TRIM R10/266567

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Investigation Report: Experiments related to the safety of PIP Implants

Executive Summary

[redacted]

The test results indicate the implants meet the requirements of the clauses tested from ISO 14607:2007 *"Non-active surgical implants - Mammary implants - Particular requirements"*. Previous testing conducted at the TGA Laboratories indicated the shell and gel materials are not cytotoxic according to the requirements of ISO 10993-5:2009 *"Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity"*.

[redacted]

Introduction

[redacted]

[redacted]

The objective of this investigation was to test the samples provided to establish the physical and mechanical properties of the implants, and to try to determine from these results whether there is an additional safety risk associated with the use of implants containing the un-approved gel. The data for the shell and gel materials is described in this report.

Testing

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	10040014199
PIP	IMGHC-LS-S-205	56206	2011-10	10040014155
PIP	IMGHC-LS-S-305	54206	2011-10	10040014144
PIP	IMGHC-LS-H-350	27909	2014-07	10040014133
PIP	IMGHC-LS-H-350	36709	2014-09	10040014122
PIP	IMGHC-TX-H-430	16609	2014-03	10050020244
PIP	IMGHC-LS-H-430	36709	2014-09	10050020300

[redacted]

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

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.

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

Experiments

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 the Type 2 dumbbell cutting die (LIMS 32134) as described 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 the Mitutoyo digital micrometer (LIMS10286). Length measurements were made using a standard rule (LIMS10001). Tensile measurements were made using the Lloyd LRX (LIMS10190) equipped with a suitable load cell 100N (LIMS10291) and the Laserscan 200 extensometer (LIMS10189).

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

[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.

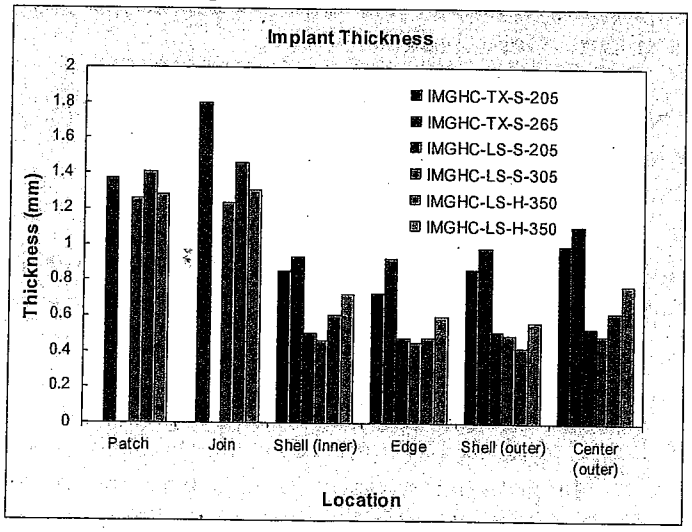

Figure 1: Thickness profiles of the PIP implants

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 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

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

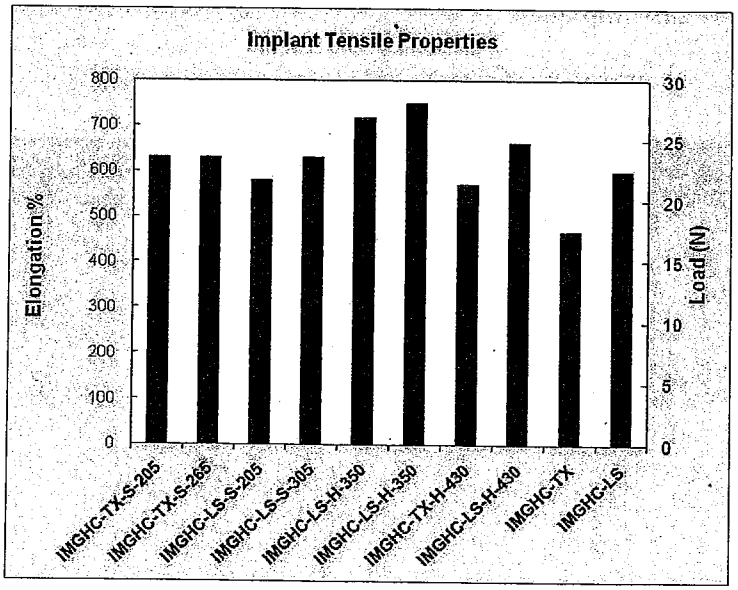

Figure 2: Tensile properties of the PIP implants

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 variation in cohesion of the gels is evident in the data shown in Table 4. The gel meets the requirements of the test if there is no detachment, and less than 30mm of material is pendant in the orifice of the geometry after 30 minutes. 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 complied with the identified sections of ISO 14607. There appeared to be an increase in the tensile properties with the thickness of the shells. There was no trend observed based on the manufacture date of the samples, however there appears to an increase in the properties compared to the data supplied by the manufacturer in the design dossier.

The measured shell tear strength is lower than the data presented in the design dossier, [redacted] This appears to reflect the differences in the test condition. In particular: samples were taken from completed implants rather than specially prepared test plaques; the thickness of the samples was substantially lower than 2mm recommended for the test; the Grave test geometry was used rather than the crescent geometry. 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]

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24 September 2010