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Long-term Study Shows Significant Influence of Implant Surface on Risk of Capsular Fibrosis in Silicone-Gel-Filled Breast Implants

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is a service offered by:

POLYTECH Health & Aesthetics GmbH
Altheimer Str. 32 • 64807 Dieburg • Germany

phone +49 (0)6071 98 63 0
fax +49 (0)6071 98 63 30

eMail: info@polytechhealth.com
www.polytech-health-aesthetics.com



Long-term Study shows Significant Influence of Implant Surface on Risk of Capsular Fibrosis in Silicone-Gel-Filled Breast Implants

by Christine Jäger, PhD, (Summary of: Neil Handel, "Long-Term Safety and Efficacy of Polyurethane Foam-Covered Breast Implants" *Aesthet Surg J* 2006; 26:265-274)

In 2006, the results of an extensive study about breast implants that had been conducted in the United States were published. The study combined the results of a 23-year observation period.

Background

For more than 40 years breast implants have been used for breast enlargement as well as for breast reconstruction. Since the end of the 1970s, MicroPolyurethane-foam-Surfaced (MPS) implants have been implanted in more than 110,000 American women. In the study, complication rates as well as the duration between implantation and reoperation and patient satisfaction were examined and compared for different implant surface types from different manufacturers.

Methods

The study covered 1,531 silicone-gel-filled implants with smooth, textured or MPS surface in 719 patients. All data of the study are based on surgical procedures carried out between 1981 and 2004 at the same center. All surgeries were performed by one of two certified plastic surgeons (Neal Handel, J. Arthur Jensen), they were executed according to standardized protocols and with the same postoperative management. Surgery indications were augmentation, breast reconstruction and secondary revision surgery. The examined characteristics were capsular fibrosis, hematoma, infection, wrinkling and waviness, implant rupture, skin rash and patient satisfaction. Data were extracted from chart reviews and a questionnaire sent to 719 patients (response rate 48%).

Results

The follow-up varied between 0 and 236 months (19.6 years) with a mean follow-up period of 37.3 months.

Capsular contracture

The capsular contracture rate, respectively the risk for capsular contracture, was determined in two ways.

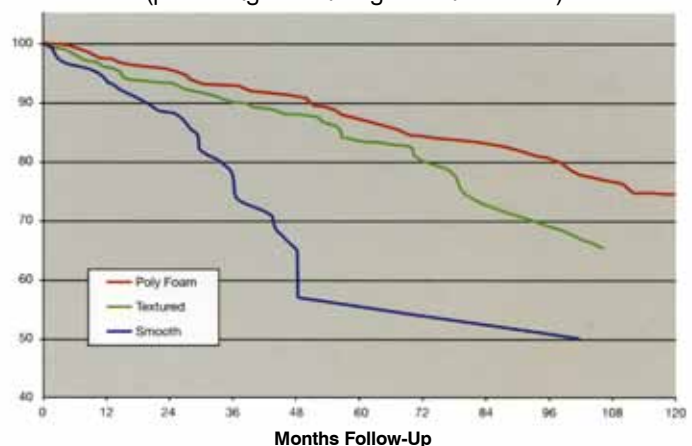
Capsular contracture (Baker III or IV) as a function per 1,000 patient months follow-up over all indications was:

- ▶ 6.29 for smooth implants;
- ▶ 3.03 for textured implants;
- ▶ 2.19 for MPS implants.

The Kaplan-Meier survival analysis confirms the significant reduction of the risk for capsular contracture with MPS implants for up to ten years after implantation.

Eight years after implantation 80% of the patients with MPS implants remain contracture free, whereas only 65% of the patients with textured implants and only 50% of patients with smooth implants are still without capsular contracture. After eight years the superiority of MPS implants to textured implants is therefore 15%, compared to smooth implants it is even 30%.

Contracture Rate
(percentage remaining contracture-free)





Implant Characteristics

| Surface Type | Augmentation (n=444) | Reconstruction (n=136) | Revision (n=949) | Unknown (n=2) | Total (n=1531) |
|------------------------|-------------------------|---------------------------|---------------------|------------------|-------------------|
| Smooth | 79 | 8 | 258 | 0 | 345 |
| Textured | 171 | 21 | 425 | 1 | 618 |
| Micropolyurethane Foam | 194 | 107 | 266 | 1 | 568 |

Hematoma, infection, implant-shell rupture

Concerning hematoma, infection and implant-shell rupture, there appeared no significant differences between smooth, textured and MPS implants.

Wrinkling and waviness

A pairwise comparison demonstrated a significant difference between MPS implants and smooth or textured implants. Wrinkling was observed in fewer cases with MPS implants:

- ▶ smooth implants: 12.2%
- ▶ textured implants: 12.9%
- ▶ MPS implants: 6.7%

Patient satisfaction

An overall high patient satisfaction was observed, with a mean satisfaction score of 4.1 (scale 1 to 5). No statistically significant difference between the individual surface types were established.

Duration until reoperation after implantation

For patients with smooth implants, the average duration until reoperation was 19.5 months, for patients with textured implants it was 27.2 months. This difference is not significant.

Definitely longer and statistically significant is the duration until reoperation in patients with MPS implants, which was 47.8 months on average. As capsular contracture is the major reason for reoperation,* the longer period until reoperation for MPS implants is probably due to the reduced risk for capsular contracture with these implants.

Conclusions

Compared to smooth and textured silicone-gel-filled implants, the risk for capsular contracture in augmentation, breast reconstruction and also in secondary revision surgeries is reduced for Micro-

Polyurethane-foam-Surfaced silicone-gel-filled implants. This advantage lasts for up to 10 years after implantation. MicroPolyurethane-foam-Surfaced implants show measurable advantages compared to smooth and textured silicone-gel-filled implants and bear no increased risk for complications.

Executive Summary

- ▶ The study includes results from an observation period of 23 years and surgeries performed by two surgeons according to standardised protocols at one center.
- ▶ Included were 1,531 silicone gel-filled implants with different surfaces (smooth, textured, Micro-Polyurethane-foam-Surfaced) in 719 patients. Indications were augmentation, breast reconstruction and secondary revision surgery.
- ▶ For the examined characteristics of hematoma, infection and implant-shell rupture, no differences between smooth, textured and MPS implants were observed.
- ▶ A high overall patient satisfaction with no differences between implant surfaces was established.
- ▶ Due to the reduced risk for capsular contracture in patients with MPS implants, the duration until reoperation is significantly longer with these implants.
- ▶ Compared to smooth and textured silicone gel-filled implants, the risk for capsular contracture with MPS implants is drastically reduced. After 8 years, the capsular-contracture rate with MPS implants compared to textured implants is 15% lower, compared to smooth implants it is even 30% lower.

Patients with MPS implants enjoy a better protection against capsular contracture and on average they have a longer distance until reoperation.

*Handel, N.; Cordray, T.; Gutierrez, J.; Jensen, J.A.: A Long-Term Study of Outcomes, Complications, and Patient Satisfaction with Breast Implants. *Plast. Reconstr. Surg.* 117: 757, 2006



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