Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Investigation Report: Experiments related to the safety of PIP Implants

Samples Tested

Eight PIP implant samples were tested in this investigation. The models, lot numbers and expiry dates of the samples tested are shown in Table 1. The model name indicates the surface finish (LS – smooth / TX – textured) the profile (S – standard / H- high) and the volume of the implant. [redacted]

Table 1: Implant Samples

Supplier	*Model*	*LOT No.*	*Expiry*	*LIMS*
PIP	IMGHC-TX-S-205	25109	2014-05	10040014211
PIP	IMGHC-TX-S-265	35008	2013-06	10040014119
PIP	IMGHC-LS-S-205	36206	2011-10	10040014115
PIP	IMGHC-LS-S-305	54206	2011-10	10040014114
PIP	IMGHC-LS-H-350	27909	2014-07	10040014113
PIP	IMGHC-LS-H-350	36709	2014-09	10040014112
PIP	IMGHC-TX-H-430	16609	2014-03	10050020124
PIP	IMGHC-LS-H-430	36709	2014-09	10050020130

[redacted]

[redacted]

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au
Telephone: 02 6232 8444 Facsimile: 02 6232 8605 ABN 40939 406 804

Standards Applied

ISO 34 *"Rubber, vulcanized or thermoplastic - Determination of tear strength - Part 1: Trouser, angle and crescent test pieces"*

ISO 37 *"Rubber, vulcanised or thermoplastic - Determination of tensile stress-strain properties"*

ISO 14607:2007 *"Non-active surgical implants - Mammary implants - Particular requirements" Annex B – Tests for Shell Integrity*

ISO 14607:2007 *"Non-active surgical implants - Mammary implants - Particular requirements" Annex D – Tests for gel cohesion*

Note: The requirements of these tests are transcribed in Attachment 1 for the reader's convenience

Note: The die type can have a significant effect on the tensile test results. Annex B of ISO 14607 refers to the tensile test methods described in ISO 37 specifying that "die H2" must be used. But ISO 37 does not describe a "die H2".

The TGA used an ISO 37 Type 2 die to cut tensile test specimens from the shell. Type 2 dies have an active specimen length of 75 mm and a width of 4 mm.

[redacted]

Sample Treatment

The implants were dissected along the outer edge and the shell was slowly peeled from the cohesive gel. The gel separated more easily from the textured shells than the smooth shells, where constant manipulation was required at the parting line.

Tensile test specimens were taken from the shells using a dumbbell cutting die that complies with specifications set down in ISO 37. Tear test specimens (ISO 34, Method B) were taken from the shells using the right-angle, cutting die. Thickness measurements were made using a calibrated digital micrometer. Length measurements were made using a standard, calibrated ruler. Tensile measurements were made using a Lloyd LRX tensile and compression testing machine equipped with a 100N load cell and a Laserscan 200 non contacting extensometer.

Gel cohesion was tested using a truncated cone vessel conforming to the dimensions described in Annex D of ISO 14607.

[redacted]

[redacted]

Results

Thickness

The thickness was measured at nine locations on the upper shell and twelve locations on lower shell. The patches from two samples were used in biocompatibility testing and were not available for testing. In the graph below "implant thickness" should be taken to mean "implant shell thickness"

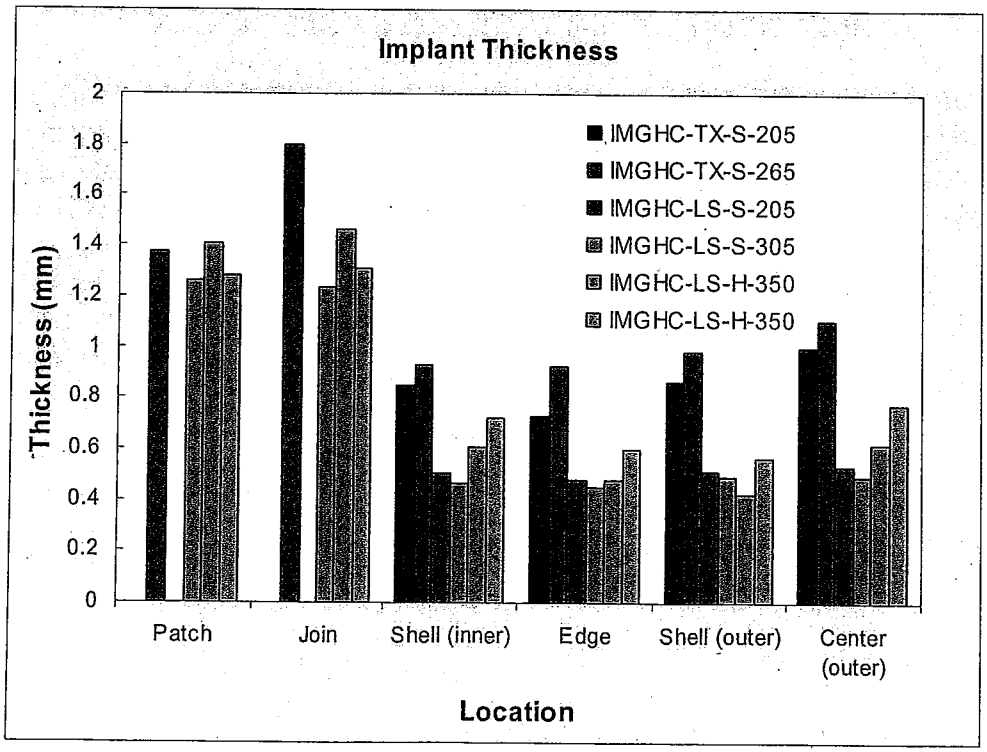

Figure 1: Shell thickness profiles of the PIP implants

[redacted]

Tensile Properties

The average shell thickness, force and elongation of the samples is summarised in Table 2. The elongation of all the samples exceeded 450% and thus complied with ISO 14607 Annex B:1.2

Table 2: Shell thickness and Tensile properties of PIP implants

Model	*Thickness (mm)*	*Force (N)*	*Elongation %*
IMGHC-TX-S-205	0.81	19	630
IMGHC-TX-S-265	0.94	21	630
IMGHC-LS-S-205	0.50	13	580
IMGHC-LS-S-305	0.47	15	630
IMGHC-LS-H-350	0.50	15	718
IMGHC-LS-H-350	0.63	20	750
IMGHC-TX-H-430	0.98	20	571
IMGHC-LS-H-430	0.70	21	662

Note: the requirement is that the elongation shall exceed 450%
There are no requirements on the force at break or thickness

The length of the dumbbells before and after extension to 300% was 75.0+/-0.5 mm indicating that the samples exhibited negligible if any tensile set, and complied with the requirement of less than 10% set described in Annex B1.3. The strength of the shell-patch junctions also exceeded the requirement of the Standard, Annex B:2.2.1.

Additional testing established that the junctions sustained a load between 12 and 16N and an elongation between 400 and 650%. The data measured from the implants is shown in Figure 2 along with information for the TX and LS series listed in the design dossier provided by the manufacturer (D1: Pg1011).

The force at break appears to be related to the thickness of the specimen.

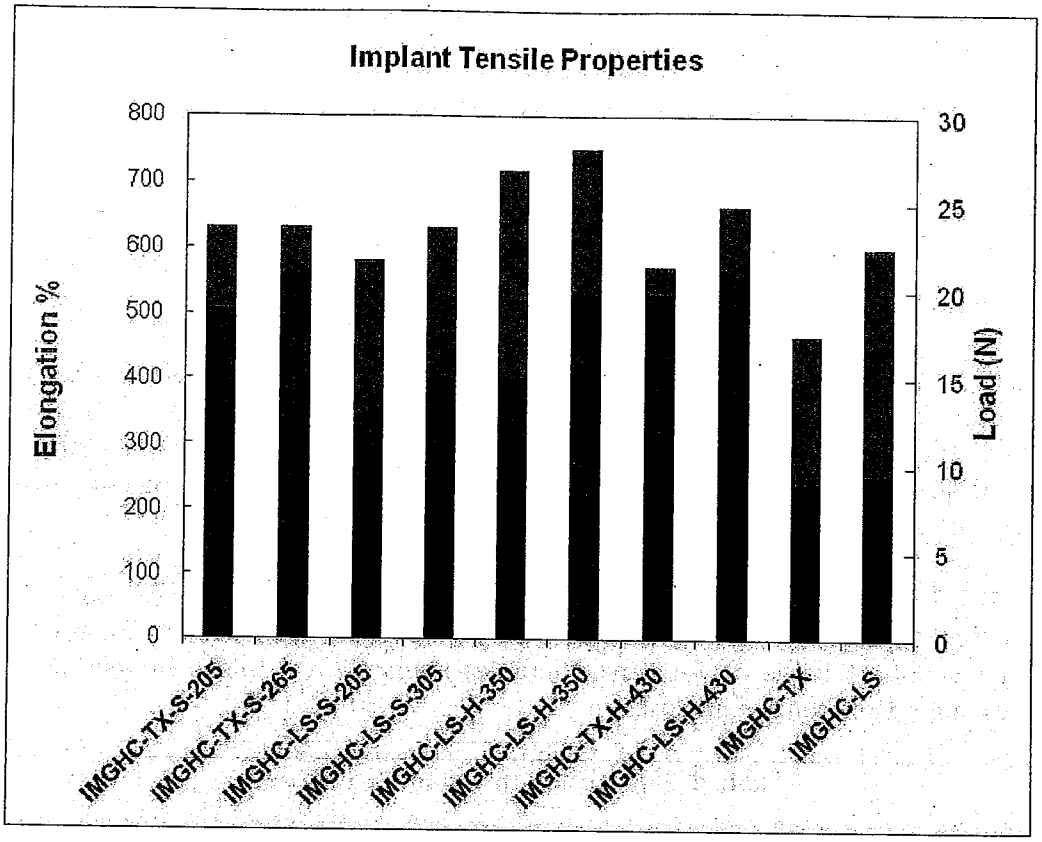

Figure 2: Tensile properties of the PIP implants

It can be seen that the tensile elongation obtained by our laboratory (first 8 bars of Figure 2) is generally higher than the specification submitted by the manufacturer for approval (last two bars if Figure 2)

Tear Resistance

The tear resistance of samples cut from four implant shells was measured using the right angle (Graves) geometry. This geometry differs from the crescent geometry specified in the standard so the results cannot be directly compared with the data supplied by PIP [redacted] Significantly, this geometry is viewed as being more sensitive to tear initiation than the crescent test.

Table 3: Tear Resistance and geometry

Model	*Supplier*	*LIMS*	*Geometry*	*Tear resistance (kN/m)*
MED-6400	PIP data		Crescent	28 to 32
IMGHC-TX-H-430	PIP	1005002024	Graves	13.3
IMGHC-LS-H-430	PIP	1005002030	Graves	16.6
[redacted]				

Gel Properties

The Results of gel cohesion tests is provided in Table 4. The following conditions must be met for the gel to pass the cohesion test:

1- The gel must not detach during the test
2- The length of material protruding through the test funnel must be less than 30 mm long.

The gels recovered from the PIP implants are strongly cohesive with no detachment and minimal drool through the orifice of the geometry in the test period. [redacted]

None of the gel materials taken from the implants detached from the cone geometry, conforming to the requirements of the standard.

[redacted]

Table 4: Gel Cohesion and extraction data

Model	*Supplier*	*Detached*	*Pendant*	*Sol fraction*	*Swell ratio*	*Mn*	*Mw*
IMGHC-TX-S-205	Pip	N	2.0				
IMGHC-TX-S-265	Pip	N	1.0				
IMGHC-LS-S-205	Pip						
IMGHC-LS-S-305	Pip	N	3.0				
IMGHC-LS-H-350	Pip	N	0.5				
IMGHC-LS-H-350	Pip	N	0.0				
IMGHC-TX-H-430	Pip	N	0.5				
IMGHC-LS-H-430	Pip	N	0.0				

[redacted]

[redacted]

Discussion/Conclusions

- The shell integrity of the PIP implants tested complies with the identified sections of ISO 14607.
- There was no trend observed based on the manufacture date of the samples.
- The elongation and force at break results results obtained by the TGA are higher than those quoted by the manufacturer in their submission to the TGA in 2004.
- The shell tear strength is lower than the data presented in the design dossier, and [redacted]. However, this appears to reflect the differences in the test conditions rather than a problem with the implants. (Samples were taken from completed implants rather than specially prepared test plaques, the thickness of the samples used for tear testing was substantially lower than the 2mm recommended for the test, and the TGA used a different test geometry to that employed by the manufacturer).
- The tear resistance measured from the prepared PIP implant appears to exceed that of another implant that is currently on the market [redacted]. This may indicate that the tear properties of the PIP implants are not unusually poor.
- The gel cohesion of all the implants exceeded the requirements required by ISO 14607:2007.
- [redacted]

Attachment 1

ISO 14607 Annex B: Tests for shell integrity

B.1.1 Sample Preparation

Unless otherwise indicated below, all test samples shall be prepared using die H2, as detailed in ISO 37. Where the implant is prefilled the silicone gel or other materials shall be removed. The tests shall include mandrel marks or orientation means if these are present on the shell. If required, propan-2-ol is recommended to aid sample cleaning.

The tests are most conveniently carried out using a commercial available tensile testing frame. In all cases, the samples shall be securely clamped at either end and then extended at a constant rate of 500mm/min

B.1.2 Elongation

Elongation shall be determined in accordance with the requirements of ISO 37
Elongation shall exceed 450%

B.1.3 Tensile Set

The test shall be carried out in accordance with the requirements of ISO 37
The sample shall be elongated to 300%, maintained at this elongation for 3 min and then relaxed to the starting position. After this the tensile set shall be a maximum of 10%

B.1.4 Tear Resistance

Tear resistance shall be determined in accordance with ISO 34-1:2004, Method C. The results shall be recorded.

B.2 Strength of joints, seams and seals

B.2.2.1 Procedure

The area of the shell adjacent to the bonded area ... shall not fail when elongated to 300% and held at this value for a period of 10s.

ISO 14607 Annex D: Test for Silicone Gel cohesion

D.4 Procedure

Allow the gel to flow unrestricted through the lower opening for 30 min
Note if any gel separates for the test volume
Measure the projection length of the gel

D.5 Requirements

The specimen gel shall meet the requirements of the test if there is no separation and projecting length of the gel is less than or equal to 30mm