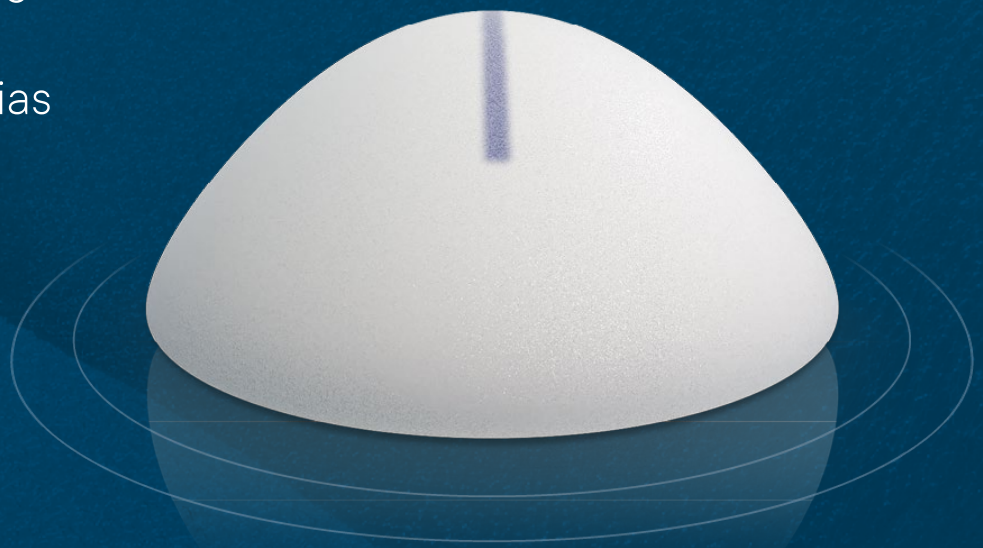

JOIN
Microthane®
IN SCIENCES
POLYTECH
Made in Germany

Reliable and rigorous clinical research

CLINICAL RESEARCH

- Conducted by leading surgeons in the field of Breast Surgery
- Journal publications with rigorous peer review and editorial scrutiny
- Scientific accuracy and relevance with statistical significance
- Publications with level of evidence up to II, with less risk of bias
- Patients groups up to 894 [21]
- Median follow-up: up to avg. 103,3 months [11]



Find out the compilation of publications at MyPOLYTECH

2015

BRUNNERT [20]

Authors observation:

- **No serious complications needing explantation, no capsular fibrosis, implant rotation or rupture**
- **Only 4 minor complications (Complication rate: 1.97%)**

Prospective study
Level of Evidence: III
N° of patients: 90 (152 breasts)
Median follow-up: 41 months
DGPW

2016

POMPEI et al.[10]

1,2% CC rate

Retrospective study
Level of Evidence: III
N° of patients: 131 (255 breasts)
Median follow-up: avg. 110 mos
Statiscal relevance: significant; P < .05
Aesthetic Surgery Journal

2017

POMPEI et al.[11]

Lower cumulative incidence of CC following 2-stage breast reconstruction, even when radiotherapy is performed

Retrospective study
Level of Evidence: III
N° of patients: 92 (115 breasts)
Median follow-up:
avg. 103,3 mos
Aesthetic Surgery Journal

STAN, BIGGS [21]

Patient's satisfaction was estimated on a scale from 1 to 5. At the end of the observation period, 90% of patients under constant control revealed to be either satisfied or extremely satisfied with the outcomes (levels of satisfaction that ranged from 4 to 5).

Retrospective case series
N° of patients: 894
Follow-up: 1 – 4 yrs
Plastic and Reconstructive Surgery

2020

LORETI et al.[12]

After mastectomy and one-stage Immediate Breast Reconstruction, the use of polyurethane covered implants is associated with a lower incidence of CC compared to textured implants. This advantage is amplified several folds for patients who necessitate post mastectomy radiation therapy.

Retrospective study
Level of Evidence: III
N° of patients: 312
Median follow-up:
avg. 2 – 3 yrs
THE BREAST

2021

COYETTE et al.[23]

- **SAFE to use in prepectoral DTI**
- **STABLE without additional mechanical support**
- **Prior breast irradiation should not be considered as a contraindication to prepectoral PU device placement**

Case series report
Level of Evidence: III
N° of patients: 50
Follow-up: 1 – 4 years
JPRAS

SALGARELLO et al.[22]

At the 12-months follow-up, the mean Q-score for satisfaction with breast was 71.73 with maximum up to 88%.

Retrospective study
Level of Evidence: III
N° of patients: 70
Clinical Breast Cancer

2022

DE VITA et al.[24]

- **VERY HIGH patient satisfaction for DTI breast reconstruction**
- **Likelihood of cost effectivenes compared to ADM[27]**

Retrospective study
Level of Evidence: III
Follow-up: 6 – 42 months
N° of patients: 453
Clinical Breast Cancer

2023

CAGLI et al.[25]

The formation of less fibrotic capsule may reduce the risk of CC occurrence, particularly with Microthane® and MESMO® surfaces.

Randomized Study
Level of Evidence: III
N° of patients: 30
Statiscal relevance: significant; P < .05
Plastic and Reconstructive Surgery

Since 2015 focus on Microthane®

2023

CAGLI et al.

Randomized Study

CLINICAL RESEARCH

BREAST

Histologic and Immunohistochemical Evaluation of Human Breast Capsules Formed around Five Different Expander Surfaces

Barbara Cagli, MD, PhD[1]
Simone Carotti, MD, PhD[2]
Francesco Segreto, MD, PhD[1]
Maria Francesconi, MSc[2]
Giovanni F. Marangi, MD, PhD[1]
Stefania Tenna, MD, PhD[1]
Michele Diomedi, MD[1]
Giuseppe Perrone, MD, PhD[1]
Sergio Morini, MD, PhD[2]
Paolo Persichetti, MD, PhD[1]
Rome, Italy

Background: Polyurethane (PU) coating and implant texturization were designed to reduce the incidence of capsular contracture (CC), even if the link between surface type and CC remains unclear. To date, the etiopathogenetic aspects have not been fully clarified. The aim of this study was to evaluate capsules formed around five different breast expanders.
Methods: Thirty patients were divided into randomized groups implanted with five different expanders: smooth, coated with PU foam (poly), with a low-microtextured, high-microtextured, and macrotextured surface (L-micro, H-micro, macro). Specimens of the capsules were removed at implant reconstruction and evaluated for morphology and immunohistochemistry expression of α-smooth muscle actin (α-SMA), collagen type I and III, CD68, CD34, and CD3. Remodeling Combined Index was also evaluated.
Results: Expression of α-SMA was significantly increased in smooth capsules versus poly, low-microtextured, and high-microtextured groups ($P = 0.007$; $P = 0.010$; $P = 0.028$), whereas the prevalence of collagen type I in smooth capsules and collagen type III in poly capsules identified a stable versus an unstable tissue. Remodeling Combined Index and α-SMA showed an inverted correlation. CD68 and CD34 cellular expression increased significantly in poly capsules with respect to smooth ($P < 0.001$; $P < 0.001$) and macrotextured groups ($P < 0.001$; $P < 0.001$). CD3 showed no significant difference among the groups.
Conclusion: In this human study, the authors observed that increased tissue remodeling and reduced myofibroblast activation, along with the inflammatory infiltration and neoangiogenesis, especially in the poly and low-microtextured groups, might promote the formation of an unstable and less fibrotic capsule, lowering the risk of CC. (*Plast. Reconstr. Surg.* 152: 388e, 2023.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

THERAPEUTIC

Microthane®
IN SCIENCES

BRUNNERT

Authors observations:

- No serious complications needing explanation, no capsular fibrosis, implant rotation or rupture
- Only 4 minor complication rate (1.97%)

N° of patients:

90 (152 breasts)

Median follow-up:

41 months

Publisher:

DGPW

2015

Brunnert KE. The micropolyurethane foam-coated Diagon|Gel®4Two implant in aesthetic and reconstructive breast surgery - 3-year results of an ongoing study. GMS Interdiscip Plast Reconstr Surg DGPW. 2015 Dec 21;4:Doc20. doi: 10.3205/iprs000079. PMID: 26713264; PMCID: PMC4686800.

POLYTECH

Microthane®
IN SCIENCES

POMPEI et al.

Authors findings:

- ⌖1,2% Capsular Contraction Rate
- ⌖P < 0.5 Statically Significance

N° of patients:

113 (255 breasts)

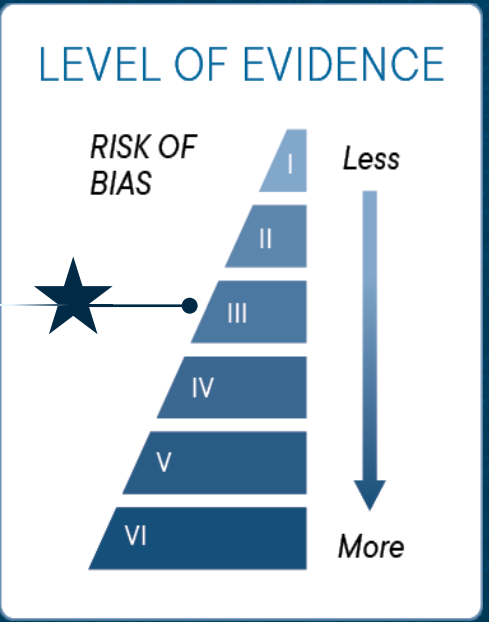
Median follow-up:

Avg. 110 months

Retrospective Study

Publisher:

Aesthetic Surgery Journal



2016 *Pompei S et al. Aesthet Surg J. 2016 Nov;36(10):1124-1129. doi: 10.1093/asj/sjw171. PMID: 27677825.*

POLYTECH

Microthane®
IN SCIENCES

POMPEI et al.

N° of patients:

92 (115 breasts)

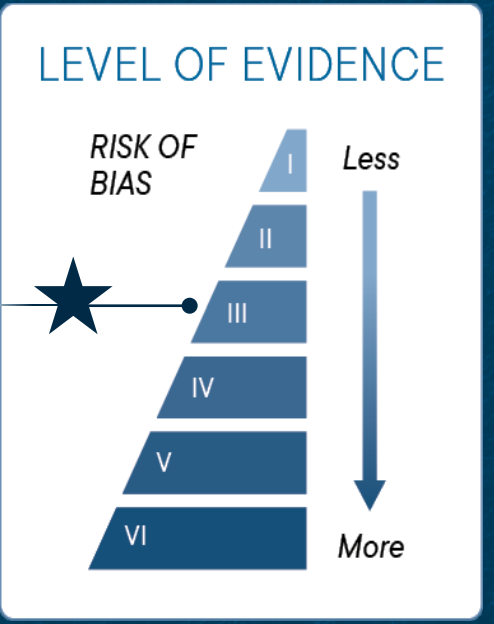
Follow-up:

Avg. 103.3 months

Retrospective Study

Publisher:

Aesthetic Surgery Journal



Authors findings:

- Lower cumulative incidence of CC following 2-stage breast reconstruction, even when radiotherapy is performed

2017 *Pompei S et al. Aesthet Surg J. 2017 Feb;37(2):171-176. doi: 10.1093/asj/sjw183. PMID: 27940908.*

POLYTECH

Microthane®
IN SCIENCES

STAN, BIGGS

Authors findings:

- Patient's satisfaction was estimated on a scale from 1 to 5. At the end of the observation period, 90% of patients under constant control revealed to be either satisfied or extremely satisfied with the outcomes (levels of satisfaction that ranged from 4 to 5).

N° of patients:

894

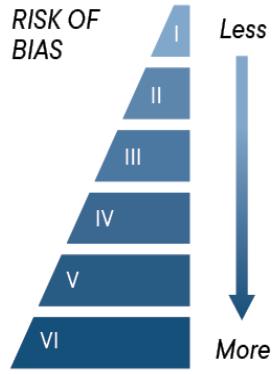
Follow-up:

4-5 years

Publisher:

Plastic and Reconstructive Surgery

LEVEL OF EVIDENCE



2017

Stan C, Biggs T. The Diagon/Gel Implant: A Preliminary Report of 894 Cases. Plast Reconstr Surg Glob Open. 2017 Jul 5;5(7):e1393. doi: 10.1097/GOX.0000000000001393. PMID: 28831340; PMCID: PMC5548563

POLYTECH

Microthane®
IN SCIENCES

LORETI et al. 1

Authors findings:

- After mastectomy and one-stage Immediate Breast Recon., the use of PU covered implants is associated with a lower incidence of CC compared to textured implants. This advantage is amplified several folds for patients who necessitate post mastectomy radiation therapy.

N° of patients:

312

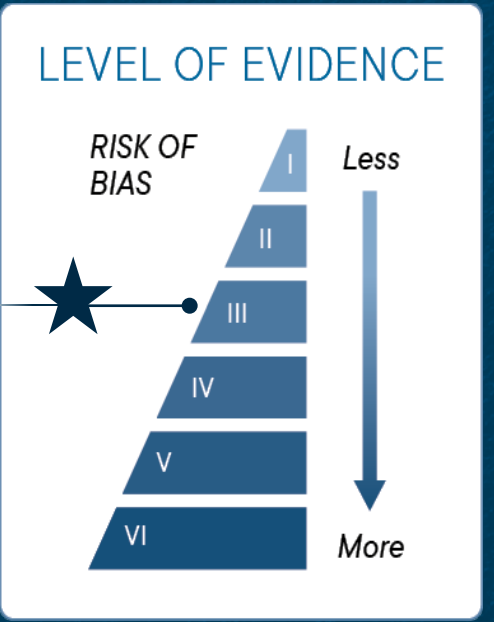
Follow-up:

Avg. 2-3 years

Retrospective Study

Publisher:

THE BREAST



2020 *Loreti A et al. Breast. 2020 Apr;50:1-7. doi: 10.1016/j.breast.2020.01.008. Epub 2020 Jan 22. PMID: 32062351*

POLYTECH

Microthane®
IN SCIENCES

COYETTE et al.

Authors findings:

- SAFE to use in prepectoral DTI
- STABLE without additional mechanical support
- Prior breast irradiation should not be considered as a contraindication to prepectoral PU device placement

N° of patients:

50

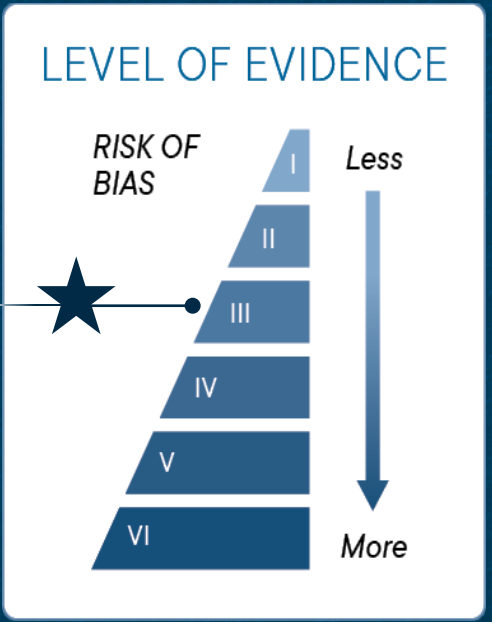
Follow-up:

1-4 years

Case series report

Publisher:

JPRS



2021

Coyette M, Coulie J, Lentini A, Gerdom A, Lengelé B. Prepectoral immediate breast reconstruction with polyurethane foam-coated implants: Feasibility and early results in risk-reducing and therapeutic mastectomies. J Plast Reconstr Aesthet Surg. 2021 Nov;74(11):2876-2884. doi: 10.1016/j.bjps.2021.03.077. Epub 2021 Apr 20. PMID: 34011475.

POLYTECH

Microthane®
IN SCIENCES

SALGARELLO et al.

Authors findings:

- At the 12-months follow-up,

  mean Q-score for satisfaction with 71.73

  with maximum up to 88%.

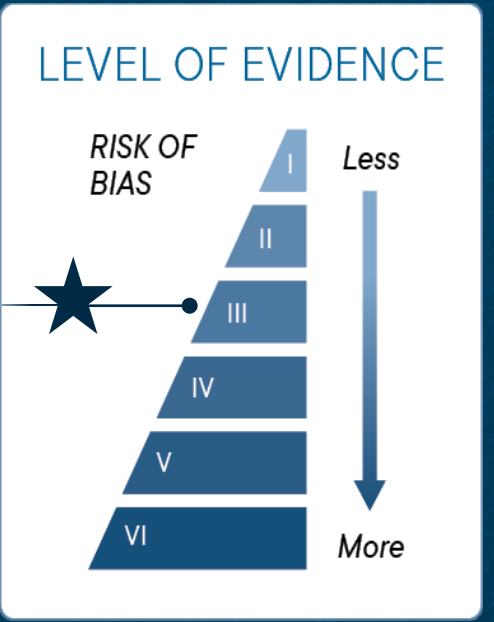
N° of patients:

70

Retrospective Study

Publisher:

Clinical Breast Cancer



2021

Salgarello M, Pagliara D, Barone Adesi L, Visconti G, Wild JB, Matey P. Direct to Implant Breast Reconstruction With Prepectoral Micropolyurethane Foam-Coated Implant: Analysis of Patient Satisfaction. Clin Breast Cancer. 2021 Aug;21(4):e454-e461. doi: 10.1016/j.clbc.2021.01.015. Epub 2021 Jan 23. PMID: 33627298.

POLYTECH

Microthane®
IN SCIENCES

DE VITA

Authors findings:

- VERY HIGH patient satisfaction for DTI breast reconstruction P < 0.5
- Likelihood of COST EFFECTIVENESS compared to ADM

N° of patients:

453

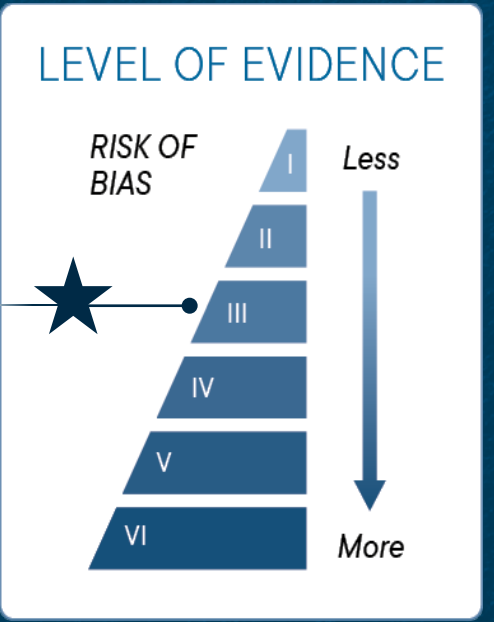
Median follow-up:

6-42 months

Retrospective Study

Publisher:

Clinical Breast Cancer



2022

De Vita R, Villanucci A, Buccheri EM, Pozzi M. Extended Clinical Experience With Nipple-Sparing Mastectomy and Prepectoral Polyurethane Implant Positioning (BRAND4P method). Clin Breast Cancer. 2022 Jul;22(5):e623-e628. doi: 10.1016/j.clbc.2022.03.005. Epub 2022 Mar 24. PMID: 35437225.

POLYTECH

Microthane®
IN SCIENCES

CAGLI et al.

Authors findings:

- The formation of less fibrotic capsule may reduce the risk of CC occurrence, particularly with Microthane® and MESMO® surfaces.

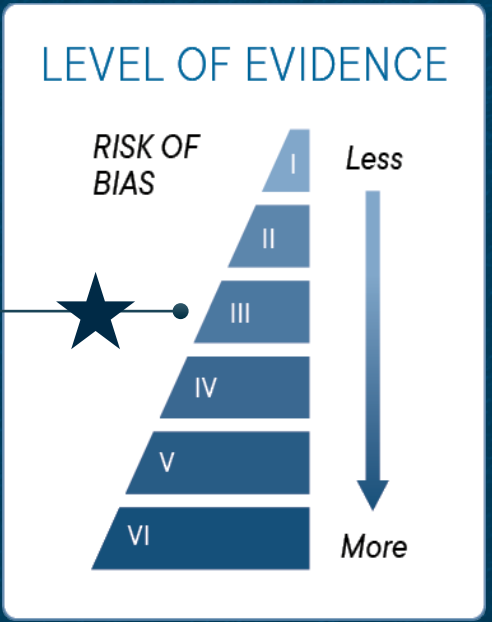
Randomized Study

Statiscal relevance:

Significant P< .05

Publisher:

Plastic and Reconstructive Surgery



2023

Cagli B, Carotti S, Segreto F, Francesconi M, Marangi GF, Tenna S, Diomedi M, Perrone G, Morini S, Persichetti P. „Histological and Immunohistochemical Evaluation of Human Breast Capsules Formed Around Five Different Expander Surfaces".
Plast Reconstr Surg. 2023 Feb 27:e010317. doi: 10.1097/PRS.0000000000010317. Epub ahead of print. PMID: 36827480.

POLYTECH

Microthane®
Indications

Primary augmentation

Revision augmentation

Reconstruction

Mastopexy augmentation

"There is no logical reason not to use polyurethane foam covered implants as **first choice** in all patients."[1]

POLYTECH

*D. Fleming,
5 - Polyurethane foam covered breast implants,
Editor(s): W. Peters, H. Brandon, K.L. Jerina, C. Wolf, V.L. Young,
In Woodhead Publishing Series in Biomaterials,
Biomaterials in Plastic Surgery, Woodhead Publishing, 2012, Pages 96-120.

Microthane®
EXPERIENCE

STABILITY • ADHERENCE • PREDICTABILITY

“They stay where they are placed”

POLYTECH