

**Over 30 years Personal Experience with
Micropolyurethane Surface (MPS) Breast Implants
in Aesthetic and Reconstructive Surgery**

**Hearing
on the SCHEER preliminary opinion
on the safety of breast implants
in relation to
anaplastic large cell lymphoma (BIA-ALCL)**



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November 2020



Nothing to disclose



Agenda

- Introduction
- Etiology of BIA-ALCL
- MPS covered implants
- Treatment
- Conclusion



Dilemma

- **BIA-ALCL is a very rare disease**
- **Etiology of BIA-ALCL is still unclear**
- **Easy to detect and with a good prognosis**
- **Malignant disease or lymphoproliferative disorder**
- **45 yrs of personal experience: not a single case of BIA-ALCL**





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Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

- **Rare disease, 3 % of Non-Hodgkin Lymphomas, 0.04-0.5 % of all malignant breast diseases**
- **Estimated incidence 0.6-1.2 / 100.000 women with implants (median age: 54 y)**
- **Mainly associated with textured implants**
- **Interval to diagnosis: 8 years (median)**
- **Clinical symptoms**
 - Swelling and seroma. (60 %)
 - Solid tumor (17 %)
 - Seroma and solid tumor (20 %)
- **Histology: CD30+ / ALK-T-Cell Lymphoma**
- **Compulsory registration as SAE (§3 MPSV to BfArM)**



BIA-ALCL – Diverging Numbers

Country		Worldwide	per Country
Germany	BfArM	800 (04.19)	30 (11.20)
USA	FDA	733* (08.20) 620 Allergan	359* registered *bilateral = 2 cases
Australia	TGA		76 (10.20)
Canada	Health Gov.	511	31** (12.19) 106 reports, incl. susp. cases



****85% Allergan biocell macrot textured**



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1995

Potential carcinogenicity sparked
by publication on
cutaneous T-Cell Lymphoma

Cutaneous T-cell lymphoma in association with silicone breast implants.

Duvic M, Moore D, Menter A, Vonderheid EC.

J Am Acad Dermatol. **1995** Jun;32(6):939-42.



BIA-ALCL

Etiopathogenetic Theories

- Distinct T-Cell-derived non-Hodgkin's Lymphoma
- Exposure to textured implants
- Clinical phenotypes:
 - small subset with a solid tumor mass and progressive disease
 - mostly delayed-onset with periprosthetic seroma
- 8-10 years following implantation, good prognosis
- T-Cells, CD 30 +, ALK (-)
- 2011 FDA approved disease entity *Rastogi P. PRS 2019;3S:23S*
- WHO 2016: provisionally classified as a malignant lymphoma



BIA-ALCL

Etiopathogenetic Theories

- **Physical particles** (e.g. silicone) are not able to induce lymphoma,
- Are not able to interact with the adaptive immune system.

Adams WP. PRS 2019;143:1293



Staging

Pathology	TNM	Stage	No.		Percentage	Mortality
			2016*	2018		
BIA-ALCL positive in fluid but negative on capsule	T1N0M0	IA (negative)	32	51	62.9	Nil
BIA-ALCL in fluid and luminal side of capsule	T1N0M0	IA (positive)	10	13	16.0	Nil
BIA-ALCL infiltrating capsule	T3N0M0	IC	6	6	7.4	Nil
Mass extending beyond capsule	T4N0M0	IIA	5	9	11.1	2
Mass with metastatic disease to one lymph node in axilla	T4N1M0	III	1	1	1.2	1
Mass with metastatic disease to multiple lymph nodes	T4N2M0	III	1	1	1.2	1

TNM, tumor-node-metastasis.

*Loch-Wilkinson A, Beath KJ, Knight RJW, et al. Breast implant-associated anaplastic large cell lymphoma in Australia and New Zealand: High-surface-area textured implants are associated with increased risk. *Plast Reconstr Surg.* 2017;140:645–654.

Magnusson M et al. PRS 143:1285 2019

Stage Ia negative: limited to seroma (84%)

Stage Ia positive: TC in the inner implant capsule



BIA-ALCL: a lymphoproliferative disease ?

- Clin. & histolog. similarities with prim. cutan. ALCL (pcALCL),
- CD30+, ALK(-), HLA-DR+, TIA-1+ patterns, SOCS3 ↑ , STAT3 ↑
- Slow rate of progression and good prognosis
- Malignant endpoint of a lymphoproliferative disease
- Lymphomatoid papulosis shows occasional spontan. regression

Rastogi P. PRS 2019;3S:23S; Fleming D. Aesth Plast Surg 2018 and 2020;44:1116;



BIA-ALCL: a lymphoproliferative disease ?

Possible driving factors

- Chronic inflammation (Gram neg. bacteria) with a greater bacterial antigen load (highly textured implants)
- Texturing of implants
- Genetic instability of an inflammatory microenvironment
- Maligne „clonal T-cells“
- Tumor promoting cytokines

Further explanations by immunophenotyping expected

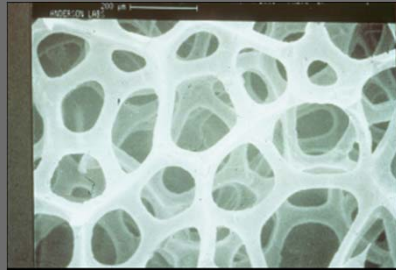


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Primary Cases up to date BIA ACL with Polytech MPS covered implants

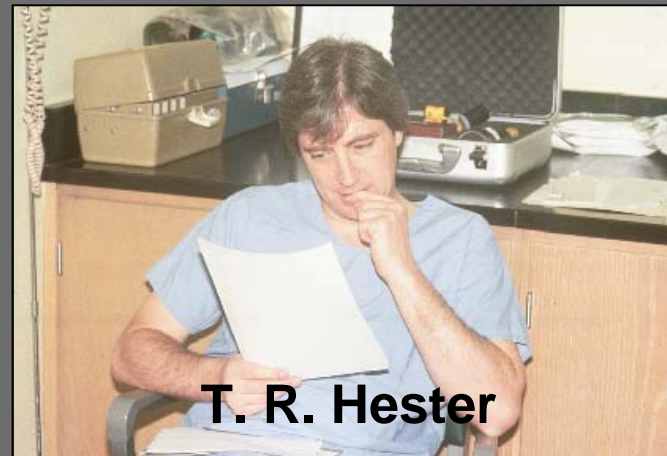
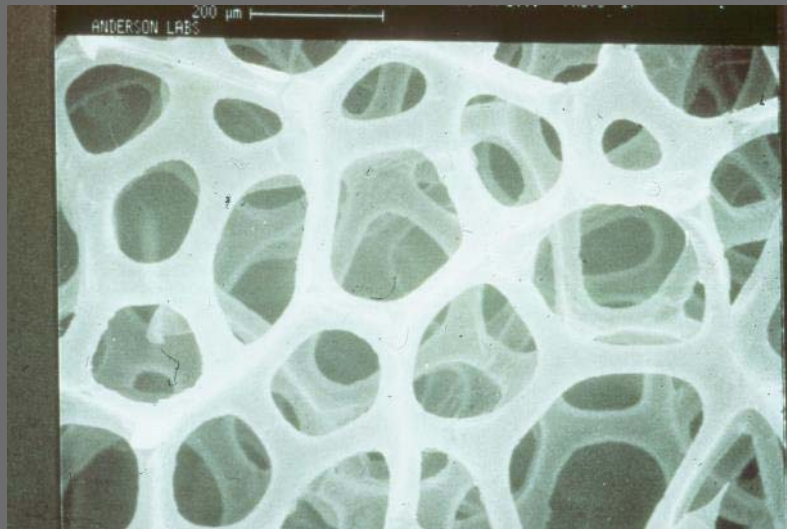
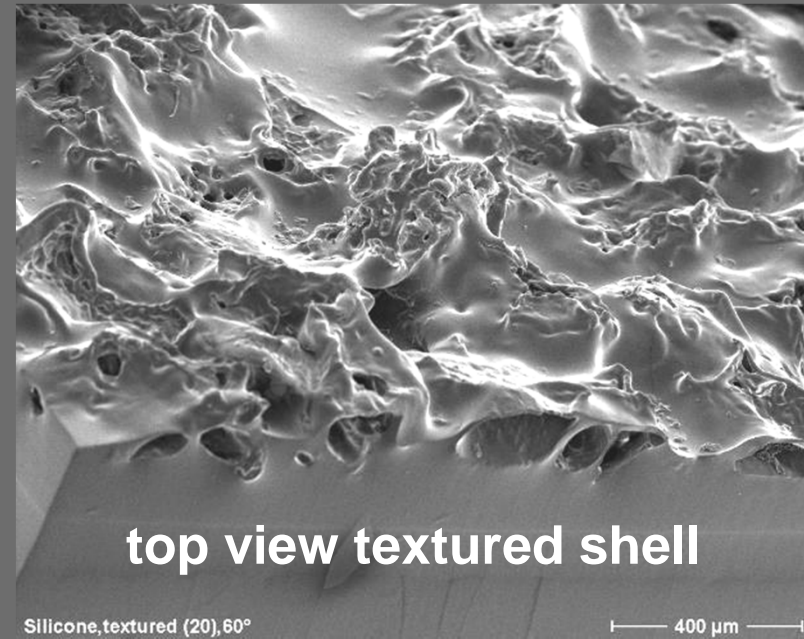
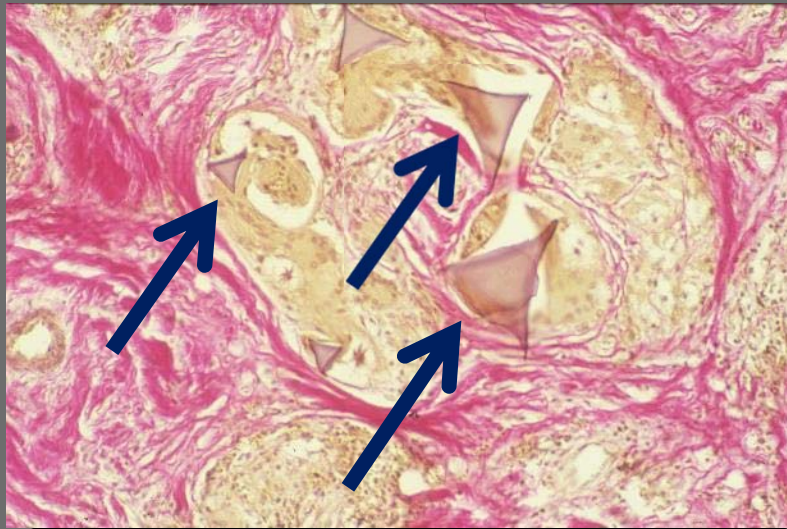


2 out of 420.000

AWOGyn Implant Registry (1991) 0 out of >60000
Personal experience with Polytech MPS implants 0/>2500



Formation of Microcapsules



T. R. Hester



Advantage of MPS-Covered Implants

- **Low rate of**
 - **Seroma and infection**
 - **Capsular contracture (even in radiated pts.)**
- **Safe positioning due to high traction coefficient and tissue ingrowth**
- **Low rupture rate**



Why incidence of BIA ALCL seems to be unlikely with Polytech MPS implants

***soft tissue integration
into the PU foam surface
(active ingrowth → excellent blood circulation)***



***decreases bacterial growth,
biodegradation,
no foam delamination***



***no dead space esp.
in augmentation***



Implantation „No“ (minimal) touch

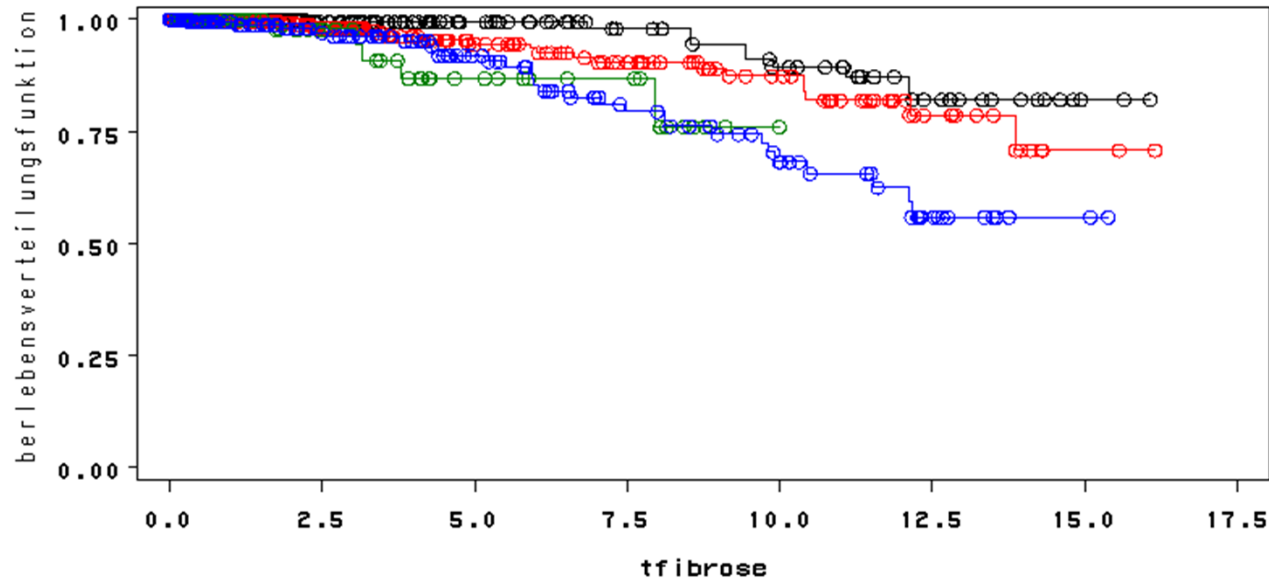
- Inframammary incision
- Nipple shield
- Irrigation with anti-infectives/antibiotics
- Change of gloves
- Handling of implant by surgeon only
- Insertion device
- No drains in primary augmentation



1988-2006 Capsular Fibrosis: 1638 MPS Implants

Liegezeiten nach Indikation bei MPS-Implantaten

3. Kaplan-Meier-Kurven fuer Liegezeiten bis zu bestimmten Komplikationen



STRATA: — Indikation=Augmentation
○ ○ ○ Censored Indikation=Augmentation
— Indikation=Implantataustausch
○ ○ ○ Censored Indikation=Implantataustausch
— Indikation=Rekonstruktion Implantat+Flap
○ ○ ○ Censored Indikation=Rekonstruktion Implantat+Flap
— Indikation=Rekonstruktion nur Implantat
○ ○ ○ Censored Indikation=Rekonstruktion nur Implantat





Personal Results PU Covered Implants*

Capsular fibrosis in relation to groups	n	%
Group 1 : Augmentation	4/378	1,1
Group 2 : Reconstruction	27/433	6,2
Group 3 : CC B III, IV(A)	5/74	6,8
Group 4 : CC B III, IV(R)	7/81	8,6
Group 5 : Other problems	6/243	2,5

Results 2002

Total 4,0 % n = 49 / 1209 breasts

1411 implants

Use of Different Implant Surface Technology

Short, moderate profile, 255 ml, 12,0x10,7x4,3 subpectoral



BIA-ALCL



20 years after implantation



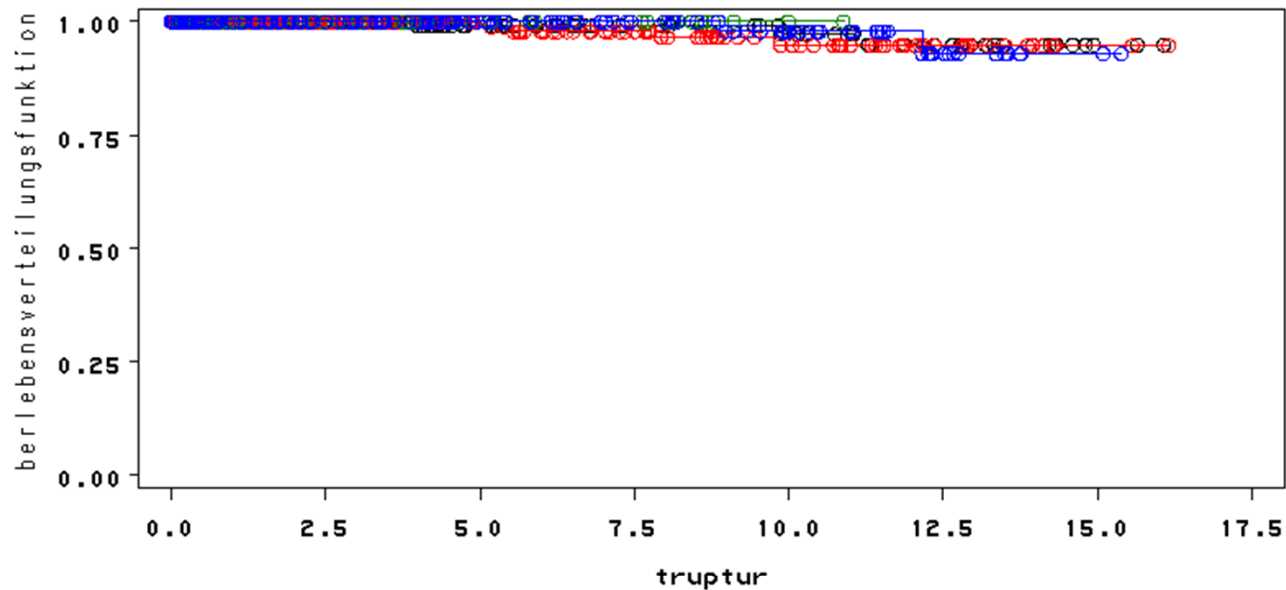
Augmentation mammoplasty with Polytech MPS Implant after 20 yrs.



1988-2006 Rupture: 1638 MPS Implants

Liegezeiten nach Indikation bei MPS-Implantaten

3. Kaplan-Meier-Kurven fuer Liegezeiten bis zu bestimmten Komplikationen



STRATA:

- Indikation=Augmentation
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- Indikation=Rekonstruktion nur Implantat
- ○ ○ Censored Indikation=Rekonstruktion nur Implantat



Imminent skin perforation/ smooth implant

Change of implant, 175 r., 160 l., MPS-covered,
small local flap



1991 Augmentation Mammoplasty with smooth implant
1993 skin perforation,
Change of Implant with Latissimus flap
135 ml, MPS covered



BIA-ALCL

Bilateral Nipple Sparing Mastectomy with MPS

Repair of skin perforation without implant exchange

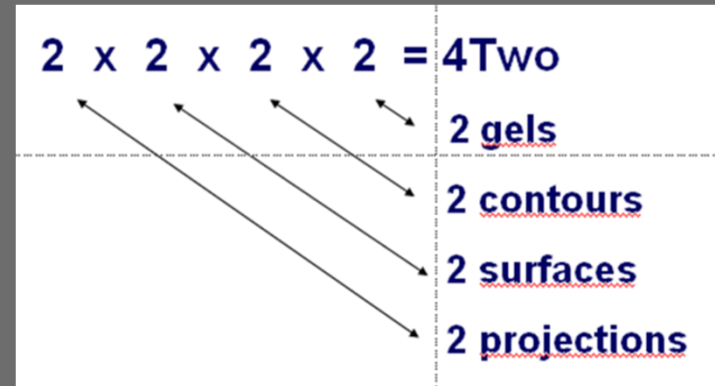
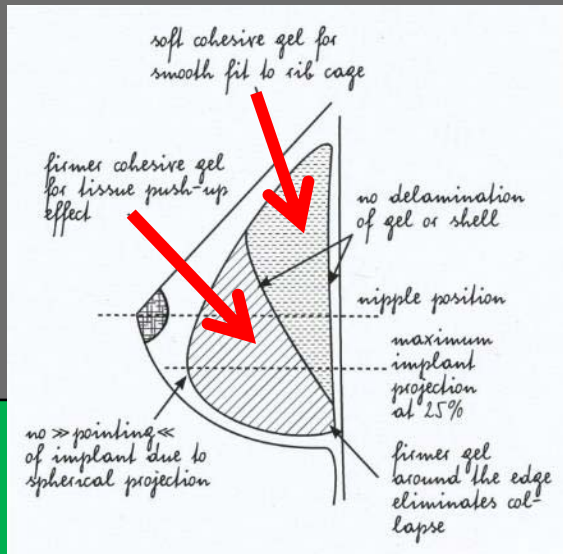
final view
preoperative



skin perforation left breast, treatment with Pico Vacuseal



4 Two Implant - MPS-Covered – DTI 2016



Implants	210	4Two	<p>Capsular Fibrosis 7,2%</p> <p>Rupture 1,4%</p> <p>Infections 0,7%</p> <p>Skin perforation 1,4%</p> <p>Total 10,9% (15/138)</p>
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Study ongoing in coop. with University of Cologne PD Dr. Eichler



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Guidelines for BIA-ALCL Provide Additional Guidance for Recognition and Diagnosis

By Hannah Slater

March 3, 2020

[Lymphoma, News](#)

Journal of Clinical Oncology *created by*
MD Anderson Cancer Center, UT
National Institutes of Health,
FDA

Symptoms: breast swelling, asymmetry
and unexplained sensation of fullness
US-guided aspiration of **fluid, minimum 10-50ml**
Cytopath. smears, **IHC CD30**, other markers,
if possible, flow cytometry and
molecular genetic studies



BIA-ALCL – Therapy



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- **Implant resection and complete capsulectomy including tumorectomy**
- **Resection of suspicious lymph nodes, no routine use of Sentinel-Node-Biopsy, no axillarx dissection**
- **Polychemotherapy (e.g. CHOP) in cases of extra capsular extension**
- **Radiotherapy in unresectable tumors**
- **Case discussion in an interdisciplinary tumor board in the presence of a specialist for lymphomas**

	Oxford		
	LoE	GR	AGO
	3a	C	++
	4	D	++
	4	D	+
	5	D	+/-
	5	D	++



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Conclusion #1 after 32yrs´ use of MPS-Covered Implants N=2587

- MPS implants have an overall low complication rate
- MPS implants are an important tool in individualized breast surgery.
- BIA-ALCL is a very rare disease with an unclear etiology, good prognosis, mostly connected with highly textured implants.
!Don´t mix up textured with MPS!



Conclusion #2 after 32yrs´ use of MPS- Covered Implants N=2587

- Incidence seems to stagnate despite intensified search.
- No case of ALCL in personal experience over 45 yrs (32yrs with MPS) and in the AWOgyn implant registry (1991-2010+)
- There must be a frequent spontaneous resolution of disease; otherwise medical history inexplicable
- Further data collection necessary





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BIA-ALCL – EUSOMA-Recommendation

- **Despite an increase of BIA-ALCL in association with texture implants the use of textured implants is still permitted!**

„For the moment, textured implants can safely continue to be used with patient's fully informed consent, and that women that have these type of implants already in place don't need to remove or substitute them, which would undoubtedly cause harm to many tens of thousands of women, to prevent an exceptionally rare, largely curable and currently poorly understood disease.“





Thank you very much for your attention!

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