

Weighing risk versus benefit of Breast implants

Standards of Care is the Gold Standard



Moustapha Hamdi, MD, PhD.
Professor & Chairman of Plastic Surgery
Co-Organizer of MRBS
Former President of Royal Belgian Society of Plastic Surgery

European Master's Degree in
surgical oncology, reconstructive
and aesthetic breast surgery

MRBS

*is mark of excellence
in breast surgery*



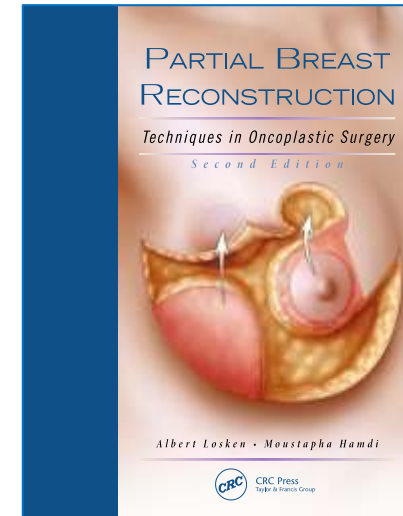
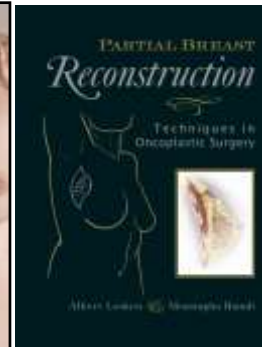
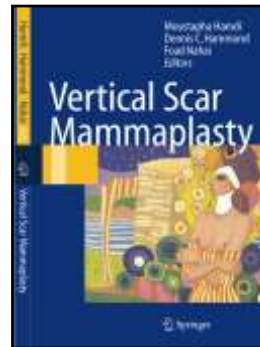
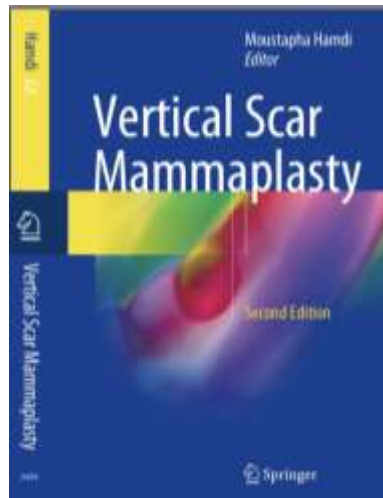
Plastic Surgery Dept-Brussels University Hospital
Delta Private Hospital - Brussels



DISCLOSURE

Consultant to Orbix , Ziess, PolyTech *

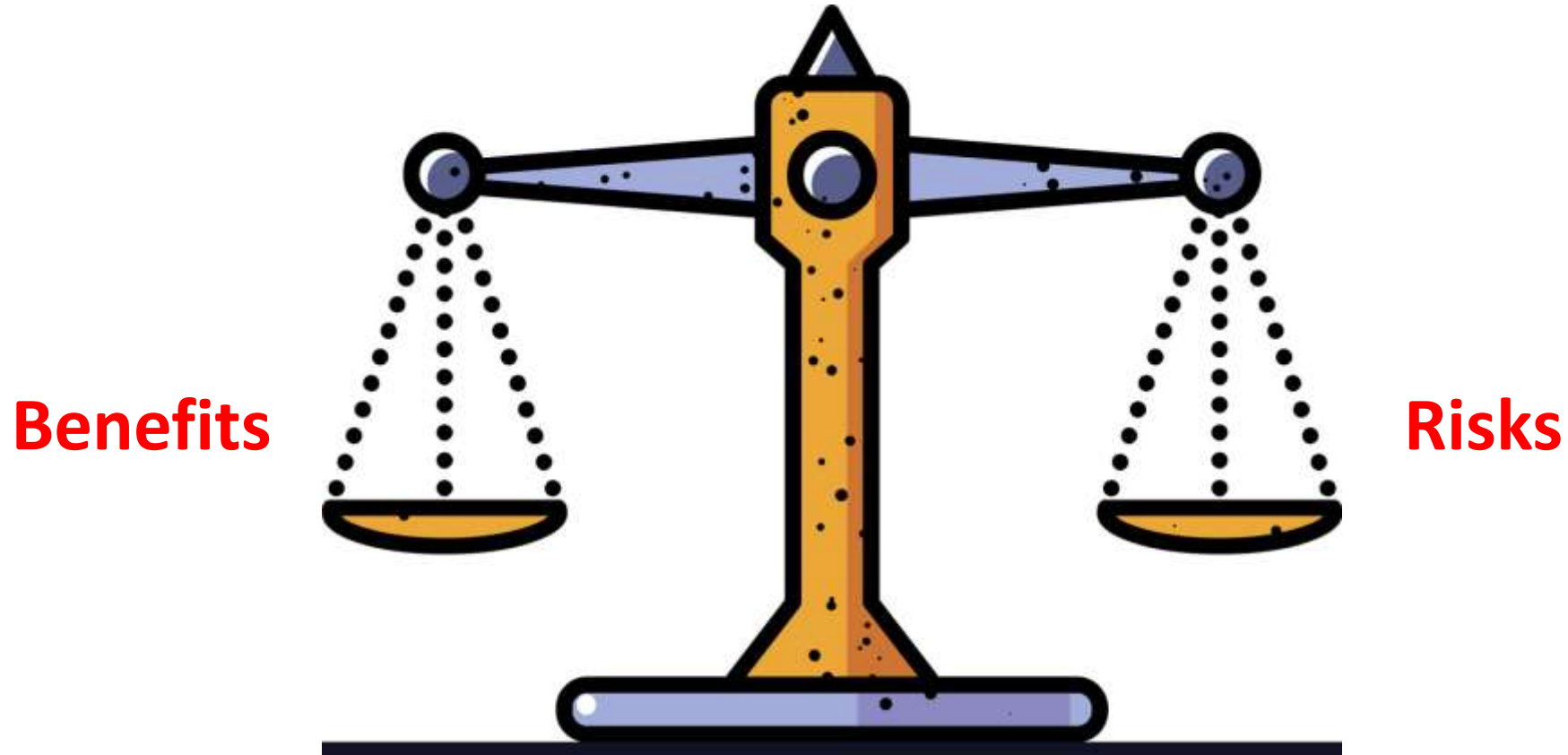
* Coverage of travel expenses for educational meetings



DISCLOSURE

- National Expert in the Belgian MoH (FAAG)
- National Expert in the Belgian Supreme Council
- National Expert for ALCL
- Member of the BIA-ALCL Global Network
- Former Member of the ALCL sub-committee in the ASPS
- National delegate for Belgium in EASAPS, ISAPS, ICOPLAST

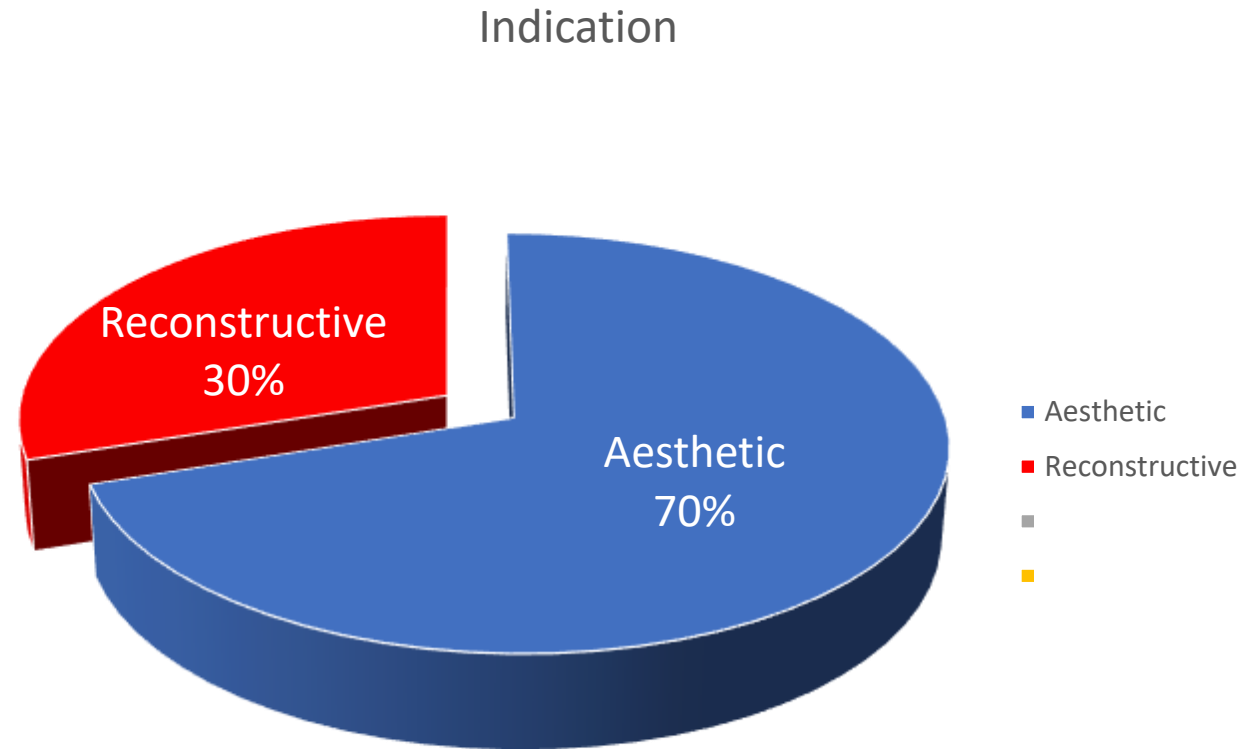
Misunderstanding and confusion!



1. We need breast implants!

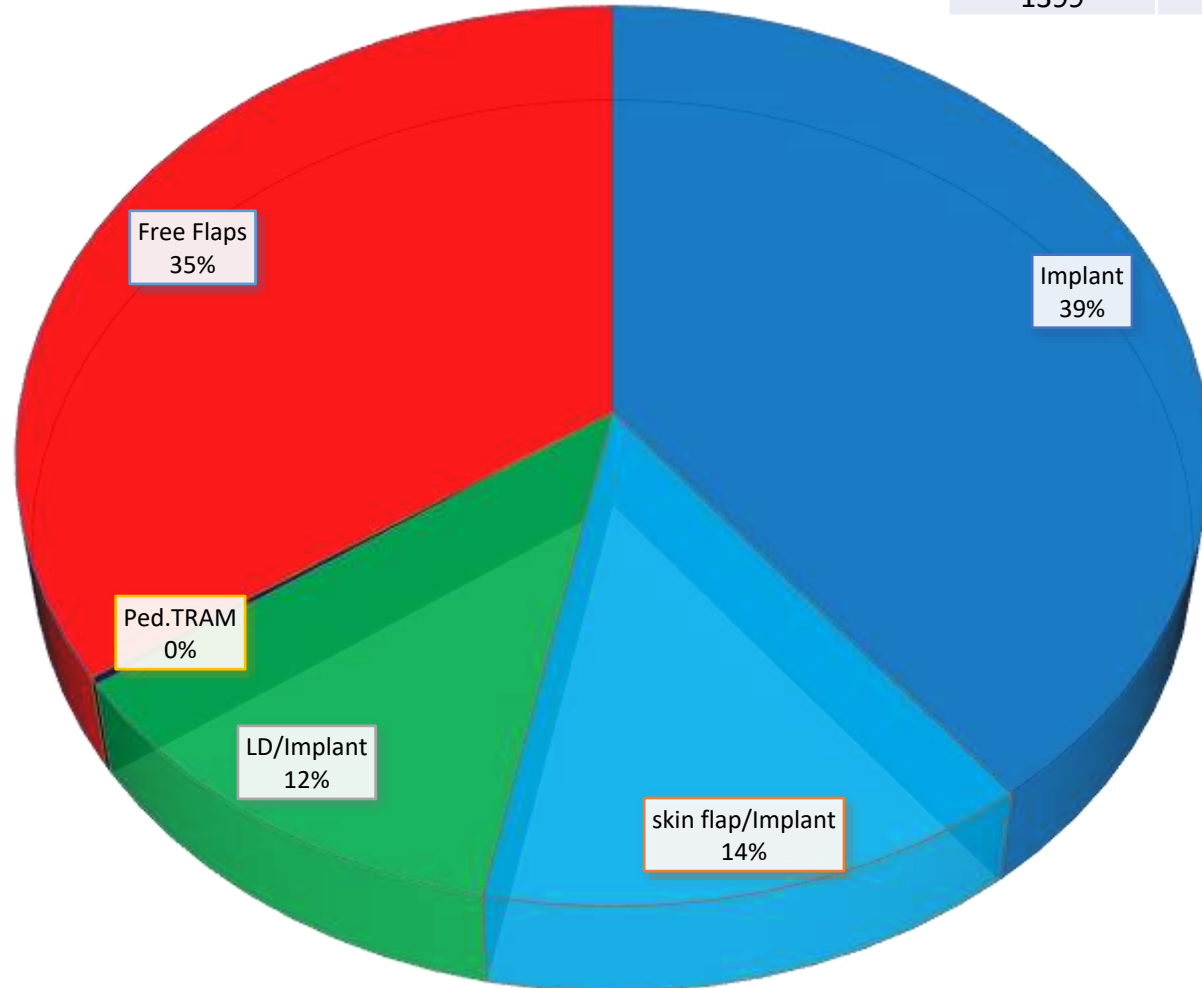
BREAST IMPLANTS

- Reconstructive surgery after breast cancer or congenital malformations
- Aesthetic surgery



Breast RECONSTRUCTION IN BELGIUM 2017

Implant	skin flap/Implant	LD/Implant	Ped.TRAM	Free Flaps	total
1399	489	430	9	1224	3551



We still need breast implants in reconstructive surgery, and much more in aesthetic surgery!

2. We need different breast implants!

Standards of Care

Implant Choice is based on clinical indications:

Tissues *versus* Issues!

Standards of Care

Attempts to reduce implant complications such as capsular contracture and revisional procedures

- Retropectoral pocket
- Textured or Polyurethan coated implants

Ideally!

Prepectoral pocket

Stable implant with least risk of capsular contracture and revisional procedures

Prepectoral pocket



prepectoral implant



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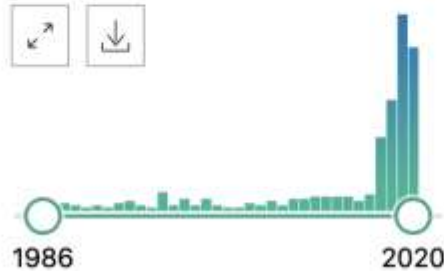
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294 results

RESULTS BY YEAR



TEXT AVAILABILITY

Abstract

Did you mean [pre pectoral implant](#) (65 results)?

[Prepectoral Implant-Based Breast Reconstruction with Postmastectomy Radiation Therapy.](#)

Cite Elswick SM, Harless CA, Bishop SN, Schleck CD, Mandrekar J, Reusche RD, Mutter RW, Boughey JC, Jacobson SR, Lemaine V.

Share [Plast Reconstr Surg. 2018 Jul;142\(1\):1-12. doi: 10.1097/PRS.0000000000004453.](#)

PMID: 29878988

Recent advances in surgical techniques and technology have made **prepectoral implant**-based breast reconstruction feasible. There are limited data on outcomes after **prepectoral implant**-based breast reconstruction and postmastectomy radiation therapy.

3. We need PU coated breast implants!

Why I still need Microthane® Breast Implants?



1. I can place the implant either *Pre-Pect* or *Retro-Pect* with the least risk of capsular contracture

Why I still need Microthane® Breast Implants?



2. a stable implant with the least revision procedures

Why I Prefer Microthane® Breast Implants?

Pre-Pect pocket

No need for ADM

Anatomical / Round Implant

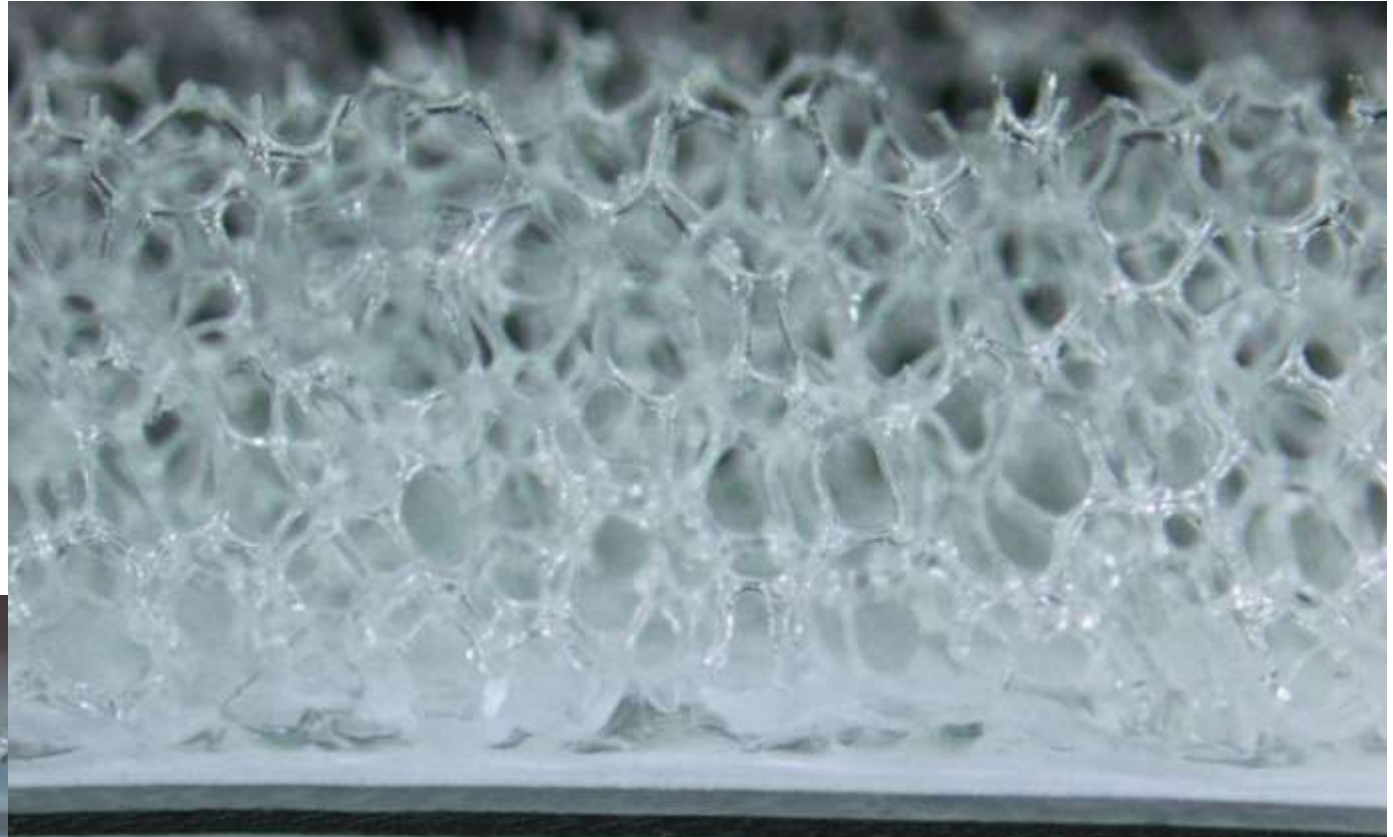
- High Aesthetic result
- High patients' satisfaction rate
- Least revision rate
- Long-term stable outcome



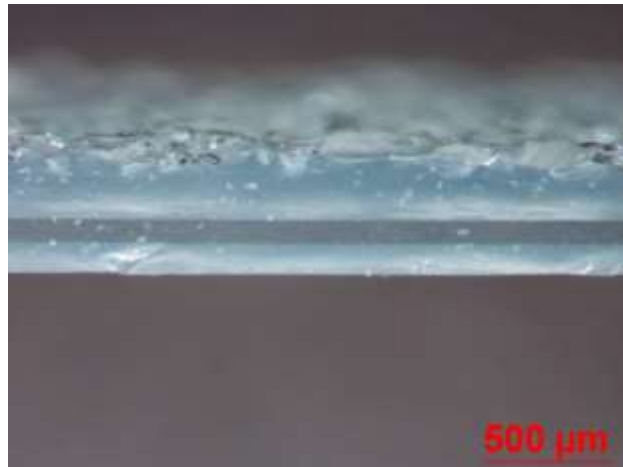
4. BIA-ALCL risk related to PU coated breast implants!

Comparing Apple to Orange:

3D PU Topology



2D Silicone Text



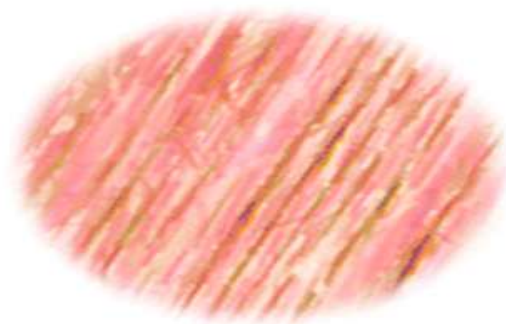
500 μm

100

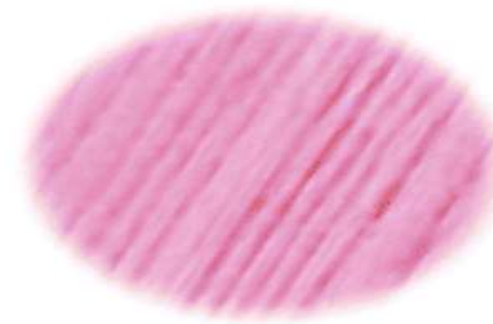
Mimicking Extracellular Matrix (ECM)

ECM Function in Native Tissue	Architectural, biological, and mechanical features of scaffolds
Provides structural support for cells to reside	Biomaterials with binding sites for cells; porous structure with interconnectivity for cell migration and for nutrients diffusion;
Contributes to the mechanical properties of tissues	Biomaterials with sufficient mechanical properties filling up the void space of the defect and simulating that of the native tissue
Provides bioactive cues for cells to respond to their microenvironment	Biological cues such as cell-adhesive binding sites; physical cues such as surface topography
Acts as the reservoirs of growth factors and potentiates their actions	Microstructures and other matrix factors retaining bioactive agents in scaffold
Provides a flexible physical environment to allow remodeling in response to tissue dynamic processes such as wound healing	Porous microstructures for nutrients and metabolites diffusion

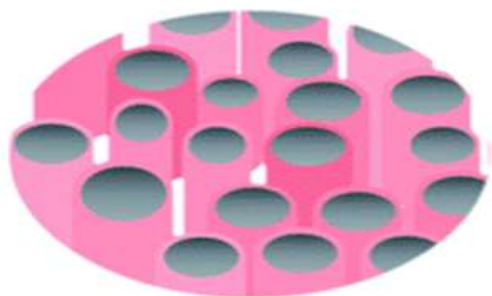
Skeletal muscle



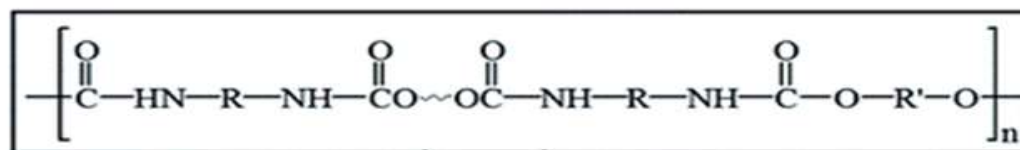
Heart muscle



Nerve

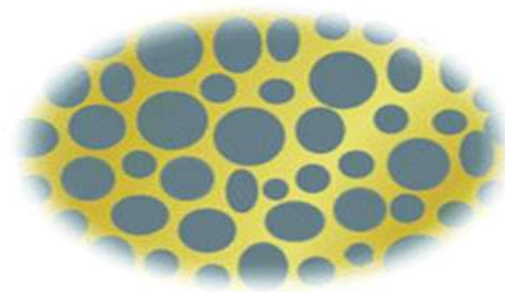


POLYURETHANE SCAFFOLDS

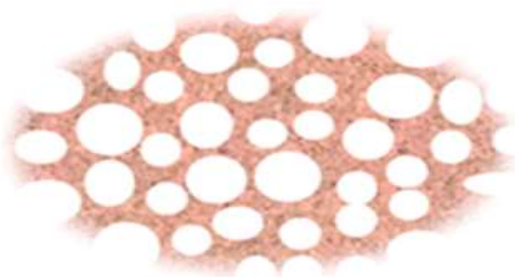


Blood vessel

Cartilage



Bone



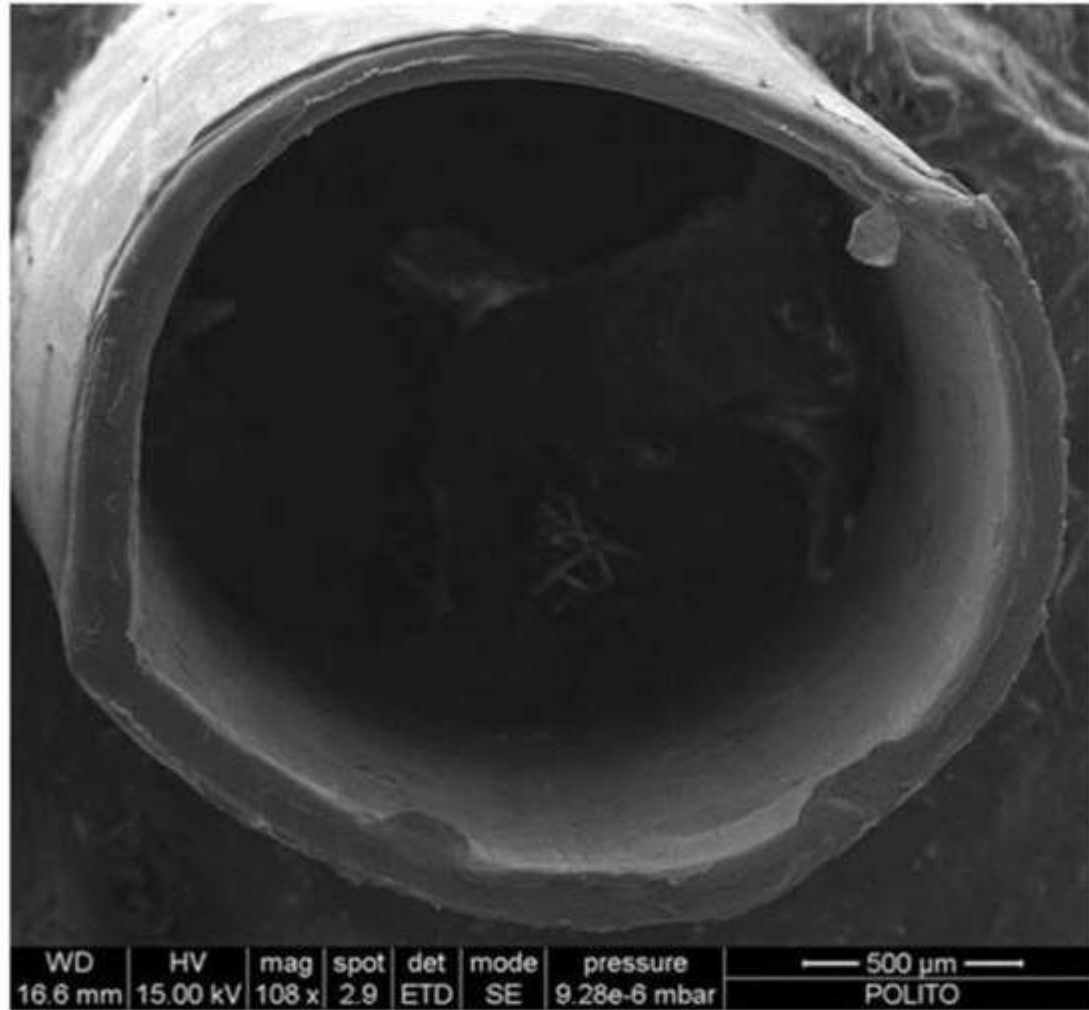


Figure 9. SEM images of a fractured section of a PU guide. Nerve guide was produced by melt-extrusion from a biocompatible novel polymer: a synthesized poly(ester urethane) having PCL as macrodiol and two commercial molecules as chain extender and linker (CDM and HDI, respectively).

Pathology BIA-ALCL

Surface versus Infection versus Genetics

Chronique Inflammation:

proliferation and oncogenic mutation of **T cells (STAT3 pathway)**

Pathophysiology: *hypotheses*

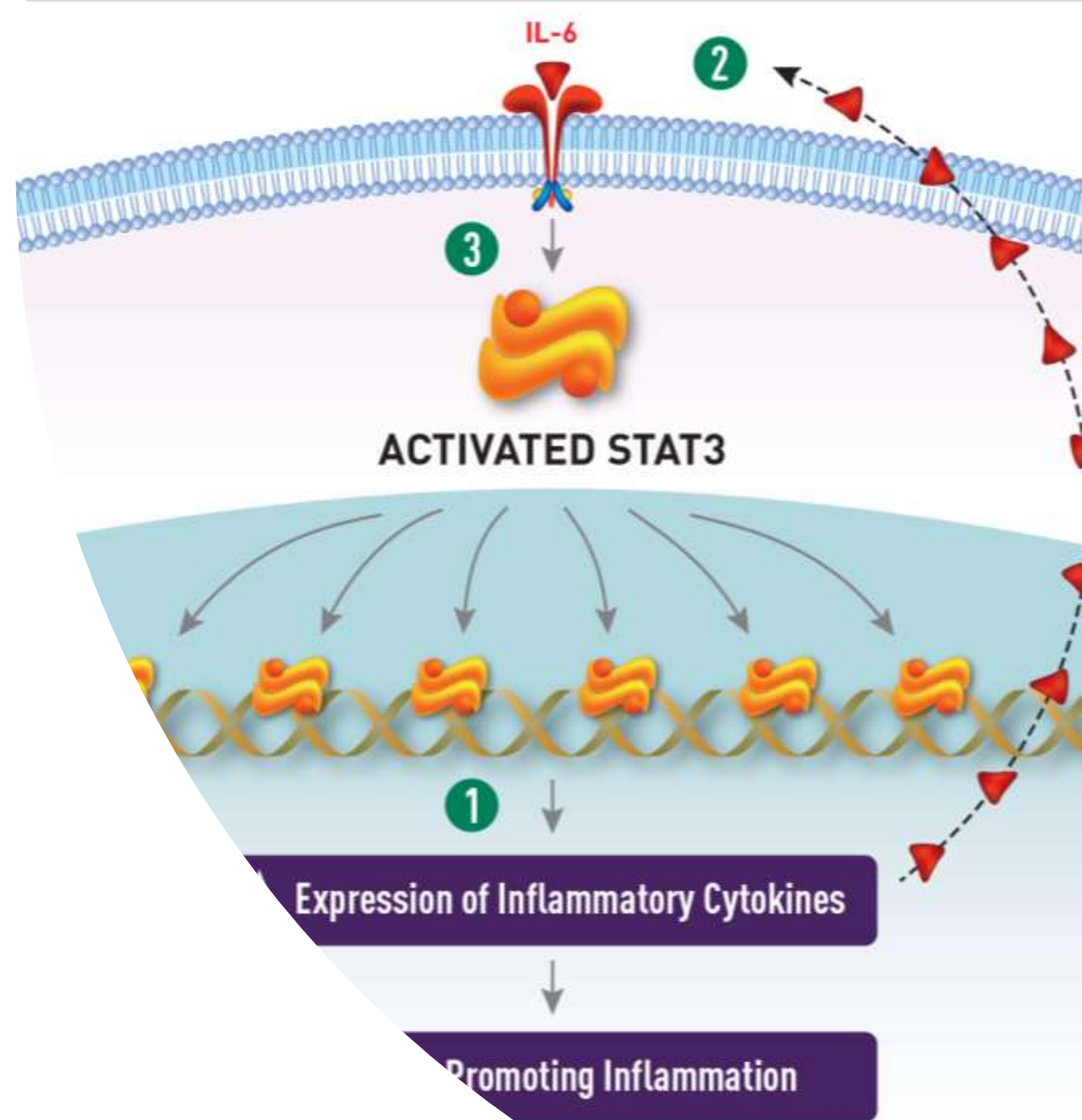
1. Immunology hypothesis

Release of **silicone particles**

→ intracapsular foreign body reaction

→ **chronic inflammation**

→ proliferation and oncogenic mutation of T cells (STAT3 pathway)



Pathophysiology: *hypotheses*

2. Tribology hypothesis

= interaction of surface with tissue

→ textured implants cause **delamination of capsule texture**

→ **chronic inflammation**

→ activation of maladaptive homeostatic mechanisms



Pathophysiology: *hypotheses*

3. Subclinical infection hypothesis

Ralstonia spp. found in affected breast capsules

→ **chronic inflammation** → T cell dysplasia

? **causal relation not proven**

? **subclinical present biofilm that doesn't cause ALCL**

Reconstructive cases are more prone to subclinical infection,
but there is **NO DIFFERENCE IN INCIDENCE** between
reconstructive and cosmetic cases



The larger the surface
the larger the harbor for
infection!

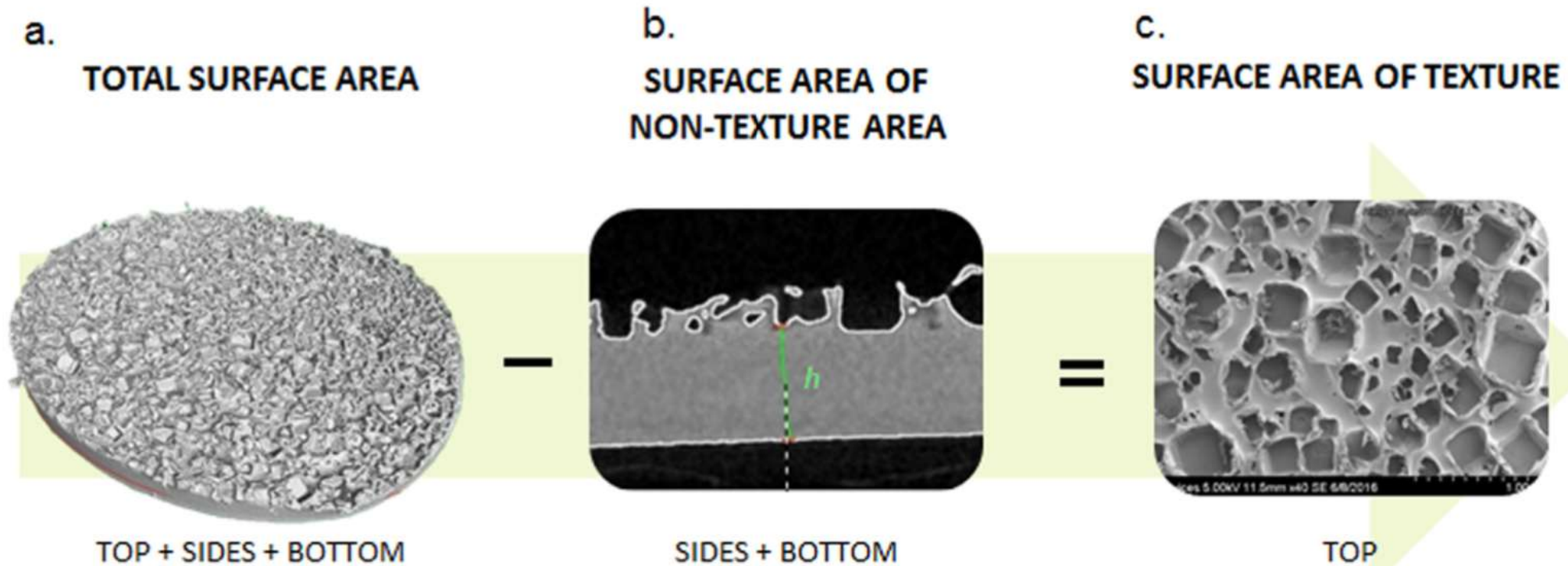


Fig. 1. Method for calculating surface area of the textured surface of a 10-mm diameter disk taken from the shell of a breast implant. (a) The implant shell disk was imaged using X-ray CT, and with the CT software, a threshold applied to distinguish between material and air was used to produce a value for total surface area of the disk. (b) The thickness of the non-textured portion of the shell was measured and used to calculate the surface area of the non-textured area ($A = 2\pi rh + 2\pi r^2$, where A is surface area, r is radius, and h is height.). (c) The surface area of texture was calculated by subtracting the surface area of the non-textured area from the total surface area based on the assumption that the bottom of the disk was a flat surface.

Texture Grading Classifications

Summary of Smooth and Textured Implant Classifications¹

ISO 2018 Average roughness by SEM		ANSM 2018 Average roughness by SEM		Atlas 2018 Surface area by Xray CT		Jones/Deva 2018 SEM, Surface area/roughness by MicroCT		James/Kinney 2018 Bact adhes, Surface area/roughness by profilometry	
Smooth <10 µm	All smooth, Motiva silk	Smooth	All smooth	Smooth/nanotexture 80-100mm ²	All smooth, Motiva Silk and Velvet	1 Minimal	All smooth, Motiva Silk/Velvet	Smooth	All smooth, Motiva Silk/Velvet
Microtextured 10 to 50 µm	Motiva Velvet, B-Lite, Allergan Microcell/	Microtextured	Arion Micro, Sebbin Micro, Motiva Silk/Velvet	Microtextured 100-200mm ²	Mentor Siltex, Allergan Microcell/BRST	2 Low	Mentor Siltex, Nagor	Rough	Allergan Biocell, Mentor Siltex
Macrot textured over 50 µm	Allergan Biocell, Silimed PU, Polytech PU	Macrot textured	Allergan Microcell/Biocell, Mentor Siltex, Eurosilicone Micro, Nagor, Polytech, Silimed	Macrot textured 200-300mm ² Macrot texture-Plus > 300mm ²	Allergan Biocell, Sientra True, Eurosilicone Nagor, Pol	3 4 High	Allergan Biocell, Polytech PU, Surgitek PU, Silimed PU		
Based upon ISO 25178-1		By ANSM per ISO-14607:2007		Peer reviewed		Peer reviewed			

Abbreviations; mm² millimeters squared, SEM scanning electron microscopy, ISO the International Organization for Standardization, Bact bacterial adhesion
 Surface area is a measure of the total area that the outer surface topography of an implant occupies and that interfaces with the patient. Surface roughness is a measure of the average height of the peaks and valleys of an implant surface.
 Reference 1: Clemens MW. Bridging the knowledge gap: Commentary on the epidemiology of Breast Implant Associated Large Cell Lymphoma in Australia and New Zealand. *Plast Reconstr Surg.* 2019.

But, somehow!
We don't have thousands
BIA-ALCL linked cases to
PU implants

Fact 1

PU coated Implant has **less**
contamination / biofilm
issues:

Sponge Effect!



Fact 2

PU coated Implant is **stable**
implant because of tissue
integration:

Scaffold Effect!

MICROTHANE versus BIA-ALCL

No sharing!

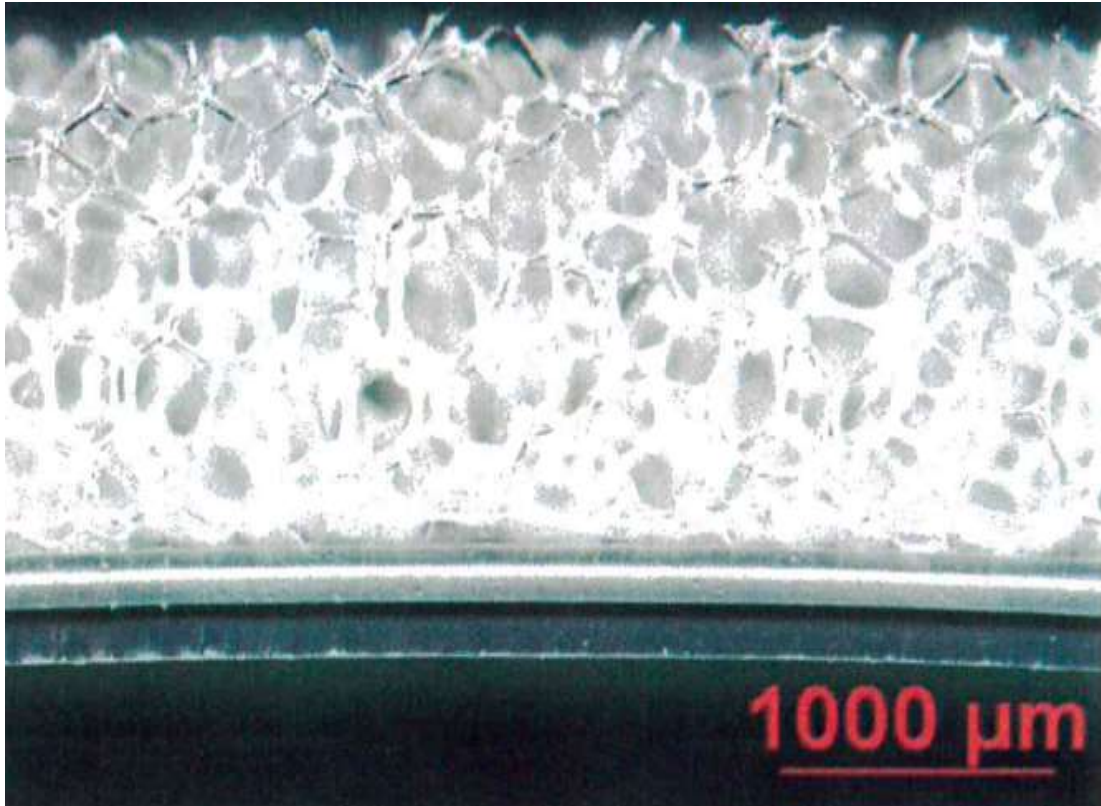
MICROTHANE versus BIA-ALCL

No sharing!

No Contamination!

Microthane[®] implants

PU Implants = “ Dynamic” Implants



Process	Polyurethane foaming	Phase Separation (Bioceramics/Polyurethane)	Phase Separation (Polyurethane/Silicone)	Salt Leaching (Nagotex)	Coating	Smooth/Nano
Surface Area	High	Intermediate	Intermediate	Low	Low	Minimal
Roughness	High	Low	Low	Low	Low	Minimal
SURFACE TYPE	4	3	3	2	2	1

Implant-Surface Classification

Polyurethane Data...

- Risk 1:1000-1:10,000?¹ for textured implants
- Allergan Biocell (1:3345)
- Silimed polyurethane (1:2832)
- Mentor Siltex (1:86029)
- 25.7 to 1 ratio of Biocell to Siltex
BIA-ALCL risk

Significance of delamination

23 ALCL cases after Polyurethane **Silimed** implants



Figure 3. An early delamination of a polyurethane Silimed breast implant (courtesy of Daniel Fleming, MD, Brisbane, Australia).

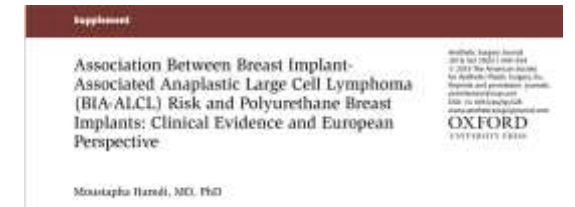
- Production defect with Silimed implants: the PU was not impeded in the shell.

In their discussion...

The cluster pattern of incidence now observed in both this and other series^{4,6} and the increasing evidence of microbiome induction and potentiation of cancer^{19–21} do suggest a role for infection in pathogenesis.

The logistic regression approach, used in the report, may only estimate risk up to a time limit, defined at the study design. Therefore, it is not clear how the authors incorporated the time issue for the risk estimation over time.

The authors state that there were cluster patterns in the data,¹ which was suspected to be related to certain surgeons and hospitals, raising a concern about implant infection as a cause.



Weighing Polyurethane-Covered Implant Benefits and the Risk of BIA-ALCL

Cintra, Henrique P. L.; Massiere Y Correa, Wanda Elizabeth; Baptista, Amanda T.; [More](#)

Plastic and Reconstructive Surgery. 145(3):651e-652e, March 2020.



PU coated **Silimed** Implant was first
implant to be used in Brazil back to 1968,
since then, millions implants have been
used!!!

Brazil halts use of Silimed silicone breast implants, follows Europe



Largest manufacturer of silicone implants
in Latin America.

Fire breaks out at Sientra manufacturer

By Staff Report / Friday, October 23rd, 2015 / Comments Off on Fire breaks out at Sientra manufacturer

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Goleta breast implant developer Sientra said there had been a fire at the factory of its manufacturer in Brazil, the company announced on Oct. 23.

Sientra did not say how big the fire was or if it would impact manufacturing at Silimed, the largest producer of silicone implants in South America. The company didn't specify whether anyone was injured.

According to Brazilian television station Rede Globo, the fire started at about 6 p.m. local time on Oct. 22.

POLYTECH

Since 1986...1988....2008



*Silicone implants
made in Germany*



CERTIFICATIONS
YOUR SAFETY

- > EN ISO 13485
- > EN ISO 9001
- > EG-Zertifikat

PolyTech sold 402.000 Polyurethane implants , used worldwide

PolyTech Microthane implant linked to ALCL!

- **3 Primary (Seroma-Only) Cases**
- **1 Primary Case Capsular Tumor**

RISK!

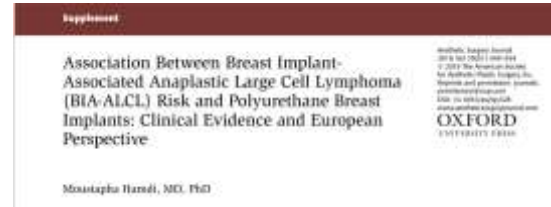
Microthane Implants and ALCL

✦ **Very low risk 1:100.000**

Polyurethane Data.



Significance of delamination



- **PolyTech** uses a different process so called **volcanization** technology in where the PU impeded in fresh Silicon liquid which explain the **No (delamination)** phenomenon!
- Should be recognized by researchers into BIA-ACCL, there are **two populations of PU foam implants which behave differently.**
- This difference is most likely to be significant in the risk of developing BIA-ALCL.

5. How BIA-ALCL changed our practice!

Panic!

What if we change to “smooth” implants?

- Patients will experience more capsular contractions, unless placed in sub-muscular pocket (even though, animation , discomfort ..etc)
- Leading to increased need for revision surgery
- Need to ADM in reconstructive surgery
- Smooth anatomical rotates
- Reconstruction patient’s choice maybe reduced/altered

Letter to the Editor

Nano-Surface Implants: Indications and Limitations

Moustapha Hamdi, MD, PhD

Editorial Decision date: September 1, 2020; online publish-ahead-of-print October 31, 2020.

Aesthetic Surgery Journal
2020, 1–2
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by guest on 09 November 2020

Non-Textured implants were indicated in only 19% of patients!

groups (conventional textured and nanotextured). The groups were further organized chronologically into 3 period subgroups for analysis of period effect.

For a surgeon highly experienced with textured anatomical implants such as Dr Montemurro and his team, it should be quite easy to utilize round/smooth implants. However, the authors experienced an increase in their complications rate after they started utilizing the new device (nanotextured implants). To reduce the learning curve with nanotextured implants, the authors described their modifications to patients' selection/surgical technique and postoperative management.

Reading this study, there seems to be no real learning curve. Rather, the authors managed to decrease the complication rate of nano-surface implants simply by avoiding utilizing them in many cases. In fact, nanotextured implants were employed only in "easy patients" with small and firm breasts with implants less than 350 mL. However, in such patients, basically any implant can potentially work fine. So where is the actual need for such a "new" implant, assuming that we really are speaking about a new implant?

Are "nanotextured" implants safer than traditional implants? The previous literature, with short follow-ups and no control groups, did not resolve my doubt.^{1,5} According to the present results, nanotextured implants do not perform better than textured implants, which makes my early skepticism more prominent than ever.

In this study, nanotextured implants cause a worrying rate of "bottoming-out," while the incidence of capsular

in the meantime, all the claimed advantages remain as speculations.

A very interesting point of this paper was a "steady decrease" in utilization of "nanotextured" implants beyond "period 3" of the study (19% of all implants; unpublished data of the authors). In other words, "nanotextured" implants are currently indicated in only 1 of 5 patients.

Lastly, the ISO classification put the so-called "nanotextured" implants within the smooth implant category, so why do the authors keep calling them "nanotextured" implants? "Nano-surface" should be the correct name of these implants. Breast implant manufacturers such as Motiva or others all have 1 important mission: to improve the quality of life of our patients. We as surgeons appreciate such efforts. The nano-surface is one of the current innovations in breast implants. However, only prospective and well conducted studies can prove the advantages of a new device over other surface implants. In conclusion, I really appreciate the honesty of the authors to make their experience available for testing "nano-surface"

Dr Hamdi is a Professor and Chairman of the Plastic Surgery Department, Brussels University Hospital – Vrij Universiteit Brussel (VUB), Brussels, Belgium.

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Breast Surgery

Transitioning From Conventional Textured to Nanotextured Breast Implants: Our Early Experience and Modifications for Optimal Breast Augmentation Outcomes

Paolo Montemurro, MD; and Vincent K.S. Tay, MD, MMed, MCI, FAMS

Aesthetic Surgery Journal
2020, 1–7
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DOI: 10.1093/asj/sjaa269
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Methods: Patients who underwent breast augmentation from the introduction of nanotextured implants in the author's practice with at least 1 year of follow-up were included. They were divided into nanotextured and conventional textured implant groups and then into 3 chronological subgroups. Patient characteristics, implant specifications, operative factors, and complication rates were compared.

Results: A total 415 cases with a mean follow-up of 26.9 months were identified, of which 38.8% utilized nanotextured implants and 61.2% conventional textured implants. Utilization of nanotextured implants increased from 26.9% in period 1 to 54.5% in period 3. Complication rates for the conventional textured group were 0.8% at 1 year and 3.5% on overall follow-up, with mostly capsular contractures; for the nanotextured group, complication rates were 6.8% and 8.7%, respectively, and "bottoming out" was most common. When analyzed across chronological subgroups, complication rates decreased for nanotextured implants by period 3.

Conclusions: A learning curve and associated complications are expected for early adopters of new implants. In our series, nanotextured implants were associated with higher complication rates at 1 year and on overall follow-up. Modifications in patient selection, intraoperative techniques, and postoperative care reduced complications in the later period.

Level of Evidence: 4

Editorial Decision date: June 11, 2020; online publish-ahead-of-print June 24, 2020.



Since the first-generation devices of the 1960s, breast implants and implantation techniques have evolved substantially over the past 6 decades. Implant-based breast augmentation has weathered through different seasons of gloom and concern. These include the historical ban of silicone gel implants by the US Food and Drug Administration in 1992,¹ the emerging risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL),^{2,3} and most

Dr Montemurro is a plastic surgeon in private practice in Stockholm, Sweden. Dr Tay is an Attending Plastic Surgeon, Changi General Hospital, Singapore, Singapore.

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E-mail: vincentkstay@gmail.com; inst@vks.com.sg

Plastische Heelkunde
UZ Brussel
Prof. Dr. M. Hamdi
www.ihreast.be

What changed in my practice:

Weighing risk versus benefit

- **Microthane** Implants are indicated:

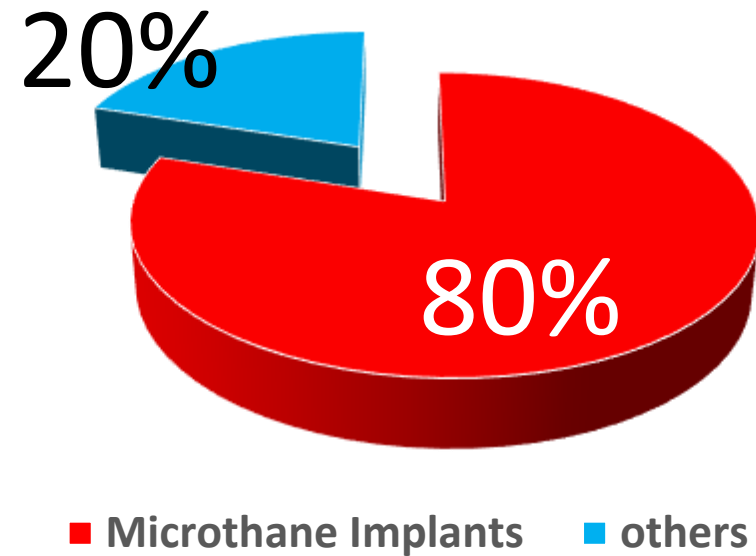
- **Primary cases**

- Indication of *anatomical implants*:
 - Reconstruction
 - Aesthetic (Low breast foot-print women)
- Bad skin quality (weight loss patients..)

- **Secondary Cases:**

- Revision cases
- Capsular contracture

- **Round Smooth / nano-surface/ Micro-Textured (B-Lite) implants** are indicated otherwise!



Listen to good practice!

[Why Do We Need Anatomical Implants? the Science and Rationale for Maintaining Their Availability and Use in **Breast** Surgery.](#)

Montemurro P, Adams WP Jr, Mallucci P, De Vita R, Layt C, Calobrace MB, Brown MH, Nava MB, Teitelbaum S, Del Yerro JLM, Bengtson B, Maxwell GP, Hedén P. Aesthetic Plast Surg. 2020 Apr;44(2):253-263.

Prespectives and Future

New implant devises Tissue engineering

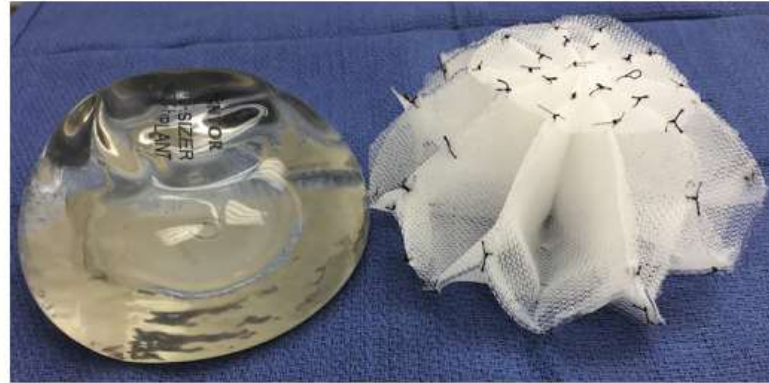


Fig. 2. Lotus scaffold after creating pleats and securing with nylon suture.



Fig. 3. Prepectoral placement of Lotus scaffold that has been coated in lipoaspirate.

Breast Reconstruction Using a Three-Dimensional Absorbable Mesh Scaffold and Autologous Fat Grafting: A Composite Strategy Based on Tissue-Engineering Principles

Robert D. Rehrke, M.D.,
M. Asher Schosterman II,
M.D.,
John M. Clarke, M.D.,
Brent C. Price, M.D.,
Uzma Wahneeb, M.D.,
Richard E. Debski, Ph.D.,
Stephen E. Rodyslak, D.V.M.,
Ph.D., M.D.,
J. Peter Rubin, M.D.

From *Rehrke, Price, and Rodyslak, Pa.*

Summary: Breast reconstruction remains an important field in plastic surgery, with most procedures using implants and/or autologous tissue. Few series report on experience with fat grafting as the primary form of breast reconstruction. The present article describes a new method of breast reconstruction using a three-dimensional absorbable mesh construct—the Lotus scaffold—and autologous fat grafting. A retrospective review was performed for all patients who underwent breast reconstruction using the Lotus scaffold and autologous fat grafting. Postoperative mammograms and magnetic resonance imaging scans were analyzed. Tissue specimens collected at subsequent procedures were harvested and stained with hematoxylin and eosin for histologic evaluation. Lastly, compression testing of the scaffold was performed using a tensiometer and digital tracking technology. Twenty-two patients underwent reconstruction of 28 breasts using the Lotus scaffold and autologous fat grafting between February of 2015 and February of 2018. Average follow-up was 19 months. All patients were satisfied with final breast shape and size. Mean patient age was 60.5 years and the average body mass index was 28 kg/m². Patients required on average two fat grafting sessions to achieve a successful result (range, zero to four). Postoperative mammography and magnetic resonance imaging showed robust adipose tissue in the breast with a slowly resorbing mesh and no oil cysts or calcifications. Histologic evaluation showed the presence of fat tissue around the scaffold and no evidence of capsule formation. Compression testing revealed the Lotus scaffold to be compliant with a high-resistance profile. The Lotus scaffold with autologous fat grafting is a viable method for breast reconstruction, giving the patient an autologous reconstruction with less morbidity compared to free-tissue transfer. (*Plast Reconstr Surg* 146: 409e, 2020.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.



The recent history of breast cancer surgery has seen an evolution toward a less invasive approach to total mastectomy when possible, and the advent of skin- and nipple-sparing

procedures.¹⁻³ The preservation of the majority of the breast envelope has changed the techniques for breast reconstruction and has provided opportunities for alternative reconstructive approaches, including direct-to-implant reconstruction and the use of autologous fat grafting. Primary reconstruction with autologous fat grafting is difficult.

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Summary

BIA-ALCL

- ✧ It is a **rare** disease
- ✧ Risk related to level of Standard of Care
 - ✧ No “**0 risk**” Implant
 - ✧ Surgeon should keep implant choices smooth/microtextured/PU
- ✧ Patient information and **Follow-Up** is essential
 - ✧ *Implant Registry should be mandatory*