chest to decide on the width and height of the implant needed, and the records of your current implant sizes will help guide the sizing. Mr Harris also uses a 3D imaging system to create a digital model of your chest, which simulates the impact of breast surgery for most patients.

From these discussions and measurements, Mr Harris will recommend a range of implant sizes. This is routinely decided on at the time of the second outpatient meeting. It is then usual for Mr Harris to order several sizes of implants for the operation, at least one either side of the recommended size. This allows the final decision to be made during the operation, thus producing the best possible result. The unused implants are returned to the manufacturer, without incurring a charge.

What will the surface of my implant be like?

Most British Plastic Surgeons use rough-walled 'textured' silicone implants, which were thought to reduce the incidence of encapsulation. The evidence for this assumption has come from our early experience with foam (polyurethane) covered implants and a major UK-based study. However, this study has been criticised by many and in the United States, smooth silicone implants are routinely used.

As a recognised expert in this area of surgery, Mr Harris believes that the surface characteristics of silicone implants does not necessarily affect encapsulation but may impact on the overall aesthetic result so he uses both smooth and textured implants depending upon the desired result. He will inform you of his recommendation for you and explain why he has made that recommendation. Polyurethane coated devices have been re-introduced into the European market for the last decade and these implants appear to convey significant advantage in cases of revision surgery with respect to encapsulation. There are however some disadvantages in their use for routine breast augmentation and hence Mr Harris does not always use them.

Which implant company does Mr Harris use and will the implants have a guarantee?

Mr Harris uses several different manufacturers and will make recommendations based on your circumstances. Currently the main company he uses is Mentor – an American company who manufacture their implants in Europe.

Mentor have had their implants approved by the Food and Drug Administration (FDA), which has stronger regulation that the European authorities. Their implants have been rigorously studied by independent researchers, and have the best ten-year follow up results available.

Most implant manufactures guarantee their implants, usually for a limited time. Importantly, these guarantees do not cover the cost of the surgeon, anaesthetist or hospital in the event of there being a need for replacement surgery.

It is also important to note that although Mr Harris makes the recommendation, the implants are supplied by the hospital where the surgery takes place, and not by Mr Harris directly. Although Mr Harris never used PIP implants, clearly similar problems with implant manufactures could happen again. Mr Harris continually reviews the available literature to recommend the most appropriate implant at the time of surgery, and these recommendations change as new data and implants become available.

Where will the implant be placed?

Conventionally breast implants are placed either in a subglandular position (between the breast tissue and the muscle on the chest wall, or in a submuscular position (beneath the muscle on the chest wall).

The site chosen depends on where the previous implants were placed, the amount of capsular contracture present (if any), the amount of breast tissue present and the breast skin laxity.

A more natural result may be achieved under the muscle because the edges of the implant will have a thicker tissue coverage. However, this does not always completely fill out the breast skin because the muscle can restrict expansion of the breast implant.

A more recent approach has been to place the implant beneath the muscle in the upper half, whilst freeing off the breast from the superficial surface of the muscle. This is known as a 'dual plane technique'. Although this technique was initially described in the United States, Mr Harris has pioneered this technique in the UK, lecturing regularly to both established and trainee plastic surgeons.

After the initial consultation, Mr Harris will advise you on the placement of your implants and why.

What will happen before the operation?

Do not take aspirin or medication containing aspirin ten days before surgery, and stop smoking three weeks before surgery, to reduce the likelihood of post-operative complications. The operation is performed under general anaesthetic with a one-night stay in hospital afterwards. Please bring with you a nightdress, dressing gown, slippers and toiletries, but do not bring cosmetics or jewellery. You should have a shower at home before attending hospital, or on the ward before the operation.

When you arrive in hospital, you will be evaluated by a nurse, the anaesthetist, and Mr Harris, who will discuss your surgery in detail with you. He will take some photographs and draw some markings to guide the surgery. It is important that you do not wash these lines off.

You will be asked to sign a consent form. Make sure you understand the consequences of the surgery prior to signing this. However, signing this form does not take any of your normal rights away, it merely states that Mr Harris has explained the operation to you and that you have had an opportunity to discuss the anaesthesia with an anaesthetist.

Do I need to buy a special bra?

It is important that the implants are held firmly in place for the first few weeks after surgery and a well fitted surgical bra helps with this. Further advice on bra selection will be provided by Mr Harris' specialist nurse (nurse@paulharrisplasticsurgeon.co.uk). Please bring one of the bras to theatre with you so that it can be put on at the end of the operation, whilst you are still asleep. These bras need to be worn for six weeks following the surgery, both during the night for sleeping, and during the day after which you should then be fitted for your new regular underwear.

How will I feel when I wake up after the operation?

The operation takes 1-2 hours. You will wake up in the recovery area before transfer to the ward. It is usual to feel a little disorientated for a short period. If you have pain or feel sick, the nursing staff will give you the appropriate medication. The breasts will feel sore after surgery particularly when the arms are moved, but this rapidly improves over the first few days.

Will there be drains and when do they come out?

As this is complex, drains are routinely used. They usually exit through a separate tiny incision on the outside part of the chest, and will be removed the day after the operation. However, if a large amount of fluid drains, it may stay for several days until this amount has reduced to an acceptable level.

When can I go home?

You will normally go home the day after surgery with painkilling tablets. It is usually best to have someone drive you home rather than taking a taxi or public transport.

What post-operative care do I need and when can I go back to work or exercise?

You will be asked to attend a dressing clinic appointment approximately one week after the operation. At that appointment, the dressings will be removed by a nurse and the wounds checked. You can shower or bath the day after surgery but it is inadvisable to soak in the bath with the wounds submerged for at least three weeks. The stitches are usually dissolvable. An appointment will be made for you to see Mr Harris two weeks following the surgery.

After ten days to two weeks you may go back to non-physical employment and resume driving a car, but check this with your insurance company as some vary. Three weeks after your operation, you may resume gentle exercise, but violent movements and physical employment are inadvisable for six weeks. You can sleep on your back or side but not on your stomach for at least four weeks. You should be back to normal by six weeks following the operation.

What effect does silicone have on my body?

Silicone is used in the body in a variety of ways from lubricating syringes to wrapping around cardiac pacemakers. Despite this, the media attention has been focussed on silicone in breast implants, particularly after the PIP implant scandal. Minute quantities of silicone can diffuse or 'bleed' through the silicone casing of the implant and it has been suggested that this silicone causes breast cancer, abnormalities in babies and a range of diseases related to arthritis.

Large studies in the United States and Europe have now shown that there is <u>no</u> increased risk of these diseases in women with breast implants. Therefore, at present there is no evidence to suggest that silicone from breast implants causes disease. However, the lifetime biological effects of silicone continue to be studied.

Although not specifically breast cancer, there have been some reports of a rare type of lymphoma associated with breast implants. This is known as Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), which is a type cancer involving cells of the immune system. ALCL has generally been found adjacent to the implant in the capsule around the implant. It is thought to occur at a rate of 1 in 30,000 cases of breast augmentation with textured implants per year, and hence is rare. It is also treatable with surgery alone in the majority of cases. Another, much rarer type of cancer, BIA-SCC, a squamous cell carcinoma, has also been reported (September 2022). It occurs in the capsules surrounding breast implants. To date there have been 20 of these cases reported world-wide, and they occur in both smooth and textured implants, and have presented at least 11 years after the implant surgery. Patients may present with swelling, pain, redness or hardness. Of course, we may also discover new problems in the future, as yet unknown.

Do breast implants affect the development or detection of breast cancer?

Several large studies have now conclusively shown that breast implants do not increase the chances of getting breast cancer. Furthermore, women with breast implants who develop breast cancer have the same prognosis (overall outcome from the cancer) as women without implants. However, the implant can potentially interfere with routine mammography by 'hiding' areas of breast tissue, making it difficult to interpret the results. If you tell the radiographer you have a breast implant, different views can be taken to overcome this problem. Patients over forty years old need to have a mammogram prior to their surgery.

Can I breast feed after having had implants?

The insertion of a breast implant does not routinely interrupt the ducts that connect the breast tissue to the nipple, and breast-feeding should therefore be unaffected. The present state of knowledge also shows that silicone does not affect breast milk and that it is quite safe to breast feed. If the nerve supply to the breast and nipple has been damaged (see below) then this may affect the ability of the milk to be produced although this is an extremely rare complication.

What complications may arise from my surgery?

Any invasive surgical procedure has risks such as infection, haematoma (blood clot), dysaesthesia (changes in sensation), post-operative pain, and delayed wound healing and having revisional surgery means the complication rates are much higher than for a standard breast augmentation. The most common complications are outlined below.

A haematoma is a collection of blood inside the body, resulting in pain, swelling and bruising. Very small haematomas are absorbed by the body and do not require treatment but large haematomas usually occur soon after surgery and a further operation is required to drain the haematoma and stop the bleeding point. If post-operatively you feel one breast getting larger than the other, especially if it is associated with pain or flu-like symptoms, then you should tell a member of the nursing or medical team as soon as possible.

Infection is rare. Antibiotics are given at the time of the surgery to reduce the chances of infection. Most infections resulting from surgery appear within a few days of the operation. Infections around implants are harder to treat than infections in normal body tissues. Some do not respond to antibiotics and the implants have to be removed. After the infection is treated and the scar has softened, a new implant can usually be reinserted about 3-6 months later.

In rare cases, the implant may become exposed. This is most likely to occur if the overlying tissue is already damaged, or becomes damaged from pressure ischaemia (lack of blood circulation) associated with a very large implant. Smoking also significantly increases your risk of implant extrusion by delaying the wound healing process. If the implant does become exposed, it needs to be removed and a new implant inserted at a later date.

All patients will experience a temporary reduction in nipple sensation, and a small number may not fully recover. These changes may also affect sexual response and the ability to nurse a baby. Very rarely there may be an increased sensitivity to the nipple, either temporary or permanent.

Most women's breasts are asymmetrical (not perfectly equal in either size or shape) and Mr Harris should mention this pre-operatively. If the same size implants are used on both sides then the small degree of asymmetry between the breasts will remain following the operation. Breast implants can be used to correct large differences between each breast either by increasing the size of one side, or by increasing the size of both sides by differing amounts. However, large differences are impossible to totally correct by surgery and in particular differences in nipple height and size will remain.

An implant may become visible with time as the overlying breast tissue becomes thinner with age; it can often be felt at the edges where there is less tissue coverage. With advancing age, the breast also tends to ptose (droop). This can usually be corrected by a mastopexy (breast uplift) operation.

Modern breast implants have an extremely tough laminated silicone shell to minimise leakage of the contents. However, it can be damaged by injury or vigorous contact. This damage is usually obvious as it results in a change in the shape of the breast with the patient often reporting a burning sensation and a change in size. Rupture releases the silicone gel filling which may remain around the implant or may migrate into the breast, the axillary (arm pit) lymph nodes and elsewhere. Rupture requires surgical removal of the implant and gel, although removal of all of the gel may not be possible. Deflation or rupture of saline implants is commoner. The released salt water, naturally present in the body, is absorbed as a harmless fluid. The implant does however need to be replaced. Another issue with implants is that the surface may wrinkle and this may be noticeable on the surface of the skin, depending on the position of the implant and the thickness of the overlying breast tissue. However, large wrinkles, or folds, occur uncommonly but when they do, may irritate or damage the surrounding tissue.

Do implants last a lifetime or will I need additional surgery?

You should not consider your implants to be lifetime devices, because although they can last twenty years or more, removal or replacement may be indicated at any time. The management of any of the complications described above may also involve implant removal. This will result in a financial implication for you if revision surgery is required.