



# Shaping the Future of the Breast

An Augmentation Masterclass

Birmingham 25 March 2010

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Over 100 surgeons, with a range of experience, attended a Mentor Masterclass study day featuring 11 eminent UK and US speakers, covering many aspects of breast augmentation and reconstructive surgery. The interactive meeting was chaired by Mr Chris Khoo, former president of the British Association of Plastic, Reconstructive and Aesthetic Surgeons, and Mr David Ross, Consultant Plastic Surgeon and Head of Surgical Oncology at Guys, St Thomas' and Kings Health Partners.

Highlights of the meeting are reported here.

### Biofilm increasingly implicated in subclinical infections leading to capsular contracture

Capsular contracture remains one of the most frequently encountered complications of breast implants, and is a leading cause of reoperations. In prospective studies of patients who develop capsular contracture, the recurrence rate has been reported to be as high as 30 to 50 per cent. Researchers are continuing to investigate the multifactorial nature of this complication with a view to identifying causes, and how to prevent or treat them, toxicologist **Dr Roger Wixtrom (PhD), President of LSCI, Springfield, Virginia, USA, told the meeting in the keynote lecture.**

With previous generation implants, gel bleed (silicone diffusion) was believed to play a potentially significant role in the development of capsular contracture. The current generation implants are associated with a lower risk of capsular contracture thanks to their multi-layer, barrier-incorporating elastomeric shell and cohesive gel, reducing the diffusion of silicone molecules from the implant. New state-of-the-art measuring techniques demonstrate that the amount of material released from MemoryGel® breast implants is extremely minute ... less than is absorbed

from daily consumer products containing silicone. It is equal to approximately 1/1000th the weight of the head of a straight pin and more than a million fold below established safety limits, based on the results of studies presented to regulatory agencies. These levels are also more than a hundred-fold below absorbed daily exposures to the same materials from commonly used consumer products, such as antiperspirants, skin care lotions and hair care products.

Of the multitude of potentially contributing factors that have been proposed over the years, mounting evidence points to the key role of subclinical infection and bacterial biofilms. Biofilms, which are now recognized to be involved in the vast majority of human infections, involve microorganisms encased within a self-synthesized, hydrated polymeric matrix, typically attached to surfaces, and exhibiting a significantly enhanced resistance to antibiotics and the immune system. Such biofilms often go undetected by standard microbiology techniques, and more rigorous methods (e.g., sonication of samples prior to culturing) have been employed to accurately assess their presence in association with implanted medical devices, including breast implants. A better understanding of how these biofilms form

and function, based on the latest scientific findings, explains a range of clinical observations (including the increased risk of contracture associated with hematomas) and suggests specific measures to reduce the incidence of capsular contracture. Applying nipple shields during surgery, to minimise contamination from bacteria expressed from nipple ducts, may significantly reduce contracture incidence, along with the use of "no-touch" or "minimal-touch" techniques that minimize potential microbial seeding of the implant and/or pocket during surgical placement. A variety of innovative approaches are currently being explored across various fields of medicine to provide better methods to prevent and treat biofilms.

### Body Logic – a method for optimising outcomes in breast augmentation

Selecting the most suitable implant for a particular patient from the choice of more than 30 currently available is a challenge, remarked **Professor Bruce Cunningham, Director of the Division of Plastic and Reconstructive Surgery at University of Minnesota.** Too often there is a mismatch between surgeons' and patients' ideas of what is wanted. Six-year data from 4000

average cases show the re-operation rate is 30 per cent including almost 20 per cent for augmentation cases, often because of dissatisfaction from increasingly informed patients "Fourteen per cent are for size change. This is way too high. We should not have patients having to take more time off work and spending more to get this right. We need a new method for combining surgical judgment and patient input," he commented.

To this end the Body Logic system has been devised by Mentor to help surgeons focus on what's most important to patients, to better understand their anatomy and to involve patients in decision-making. Although there have been previous algorithms for implant selection these have been rigid, too mathematical and unpopular, he said.

Body Logic involves taking a complex array of measurements and eliciting the patient's desired outcome regarding shape and volume. Potential pitfalls of their choice can then be pointed out to them along with any asymmetries and postural anomalies. Getting the right implant width is key. "This is pretty immutable; the chest is only so wide and you have to accommodate the implant to that," he noted. Measuring the skin envelope is also crucial.

"The most important thing however is time spent with the patient," he told surgeons. They then see how concerned you are to get the right outcome for them. "Its an integrated process where the patient is invested in the decision." This makes it harder for them to complain later. Documenting each step and explanations given provides a useful record should medico-legal issues arise later. The Body Logic system doesn't replace

independent professional judgment and doesn't dictate specific implants to use. It just provides guidance on selecting an implant so as to improve the likelihood of patient satisfaction, he concluded.

### Imaging the altered breast

Breast implants can represent a challenge in imaging the breast, pointed out **Dr Roger Whitney, consultant radiologist and Director of Breast Screening at Chelmsford and Colchester Breast Screening Service.**

For conventional mammography, the implant is unhelpful as it obscures most of the breast tissue. Techniques such as the Eklund technique have therefore been developed to displace the augment backwards and pull the breast forwards to increase the amount of tissue that can be compressed in a breast mammogram. This is easier to do with a subpectoral than subglandular implant, he added. "Compression is a vital part of mammography so the degree to which this is limited by the implant and the degree of capsular contraction is as much an obstruction to the imaging process as the implant itself." Patients are concerned about damage to the prosthesis by the procedure but although rupture can occur, with well-trained mammographers the risks are extremely small, he remarked.

Imaging may be required to assess implant surgery and diagnose complications. MRI, if available, is the investigation of choice if problems arise, particularly in looking at silicone. "Implant failure is not easy to see on a mammogram. Ultrasound is a more practical alternative but the appearances can be difficult to interpret." In the case of silicone bleed the implant may

appear normal but silicone can be taken up by lymph nodes increasing their reflectivity. "Essentially the approach to investigating the altered breast is no different to other breast problems; image guided biopsies mean that a tissue diagnosis can be made in most cases without endangering the integrity of the implant."

### Cancer and the augmented breast

Early concerns of breast implants were whether or not they could cause cancer or alter its detection, staging and prognosis, **Mr Simon Smith, Consultant Oncoplastic Breast Surgeon at Broomfield Hospital, Chelmsford** recalled. Studies of over 3150 US women followed between 1953 and 1980 however show fewer than expected cancers in augmented breasts compared to controls.

Mammographic screening sensitivity is reduced from 67 to 46 per cent, he noted, but detection of symptomatic breast lumps is the same in women with or without breast implants. "In fact augmentation may make tumours easier to detect as the implant gives a good solid base when pressure is applied in palpating." Experience of breast cancer in augmented breasts include around 45,000 cases in the US each year but clinicians are divided on whether or not they present at a later stage. A lower incidence of DCIS has been reported and a greater chance of lymph node positivity. But overall tumour size, stage and survival are identical in women regardless of implants. Core biopsies are recommended and are not associated with an increase in implant rupture, he claimed.

With regard to surgical treatment of cancer in augmented breasts, breast conserving surgery is often hampered by the small

volume of native breast tissue. The efficacy of radiotherapy is not diminished by implants but its cosmetic detriments affect implants of all types, he noted. "Radiotherapy is the absolute bugbear for surgeons because of its associated high capsular contraction rate (affecting up to two thirds) but its use is inevitable," he stressed. In 10 years of follow up to 2005, the Oxford EBCTG Overview shows a 20 per cent difference in local recurrence between irradiated and non-irradiated breasts and this translates to a survival benefit.

Cosmetic outcomes are poor so consideration of implant removal and therapeutic mastoplasty is a possibility. This is not possible after radiotherapy. In a small survey of UK surgeons, 50 per cent report routinely removing the implant saying this facilitates further imaging and reduces risk of seed cancer cell contamination. "Currently there is no consensus on breast cancer management in augmented breasts. There is massive variability in practice across both the US and UK," he added.

### Anaesthetic considerations for breast augmentation

Although candidates for breast implant surgery are usually young and relatively fit, it is important to take a good medical history well ahead of administering an anaesthetic for an elective procedure, **Dr Stephen Oakey, Consultant Anaesthetist at St Andrews Centre for Plastic Surgery and Burns, Broomfield Hospital, Chelmsford,** reminded the audience.

A pre-operative questionnaire can hopefully flag up concerns, enabling the surgical

team to pre-empt problems and avoid last minute cancellations. A good history is used to determine the patient's ASA (American Society of Anaesthetists) grade and highlight patients at moderate or severe risk of cardiovascular (CV) complications. "There is a 10-fold difference in mortality between patients in class II (mild systemic disease) and class III (severe systemic disease)," he pointed out. Hypertension, diabetes, smoking and long surgical procedures all increase the risk of peri-operative complications. Operating on patients with CV risk factors leaves the surgeon and anaesthetist vulnerable to litigation should problems result such as a patient suffering a stroke. "We do come under a lot of pressure from patients who are considered borderline risks for complications. But we can't allow them to dictate to us what procedures they undergo. We have a responsibility to say no if we are concerned," he emphasised. It is no good just demonstrating that you have advised weight loss and stopping smoking if patients do not comply.

Some patients are likely to need reassurance about undergoing surgery and anaesthesia. "The best anxiolytic is a pre-op visit from the anaesthetist to explain what will happen before, during and after the operation," he suggested.

The choice of inhalation or total intravenous anaesthesia (TIVA) will be a matter of cost and anaesthetists' preference but TIVA offers advantages in ventilation, more rapid waking up and less shivering afterwards. Similarly choice of analgesia may be influenced by cost but can affect speed of full recovery post-op. If pain is not controlled initially, it is better to increase the dose of the original analgesic than to add in others, he noted.

When using local anaesthesia, it is easy to miscalculate the dose but surgeons should not rely on the anaesthetist to check as this would not constitute a defence in a medico legal action, he added.

### Choosing an implant: round vs contoured

The massive range of implants available today makes choice difficult, noted **Mr Stephen McCulley, Consultant Plastic Surgeon, Nottingham.** Choice is a matter of patient preference for profile and volume but also depends on the natural breast tissue available. The width of the breast, along with quality and thickness of skin are important influencing factors.

Choice of round or anatomical shaped implants will have the biggest impact when patients are very slender. Round implants will appear rounder because less covering is available. "Obviously, the greater the percentage of implant to breast volume the greater the impact will be on shape," he pointed out. Where patients have larger breasts to start with, choice makes less difference to final appearance. But anatomical implants generally produce a softer upper pole and give a good natural breast shape. If a patient opts for a fuller upper pole, round implants are a better choice. "Where ptosis is marked a high projecting anatomical will give more lift for a set volume, although a round implant can be more forgiving" he suggested.

With anatomical implants it is an important principle is to ensure the pockets are accurately measured. This helps avoid rotation. This complication tends to occur more with high projecting anatomical implants, he added.

### Adjustable implants can enhance projection and correct asymmetry

Breast asymmetry noticeable after implant surgery can be a big problem for patients, as can dissatisfaction that volume has proved too small. With this in mind two new implants, SPECTRA (gel-filled implant) and SPECTRUM (a saline-filled implant) have been produced both of which contain an expandable inner sac that allows the surgeon to pump in additional saline, explained **Mr Venkat Ramakrishnan, Service Director for Specialist Surgery at Broomfield Hospital, Chelmsford.** This facility allows the surgeon to correct any asymmetry and increase volume where patients decide they have been too cautious in their initial choice of implant size and would like additional volume.

“Just about all patients will have some breast asymmetry in their pre-operative state,” he pointed out. Any pre-existing thoracic anomalies have to be brought to the patient’s attention pre-operatively and careful measurements taken and documented. Post operatively patients notice any discrepancy more acutely. “This is where a device like SPECTRA can be very handy,” he commented. A small chamber within the implant attached to a very small tube, less than 1.5mm in diameter, allows the surgeon the opportunity to adjust for asymmetry by pumping in up to 50cc of saline. “The implant retains the consistency of gel,” he added.

After the patient is satisfied with the symmetry and size viewed from the recumbent and sitting position, you slide the tube out after the breast is sealed, he said. Of his 13 patients given 23 SPECTRA implants over the past two years, 19 implants were adjusted within 24 to 48 hours and 3 within 72 hours.

“I am very aware there is a tube coming out of the implant and therefore potential for infection but to date none of my patients has developed an infection or required acute reoperations,” he commented. Avoiding infection generally requires attention to surgical technique, he pointed out. “It is not just a matter of throwing in antibiotics, you also have to do the procedure as quickly and as bloodlessly as possible.”

### Meet patients’ expectations to avoid litigation

Cosmetic surgery procedures, especially those concerning breast augmentation are the focus of many legal actions. A disturbing new development is that patients who sue their surgeons may now need only to show that their expectations have not been met, and they are consequently distressed, to win damages, warned **Mr Chris Khoo, a Plastic Surgeon in independent practice.** Proving negligence is not required for cosmetic surgery patients and the fact that a surgeon has acted reasonably is not a guaranteed defence. However skilfully a procedure has been performed, patients must be warned about all risks and informed about the realistic outcome that will be achieved. Surgeons who neglect to do this, do so at their peril, he suggested.

In cosmetic surgery, patients’ expectations are high and must therefore be managed, he advised. TV programmes and celebrity magazines showing before and after images continually fuel unrealistic expectations. Increasingly, practitioners are being urged to spell out to patients what is likely to be achieved and to document all advice, warnings and information they provide. “Claims can only be defended if they are documented,” he pointed out. “It’s difficult to say no to patients but sometimes that is

the best option, especially when there are contra-indications.” If surgery is performed, full consent must be obtained given that patients are undergoing non-essential, non-therapeutic procedures. Early warning signs of complications must be spelled out, he added.

A cosmetic surgeon needs a good grasp of psychology and to be prepared to spend time giving patients information, support and sympathy even when they are seeking redress for a procedure carried out by a surgeon elsewhere, he suggested. Doing so may prevent them taking legal action. “This is not just for your benefit but also for colleagues; one day they may do the same for you.”

The advent of no-win, no fee litigation means more actions are likely, he suggested. Although patients are told most cases are won by doctors, and huge settlements are rare, this will not deter them.

### ASAM - an adjustable single stage augmentation mastopexy technique with a low complication rate

Patients with ptotic breasts, especially after massive weight loss, present a difficult problem to achieve a pleasing aesthetic result. Usually surgery to remove excess skin, lift the nipple and restore fullness to the breast with an implant is performed in two stages, pointed out **Mr Jeyaram Srinivasan, Consultant Plastic Surgeon at Preston, Lancashire.** He described his experience with 18 patients treated over a 30-month period with an adjustable single stage augmentation mastopexy (ASAM). This works well for patients with moderate ptosis and carries fewer complications, he believes.

The operation involves using LeJour type skin markings with one single vertical incision in skin that will later be excised and creation of a submammary pocket at right angles to the skin incision. This limits skin undermining and avoids two incisions lying on top of each other. An inflatable sizer is inserted to choose the right volume and shape for the breast width and height of the patient. Skin markings are then checked with the sizer inflated to the right size and adjustments made. Skin adjustment is decided on with the patient partly sat up merely by skin-pinching. De-epithelialisation is then performed, the sizer removed, and the nipple area complex elevated. The implant can then be inserted and skin closure performed in three layers.

“I find this technique is easier and can give a reasonable shape and volume to people who have experienced massive weight loss and have continual skin laxity with ptotic breasts” he remarked. “Skin laxity is the main enemy causing residual ptosis that allows the implant to droop. It may require you to go back later for further skin tightening.”

To date the complications experienced in his series have been two minor wound breakdowns, possibly due to pyoderma, one peri-implant infection, and three cases requiring skin revision surgery.

### Fat grafting has potential to revolutionise breast surgery

The developing technique of fat grafting to fill the breast and soften radiotherapy scars could be a major breakthrough in breast augmentation and reconstruction, Mr David Martin, Consultant Plastic and Reconstructive Surgeon at Chelsea and Westminster NHS Trust, London, told the

meeting. “Fat is a fantastic tool that I’ve been using since 2002,” he disclosed. There are many possible applications for the technology, which is as yet in its infancy but already revolutionising treatment of irradiated breast implants. “We are breaking new ground and learning amazing new things.” But surgeons should be cautious before rushing to use it, he warned. They should learn the technique rather than experiment. “Fat grafting is technique dependent and if not done right will not give good results. You have to learn to do it properly.” Putting in a large composite graft will be doomed to fail. “The key is to put it in using small packets of fat of 1-2mm diameter”

Like any other reconstructive procedure it is done in a window in time so results will change as patients gain or lose weight or become pregnant, he advised. Patients need to understand this and that their operation will probably need revision at some point in the future. “You have to be honest and tell patients they are on the cusp of a new wave of development and you don’t know how successful it will be over time.” Patients need to be forewarned that lumps may form which will be relatively easy to diagnose. You have to see them before their surgery more than once, he added, because if anything goes wrong the novelty of the procedure could create difficulties if patients resort to litigation.

In fact, far from going wrong, fat grafting is defying expectation. A great discovery is the ability of fat grafts to modify scar tissue. “This is the wonder of fat,” he said describing the restoration of an irradiated breast implant resembling “a lump of cheddar cheese” to the soft pliancy of normal texture. Two years on there is no sign of capsule formation around the implant. “We now have a tool that can do

that and that is fascinating. We may be looking at a whole new way of doing things.”

To date the long term safety of the procedure and its impact on cancer recurrence is unknown. Caution is therefore urged in using lipofilling to correct asymmetry in a young breast pending publication of long term studies in the near future. Professional bodies are currently formulating guidelines. Until then surgeons should proceed with caution because they are stepping out of their safety zone, he advised. “But if we don’t use it we are never going to advance something very special; that’s our dilemma.”

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