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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- BRCA (breast cancer antigen)
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Schlüsselwörter
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- Mammakarzinom

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 occured 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.

Zusammenfassung

Aufgrund unzulässig hoher Rupturraten von Brustimplantaten des französischen Herstellers Poly Implant Prothèse (PIP) nahm die französische Aufsichtsbehörde für Medizinprodukte (Afssaps) diese Produkte im März 2010 aus dem Handel. Laboruntersuchungen bestätigten die Verwendung von minderwertigem Silikonmaterial für Hülle und Füllung der Implantate, eine akute Toxizität oder Mutagenität konnte bisher nicht nachgewiesen werden, jedoch sind mittlerweile (12/2011) bei insgesamt 20 Trägerinnen von PIP-Implantaten Krebserkrankungen aufgetreten. Anhand eines klinischen Falles sollen hier die aktuellen Empfehlungen der Afssaps sowie des Bundesinstituts für Arzneimittel und Medizinprodukte (BfArM) zusammengefasst werden. Ebenfalls soll darauf hingewiesen werden, dass identische Produkte vom niederländischen Hersteller Rofil sowie der Firma GfE Medizintechnik unter anderer Bezeichnung in den Handel gebracht wurden. Ergänzend sollen die sich aus dem „PIP-Skandal" ergebenden medizinischen und medizinrechtlichen Konsequenzen erörtert werden.

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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 at 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] include 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 Gezondheidszorg (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 *TiBREEZE*. 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 *TiBREEZE* 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 discussed between the doctor and each individual patient before the operation" [9]. Similarly, emphasis is placed on reporting incidents of damage as these are required for more extensive risk minimising measures.
French experts further recommend a preoperative imaging of the breasts (MRI or sonography) and a sonographic examination of the axillary lymph nodes. Where explantation is performed, it is recommended that the implant capsule be removed as extensively as possible at the discretion of the surgeon and a systematic histological examination conducted; any periprosthetic fluid should also undergo cytological examination. Special after-care following explantation is not required.
The BfArM internet site provides an unofficial translation of the expert advice of the French National Cancer Institute, INCa, based on the Afssaps recommendations [10].
The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) made its position on the topic known at European Community level with a statement issued on 1 February 2012. On the basis of this opinion, the European Commission has requested further extensive studies. The lessons from this situation are also to be included in future revisions of the European Medical Devices Directive [11].

Clinical Case Study

We realised the hitherto lack of awareness of the connection between PIP and Rofil, when a 27-year-old patient presented herself to our department in July 2010. She had undergone aesthetic surgery in another clinic 3 years ago for breast augmentation with 350 ml Rofil bilateral implants. The patient now indicated acute infection signs of the right breast with fever and local swelling, as well as axillary lymphadenitis and elevated inflammatory markers. A suspected ruptured implant and periprosthetic infection was confirmed by MR imaging. Surgery was immediately performed. Thin liquid pus was removed (**Fig. 1**) from the area of the implant, but a causative pathogen could not be established. A tear was visible on the side of the implant facing the thorax (**Fig. 2**) as well as a diffused gel seepage (bleeding). A histological analysis indicated a florid purulent, partly abscessed lymphadenitis with silicone traces in the excised lymph nodes (**Fig. 3**).

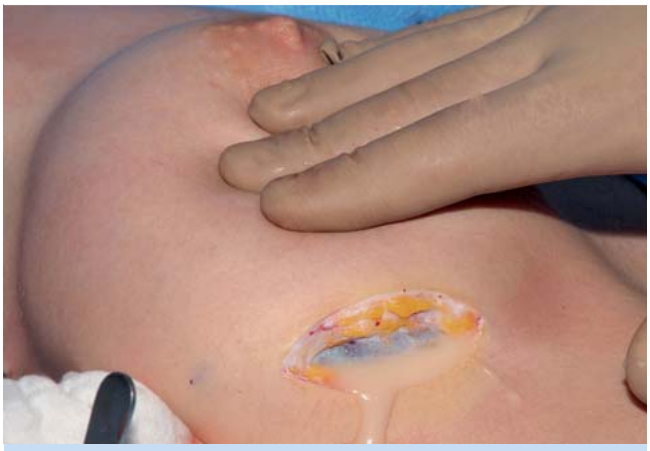

Fig. 1 Intraoperative findings after opening of the implant pocket.

Fig. 2 Defective implant indicating gel bleeding and visible tear.

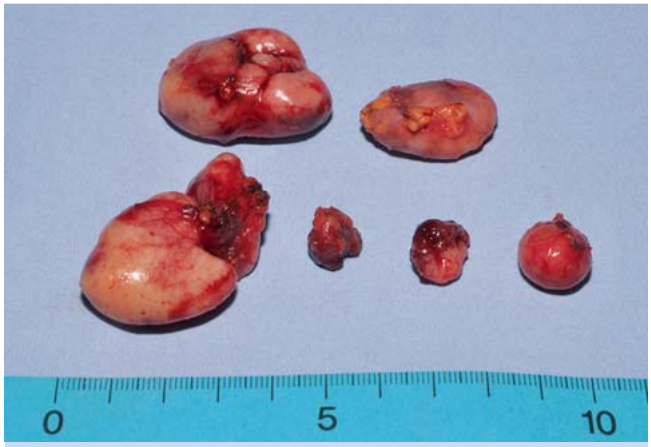

Fig. 3 Macroscopic view of excised, inflamed lymph nodes.

After further unobtrusive therapy and 6 months free of infection, the remaining left implant could be removed and a bilateral reaugmentation 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 Prothèse 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 the 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 a purely aesthetic breast augmentation, treatment due to complications is considered a medically required revision surgery following previous measures which were not medically indicated. German state health insurance funds agree to cover such costs; however, according to the revised Section 52, Para. 2 of the German Social Security Code, SGB V (limitation of benefit based on personal responsibility) dated 1 April 2007, the patient is expected to contribute "an appropriate amount" [12], resulting in potentially considerable follow-up costs for the patient. Some health insurance companies have, however, declared that they will be applying their own discretion to each individual case, in particular since the issue involves third party liability. Similarly to the regulations governing French state health funds, private health insurers will cover at least the full costs of diagnosis and explantation in the case of aesthetic implants.

The PIP scandal once again poses the question of how to justify the clearly lower requirements in approval procedures for medical devices compared with those applied to pharmaceuticals. A mandatory central register could contribute to identifying and remedying quality deficiencies more quickly after the products are put on the market.

Based on the dynamics of the events in the past months and the on-going investigations, persons concerned are urged to follow developments with reference to the medical and legal consequences for clinical practice.

Conflict of Interest

None.

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