

Special Article - Breast Implant

A Changing Philosophy on Breast Implant Selection

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Editorial

Since 1964 Silicone implants have provided wellbeing to the considerable majority of Women who had clinical or cosmetic need but have also caused significant morbidity and scientific concern. In the early 1980's Dow Corning was the King of Breast Implant Manufacturers. The 'lure of the loot' created an excitable media reaction and attracted US Plastic Surgeons and other Corporations to invest in the manufacture, global distribution and insertion of thousands of largely untested Silicone shell implants, initially containing both low and high molecular weight polymers of silicone dioxide. Essential chemicals used in the manufacturing process were also known carcinogens and there is little wonder that Silicone was incriminated in causing illness, including autoimmune disease and 'Silicone Associated Disease'. There has never been a scientific paper that describes an increase in breast cancer, contrary to concerns at the time [1].

From 1988 the implant manufacturers were asked by the FDA to provide data on the safety of their implants and because no information was forthcoming there was a moratorium to the use of these products in the USA and Canada that lasted until Core Studies were published by the FDA. These studies were carried out by the two remaining US manufacturers, McGhan and Mentor, in 2005 [2]. The rest of the world remained a market for McGhan and Mentor, including the UK and it was not until 2012 that approval was given for the use of anatomical implants by McGhan in the USA, although they had been used extensively throughout the UK from about 1994. In the 1990's Surgeons were also brainwashed into using radioleucant implants containing soya oil (Trileucant) and Hydrogels (Misti Gold) but this was a huge mistake and all were supposedly replaced at no cost to the patient because of poor outcomes and morbidity. In the UK McGhans anatomically shaped implants were marketed as being natural in shape and 'what women wanted', which actually was far from the truth. The concept of texturing was considered the reason for lower capsular contracture rate after studies on Polyurethane Implants showed significant benefit compared to smooth implants [3]. The duopoly of McGhan and Mentor (now of course Allergan/McGhan and Ethicon respectively) and their 'consultants' managed to obfuscate their own manufacturing problems by highlighting the fact that the degradation of polyurethane from rival companies polyurethane implants caused the release of 2,4 Toluene Diamine (2,4TDA) [4]. This was always brought up at meetings and so hiding the fact that their own silicone itself was being investigated as a possible carcinogen. Polyurethane degradation products are proven carcinogens though, producing a sarcomatous reaction in

genetically susceptible rodents, but 2,4 TDA has never been shown to be carcinogenic in women, in fact there is a 17 fold reduction in all complications compared to Silicone Gel implants including cancer. It should be noted that the first anatomically shaped implants were developed by Ashley with his Polyurethane covered implants, in 1970 [5]. Polytech Silimed started to compete on the global market, except in the USA and Canada, from 1989 with upgraded models of round, shaped and conical polyurethane covered implants, all with excellent long term data showing capsular contracture rates less than 1% at 15 years and a very low reoperation rate [6,7]. Unfortunately Silimed became embroiled in a surface particles scare in 2016 causing loss of CE marking and inability to use these implants within the UK.

As is now obvious from recent data from the USA, but was obvious to UK Surgeons 10 years earlier, the coarse texturing created using salt extraction technology in McGhan implants leads to problems with partial adherence, double capsule, rotation, displacement and sliding ptosis, but more worrying a higher risk of developing Anaplastic Large Cell Lymphoma (BIA-ALCL) [8]. The fine texturing on Mentor implants is a negative imprint created by removing a layer of polyurethane from the outside of the elastomer during the manufacturing process. These implants, unlike polyurethane [9], never biointegrate and this is the clue to where we should be moving on implant selection and placement. Although Mentor implants are good they are slightly and irritatingly underfilled, meaning that they have to go under the muscle to avoid rippling in smaller breasted women [10]. Smooth implants will also never adhere to the surrounding tissues therefore Surgeons have to insert implants into a larger, strategically placed pocket

Data comparing smooth and textured implants is inconclusive mainly because of poor study designs and the fact that manufacturers have never supported comparative clinical outcome studies even of their textured implants. In fact they never wanted to discuss their implants on a shared podium with their main competitors choosing instead to financially support large meetings of often financially supported Plastic Surgeons. Even the FDA extended clinical studies did not compare like for like implants or standardize patients and there was poor follow up and adherence to protocol [2]. This data is all that we have though. Whatever we must stop comparing textured McGhan or Mentor implants with the first generation of Dow Corning thin shell less viscous gel filled implants that we used up until the late 1980's [11].

Today's smooth implants are covered with stronger elastomer and contain firmer cohesive gels. Although most implants according to FDA data appear to be Surgically placed behind the Pectoralis Major Muscle, at least in part, if capsular contracture rates can be reduced by reducing risk of biofilm and haematoma by a combination of careful Surgery and better implants we should always consider going in front of the Pectoralis Major muscle except in women with extremely small breasts or certain anatomical variances. The reasons are because it is the anatomically correct position to prevent sliding ptosis,

abnormal and often painful lateral displacement of implants during muscle contraction, but most importantly in ensuring complete capsulectomy in the rare event of BIA-ALCL. In this event why do we even consider using fine textured implants surely Surgeons should all follow the Australians advice and go back to using modern, smooth elastomer shelled implants.

I now use Sebbin Smooth implants on the advice of UKAAPS Surgeons and have no regrets so far after 3 years and ever since being denied access to my favoured conical Silimed implants, by EU regulation.

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