Breast augmentation: Part I — a review of the silicone prosthesis

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Summary
The present importance of breast augmentation (BA) is shown by year-on-year increases: with 8439 augmentations performed by BAAPS members in 20071 the UK still lags America where 307,000 were performed.2 Having survived an almost hysterical media reaction to perceived silicone health risks in the 1990s, a growing body of evidence attests to the demonstrable benefits of BA.3–6 Improved implant design coupled with surgical advances mean that high quality results with few complications can now be expected in the majority and a précis of progress is perhaps timely. This article forms part of a series that has been written to provide a ‘state-of-the-art’ review of contemporaneous BA practice.

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History of breast augmentation

Although today synonymous with silicone-shelled prostheses, either silicone- or saline-filled, BA has seen the trial of numerous other materials. The list includes lipoma auto-transplantation,7 paraffin injections and such esoterica as ivory and glass balls, ground rubber, ox cartilage, gutta percha, polyethylene chips, polyurethane foam sponge (Ivalon),8 silastic rubber and liquid silicone. Autologous tissues in the form of local thoracic flaps and distant gluteal adipodermal grafts9 were tried in the 1950s, but suboptimal results and donor scars prevented their widespread adoption. Interestingly, similar grafts have recently been revived for aesthetic contouring during cancer surgery.10 The modern era of silicone prostheses commenced with Frank Gerow’s implantation of the patient Timmie Jean Lindsey in 1962.

Despite its ubiquity and generally inert nature, silicone-based implants generated intense debate, and litigation, particularly in America. With large-scale studies repeatedly confirming the lack of association with connective tissue disease and cancer,11–16 the pendulum has swung back in silicone’s favour. Its history is, however, an interesting one: Spear’s ‘inside view’ makes a fascinating read of ‘junk science, venality and incompetence’.17 Tebbetts holds the trenchant view that the ‘silicone debate’ constituted ‘one of the greatest hoaxes ever perpetrated on American...
women by the FDA and plaintiff lawyers. However, much-needed scientific research was stimulated so we now have solid evidence on which to base and guide informed consent.

The silicone breast implant

Silicone biochemistry

Silicon is a naturally abundant element existing as obligatory oxides, of which silica (SiO₂) has numerous applications in building products, glasses and as a dessicant. Humans contain 5–10 g of silicon, chiefly environmentally-acquired from silicic acid in potable water and airborne silicate dust, and studies show an important role in nail, bone and hair growth. Silicone is, however, a synthetic polymer, the most common linear form being polydimethylsiloxane (PDMS; (CH₃)₂SiO). Silicones are ubiquitous in modern life and medicine being found in non-stick cooking utensils, feeding tubes, intravenous cannulae, cardiac valves, neurological shunts and joint prostheses.

Although silicon was first isolated in 1824, the process was prohibitively expensive and it was not until 1945 that Rochow pioneered commercial silicones. Their beneficial properties, including stability at a wide temperature range, flexibility with ‘memory’, water repellence (despite not being lipophilic), low toxicity and chemical reactivity, were soon apparent. There are six classes of silicone: fluid, emulsion, compound, lubricant, resin and elastomer; the latter so welcomed fifth generation implants characterised by increasing gel cohesivity. Whilst all gels are to some degree cohesive in the descriptive sense of the term, cohesive implants are understood to be those that are ‘form stable’. These are closer to a solid than a liquid and are formed by increasing the ratio of cross-linking so that the form is retained even without an elastomer. Not only is shape maintained longer (by resisting gravitational effects), but implant longevity should be enhanced. Explantation is also much facilitated because such gels do not disperse, even in cases of complete elastomer disruption (Figure 2), so avoiding the unpleasantly sticky removals of the older, viscous-filler prostheses. Asymmetric implants, tailored for each side, are the latest development. Disadvantages of cohesive devices include their comparatively high cost and the form-stability itself, which mandates inframammary access, larger incisions and accurate selection. Implant rupture may be harder to diagnose, but the long-term

Implant evolution

Although criticised for imprecision and overlap, the ‘generational’ system serves as a useful guide to implant evolution (Figure 1). The historic first silicone implants from 1962 were apparently still in situ after 43 years. These ‘teardrop’-shaped first generation implants had a thick shell, viscous filler and a posterior Dacron patch for adherence. They felt rather firm so second generation implants with both thinner shells and filler appeared in 1972. Although more natural to the touch, they are the least durable, most prone to gel bleed, rupture and adverse capsular contracture (ACC) and predominated in the 1990s’ class action lawsuits. This era also introduced polyurethane-coating to reduce ACC and double-lumen implants. Whilst gel bleed did reduce with the latter, complex construction increased failure rates, however, they found a role in expander-based reconstruction.

Third generation implants had an additional fluorosiloxane barrier layer to combat bleed and rupture, for example, Mentor produced a quadruple-layered shell thicker anteriorly by 60% and posteriorly by 20%. Gel cohesivity increased, but these implants were firmer to the touch and required adequate soft tissue cover to minimise visibility and palpability. Following the FDA’s moratorium, saline was the only filler, outwith a trial, permitted in America despite being widely accepted to have both a less natural feel and longevity: with saline not filling the shell fully, ‘fold flaws’ combined with the higher abrasiveness of saline, predisposed to failure. Fourth generation implants had textured elastomers, based on the low rates of ACC seen with polyurethane-coating. Return to an anatomical configuration was also seen during this era, championed in breast reconstruction by Maxwell. The early 1990s welcomed fifth generation implants characterised by increasing gel cohesivity. Whilst all gels are to some degree cohesive in the descriptive sense of the term, cohesive implants are understood to be those that are ‘form stable’. These are closer to a solid than a liquid and are formed by increasing the ratio of cross-linking so that the form is retained even without an elastomer. Not only is shape maintained longer (by resisting gravitational effects), but implant longevity should be enhanced. Explantation is also much facilitated because such gels do not disperse, even in cases of complete elastomer disruption (Figure 2), so avoiding the unpleasantly sticky removals of the older, viscous-filler prostheses. Asymmetric implants, tailored for each side, are the latest development. Disadvantages of cohesive devices include their comparatively high cost and the form-stability itself, which mandates inframammary access, larger incisions and accurate selection. Implant rupture may be harder to diagnose, but the long-term
consequences are as yet unknown. Being so recent, long-term follow up data is not available, but early results for both patient satisfaction and ACC are encouraging, particularly by those who have applied analytical surgical methodology.6,32

Polyurethane-coating

Although withdrawn in 1991, polyurethane implants are staging a comeback and, in fact, predated silicone implants appearing as they did in the 1950s. Concerns about disintegration of the external polyurethane coating had been mounting, but the final nail in the coffin were animal studies linking its breakdown product, 2-toluene diamine (TDA), to carcinogenesis.23 It is now accepted, however, that any human risk is negligible given that cancer-prone animals were subjected to supra-physiological TDA concentrations.35 There are now many tens of thousands of patients with polyurethane-coated prostheses in situ for over a decade without any concerns. Polyurethane itself is probably relatively stable as shown by a recent report of a solid polyurethane sponge augmentation that ran into difficulties unilaterally, only after 41 years.8 Early studies showed impressively low ACC explained by polyurethane eliciting a vigorous, vascular foreign body reaction that, by persisting, prevented fibroblasts from laying down collagen in a continuous, plane thereby neutralising the circular vector forces that produced ACC. The lack of durability of the external coat led to a delayed peak of ACC, for example 10% at 4 years, but 25% by 10 years, as the prevalence returned to that of contemporaneous implants.37 There were also reports of difficulties with explantation resulting from extensive host ingrowth.38 The associated, generally transient, skin rash may have been an allergic reaction to the adhesive used for affixing the polyurethane coat. At present, improved polyurethane-coated prostheses are being marketed for revisional surgery in ACC, based on a recent prospective study showing that

<table>
<thead>
<tr>
<th>Year</th>
<th>Generation</th>
<th>Cronin &amp; Gerow (1962)</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>1960</td>
<td>1st generation</td>
<td>thick (mean 0.25mm), smooth shell</td>
<td>very high ACC rate</td>
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<tr>
<td></td>
<td></td>
<td>thick, viscous silicone gel</td>
<td>firm to touch</td>
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<td></td>
<td></td>
<td>‘teardrop’ shape and Dacron patch</td>
<td>high rate of gel bleed</td>
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<tr>
<td>1970</td>
<td>2nd generation</td>
<td>thin (mean 0.13mm), smooth shell</td>
<td>highest rupture rate</td>
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<td></td>
<td></td>
<td>less viscous gel</td>
<td>very high ACC rate</td>
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<td></td>
<td></td>
<td>more natural feel,</td>
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<tr>
<td>1980</td>
<td>3rd generation</td>
<td>barrier layer</td>
<td>improved longevity</td>
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<td></td>
<td></td>
<td>thicker, more cohesive gel</td>
<td>reduced bleed</td>
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<td>reduced rupture</td>
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<td>1990</td>
<td>4th generation</td>
<td>surface texturisation</td>
<td>reduced ACC</td>
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<tr>
<td>1995</td>
<td>5th generation</td>
<td>‘form-stable’</td>
<td>IMF access</td>
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<tr>
<td></td>
<td></td>
<td>asymmetric</td>
<td>very low rupture and ACC rates</td>
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Figure 2 Five generations of silicone gel mammary prostheses (after Independent Review Group). ACC — adverse capsular contracture; IMF — infra-mammary fold.
dramatically lower ACC rates persist beyond 10 years of implantation.39

Silicone alternatives

There have been several alternative fillers in the 1990s when silicone-phobia peaked: unfortunately, these products were rushed to the market after cursory pre-clinical trials. Three were based on hydrogels, another on soya bean oil. Hydrogels are polymeric macromolecules that retain water without dissolution. Hydroxypropylcellulose, formed the basis of the Polyimplant Prosthesis34 (PIP; Clover Leaf Products, UK) and was implanted into 4000 UK women. The Misti Gold prosthesis (Bioplasty Inc., Mn., USA), based on synthetic low molecular weight polyvinylpyrrolidone, was trialled in 1990–1, but combined disappointing results with high cost.40 Novagold™ comprised the synthetic polymer polyvinylpyrrolidone (povidone) and guar gum. Povidone has seen service for plasma expansion, biomedical coating and the iodine carrier in Betadine. Guar gum, from Cyamopsis tetragonoloba, is a foodstuff stabiliser-thickener and was added to povidone for the same reason. A recent review of patients with Novagold™ prostheses confirmed a high rupture rate (double that of saline) due to oncotic swelling.41 Although non-toxic, these fillers induce a vigorous subcutaneous inflammatory reaction and explantation is recommended when symptomatic.

Simultaneously, triglycerides were being promoted for improved radiolucency and biocompatibility,42 although a 5.5% bleed rate within 6 months was explained away by the measuring process.28 The Trulcent (LipoMatrix, Neuchâtel, Switzerland) implant, named from triglyceride and radiolucent, was implanted in almost 5000 women in the UK between 1995 and 1999. It contained refined USP medical grade soyabean oil within a silicone elastomer, which had a metallic data transponder that was soon found to some-what limit magnetic resonance imaging (MRI). Kirkpatrick et al’s study of soyabean oil, particularly its peroxidation to genotoxic degradation products observed that, limited, pre-market trials were undertaken in America, yet the device was never used there.43 They were voluntarily withdrawn in March 1999 after adverse reports44 and the Medical Devices Agency made a formal recommendation for removal in June 2000. Explantation studies showed variable satisfaction and problems including shell fragility, lipid absorption, firm adherence to thick vascular capsules, delamination and a bleed rate of 34%.44,45

Until recently the sole option in the US, the first saline-filled implant was developed by the Frenchman Arion, however, it is worth noting that these too are silicone-shellled. Although one might expect easier mammography, in fact, their radiolucency is, due to a high atomic number, little different to silicone. Furthermore, they suffer from more visible and palpable rippling so are not ideal for thin patients.4 Finally, their consistency is said by some to be firmer than modern gels, they have the potential for ‘fold flaw’ disruption and complete deflation, although saline is, of course, entirely safe and will simply be absorbed.

To avoid silicone altogether biological substances such as hyaluronic acid (HA), a major constituent of extracellular matrices, have been trialled. Although more radiolucent, and softer than silicone,46 HA is naturally degraded thus is non-permanent and rather expensive.47 An improved volume restoration-factor of the HA Macrolan™ (Q-Med AB) has shown promise for so-called ‘minimally invasive’ BA.48 but the costs of the initial, and necessary supplementary injections, are similar to that for silicone augmentation, which is permanent.

Contemporaneously, fat transfer is increasingly popular and Coleman recently reported impressive results in primary BA grafting a remarkable mean of 277 cc fat per breast.49 That fat transfer is de rigueur is evidenced by the Canniesburn group’s BAPRAS presentation50 and an accredited reconstructive and aesthetic seminar.51 That autografted fat improves overlying skin and soft tissue quality49 and, via adipose-derived stem cells, heals radio-necrotic ulceration52 suggests a potentially useful future role especially in revision surgery. Non-surgical alternatives have also been explored. Suction devices first used in the 1920s were revived recently as the BRAVA system, which functions through tension-induced neo-tissue generation; similar to tissue expansion and distraction osteogenesis.53 Despite some enthusiasm, results have not been replicated chiefly for functional difficulties and compliance: most finding the recommended 10 h daily for 10 weeks onerous given the modest and transient results.54 There is also the potential for aggravating ptosis. Unsurprisingly, the internet and non-medical literature abound with herbal and homeopathic remedies, but none have as yet been subjected to any degree of scientific validation.55

Implant regulations

As an implantable medical device, breast prostheses are subject to a number of regulations including the 1993 European Medical Devices Directive56 and 2002’s national UK law.57 They require notification of certain adverse incidents, under the ‘vigilance system’, to both protect the patient and reduce similar incidents occurring elsewhere. Importantly, procedures must exist to both systematically audit post-production experience and implement corrective action such as a product recall. Notifiable incidents include device deterioration or failure and poor instructions resulting in improper use. Interestingly, delayed ACC is specified, presumably to avoid a repeat of the polyurethane issue.

There are four classes of medical devices according to risk: low (Class I), moderate (Classes IIa/b) and high (Class III). In 2003 breast implants were reclassified level III in order to bring all European implants in line with the UK.58 CE (Conformité Européene) marking is a manufacturer’s declaration that the product complies with the health, safety and environmental requirements of the relevant Product Directive. It is a mark of quality assurance and allows free trade throughout Europe, though is not required for export.

The UK Breast Implant Registry, or in its earlier guise the National Breast Implant Registry, was established in 1993. Unfortunately, it was disbanded in March 2006 following independent audit that found it unable to produce scientifically apposite results due to poor participation. Registration was perhaps hampered by the voluntary nature and requirement for patient consent.
Silicone safety aspects

Teratogenicity

Despite reports of rashes and oesophageal dysmotility in children of silicone-augmented mothers, the IRG found no evidence that exposure was greater from maternal than environmental silicone. Although capsule and breast levels are elevated, cadaveric silicon levels remote from the breast in augmented women are equivalent to non-augmentees indicating ubiquitous environmental exposure. A detailed study established that silicon (used as a proxy for silicone, which is not directly assayable) was found in equivalent levels in the milk of breastfeeding women with and without silicone implants. Furthermore, much higher levels of silicon were found in cow’s milk and infant formulae, in excess of 10- and 90-fold respectively.

Breast cancer

The role of silicone implants in breast cancer has been subject to much debate and many of the keynote publications are common to connective tissue diseases (CTDs), but cancer brings the further issue of screening and surveillance. Both silicone and saline, with similar radiodensities, may interfere with the sensitivity of imaging, so specialised views are required. Eklund added a lateral view and displacement techniques to move the implant posteriorly. Logically, submuscular implants allow for better visualisation and ACC less. For both stage at diagnosis and subsequent prognosis there is no evidence of a difference and, indeed, some have shown smaller tumours on presentation in augmentees with similar axillary node involvement. That tumours are more often diagnosed following palpation yet are no larger, more advanced or with poorer prognosis suggests that augmentation renders tumours more obvious or that augmentees are more breast-aware. Interestingly, evidence exists for a trend towards a lower rate of breast cancer in women with implants. Whilst the reason for a lower prevalence is unknown implants themselves may possess an antitumour effect, either as a barrier to spread or via pressure-mediated tumour blood flow inhibition, or through a collateral effect of the foreign body reaction. It may simply reflect the smaller breast parenchyma a priori. A recent review reiterated that augmentees: i) are more likely to present with palpable tumours, ii) have a similar incidence of nodal metastasis and iii) have no worse a prognosis. As to cancer management, sentinel node biopsy is usually possible, unless implantation was transaxillary and, although more challenging, acceptable results are possible with therapeutic mammoplasty techniques.

Whilst recent long-term studies confirm the lower incidence of breast cancer there is some evidence of increased bronchopulmonary and vulvar carcinoma, at present attributed to lifestyle factors. It is becoming clear that BA patients form a population subset, which is thinner, younger at first pregnancy and multiparous. Smoking seems to be a risk factor in European, but not American patients. There may also be an increased risk of suicide, drug and alcohol dependence.

Autoimmune and connective tissue disease

The first documented association with several autoimmune conditions including systemic lupus erythematosus, scleroderma, dermatomyositis, Sjogren’s syndrome and rheumatoid arthritis appeared in 1964 following silicone injection mammoplasty. In Stern vs. Dow Corning, the jury adjudged autoimmune disease to result from silicone prostheses based on limited medical evidence and in 1991, a $5.4 m award followed the demonstration of immunee system silicone in Toole vs. Baxter. In 1992, the FDA imposed a voluntary moratorium, which became a de facto ban, of silicone-filled prostheses for anything other than reconstruction: the implant shells, of course, remained silicone. 1994 saw the first large-scale report, which found no increase in 12 common CTDs. The American College of Rheumatology’s 1995 statement concluded the evidence to be ‘compelling’ that silicone implants exposed patients to no demonstrable risk for CTDs. The Harvard Nurses’ Study of 14-year follow up showed a relative risk of 0.6 for any and 0.3 for silicone gel implants: importantly this data was collected prior to widespread media coverage. By 1999, the Institute of Medicine-National Academy of Sciences confirmed the absence of causal association with immunological or systemic diseases. Whilst the FDA acknowledged these conclusions, they imposed stringent conditions that device failure was to be tested and rates known prior to restoring vending privileges. The UK view was more measured and the 1998 Independent Review Group publication remains a thorough and concise resume and one which all patients should be encouraged to read. The IRG last met in April 2004 and was satisfied that silicone breast implants posed no greater health risk than other implants. A Swedish study, with nationwide registration and relative American media isolation, found a relative risk of 0.8% for augmentees. The most comprehensive meta-analysis to date confirmed lower relative risks for silicone-filled implants and a recent review reiterated the lack of association over a 24 year period. The FDA finally approved silicone gel-filled breast prostheses for augmentation in December 2006.

Implant rupture

The excellent summary of complications by Iwuagwu remains apposite in its breadth, even if the frequencies have diminished of late. Recent Scandinavian population reviews have showed that most early complications, are clinically insignificant and super-specialists indicate a 0% reoperation rate at 3 years. The chief concerns necessitating additional surgery remain ACC and rupture; the former will be addressed in a future article. Despite significant advances, implants are mechanical devices so do not have an indefinite life in vivo and elasrometer integrity declines with time, possibly as a consequence of lipid infiltration. The difficulty in counselling lies with risk quantification as the longest follow up data relates to the oldest, and therefore least durable, implants. Failure is undoubtedly multi-factorial, but causes include per-implantation damage, thoracic trauma, mammography and closed capsulotomy.
subpectoral placement may also contribute, but the majority appear idiopathic. Implant rupture may be intra-
capsular, where external appearance is dictated by the capsule, or extra-capsular where silicone breaches. Saline-
filled implants, of course, herald their failure with deflation.

With clinical detection by experienced Plastic Surgeons less than 30% accurate, the 91% specificity of MRI makes it the investigation of choice for suspected rupture. Whilst the FDA recommend MRI 3 years post-implantation and biennially thereafter, outwith the US it is reserved for suspected rupture. Features include a ‘doughy’ consistency, calcification, granulomata and pain. With 3rd/4th generation implants the rupture risk is estimated at 8–15% for the first decade: put another way there is a 95% probability of an implant being intact at 5 and 83–85% at 10 years. The most recent cohesive anatomical devices are showing encouraging initial rates of 0% at 3 and ≤1% at 6 years.

Rupture ranges from focal (pin-hole), through a visible tear to major shell disruption and is probably progressive. The three characteristic MRI features are: ‘subcapsular line’ — an interface between shell and capsule caused by a small quantity of leaked gel. Further extravasation produces the ‘inverted teardrop’ as silicone is trapped within elastomeric folds. Major disruption, where the shell collapses onto itself is seen as the ‘linguine’ sign. Although intra-capsular can progress to extra-capsular rupture, complications tend to be limited loco-regionally. At present there is no consensus as to the long-term consequences of interstitial silicone.

Although useful, imaging is imperfect and several explantation studies have been published. Robinson et al, found 71.3% of 300 explantees had time-dependant disruption of one or both implants: 75% had, however, undergone closed capsulotomy and elective removal was recommended. Another retrospective series, of 478, found rupture not to be temporally-dependent. A prospective series of 38 explantations for health concerns rather than suspected rupture concluded that those with silicone implants noted more bodily pain, however, were happier with their appearance and 50% were re-augmented within 2 years. For advice to patients, Holmich’s study of sequential MRIs concluded that rupture was harmless in the majority. Whilst there was a 1-in-10 risk of progression, either intra- to extra-capsular or extra-capsular extension, the majority could be followed expectantly.

Summary

Breast augmentation remains an increasingly popular option today where the idealised female physique has morphed from the curvaceous Botticellian to one increasingly thin and androgynous, but with prominent breasts. From humble, and perhaps somewhat disorganised, beginnings the silicone gel prosthesis has now been accorded an, almost, clean bill of health. Whilst the dark years of the 1990s make for interesting reading, they at least catalysed a body of scientific evidence for surgeons and patients alike. It also demonstrates the requirement for science to be sufficiently robust to withstand highjack and subversion from a sensationalist, and not always patient-centred media, and for all parties to show patience with pioneers of novel techniques. The knee-jerk, anti-silicone foray into hydrogel and soya bean fillers was readily accepted due to the pervasive ‘junk science’ furor, but may now be regarded as ill-considered. Certain legal teams enriched themselves massively at the expense of ill-prepared organisations, such as Dow Corning, and one can only wonder at the outcome of a challenge against such a plaintiff counsel from a patient forced into accepting a Trilucent implant. BA is a safe, well-accepted technique, which can be undertaken with ever-less frequent complications thanks to continued advances in both technique and implant design.

Conflict of interest

Neither author has a conflict of interest or funding to disclose.

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