The “PIP scandal” – Complications in Breast Implants of Inferior Quality: State of Knowledge, Official Recommendations and Case Report

Der „PIP-Skandal“ – Komplikationen minderwertiger Brustimplantate: aktueller Wissensstand, behördliche Empfehlungen und Fallbericht

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Abstract
Following the clinical observation of high rate of ruptures of breast implants of the French manufacturer Poly Implant Prothèse (PIP), the French Health Products Safety Agency (Afssaps) removed these products from the market in March 2010. Physical and toxicological tests confirmed the use of silicone of improper quality both for the shell and the gel filling. Until now (12/2011), no acute toxicity or mutagenicity could be observed, but 20 cases of malignancies occurred in carriers of PIP-prostheses. By means of a clinical example, we summarize the official recommendations of the Afssaps and its German equivalent, the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) for diagnosis and treatment in women with PIP breast implants. Furthermore, we intend to raise awareness for the fact that the German GfE Medizintechnik and the Dutch manufacturer Rofil distributed the identical product with a different label. Supplementary, the medical and medico-legal aspects of the “PIP scandal” are discussed.

Introduction
Back in May 2000, the US Food and Drug Administration (FDA) had already inspected the production facilities of the implant manufacturer, Poly Implant Prothèse (PIP), based in the south of France. Irregularities found resulted in PIP losing its US marketing permit. Following the first public reports of defects in PIP breast implants in 2006 [1] and 2007 [2], the French medical products inspecting authority (Afssaps) ordered the suspension of the sale and use of the PIP breast implants as of 29 March 2010. The decision was based on the number of complaints and clearly increased rupture and leakage rate of the products, ranging between 10 and 11% [3]. The defects were due to the use of unapproved silicone material which did not comply with manufacturing specifications. Equally affected were the M-Implants manufactured by the Dutch company Rofil, as well as Tibreeze breast implants made by the company formerly known as GfE Medizintechnik GmbH. An increased mutagenicity of the implant material had not been detected until then; however, figures as of 28 December 2011 show that a total of twenty patients with PIP implants had been diagnosed with tumours. Since awareness of these issues in professional circles and the media was...
initially low in German-speaking countries, the occurrence of these incidences caught the public’s attention. Since PIP implants had been used in German-speaking countries in reconstructive and aesthetic surgery; one should be aware of incidents involving the company and the medical and legal consequences for hospitals and practices.

**Official Recommendations and Conclusions**

From the moment the PIP implants were suspended up to the end of last year, the recommendations of the Afssaps (also adopted by the German Federal Institute for Drugs and Medical Devices, BfArM) advised PIP implant patients to undergo sonographic (or mammographic if necessary) check-ups of the implants and axillary lymph nodes every six months. In the event of a suspected implant rupture (even on one side only), both implants should be removed as soon as possible.

Current physico-chemical analyses confirm clinical observations of unacceptably high rupture rates of the implant envelope, as well as the use of unapproved industrial silicone, which can cause local inflammation and axillary lymphangitis. Reports in literature [4] indicate the occurrence of cutaneous manifestations in the form of siliconoma. Previously, cytotoxicity or mutagenicity of the silicone filling had not been indicated [5]; however, figures from the French Department of Health as at 28 December 2011 show that tumors have been diagnosed in twenty PIP breast implant patients [6]. Sixteen cases indicated intramammary tumors (fifteen adenocarcinomas and one anaplastic lymphoma) and four cases indicated tumors in areas other than the breast. However, current investigations have not established a causal link between the breast implants and the tumors. The incidence rate of tumors in PIP patients remains below that of the total population.

Due to the number of reports of diffused seepage of the implant gel filling even without clinical or radiological suspicion of rupture (gel bleeding), Afssaps changed its recommendations on 23 December 2011, recommending the explantation of the implants [7]. The BfArM adopted this recommendation on 6 January 2012, extending it to implants made by the now insolvent Dutch company Rofil Medical Nederland B.V., which marketed similarly designed implants under its own name, i.e. the M-Implants models IMGHC-TX, IMGHC-MX and IMGHC-LS. An equivalent warning had been issued by the Dutch inspections authority, Inspectie voor de Gezondheidsszorg (IGZ), on 19 April 2010 [8]. Other products to be equally impacted include titanium-coated implants manufactured with PIP components and marketed by the company formerly known as GfE Medizintechnik GmbH from September 2003 to August 2004 under the brand name TibBREEZE. There are no accurate figures for the number of PIP and Rofil products implanted; estimates range from about 30 000 in France to 500 000 worldwide. In Germany, BfArM has requested the federal state health authorities to provide figures on PIP/Rofil implants, but to date none have been made available (as at 2 February 2012). The successor of GfE Medizintechnik GmbH, pfm medical titanium GmbH, has indicated that 728 TibBREEZE implants have been put on the market. BfArM recommends “that the implants in question be explanted as a precautionary measure”. Treating physicians are requested to contact affected patients and communicate the recommended procedure. “The urgency of each individual explantation depends on how long the patient has had the implant. This should be dis-
After further unobtrusive therapy and 6 months free of infection, the remaining left implant could be removed and a bilateral re-augmentation performed. The clinically asymptomatic remaining implant also indicated silicone exudation and a perforation of the envelope.

Discussion

The aim of this publication is to provide our professional colleagues with an overview of the so-called “PIP Scandal” concerning the company Poly Implant Prothése through the description of a typical case. The roles of the companies Rofil and GfE should also be known in this context, as this has consequences for decisions on therapy, as well as legal significance. With low-grade implants, the issue is one of product liability and not of negligence on the part of the surgeon. Since the physicians were not aware of the defectiveness of the implant and trusted the product on the basis of the CE mark of quality, it is highly unlikely that compensation claims can apply to the treating physicians. However, the damage to the reputation of the practices or institutes involved is considerable. The certification body, TÜV Rheinland, has also been subject of public criticism for insufficient quality control; however, it claims to have been deliberately deceived by the manufacturer and has lodged a complaint against PIP stating that during its (announced) on-site inspections, only approved products and documents had been presented.

It is not clear to what extent Afssaps was informed by the FDA of the deficiencies already detected in the year 2000. A further medico-legal issue in this matter is that in the case of aesthetic implants, the issue is one of product liability and not of negligence on therapy, as well as legal significance. With low-grade implants, the issue is one of product liability and not of negligence on the part of the surgeon. Since the physicians were not aware of the defectiveness of the implant and trusted the product on the basis of the CE mark of quality, it is highly unlikely that compensation claims can apply to the treating physicians. However, the damage to the reputation of the practices or institutes involved is considerable. The certification body, TÜV Rheinland, has also been subject of public criticism for insufficient quality control; however, it claims to have been deliberately deceived by the manufacturer and has lodged a complaint against PIP stating that during its (announced) on-site inspections, only approved products and documents had been presented.

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