Silicone safety revisited

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Editor's Note

In the New Year, silicone breast implant surgery is challenged by new safety issues. A registered and authorized medical device – breast implants produced by the French company “Poly Implant Prothèses” (PIP) – obviously not only contained non-medical grade silicone (industrial) but also traces of toxic substances. The world market has been flooded by these cheap, inferior and defective implants. Plus, the present scandal might only be the “tip of the iceberg” – it is yet unknown which licensed implants can be traced back to the PIP factory in La Seyne-sur-Mer. In June 2010, the authorities informed that some “Rofil” implants were identical with PIP. The same was detected for a series of “TiBreeze” products in January 2012.

The dimensions are enormous: Around 30,000 French women have been advised to have PIP breast implants removed following fears over possible health risks. Medical experts and authorities have, however, continued to stress that there is no confirmed link to cancer. More than 40,000 women in the UK are thought to have received PIP implants, which have been linked to eight cases of cancer in France. Several thousand women may be affected in Germany.

As of today we know this manufacturer of breast implants – which are among the most implanted medical devices worldwide – has obviously violated all rules of proper production as well as European legislation, and has betrayed patients, plastic surgeons, and authorities. The safety issue of breast implants has kept authorities busy for many years now. As early as in 1992 safety concerns over silicone breast implants caused the Food and Drug Administration (FDA) in the United States to pull silicone implants off the market. In November 2006 the FDA re-approved them with a number of conditions: First, manufacturers were obliged to conduct large, long-term safety studies – second, patients were advised to have Magnetic Resonance Imaging (MRI) performed every two years starting three years after the implantation. Meanwhile, recognized implant manufacturers started ten year follow-up studies and released intermediate data on the performance of implants in the ongoing studies.

According to the FDA, these conditions were necessary to fill in scientific gaps in the understanding of implant safety and durability. Plastic surgeons in the US have kept complaining about an overregulation. Being a European plastic surgeon and talking with colleagues in the US I could appreciate their longing for the freedom within Europe concerning silicone breast implant availability. Also US patients frequently went to countries outside the US to receive silicone implants. But was the FDA so wrong then and overreacting by even preventing their patients from the access to silicone breast implants outside of reconstructive indications? Maybe the reluctance and concerns are justified. Meanwhile, new breast implant problems have occurred years after the FDA had banned them. Physicians and manufacturers experimented by filling silicone shells with alternative content such as soy bean oil, polivinyl pyrrolidone. Conceived by a group of US plastic surgeons soy oil filled implants in the early 1990s were expected to be an alternative to saline and silicone gel allowing for a better reading in the mammogram. In case of an accidental rupture the oil was believed to be absorbed by the body without toxicity. The filler was purified soy oil tested in animal injection studies in rabbits without adverse reactions. According to the animal studies and the fact that for many decades soy bean oil was safely used as an intramuscular drug carrier and as intravenous nutrition for critical care patients no safety concerns occurred. But the experts failed. After approval following clinical studies the “Trilucent” breast implants which contained soy bean oil were marketed and up to 5,000 European women received the implants. After soy oil had leaked out and infiltrated body tissue local reactions were reported. Severe inflammation and swelling fortunately subsided when the implants were removed [1]. No long-term health problems were observed after removal. In 1999, the UK Department of Health MDA (Medical Device Alert) recommended that the implants should no longer be used. In Germany, the former German health authority (“Bundesgesundheitsamt”, BGA) recommended no further use in 2000.

The problems related to these implants had a great impact on conformity assessment procedures for medical devices.
devices. In February 2003, breast implants were reclassified as class 3 products in order to provide the best guarantee for health protection [2]. Unfortunately, the standard of regulations and the level of surveillance are not a guarantee for safety when manufacturers behave in a criminal manner as the French company PIP did. Properly manufactured silicone implants of the “third generation” contain formulations of shells and gel contents that are stronger and have a second barrier coat of diphenyl silicone. This coating almost entirely prevents gel bleed or diffusion of the silicone oil through the implant shell. The gel content of these implants is also more viscous and cohesive. Contained in a textured or smooth shell it has become a world-wide standard.

Silicone breast implants are an indispensable tool for a wide spectrum of reconstructive and aesthetic indications. Even though the list of potential unfavourable side effects of breast implants is long – due to a lack of alternatives – there is no doubt about the value of this device in reconstructive and aesthetic indications. However, plastic surgeons have the responsibility to inform their patients about the full spectrum of adverse events and complications – especially in aesthetic surgery. Although the dimensions are large in the current implant scandal, rupture and leaking is not an unexpected occurrence in the whole spectrum ranging from “A” for asymmetry to “U” for unsatisfactory appearance.

Breast implants are no lifetime devices and breast implantation is likely not to be a one-time surgery. In the first line of implantation a 15% rate of revisions has to be expected with an average implant failure rate of less than one percent in three years. Factors such as revision-augmentation, mainly due to capsular contracture, patients request for style and size change, hematoma, seroma or scarring increase the risk for further complications to an average of 28% and also the rate of implant rupture will increase to 7.7% (Mentor Corporation MemoryGel® Silicone Gel-Filled Breast Implants P030053/S06/A03).

It should always be made clear to the patient that many of the changes to the breast following implantation are irreversible. In Germany, according to new legislation the medical consequences of purely cosmetic breast surgery are not covered in total by the medical insurance anymore. In February 2003, breast implants were reclassified as class 3 products in order to provide the best guarantee for health protection [2]. Unfortunately, the standard of regulations and the level of surveillance are not a guarantee for safety when manufacturers behave in a criminal manner as the French company PIP did.

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It should always be made clear to the patient that many of the changes to the breast following implantation are irreversible. In Germany, according to new legislation the medical consequences of purely cosmetic breast surgery are in the financial responsibility of the patient and will not be covered in total by the medical insurance anymore. Following the PIP scandal the general awareness of implant rupture will change. There are clear data that the rupture of a silicone gel-filled breast implant is most often silent. The rate of clinical detection of implant rupture by an experienced physician is 30% compared to 89% with MRI [3], [4]. This also shows there is never a 100% rate of detectability of an implant rupture – silent implant rupture consists to be a diagnostic problem. Therefore, regular MRI has been recommended in the US – leading to increasing long term costs for the patients in addition to regular breast palpation by the patient herself. Fortunately, also resulting from the strict regulations by the FDA, world leading manufacturers are now conducting studies on long term safety and effectiveness of their implants. Endpoints in the large post approval study will include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and results. Meanwhile, the consumers themselves, especially the surgeons have to carefully monitor their patients with respect to the known side effects. Among these the ana-plastic large cell lymphoma (ALCL) observed related to late seroma formation in a very small number of cases of fibrous inflammatory capsule of breast implants raises new questions about long term body reactivity of breast implants. Despite the comparatively rare incidence of ALCLE this potential effect needs to be clarified and to be evaluated by larger patient numbers [5]. In the context of the PIP implant scandal the question was raised whether silicone breast implants should be handled as medical devices or as drugs. The German regulation office “Bundesinstitut für Arzneimittel und Medizinprodukte” (BfArM) has not considered to change the regulations of class III medical devices (e.g. silicone breast implants) so far. The German Society of Plastic, Reconstructive and Aesthetic Surgeons (DGPRÄC) will continue to put patients care and safety on the first place. Therefore, plastic surgeons and authorities will have to continuously cooperate in our effort to improve the safety of patients receiving silicone breast implants.

References

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