afssaps
Agence française de sécurité sanitaire des produits de santé

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Silicone filled breast implants from Poly Implant Prothèse Company
Tests results

On March 29th, 2010, Afssaps suspended the marketing and use of breast implants pre-filled with silicone based gel manufactured by Poly Implant Prothèse company (PIP).
This decision followed both the observation made in 2009 of an increase in shell ruptures of the breast implants and the findings of the inspection conducted by Afssaps in the premises of this company following this vigilance observation. The inspection had highlighted the use by Poly Implant Prothèse of filling gel different from the one declared both in the design file and manufacturing file of these implants.

The vigilance data updated since March 2010, confirm that the incidents reported by professionals are in the majority ruptures. The observed rate of rupture is higher than the rate of rupture observed with prosthesis of other manufacturers on the same implantation period and that, since the first years of implantation. (Cases recorded to date, show a high rate of rupture at 5 years) Clinical observations relate a sweating aspect of the explants, even without rupture. Cases of adenomegaly (enlargement of lymph gland due to accumulation of silicon) without rupture of the prosthesis were also noted for some women. At this stage, we can't determine if their frequency is higher than for other prosthesis on the market.

Afssaps also performed and commissioned jointly with the departments of Justice, analysis on implants taken from the premises of PIP. The different tests were performed between June and September 2010 according to standards applicable to breast implants. The objectives were to characterize the raw materials used and the mixtures constituting the filling gels, to determine the resistance of the prosthesis and finally to investigate the tolerance of biological tissues in contact with the filling gel.

Results

The physicochemical analysis confirm that gels filling tested breast implants of PIP company are not those described in the manufacturer's design file. Indeed, It is a gel obtained from raw materials of the silicone family, but it does not reach the level of quality required for a silicone gel dedicated to breast implants.

Two tests of mechanical strength are compliant with requirements of existing standards for breast implants. However the test for elongation until rupture is not in accordance with the standards. This result demonstrates the fragility of the PIP gel-filled shells and corroborates the findings of a vigilance enquiry, which revealed a failure rate higher than average.

Regarding tolerance tests of biological tissues in contact with the filling gel :

- A test shows that the gel of PIP breast implants has no acute toxic effects on tissues (cytotoxicity).

The results of the intradermal irritation test show an irritant behaviour of PIP gel that is not found on other silicone gels of other breast implants and nor the one described in the technical file for the placing on the market. The contact of the gel with the tissues can be caused by a rupture of the shell

or by leakage of the gel through the shell. This can lead to inflammatory reactions in some patients, because of irritant character of this gel.

- Three tests for assessing possible effect of the PIP gel on DNA of the cells (genotoxicity) were carried out, 2 in vitro and 1 in vivo in mice. If both in vitro tests have shown negative results, finding obtained in vivo do not allow in the present state to conclude on the absence or presence of a genotoxic effect.
  This in vivo test, known as micronucleus test consists, after exposure of mice to the filling gel, in identifying the occurrence of micronuclei, indicating an alteration in the DNA of cells, together with possible disruption of cell division. The observation of an interaction on the bone marrow cells and the presence of micronuclei at levels not statistically significant, which does not allow to conclude on a possible genotoxic effect, therefore require the completion of additional tests. These extensive tests require 3-4 months of investigation. The final conclusions of Afssaps may be made in early 2011.

In any case, all data from vigilance system and tests performed lead to the conclusion that the performance and safety of PIP prosthesis are not in accordance with current state of the Art. They demonstrate a significant heterogeneity in the quality from a prosthesis to another, so that all implants don't present the same level of weakness.

Afssaps recommendations

Given the foregoing, AFSSAPS recommends:

- That any person with PIP implants undergoes a clinical examination completed with an ultrasound scan dated less than 6 months.

- That any rupture or suspected rupture of a prosthesis leads to its explantation, as well as that of the second prosthesis.

One contact with the surgeon will also be an opportunity to discuss a possible explantation without clinical signs of deterioration of the prosthesis: the concerned women will consider the most appropriate attitude based on their personal situation, of their felt, of the age of their prosthesis and of their expectations at the aesthetic level. This choice will be reached after evaluation of the individual benefit/ risk with the surgeon, based on a preoperative assessment that takes into account medical history, anaesthetic risk and the risk of complications inherent in the surgery. To make this discussion easier, a guideline will be drafted in the next weeks, by Afssaps with professionals on a multidisciplinary and collegial basis and with consulting patient associations.

All the documents and information are available on Afssaps website at www.afssaps.fr.