



SCHEER HEARING

Preliminary Opinion on the Safety of Breast Implants in
relation to BIA-ALCL

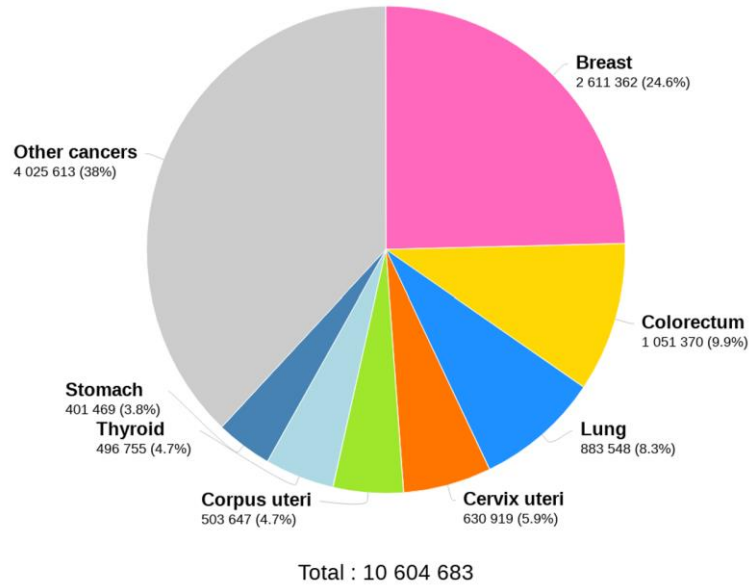
The EUSOMA perspective and proposed actions

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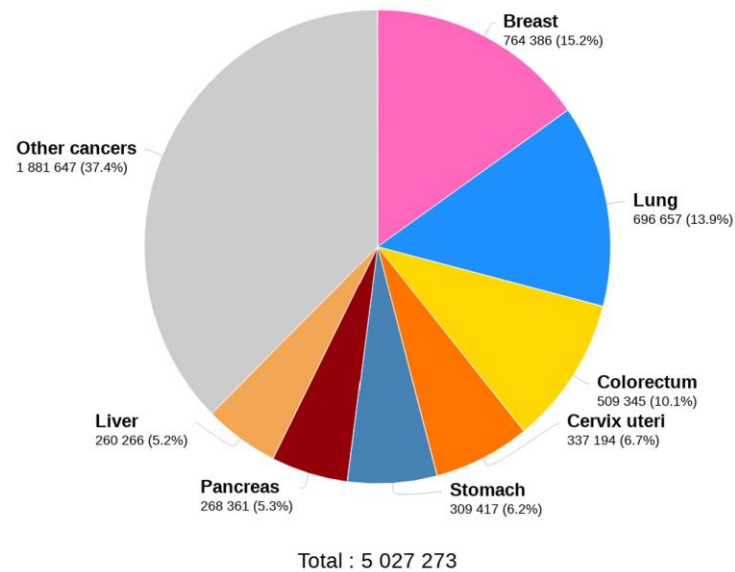
No conflict of interests related to the current presentation

EUROPE

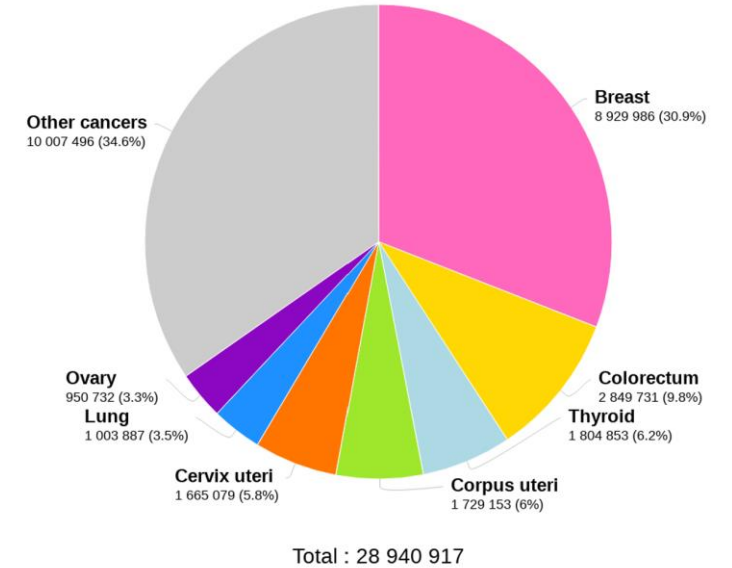
Incidence



Mortality



Prevalence



Data source: Globocan 2018
 Graph production: Global Cancer
 Observatory (<http://gco.iarc.fr>)

EUSOMA aims to:

- Promote scientific research and increase contacts between scientists and health care professionals involved in breast cancer care
- Improve and harmonize the level of patient care throughout Europe by identifying the most suitable diagnostic and treatment procedures and promoting their use, making available for all women in Europe a high quality specialist breast service, defining the standards for such a service and contributing to the process of certification and audit of Breast Centres.
- Bring these to the attention of the appropriate Authorities
- Foster training and post-graduate programmes in breast disease at National and International levels

Quality indicators in breast cancer care: An update from the EUSOMA working group. Eur J Cancer 2017. Biganzoli L et al.

Eusoma Quality Indicators for Breast Centre Certification

based on “Quality indicators in breast cancer care: An update from the EUSOMA working group” EJC 86 (2017): 59-81

5	Proportion of patients (BRCA1 and BRCA2 patients excluded) with invasive breast cancer not greater than 3 cm (total size, including DCIS component) who underwent BCT as primary treatment.	M	70%	85%
6	Proportion of patients with non-invasive breast cancer not greater than 2cm who underwent BCT	M	80%	90%
13	Proportion of patients receiving immediate reconstruction at the same time of mastectomy	R	40%	NA

EUSOMA DATABASE - DATA FROM 51 BREAST UNITS					
	Surgery Total	BCS	Mastectomies	Mastect without IR	Mastectomy with IR
2018	23424	14626 (62%)	7863 (34%)	4013 (51%)	3850 (49%)
2019	22961	14350 (62%)	7102 (31%)	3246 (46%)	3856 (54%)

EUROPE BREAST IMPLANT MARKET

Product

Shape

Application

Implant Texture

End-use

Saline

Silicone

Round

Anatomical

Breast Augmentation

Breast Reconstruction

Smooth

Textured

Hospitals

Clinics

Others

Breast implant market estimates in European Countries (Euros)

Country	2016	2017	2018	2019	Population
Germany	54,0	59,1	64,7	70,8	83 879 886
UK	15,2	16,7	18,4	20,2	68 013 429
France	46,9	51,7	56,9	62,7	65 625 294
Italy	52,6	58,2	64,4	71,3	60 429 824
Spain	39,0	43,2	47,9	53,2	46 761 284
Belgium	11,9	13,3	14,8	16,5	11 607 663
Greece	7,8	8,6	9,6	9,6	10 402 662

EUROPE estimates by product (Euros)		
Product	2015	2016
Saline	14,9	16,4
Silicone	347,6	384,2
TOTAL	362,5	400,6

EUROPE estimates by application (Euros)		
Application	2015	2016
Breast Augmentation	313,8	347,1
Breast Reconstruction	48,7	53,5
TOTAL	362,5	400,6

EUROPE estimates by shape (Euros)		
Shape	2015	2016
Round	313,4	347,3
Anatomical	49,1	53,3
TOTAL	362,5	400,6

EUROPE estimates by implant texture (Euros)		
Implant texture	2015	2016
Smooth	38,1	41,9
Textured	324,4	358,7
TOTAL	362,5	400,6

EUROPE estimates by end-use (Euros)		
End-users	2015	2016
Hospitals	148,3	163,7
Clinics	163,0	180,2
Others	51,2	56,7
TOTAL	362,5	400,6

EU Country	Female 17-70 yo	Women WI	Female Trans WI	Active population	Cases	Prevalence	Mortality
EU -28 (100%)	178 493 335	5 252 334 (2,9%)	520 579	5 772 913 (3,23%)	420	1:13,745	13
Projection					592		20

Note: declared cases are dependent from registry accuracy
Incidence is higher in The Netherlands – better registries
Underestimation?

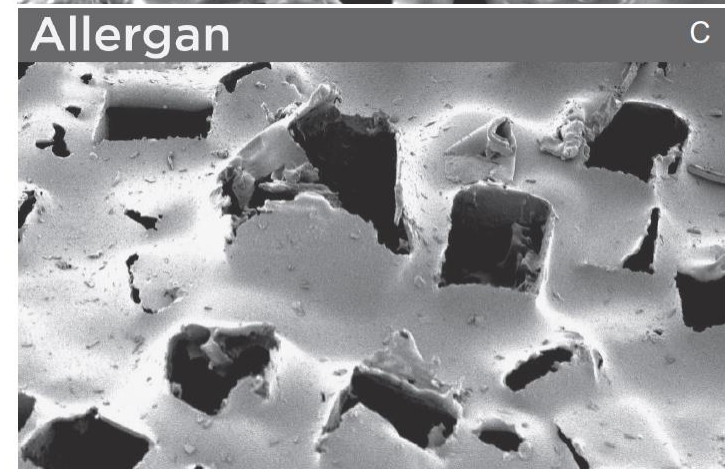
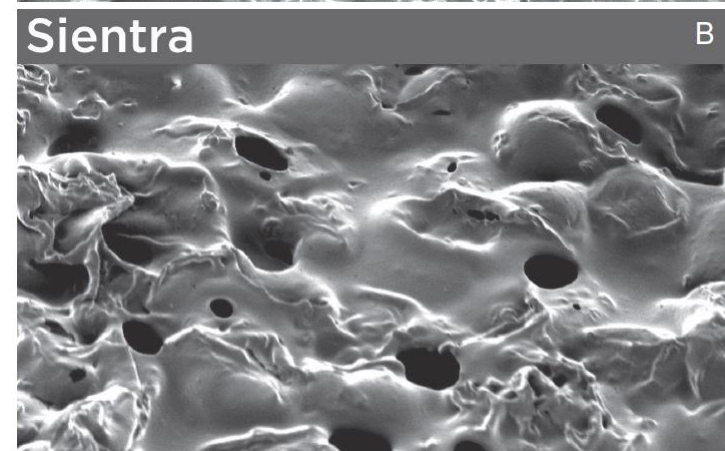
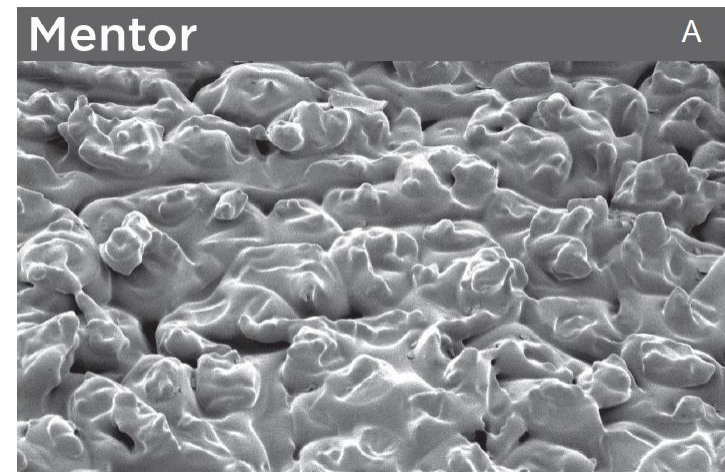
Adapted from

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL): review of epidemiology and prevalence assessment in Europe

Santanelli di Pompeo et al. Aesthet Surg J. 2020

TABLE 2 - Country recommendations towards BIA-ALCL and attitudes towards textured implants by January 2019

Country	National Regulatory Board	Report mandatory	Recommendation towards all textured implants	Scientific Societies Ministry of Health Recommendations	Withdraw of Textured Implants by Allergan	Still using other brands textured implants	Estimated Rates of BIA-ALCL (per implant placed)	Recommendations for early diagnosis
AUSTRIA	Österreichisches Register für Medizinprodukte-MP	NO	NO	NO	Unknown	YES	1/20000	YES
BELGIUM	Federal Agency for Medicines and Health Products, FAMHP	NO	YES	NO	YES	YES	Unknown	YES
BULGARIA	Bulgarian Drug Agency, Direction "Market control and inspections"	YES	NO	YES	YES	YES	Unknown	YES
DENMARK	Danish Medicines Agency	YES	YES	YES	YES	YES	Unknown (7 reported cases)	YES
ICELAND	Lyfjastofnun Islands	YES	YES	YES	YES	YES	Unknown (None reported)	YES
IRELAND	Health Products Regulation Association, HPRA	NO	NO	NO	NO	NO	1/25000	YES
ITALY	Ministry of Health (Dec 18.2018)		NO	YES	YES		1/2227	YES
FINLAND	Social and Health Ministry	YES	NO	NO	YES	Unknown	Unknown (8 reported cases)	YES
FRANCE	Agence nationale de sécurité du médicament et des produits de santé (ANSM)	YES "LYMPHOPATH"	YES	YES	YES	NO	1/8928	YES
GERMANY	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	YES	NO	NO	YES	YES	Unknown (7 reported cases)	NO
GREECE	National Medicines Agency	NO	NO	YES	YES	YES	Unknown	YES
LATVIA	State Agency of Medicines of Latvia	YES	NO	NO	YES	YES	1/300000	YES
POLAND	The Office for Medicinal Products, Medical Devices and Biocidal Products	YES	NO	YES	YES	YES	Unknown (3 reported cases)	YES
PORTUGAL	INFARMED	YES	NO	NO	YES	YES	Unknown	YES
SPAIN	NO	YES	NO	NO	NO	YES	Unknown	YES
SWEDEN	Läkemedelsverket	YES	NO	NO	NO	YES	Unknown	YES
SWITZERLAND	Swiss Medics	YES	NO	YES	YES	YES	1/4500	YES
UK	Medicines and health care products regulatory authority (MHRA)	YES	NO	YES	YES	YES	1/24000	YES

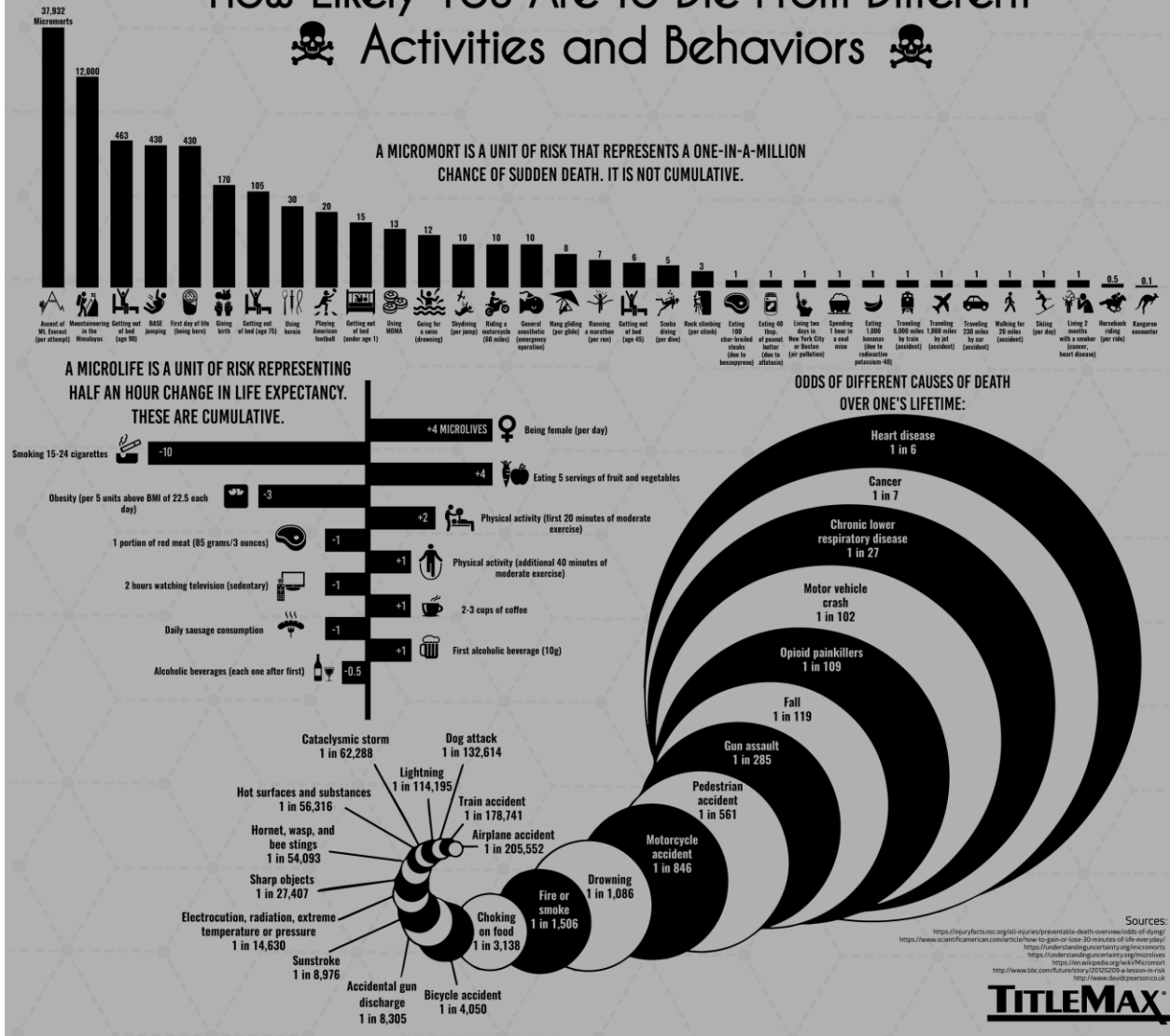


INFORMATION ON BIA-ALCL CURRENT STAGE

- Mainly associated with textured implants
 - Mainly associated with macro-textured implants
 - Infra-estimation of numbers (registry accuracy)
 - Textured implants are the vast majority in breast reconstruction
 - Heterogeneous reporting
-
- Genetic predisposition – scarce and doubtful evidence from retrospective cohorts with bias
 - Bacterial contamination- not proved
 - Association of Implant texture with Breast Cancer Recurrence (Lee KT Jama Surg 2020)
 - Incidence of CL events – indication for CL Surgery
 - Spontaneous resolution (Fleming D. Aesthetic Plast Surg 2020)
 - Interaction with Coverages (ADMs/ Mesh- complete pocket)

COMPARATIVE RISKS	%	1 in number
Risk of breast implant rupture (10 years)	8,7%	1 in 11,5
Risk of capsular contracture (10 years)	13,5%	1 in 7,4
Risk of reo-peration (10 years)	31,6%	1 in 3
Average women's lifetime risk of breast cancer	12,5%	1 in 8
Risk of developing recurrent breast cancer after mastectomy	5-8%	1 in 12,5-20
Risk of death in a car accident in a lifetime	0,15%	1 in 645
Risk of death from complications from cosmetic proccedure	0,002%	1 in 50000
Risk of developing BIA-ALCL	0,003%	1 in 30000
Risk of developing BIA-ALCL with lymph node metastasis	0,0004%	1 in 250000
Risk of developing BIA-ALCL and not resolved (3 years)	0,0002%	1 in 500000

How Likely You Are to Die From Different Activities and Behaviors



Numeracy includes minimal statistical literacy

Health numeracy is a person's ability to access, interpret, and use numeric information to make health decisions.

Breast Cancer diagnosis – Very thin women Multifocal Cancer (Luminal Grade 1, ER positive) – Strategy?



The Breast 35 (2017) 32–33



Contents lists available at ScienceDirect

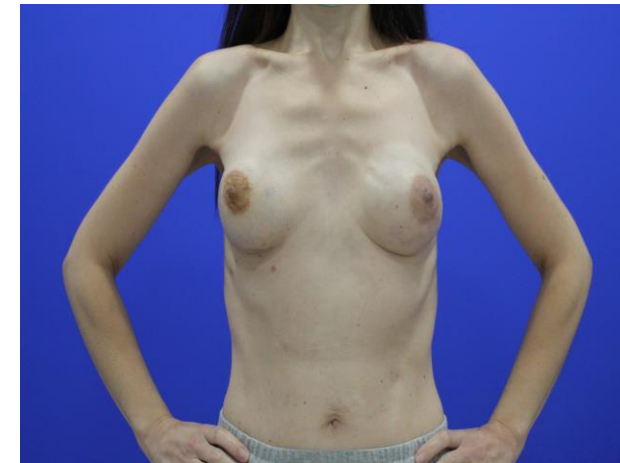
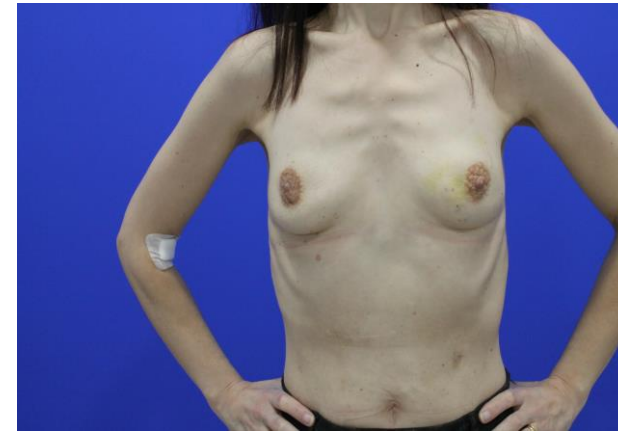
The Breast

journal homepage: www.elsevier.com/brst



Viewpoints and debate

Less is more. Breast conservation might be even better than mastectomy in early breast cancer patients



With permission

EVERYDAY PROBLEMS IN A BREAST UNIT

- Levels of expertise - reconstructive surgery in breast units (absence of alternatives)
- Availability of different implants - price – negotiation among diverse providers
- Lack of information – high level of evidence regarding causes and incidence of BIA-ALCL
- BCS/Mastectomy ratios

EUSOMA possible contribution

- Add the information on the type of reconstruction –detail on implant type – to the Eusoma dataset
- In the next up-dating of Eusoma Breast Centre requirements add as mandatory the presence of an informed consent regarding the risk of BIA-ALCL for patients proposed for implant based reconstruction.
- Lobby towards the rise in Breast Conserving Surgery to the ideal levels – with EUROPA DONNA at EU Level
- Lobby towards the diversity of techniques in breast cancer reconstruction - with EUROPA DONNA at EU Level
- Support and endorse research on the topic –with ESO, BRESSO, ESMO, ECCO
- Contribute to the spread of information on the topic on diverse EUSOMA initiatives –with ESO, BRESSO, ESMO, ECCO
- **Establishment of an EUROPEAN DATABASE in BREAST RECONSTRUCTION** (if needed-vast previous experience on the setting up of large European databases with all the requested privacy settings across diferente countries)

EUSOMA

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