SOME INFORMATION FOR PATIENTS WORRIED ABOUT PIP BREAST IMPLANTS

INTRODUCTION

Breast implants are made of silicone. The majority are made of two types of silicone with a sticky soft silicone gel inside and a shell of a stronger form of silicone on the outside and this is called elastomer. The physical characteristics of different brands of implants can vary a great deal and it is up to the manufacturer to choose the best combination in order to achieve different shapes, sizes and consistencies of implants. Most Surgeons don't know much about the actual manufacturing process because this is usually a trade secret and we are not told about the thickness of the shell or how strong it is and we have to assume that the manufacturer has made it as durable as possible.

When implants were first made in the late 1960's everything was very new and experimental and there were very few companies making silicone implants but relatively early on it became obvious that the implants with the thicker shells were strong and would last longer without rupture than those that were made with very thin elastomer. The main problem at that time was to work out how to control the scar that formed around the implant after it had been inserted. The reaction between the implant and the breast tissue is very different in different people and the commonest result of inserting a silicone implant into a breast is the development of scar tissue around the implant. If the scar becomes thick and shrinks it tightens around the implant and will distort the shape of the breast and the feel of the breast and it locks the implant into a certain position which can look very unnatural.

In order to try and reduce this overproduction of scar tissue the manufacturers in the early days experimented with changing the outermost layer of the silicone in the hope that it would reduce the amount of scar tissue. Some manufacturers made the elastomer shell very thin in the hope of reducing the scar, but unfortunately it didn't and these implants often ruptured. It was found that an implant which was coated with a polyurethane foam had the least reaction from the tissues and there was only a small amount of scar tissue.

In the early 1980's the implants with the polyurethane foam surface became very popular but then there was a scare about their safety and so they were withdrawn. The company making them had to stop making them and they were no longer available in the UK, although within a few years it was apparent that they were perfectly safe but we weren't allowed to use them in the UK even though the ban on the polyurethane had been lifted in America. We have been able to use these polyurethane surfaced implants in the UK for the last 5 years and I use them almost exclusively now.

The problem of the scar around the implant, known as a capsule, and the thickening of the capsule had one beneficial side effect which was that if the membrane or elastomer of the implant should fragment or disintegrate or break, the silicone gel inside the implant would not always penetrate through this scar capsule and the rupture of the implant would pass silently and the patient would be none the wiser and would not suffer any symptoms even though the implant was no longer in tact. It was because it was nicely contained inside the scar.

For this reason, it is very difficult to know quite how many implants have actually disintegrated and it is only when patients notice changes in the feel of the breast or the appearance of the breast that they may go and seek advice and have scans which may reveal whether or not there has been a rupture. If the implant ruptures the silicone gel in some patients will penetrate through the capsule of scar tissue and cause irritation in the breast tissue surrounding the implant. The patient often feels this as a lump or a swelling or as an abnormal feeling in the breast and in some patients it causes a very intense soreness and tenderness and so they have a scan which shows the rupture has occurred. Sometimes tiny particles of this silicone are taken up by the white cells in the body and they are transported through lymphatic channels to the lymph glands on the outer aspect of the breast and up towards the armpit. If a lymph gland is swollen from taking up silicone from the breast it is described as silicone lymphadenitis. It is not hazardous by itself but no-one likes to have a lump which is undiagnosed just in case it is a cancer. Therefore there are patients who have a ruptured implant and the silicone has escaped through the capsule into the breasts and then they develop hard lumps in the armpit.

There didn't seem to be any very obvious reason as to why some people suffered from severe encapsulation and why a small number of people found that their implants ruptured spontaneously. Unfortunately there was no test to be able to distinguish between those women who are likely to have problems of one kind or another from those who are not going to. The evidence of a ruptured implant wasn't always related to how long they had been there. It seemed that a significant number of capsular contracture problems had probably been sparked off by internal rupture of the implant within the capsule.

By the late 1980's the manufacture of breast implants had become a multimillion dollar business and there was tremendous competition between companies to try and produce a cheaper and better implant. The cost of the implant was often a significant part of the total cost of having a breast enlargement operation and so if a company could sell an implant for 20% to 30% less than their local rivals they would almost certainly capture the market and this is what PIP did. They had a big factory which was approved by Government inspectors and they managed to get European approval and E-marking of their product and they were able to undercut their nearest rivals by at least £100 per implant and sometimes more.

Some of the cosmetic surgery companies started to use the PIP implant in preference to American and British made implants and for several years there seemed to be no problems at all arising from this decision until about 2004 when the first reports of ruptures of the PIP implants appeared in some of the scientific journals. Some people believed that these reports were just one off anecdotes but very slowly it became evident that more and more PIP implant ruptures were being noted and at some point the Regulatory Authority in the UK had to decide whether or not to withdraw the license for PIP implants. They were in a very difficult position because until the evidence was more clear cut the agency was damned if it did ban the implants and could be dammed if they didn't. It was only in March 2010 that the license was withdrawn. With the benefit of hindsight it probably should have been withdrawn several years earlier.

The number of cases of rupture of implants amongst the American and British implants has become very small indeed in the last 20 years and in my own experience it amounts to far less than 1% in implants that have been present for less than 10 years. I never saw a single rupture of an implant that had been coated with the polyurethane foam.

The difficulty about getting statistics is that there was no compulsion to keep records of the fate of implants. For many years the Government funded a registry of implants so that it was possible to track how many patients were getting implants and what type they were and when they were inserted and there was a facility for recording when these implants were withdrawn and why. However it was a voluntary scheme and not a compulsory one and the registry stopped in about 2006 because the Government withdrew the funding.

There is a very small number of patients in the UK who have received implants which contain saline rather than gel. It is well known that these saline filled implants are quite likely to break somewhere in the region of 10 to 15 years after insertion. These patients don't have any particular worries apart from the fact that once the implant breaks it will have to be replaced like for like and it is usually a simple matter to take out the old ruptured implant and put in a new one. There is no risk of any serious complications from saline filled implants. We may therefore see a trend towards more saline filled implants being put in, in the future.

I will now try and explain one or two of the things that we do and do not know related to silicone implants.

<u>THINGS WE DO KNOW</u>

There are several implant manufacturers who retail their implants in the United Kingdom. They are in hot competition with each other claiming better results than rival companies and it is very difficult to know the absolute truth about the complication rate and reliability rate of the different implants.

The rupture rate of implants made by the established and respected manufacturers is certainly less than 1% over a 10 year period. We recognise that ruptures are more likely following accidents in which there is a sudden force or blow to the breast, for example a fall from a horse or a car accident where a seatbelt suddenly compresses the breast and can cause a rupture.

We know that when a rupture occurs it can be associated with a very variable response in the body. In some patients it takes many months between the rupture and the onset of any symptoms but in some patients the response is rapid and severe, ie pain, inflammation, distortion, lumpiness, swelling and involvement of the lymph glands in the armpit.

We know that the internal silicone gel can escape not only out of the ruptured shell of the implant but through the scar capsule which has formed around the implant and pass in to the breast. This may induce a minor or major inflammatory response so that there are some people who will barely notice any change in their breasts but others who will get a painful tender inflamed sore breast within hours or days of the rupture.

Since about 2004, there has been an increasing number of published reports about apparent spontaneous rupture of implants made by PIP. It became evident that there was criminal use of industrial rather than medical grade silicone in the manufacture of some but not necessarily all PIP implants. The number of reported spontaneous rupture of PIP implants became alarmingly high and the agency responsible for the safety of medical products in the United Kingdom banned the use of any further importation or use of PIP implants in March 2010.

Because of the immense anxiety and distress of some patients who have had PIP implants and because of the recent publicity given to this group of people, there are now a large number of solicitors in the United Kingdom looking into claiming compensation for their clients who have had PIP implants, whether ruptured or not ruptured.

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Plastic Surgeons know that it is always much easier to remove an unruptured implant than a ruptured one because the technique of the surgery is much easier for an unruptured implant. If one has to remove a ruptured implant it may require the removal of breast tissue which has been infiltrated by the silicone and sometimes it requires the removal of lymph glands if these are involved as well. This could mean that the patient needs quite major surgery to remove the affected lymph glands. However, it has to be acknowledged that there are a very small number of patients in whom it is evident that silicone has reached the lymph glands without there being any evidence of rupture of the implant and for these people it is assumed that the outermost layer of the shell of the implant has shed particles of silicone into the breast and these particles have migrated to the armpit and been taken up by the lymph glands which have swelled as a consequence and made firm lumps.

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<u>THINGS WE DON'T KNOW</u>

We don't know whether there are certain types of elastomer which are essentially stronger and more durable than others and what the physico-chemical differences are which affect the durability. The manufacturers usually do not publish details of the thickness of the elastomer shell of their implants and usually don't publish evidence about the absolute manufacturing qualities of the particular elastomer that they use because this is commercially sensitive information.

We don't know whether some people's tissue fluid or serum can cause a breakdown in the bonds of the silicone elastomer more than in other people. It seems as though some people appear capable of causing fragmentation of the elastomer more easily or much sooner than other people and we don't understand why this is the case. We don't know in regard to PIP implants whether the company made a small percentage or a high percentage of implants with substandard grade silicone and so whether there are batches of unreliable implants and batches which are perfectly ok and if further investigation into the records of the company will demonstrate whether it is possible to identify reliable from unreliable implants.

We don't know whether there is a time relationship between when the elastomer is put in and when it breaks. We don't know whether the elastomer always breaks in the same place or whether it can occur in any part of the shell of elastomer. In my own experience it seems that the break occurs more on the back side of the implant, where it is sealed or has a seam, than on the front aspect.

We don't know whether the implants are more or less likely to rupture from pressure or manipulation of the breasts and whether people with a vigorous active lifestyle have a greater or lesser likelihood of a rupture of a PIP implant or any other kind of implant.

ADDITIONAL INFORMATION

The UK Government is doing its best to formulate sensible policies for patients who are worried about their implants, particularly those patients who know that they have had PIP implants. At the moment the advice being given is not entirely clear and, although there may be some central government edicts, it is quite possible that individual Primary Care Trusts will not necessarily adopt all the Government recommendations uniformly.

It is quite probable that in the long-term patients with PIP implants will be allowed to have their PIP implants removed under the National Health Service if they are not able to get the hospital who inserted them to pay for such a procedure. There are plenty of patients who have had breast augmentation done by companies that are now insolvent and it is very likely that such patients will be able to get their implants removed if they want to but it is very unlikely that the National Health Service will offer them replacement implants. It is also unlikely that the NHS will allow them to have replacement implants which the patient pays for because it has never been the policy of the NHS to allow for partial payment of procedures.

It is very likely that some of the larger private health companies, such as Nuffield, Spire and BMI will offer removal and replacement of PIP implants simply because from an economic point of view it is not going to hurt them very much financially because they haven't used large numbers of PIP implants. However, some of the big commercial organisations who have used very large numbers of PIP implants may be in financial difficulties if they are expected to carry out removal and replacement of implants. It is to be hoped that the Government will in future take a closer interest in the regulation of the cosmetic surgery industry.

It should be noted that a special register was kept of all implants being used in the UK and this was known as the British Implant Registry and it lasted for about 10 years and was funded by the Government but it was a voluntary scheme and it never involved long-term tracking of the implants or their fate. The Government decided to withdraw from funding of this, which was a shame, but there was no collective will on the part of the different groups forming the cosmetic surgery industry in the UK to take over responsibility for funding of this register or to improve its scope.

It is possible that it will become mandatory again to have implants registered centrally. This will almost certainly have to be funded by the manufacturers within the pricing of the implants.

MY PERSONAL ADVICE

As of January 2012 Mr Henderson offers the following advice to patients who have PIP breast implants.

1) Mr Henderson has never used PIP implants himself because he did not trust the company that was manufacturing these implants at such a discounted price. He thought there might well be something wrong with them and therefore avoided using them.

2) It appears that the incidence of rupture of PIP implants increases with time and Mr Henderson has not come across any cases for medico-legal reasons or within his own clinical experience of rupture in less than 3 years following insertion of the implants. Thus, his advice at the moment is that if the implants have only been there for one or 2 years, it is probably safe to leave them as they are for another year or possibly 2 years but after that, because of our level of ignorance about whether some are safe and some are not safe, it would be sensible to consider having the implants removed and replaced sometime after the third year following insertion.

3) For those patients who have had PIP implants without any apparent problems for more than 5 years, it may be worth obtaining an ultrasound scan of the breasts and to have regular scans every 6 months or so thereafter. Mr Henderson has a suspicion that the pressure required to get a good mammogram is sufficient to rupture a weakened implant.

He has come across several instances in which patients have been required to have a mammogram who also have implants which are quite old, ie over 10 years old and who have not suffered from capsular contracture and therefore have relatively weak capsules around the implant in whom, following a mammogram, there appears to have been a rupture of the implant with spillage of silicone into the tissue of the breast and sometimes to the axilla. It should be emphasised that Mr Henderson doesn't think that mammograms are unsafe because they are going to cause rupture in all patients with implants because this simply is not true. However, most silicone implants induce a capsule around them which become stronger with time and because of the strength of this capsule compression of the breast for a mammogram does not cause significant damage to the implant inside the capsule but if the breasts have developed very little capsular scar then the compressive force of the mammogram may be sufficient to break a weakened implants. For patients who are coming up to the age of 50 and require a mammogram, this is something which is worth thinking about. It is likely that patients with very strong capsules will not have any problem of rupture but patients with very thin elastic capsules may be at risk of rupture of the implant. (NB: This is a personal opinion and is not official policy).

SUMMARY

My personal advice is that if you have got PIP implants and they are less than 3 years old; don't panic because the risk of them rupturing in the immediate near future is very small. If the PIP implants have been in for longer than 3 years, then if you want to play safe it is probably best to see if you can get them removed and replaced with alternative implants or to leave them out altogether and not have them replaced. It may be difficult deciding how best to do this because the organisation through which you had the implant may not yet have formulated a policy for dealing with you. It may complicate matters if you try to get legal advice about it.

If you have had the PIP implants for more than 4 years, it seems that you may be at a greater risk of spontaneous rupture than a person who has only recently had PIP implants and it therefore seems reasonable for you to seek removal and replacement with a different kind of implant. Where, when and how this is going to be funded remains an open question at the moment and there is no doubt that there is going to be

competition between different organisations and possibly between lawyers to capture this market of many thousands of women who are all extremely upset and anxious about it.

If you want face to face advice, then I shall be very happy to meet you at a private consultation which can be arranged through my secretary on 0116 265 3043. My charge for a consultation is £100 and consultations usually last between 20 and 25 minutes.

If you do want to come to see me, please obtain as much information about what implants you have, where they were put in and when and by whom and bring this information with you.

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