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FDA Backgrounder on Platinum in Silicone Breast Implants

Platinum is a metal used as a catalyst in the manufacture of the shell and gel components of silicone breast implants. Because small amounts of platinum remain in the product following manufacturing, concerns have been raised that platinum may enter the body, either by diffusing through the intact shell or through an implant rupture, and cause adverse effects.

This backgrounder provides a brief summary of some of the key scientific studies on platinum in silicone gel-filled breast implants.

STUDIES INCLUDED IN THE 2000 INSTITUTE OF MEDICINE REPORT ON THE SAFETY OF SILICONE GEL BREAST IMPLANTS

In 2000, the Institute of Medicine (IOM) published its report on the safety of silicone breast implants.¹ The report provides an authoritative and unbiased review of the chemistry and toxicology of platinum and breast implants, based on evaluation of published studies into 1999. Below is a brief summary of some of the pertinent platinum articles included in the IOM report.

In 1997, Lykissa, et al.² reported that platinum leaked from breast implants. The experiments were carried out by exposing three intact explanted silicone gel-filled implants to 10% soy oil in a water-based mixture or to soy oil alone for 24 hours at body temperature. The explants had been removed 2 to 5 years after implantation, but the time between explantation and analysis was not reported. The author's measurements showed that 20 to 24 micrograms of platinum were present in the media after soaking for 24 hours. Using this number, and the estimated amount of platinum in a 250-gram implant (175 micrograms), the authors calculated that 10 to 15% of the total platinum in the gel was released per day. This estimate raises a question, however, since according to this method, all of the platinum in the gel in a typical breast implant would be released after 7 to 10 days. We know that this cannot be the case because the samples that were used in this experiment had been implanted for up to five years before analysis. This raises concerns about the experiment and whether the soybean oil mixture is an appropriate fluid to simulate body conditions. Therefore, FDA believes that the results of this study do not provide an accurate indication of the leakage rate in women with breast implants.

Although the authors of this study speculated that the platinum in breast implants may be toxic, they did not identify any particular molecular or ionic form of platinum in their test samples, or report any toxic effects in their subjects. The concern is that some chemicals that contain platinum in certain charged forms (i.e., oxidation states) are known to be toxic (e.g., cause allergic effects). Claims have been made that one of these chemicals, called hexachloroplatinate (or platinate), is present in silicone breast implants. However, the IOM report states that, "Platinum is present in small amounts in implants... Reports that this platinum is in the form of platinate (Lykissa, et al., 1997) are unconfirmed."

In 1999, Harbut and Churchill³ hypothesized that hexachloroplatinate was responsible for asthma reported in eight women who either currently, or in the past, had silicone gel breast implants. However, no platinum measurements were reported, and there was no evidence presented that the women's implants contained hexachloroplatinate. With regard to this study, the IOM report states, "The authors speculated that the respiratory signs and symptoms were the result of exposure to hexachloroplatinate in their implants. No evidence for this was reported. Conclusions regarding platinum toxicity in women with breast implants should await further evaluations that positively relate platinum to the symptomatology."

Other studies have reported that the platinum in breast implants is in the zero oxidation (zero valence) state, which has low toxicity.⁴ Based on a review of those studies, the IOM report concluded that "Some investigators have asserted that platinum catalysts in breast implants may diffuse through the implant shell, be present in multivalent states, and provoke toxic effects. The evidence currently available suggests that platinum is present only in the zero valence elemental state. Evidence does not suggest there are high concentrations in implants, significant diffusion of platinum out of implants, or platinum toxicity in humans."

PUBLICATIONS SINCE THE 2000 IOM REPORT

After the IOM report, FDA scientists reviewed the available studies from the medical literature on platinum and breast implants and did not find evidence that platinum present in silicone gel breast implants causes illness in women with breast implants.⁵

Three other studies on platinum analysis have been published since the IOM report and the FDA overview article were published.

Flassbeck, et al.⁶ used mass spectrometry to analyze tissue samples collected from three women at the time their implants were removed and three women who had never received breast implants. The women with implants had their devices in place for 16, 8, and 7 years. Two implants were intact and one was removed because of suspected gel bleed. Samples were taken from the tissue immediately surrounding the implant (i.e., the capsule) as well as from breast fat, muscle tissue, and the fibrin (i.e., protein) layer. In two of the subjects, the analysis method had a detection limit of 2 to 6 parts per billion. In the first subject, approximately 90 parts per billion platinum were found in fat tissue surrounding the implant and no platinum was detected in the samples of breast muscle or fat tissue. In the second subject, platinum was not detected in any of the samples analyzed. In the third subject, a more sensitive assay was used that had a detection limit for platinum of 0.05 parts per billion. For this subject, the capsule and fibrin layer surrounding the implant contained 2.1 and 25 parts per billion. Using this same method, 0.3 and 1.0 parts per billion of platinum were detected in breast tissue from two of three women who never had breast implants. No platinum was detected in tissue from the third control subject. FDA believes the methodology used in this study is appropriate. However, because there were only three test and control subjects, a larger study is needed to establish the significance of these results.

Maharaj⁷ also used mass spectrometry to measure platinum levels in explanted breast implants and in the surrounding capsular tissue. The detection limit was 1 to 2 parts per trillion, and 0.5 gram tissue samples were analyzed. All explants were intact based on medical reports of implant status verified by visual inspection. Platinum levels in the 15 capsular tissue samples analyzed were very low, ranging between 3 and 272 parts per billion. Implant components (e.g., gel and elastomer shell) showed platinum levels ranging from 0.26 to 126 parts per million. FDA believes this study is seriously flawed because control tissue samples from women without breast implants

were not included for comparison. Therefore, it is not possible to determine if the test samples contained higher levels of platinum than tissues from women without implants.

Lykissa and Maharaj⁸ recently reported on the presence of platinum in blood and other samples from 18 women who had breast implants (16 with silicone gel-filled breast implants and 2 with saline implants). Some of the silicone gel-filled implants were older generations for which gel bleed rates may differ from currently manufactured implants. At the time of sampling, 16 of these 18 subjects no longer had their implants. The authors were able to obtain explant histories from 10 of the 16 explanted women. For these 10 patients, the implants were removed from 1 to 8 years before the platinum testing was performed (average of 5.4 years). The authors also included a comparison group of 5 control subjects who never had breast implants. A limited amount of information is available on these 5 control subjects; however, it appears that they were significantly younger than the patients in the breast implant group (average 32.3 years old versus 51.4 years old). This raises questions as to how similar the two groups were at baseline.

Although the authors state that platinum levels were measured in whole blood, urine, hair, nails, sweat, and breast milk, not all women had each of these samples evaluated. For example, only 10 of the 18 women in the implant group had their whole blood and urine evaluated and only 6 of the women in this group had their breast milk tested. In the control group, all 5 patients had their whole blood evaluated, only 2 had urine evaluated, and none had hair, nails, sweat, and breast milk tested.

Small amounts of platinum were detected in the blood (parts per trillion) and urine (parts per million based on a comparison with creatinine levels) of several women in the group exposed to breast implants. However, the levels were not significantly different than those found in samples from women without breast implants (comparison or control group). In fact, some of the control samples had higher platinum levels than the implant group. The authors also reported finding small amounts of platinum (between 0.3 and 10 parts per billion) in the hair, nails, sweat, and breast milk from some women with breast implants.

The authors also reported that the platinum found in seven blood samples, one urine sample, one sample of brain tissue, and the gel from the explanted breast implants was present in various charged forms (referred to as oxidation states). However, current knowledge of platinum chemistry would make the finding of all theoretically possible "charged" forms of platinum (e.g. Pt+6) very unlikely.

The study also had other shortcomings that make the study of limited value. As mentioned above, samples from no more than half of all women exposed to breast implants were actually tested for platinum. Also, because comparable samples from the control women were not available for testing, the meaning of the results for the women exposed to implants is not clear. That is, it is not possible to determine if the platinum found in the test samples is higher than in samples from women without breast implants. Test sample results were compared with historical data from the literature. However, the only appropriate comparison would have been with samples collected and analyzed concurrently, because the study populations, sample collection, and analytical methodology likely were different in the earlier studies.

Brook⁹ has recently published a review of platinum in breast implants, including the chemistry of platinum, the catalysts used in the manufacturing process, migration of platinum from breast implants, and its biological effects. The author provides his assessment of four of the studies^{2,3,7,8} discussed in this Backgrounder. In his review article, Brook concluded that platinum is found in its zero oxidation state at parts-per-million levels in silicone breast implants. He stated,

“The experimental evidence supports the conclusion that there are no clinical consequences of the platinum in silicone breast implants.” FDA concurs with Brook’s conclusions.

CONCLUSIONS

Some studies have shown that small quantities of platinum may bleed through an intact implant shell and be present in trace amounts (parts per billion) in surrounding tissue. However, these results need to be confirmed using a larger number of subjects. Other studies have serious scientific flaws that raise concerns about the validity of their results and conclusions. Even if the analytical results of large, well controlled studies were to show relatively high levels of platinum in biological samples, the toxicological significance would still need to be determined.

Based on the existing literature, FDA believes that the platinum contained in breast implants is in the zero oxidation state, which would pose the lowest risk, and thus that the small amounts of platinum that leak through the shell do not represent a significant risk to women with silicone breast implants. FDA will continue to review and analyze the literature on the issue of platinum in breast implants, as part of its ongoing assessment of the safety of these devices.

¹ Bondurant, S, Ernster, VL, and Herdman, R, Eds. 2000. Safety of silicone breast implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. Washington, D.C.: National Academy Press.

² Lykissa, ED, Kala, SV, Hurley, JB, and Lebovitz, RM 1997. Release of low Molecular Weight Silicones and Platinum from Silicone Breast Implants. *Anal. Chem.* 69:4912-4916.

³ Harbut, MR and Churchill, BC 1999. Asthma in patients with silicone breast implants: report of a case series and identification of hexachloroplatinate contaminant as a possible etiologic agent. *Israel J. Occup. Health* 3:73-81.

⁴ Stein, J, Lewis, LN, Gao, Y, and Scott, RA 1999. In situ Determination of the Active Catalyst in Hydrosilylation Reactions Using Highly Reactive Pt(0) Catalyst Precursors. *J. Am. Chem. Soc.* 121(15):3693-703. Chandra, G, LO, PY, Hitchcock, PB, and Lappert, MF 1987. A convenient and novel route to bis(alkyne)platinum(0) and other platinum(0) complexes from Speier’s hydrosilylation catalyst. *Organometallics.* 6:191-2. Lappert, MF and Scott, FPA 1995. The reaction pathway from Speier’s to Karstedt’s hydrosilylation catalyst. *J. Organomet. Chem.* 492:C11-C13. Lewis, LN, Colborn, RE, Grade, H, Bryant, GL, Sumter, CA, and Scott, RA 1995. Mechanism of formation of platinum(0) complexes containing silicon-vinyl ligands. *Organometallics.* 14:2202-13.

⁵ Arepalli, S, Bezebah, S, and Brown, SL 2002. Allergic reactions to platinum in silicone breast implants. *J. Long-Term Effects Med. Implants* 299-306.

³ Harbut, MR and Churchill, BC 1999. Asthma in patients with silicone breast implants: report of a case series and identification of hexachloroplatinate contaminant as a possible etiologic agent. *Israel J. Occup. Health* 3:73-81.

⁶ Flassbeck, D, Pfeleiderer, B, Klemens, P, Heumann, KG, Eltze, E, and Hirner, AV 2003. Determination of siloxanes, silicon, and platinum in tissues of women with silicone gel-filled implants. *Anal. Bioanal. Chem.* 375: 356-362.

⁷ Maharaj, SVM 2004. Platinum concentration in silicone breast implant material and capsular tissue by ICP-MS. *Anal. Bioanal. Chem.* 380:84-89.

⁸ Lykissa, ED and Maharaj, SVM 2006. Total Platinum Concentration and Platinum Oxidation States in Body Fluids, Tissue, and Explants from Women Exposed to Silicone and Saline Breast Implants by IC-ICPMS. Anal. Chem. 78:2925-2933.

⁹ Brook, MA 2006. Platinum in Silicone Breast Implants. Biomaterials 27:3274-3286.

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