



Information on reconstructive and aesthetic plastic surgery

Issue 01/2018

3 New Studies on Microthane® Implants in Breast Surgery



POLYTECHinformed® is a service offered by:

POLYTECH informed®



3 New Studies on Microthane® Implants in Breast Surgery

This type of implant is characterised by being covered with an additional coating of polyurethane foam (PU). Microthane® implants belong to the new generation of implants coated with PU, which have been on the market since the early 1960s. Today, they are produced exclusively in Germany by POLYTECH Health & Aesthetics located in Dieburg (Hesse).



Primary augmentation with Microthane® implants:
Long-term study finds low capsular
contracture rates, high level of overall
tolerability and sustainable aesthetic results

In the November 2016 issue of the Aesthetic Surgery Journal the results of the first long-term study on primary augmentation with Microthane® implants¹ were published. Due to the proven high level of tolerability of this implant, risky and cost intensive reoperations as a result of capsular contracture or an implant dislocation can be largely avoided.

Low rates of complications and capsular contracture in breast augmentation

The study was carried out in Italy under the direction of Professor Stefano Pompei and refers to 255 Microthane® breast implants and 131 patients, who have been examined at regular intervals during an average postoperative follow-up period of nine years. The findings show that the long-term rate of capsular contracture with Microthane® implants is very low and, generally, these implants produce very small complication rates. In fact, during the long-term study only three recorded incidences of capsular contracture (Baker grad III or IV) occurred, corresponding to a complication rate of 1.2%. A capsular contracture with no other complications was observed in only one patient. Furthermore the study demonstrated that the surface of these implants is highly adhesive to the surrounding tissues, and once positioned, they never changed position.

Expert opinion: very good overall tolerability and stable aesthetic results

Experts with long-time practical experience confirm the results of the study: "For the past three years, we have almost exclusively used Microthane® implants for primary augmentation", reports Dr. Dr. Andreas Dorow, founder of the Dorow Clinic in Waldshut and Lörrach (Germany). "On the one hand, the capsular contracture rate is, in our experience, indeed lower than observable with other implant types. On the other hand, we can rule out complications due to implant rotation or dislocation", explains Dr. Dorow.

Dr. med. Olaf Kauder, plastic and aesthetic surgeon in Berlin (Germany), also confirms: "Thanks to the special positional stability of the Microthane® implants, I can achieve an aesthetically optimal and above all a

POLYTECH informed®



sustainably safe result with my patients. In combination with a demonstrably lower capsular contracture rate, these implants are the first choice for me and they are the ones I have used almost exclusively in my practice for the past three years for every breast augmentation", concludes Kauder.

Breast reconstruction with Microthane® implants: Long-term study finds markedly reduced capsular contracture rates in patients with and without radiation therapy

One of the most common complications in breast reconstruction with silicone implants, in particular after radiation therapy, is the formation of a capsular contracture, which in most cases leads to implant exchange surgery. Using Microthane® implants can notably reduce the risk of this complication. This is demonstrated by the results of the first long-term study worldwide on two-stage breast reconstruction with Microthane® implants, which were published in the Aesthetic Surgery Journal². In many cases, the use of these implants will protect patients from sometimes risky and cost intensive reoperations.

Average long-term cumulative capsular contracture rate of 8.1%

The study was carried out in Italy under the direction of Professor Stefano Pompei and refers to 155 Microthane® breast implants and 92 patients, who were examined at regular intervals during a median postoperative follow-up period of 8,46 years, after two-stage breast reconstruction. The findings show that Microthane® implants reduced the risk of capsular contracture significantly for patients treated with or without accompanying radiation therapy:

During the long-term study, a mere nine patients experienced a capsular contracture (Baker grade III

or IV), which corresponds to a general complication rate of 8.1%. Six of these nine patients had undergone radiation therapy with tissue expanders; this equates to a capsular contracture risk of 10.7%, well below the post-radiation capsular contracture rate experienced by patients reconstructed with textured or smooth implants. Equally convincing is the result shown in patients who had not undergone radiation therapy; only three patients developed a capsular contracture, which corresponds to a complication rate of 5.5%. The authors advocate recommending Microthane® implants as a first choice for patients who undergo 2-stage breast reconstruction, even when radiotherapy is performed.

Expert opinion: almost no capsular contracture, despite radiation

Prof. Dr. Dr. med. Lukas Prantl, plastic and aesthetic surgeon, and Director of the Plastic Surgery Clinic at the Caritas Hospital St. Josef and University Clinic in Regensburg (Germany), explains: "Apart from using the patient's own tissue, I have now for 20 years been using this type of implant in breast reconstruction. For me – especially if patients are concerned who have to undergo radiation therapy – there is no viable alternative, as in my experience using textured or smooth implants in these cases will lead to extremely high capsular contracture rates of up to 80%. I also exclusively use Microthane® implants in reoperations, for example after serious capsular contracture, and have had excellent experience with them over the years."

Dr. Sabine Schmatloch, Chief physician at the breast centre of the Elisabeth Hospital in Kassel (Germany), strongly relies on the PU coating when treating breast cancer patients: "Microthane® breast implants, in my opinion, provide another immense benefit apart from the notably reduced capsular contracture rate: Thanks to the special surface structure, they remain exactly where they are positioned. Problems, which can arise through



POLYTECH informed®



implant rotation or dislocation, can therefore be avoided. Especially for patients who have been left with very thin skin and limited soft--tissue coverage, this is particularly advantageous and achieved by no other type of implant."

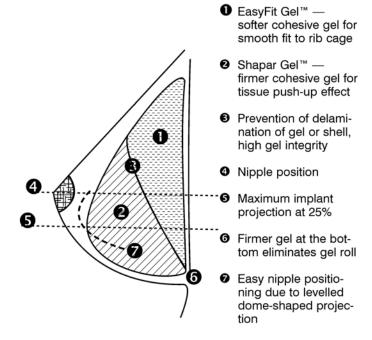
Microthane® covered DiagonGel® implants in Breast Surgery:
High level of shape stability, natural results and low complication rates

The results of the study³ on the use of DiagonGel® implants with Polyurethane foam coating (PU) in breast augmentation were published in July 2017 via the online platform "Global Open" of the renowned PRS Journal. DiagonGel® implants have an anatomical shape and are filled with two different types of silicone gel: a softer gel on the rear side and a firmer gel on the front side. The firmer Shapar Gel™ in the front part of the implant supports the tissue with a push-up effect, which ensures an aesthetically natural result. Additionally, it helps preserving the shape of the breast as well as the position of the nipple long term. The softer EasyFit Gel™ on the rear side provides a more natural movement of the breast, adhering perfectly to the ribcage. A further benefit is the special design of the implant with its spherical projection and stable caudal edges. DiagonGel® implants are exclusively manufactured by POLYTECH Health & Aesthetics in Germany.

Low rates of complications and capsular contracture

The study, which was carried out at the S Clinic in Bucharest, Romania, under the direction of Dr. Constantin Stan and Dr. Thomas Biggs, refers to around 1,800 PU coated DiagonGel® implants and 894 patients, who were examined at regular intervals during a postoperative follow-up period of more than 5 years. The findings show that DiagonGel® implants with PU coating reduce the risk of capsular contracture significantly, and generally produce low complication rates. In fact, no capsular

contracture (Baker-Grade III or IV) occurred during the study. Furthermore, no complications caused by implant rotation or dislocation were documented. Also, the amount of late seromas – two cases after three years – is well below average, with no pathological sign of ALCL (Anaplastic Large Cell Lymphoma).



Expert opinion: very high level of overall tolerability and stable aesthetic results

"I work almost exclusively with this type of implant, both in primary augmentation and in reoperations. On the one hand, I can completely avoid complications caused by the occurrence of implant rotation or dislocation. On the other hand, capsular contracture develops, in my experience, indeed less frequently than with other types of implants," explains Dr. Hans-Peter Heckel, plastic and aesthetic surgeon in Bayreuth (Germany). "Moreover, the long-term shape stability, provided by the differing silicone gel's consistencies and the special anatomical shape, is markedly better than that of other implant types," concludes Heckel.

11.2.23 2018-01 © Copyright POLYTECH Health & Aesthetics, Germany M1102023





Combined implant breast lift mastopexy in cases of pseudo ptosis

"With patients exhibiting slight ptosis, i.e. grade 1 or 2, I have had very good experience with PU-coated DiagonGel® implants. When the implants are combined with a so-called internal lifting, during which the mammary

parenchyma are fixed and the implant positioned under the muscle, then an additional lifting operation can be dispensed with in most cases", finishes Heckel. This "multi-plane technique", developed by the study director Dr. Constantin Stan, means that additional scars, which would occur in the course of a breast lift, can be avoided.

EXPERTS

Study 1:

- **Dr. Dr. Andreas Dorow** is the founder and director of the Dorow-Clinic in Waldshut and Lörrach, Germany. Has been active in the fields of plastic aesthetic surgery for over ten years with a focus on aesthetic breast surgery.
- **Dr. med. Olaf Kauder** is a plastic and aesthetic surgeon with his own practice in Berlin, Germany, since 2003. Dr. Kauder is specialised in aesthetic breast surgery.

Study 2:

- **Prof. Dr. med. Lukas Prantl** as a aesthetic and reconstructive plastic surgeon as well as hand surgery specialist, has been appointed professor for plastic surgery in 2010 as well as head of the University Centre for plastic and aesthetic, hand and reconstructive surgery at the University Clinic Regensburg and Caritas Hospital St. Josef in Regensburg, Germany. Prof. Prantl has been researching tissue tolerance of implants and the formation of capsular fibrosis for more than 15 years.
- **Dr. med. Sabine Schmatloch** is a specialist for gynaecology and obstetrics, focussing on senology. She has been working for the breast centre at the Elisabeth Hospital in Kassel, Germany, since 2012, first as Senior Physician and promoted to Chief Physician in 2015.

Study 3:

Dr. med Hans-Peter Heckel is a plastic and aesthetic surgeon and established his own practice in Bayreuth, Germany, in 2005. Before, he was employed at the Dr. Erler Clinics in Nuremberg. Since 2012, Dr. Heckel has also been performing surgery at the New Birkdale Clinic in Liverpool, UK, and the Camusclinic in Nuremberg, Germany.

REFERENCES

- Pompei, Stefano, et al: The Modern Polyurethane-Coated Implant in Breast Augmentation: Long-Term Clinical Experience. Aesthetic Surgery Journal, Volume 36, Issue 10, 1 November 2016, Pages 1124–1129, https://doi.org/10.1093/asj/sjw171
- Pompei, Stefano, et al: Polyurethane Implants in 2-Stage Breast Reconstruction: 9-Year Clinical Experience. Aesthetic Surgery Journal, Volume 37, Issue 2, 1 February 2017, Pages 171–176, https://doi.org/10.1093/asj/sjw183
- Stan, Constantin / Biggs, Thomas: The Diagon/Gel Implant: A Preliminary Report of 894 Cases. Plastic Reconstructive Surgery Global Open, 2017 Jul; 5(7): e1393. Published online 2017 Jul 5. doi: 10.1097/GOX.000000000001393







@polytechhealth







POLYTECH Health & Aesthetics

Altheimer Str. 32 | 64807 Dieburg | Germany © 0049.6071.98630 | 🖶 0049.6071.986330 w info@polytechhealth.com | www.polytechhealth.com