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Dear colleagues,

please find enclosed the links to the report which we, the members of the expert group for PIP implants of the Scientific Committee of the European Commission published yesterday.

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf

http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/96&format=HTML&aged=0&language=EN&guiLanguage=en

Let me point out the most important facts for you:

We all are aware of the fact that there are no long term studies on PIP implants. Therefore our decision making process had to be based on the material testing results, the irritation test performed by the French Health Authorities, AFSSAPS and the case reports, that you have sent to me. All the members of the expert group were grateful for your input.

The recommendation now is based on the positive animal irritation test performed by AFSSAPS as well as the material tests. It became quite obvious that the implant shell is less stable due to the amount of low molecular weight species silicone which migrates into the shell and makes it swell and instable. The gel also migrates through the shell into the surrounding tissue and into the lymphatic system where it causes irritations. This may occur with or without rupture.

The most important part of the report is in the executive summary on page 10:

“A controlled prophylactic explantation definitely carries less risk than an explantation after rupture or after the onset of symptoms of inflammation and/or lymphadenopathy. Considering the reduced stability of the shell of PIP silicone breast implants it is possible that the implant will have to be exchanged for most of the women with such implants within the next 10 to 15 years.”

This is what we should have in mind when we discuss the risks and benefits of prophylactic explantation with our patients. Please have also in mind that monitoring the patient with MRI does not mean that a pending rupture can be detected.

On the other hand we currently do not know how many patients carry the industrial gel within their implants and how many the medical grade gel.

The probability that the implants produced before 2003 are filled with medical grade gel is quite high, while the implants produced in 2005 or later probably are filled with industrial gel.

We also do not know how the implants were distributed. Therefore it is possible that medical grade silicone might have been used for export in a higher percentage, but we do not really know what the investigation ultimately will reveal.

Let me also add some legal aspect considerations: As mentioned in our previous letter, we as plastic surgeons cannot judge the quality of a medical product. We have to rely on the CE mark. However we need to discuss all possible complications with the patients, including rupture. It seems that informed consent will play a major role in the assessment.

We have to make sure that all patients with PIP implants are informed that they have to come back for a physical exam and a consultation about the risks and benefits of explantation. In those countries where the Health Authorities have announced that explantation is necessary we are obliged to make sure that the patients are aware of it. We already have information that the fact that a plastic surgeon has not contacted his patient has resulted in a law suit.

In summary I believe that our report is balanced in terms of allowing a risk/benefit evaluation for each individual patient.

Please do not stop to send me case reports or studies, even in small series.

All your contributions add to better understanding and evaluation.

I am very much aware of the fact that some of you are undergoing very difficult times now. Please let us know how we can support you.

With my best personal regards.

Marita Eisenmann-Klein
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