**Supplemental Digital Content 2: Comparison of pre-clinical signs and intra-operative findings in ten patients with ruptured PIP implants**

| Patient | Pt 1 | | Pt 2 | | Pt 3 | | Pt 4 | | Pt 5 | | Pt 6 | | Pt 7 | | Pt 8 | | Pt 9 | | Pt 10 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt | Rt | Lt |
| **Rupture on scan** | N/A | N/A | Y | Y | N/A | N/A | Y | Y | Y | Y | Y | N | N/A | N/A | N | Y | Y | N | N/A | N/A |
| **Baker grade capsule** | | | | | | | | | | | | | | | | | | | | |
| (I-IV) | III | I | I | I | II | II | I | I | II | II | I | I | I | I | III | I | I | III | I | I |
| **Signs detected by surgeon** (N No/Y Yes) | | | | | | | | | | | | | | | | | | | | |
| Asymmetry | Y | | Y | | Y | | Y | | Y | | Y | | Y | | Y | | Y | | Y | |
| Enlargement | N | N | N | N | N | Y | Y | Y | N | Y | N | Y | Y | N | N | Y | Y | N | N | Y |
| Lower pole fullness | Y | Y | N | N | N | Y | Y | Y | N | Y | N | Y | Y | N | N | Y | Y | N | N | Y |
| Loss projection | Y | Y | N | N | N | Y | Y | Y | N | N | N | Y | N | N | N | Y | Y | N | N | Y |
| Lymphadenopathy | N | N | Y | Y | N | Y | N | Y | N | N | Y | Y | N | N | N | Y | Y | N | N | N |
| **Exudate** | | | | | | | | | | | | | | | | | | | | |
| C Cloudy | Nil | W | Nil | Nil | Nil | W | W | W | Nil | W | C | W | W | Nil | nil | W | C | C | Nil | W |
| W White | | | | | | | | | | | | | | | | | | | | |
| **Thickness Intra-operative capsule** | | | | | | | | | | | | | | | | | | | | |
| 1 Mild | 2 | 1 | 1 | 1 | 2 | 1 | 1 | 2 | 1 | 1 | 1 | 2 | 1 | 2 | 3 | 1 | 2 | 3 | 2 | 1 |

2 Moderate

3 Severe

**Rupture Implant**

| 1 Minor tear | 3 | 2 | 2 | 2 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 3 | 2 | 2 | 3 | 3 | 2 |

2 Total disruption

3 intact

**Colour of implant**

| (B Brown/W White) | W | B | B | B | W | B | W | W | W | B | B | B | B | W | B | B | B | W | W | B |

**Patient pre-operative**

**complaint**

(N No/Y Yes)

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Asymmetry | | N | | N | | N | | N | | Y | | Y | | N | | Y | | Y | | N |
| Loss projection | | N | | N | | N | | N | | Y | | Y | | N | | Y | | Y | | N |
| Enlargement | | N | | N | | N | | N | | N | | N | | N | | N | | N | | N |
| Pain | N | N | Y | Y | N | N | N | N | N | Y | N | N | N | N | N | N | Y | N | N | N |
| Lymphadenopathy | N | N | N | Y | N | N | N | N | N | N | N | N | N | N | N | Y | Y | N | N | N |

**Analysis by Inductively coupled plasma mass spectrometry of the elastomer shell and gel content of a brown ruptured PIP implant.**

## Analytical Methodology

The amount content of iodine in silicone breast implant products was determined by inductively coupled plasma mass spectrometry (ICP-MS) using external calibration with internal standard correction after alkaline leaching. In order to determine the total iodine content, complete sample digestion is required. This is extremely difficult for silicone products. Therefore, with the conditions reported below, only the leachable iodine from silicone breast implant products can be determined.

## Sampling Protocol

The method subsequently described was developed and validated for total quantitative analysis of iodine content in food samples[S1]. This was demonstrated using food-based certified reference materials in this work, namely NIST SRM1548a Typical Diet and ERM-BC402 Potato Powder (LGC Standards, UK). An aliquot of each silicone product was accurately weighed into a 20 ml screw cap glass vial, with each sample prepared in duplicate. A solution of 5% w/w tetramethylammonium hydroxide (TMAH, ≥97% Sigma Aldrich, UK) was prepared using ultrapure water (>18 MΩ cm, Elga, UK) and 5 ml of this solution was added to each vial. The vials were shaken and placed in a preheated oven at 100°C for 3 hours. Once cool, the contents were transferred to a pre-cleaned 50 ml glass volumetric flask with several washing of ultrapure water. An aliquot of 1 ml of internal standard (2000 ng/ml Tellurium, Romil, UK, in 1% TMAH) was then added and made up to a final weight of 50 g with water. The sample leachates were analysed immediately.

## Instrumentation and Analysis

Calibration standards within the range of 0 - 50 ng/g were prepared in 1% TMAH from a stock standard of high purity potassium iodide (+99.99%, Alfa Aesar, UK) dissolved in 5% TMAH. The correlation coefficient value of >0.999 was obtained for the calibration graph.

An Agilent Technologies 7700x ICP-MS was utilised in standard mode for the analysis. Table S1 provides the operating parameters for the ICPMS. All glassware (nebuliser, spray chamber and torch) were soaked for 4 hours in 5% TMAH and rinsed with ultrapure water. The ICP-MS was optimised to achieve maximum signal to noise ratio for $^{127}$I.

**Table S1:** Operating parameters for ICP-MS

| Parameter | Value |
|---|---|
| RF Power | 1550 W |
| Coolant gas flow | 15.5 l/min |
| Auxiliary gas flow | 0.80 l/min |
| Sample gas flow | 1.16 l/min |
| Nebuliser | Micromist® 400 µl glass, self aspiration |
| Spray chamber | Scott double pass, cooled to 2°C |
| Cones | Nickel |
| Dwell time per acquisition point | 0.1 s |
| Number of acquisition points per peak | 3 |
| Isotopes monitored | $^{127}$I for iodine and $^{125}$Te for tellurium |
| Number of replicates | 5 |

**Results and Discussion**

The limit of detection and quantification were calculated as the mean blank concentration plus 3-times and 10-times respectively the standard deviation of the blank, followed by multiplication of the average digestion dilution factor. The % recovery of the certified reference material (dry weight basis) and independent standard are also provided for information.

The concentration results for the samples are presented in Table S2 as the observed range of iodine as these values only represent the leachable iodine fraction from the implant products as total sample digestion was not undertaken. Therefore, the surface area and shape of the sample aliquot may have played a role in the leaching efficiency.

**Table S2:** Concentration results for leachable iodine in silicone breast implant products (µg/g)

| Sample ID | Leachable Iodine Concentration µg/g |
|---|---|
| Limit of Detection (LoD) | 0.001 |
| Limit of Quantification (LoQ) | 0.002 |
| Heavily stained GEL | 1.3 – 2.6 |
| Heavily stained SHELL | 181 – 253 |
| **Quality Control** | **% Recovery** |
| Independent Standard | 96% |
| NIST SRM1548a Typical Diet | 98% |
| ERM-BC402 Potato Powder | 107% |

The purpose of this work was to establish the presence of iodine from a heavily stained explanted PIP product. It was found that iodine was identified in both the shell and gel at concentrations significantly above the limit of quantification. Additionally, the shell sample contained iodine at a level of two orders of magnitude above the gel.

**References**

S1) Santamaria-Fernandez,R., Evans, P., Wolff-Briche, C. S. J. and Hearn, R. A high accuracy primary ratio method for the determination of iodine in complex matrices by double isotope dilution using MC-ICPMS and 129I spike. J. Anal. At. Spectrom., 2006, 21, 413–421