PYROGENIC NANO SILICA IN BREAST IMPLANTS

Short introduction history

A few years after breast implants came on the market and were placed in women, the problems and complaints of women started. Often local, but the longer they were in the body systemic health issues , autoimmune-like complaints were also reported by women. In the early 1990s, media attention for the women who were sick in America eventually resulted in a ban after the FDA's Commissioner Dr David Kessler discovered that the largest silicone manufacturer had been convicted of scientific misconduct and fraud.

Few knew the real reason for the ban. We didn't find the 'hard' evidence (video)[1] until 2018. There were rumors about secret documents, but we wanted to hear this from an official source (FDA).[2]

Apparently the governments of Europe didn't know this either. It was said here that American women care about the money because of the suing culture in America.[3]

Here, too, more and more women developed health problems. It was in 1992 that our Foundation was founded.
The large American manufacturers Allergan and Mentor settled in Europe, after all there was no ban here, in fact Mentor received a subsidy for a factory in Leiden.

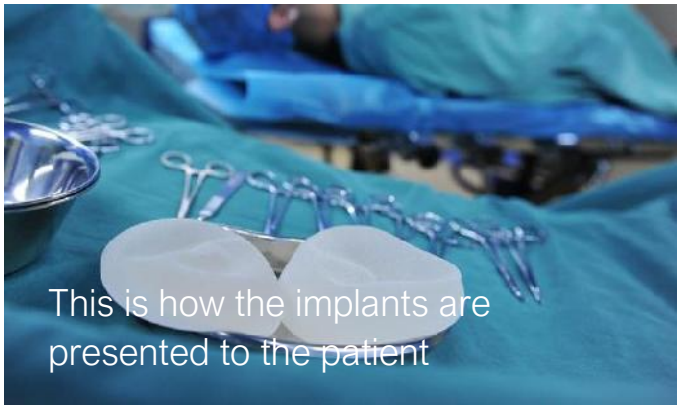
Meanwhile

In the meantime, all kinds of studies were initiated in America to clear the name of Dow Corning. Also to prove that according to Dow Corning they were safe after all. According to court documents (in our possession), studies were designed in such a way that there was no conclusive evidence. Epidemiological studies in particular were subject to COIs and were regularly manipulated.[4]

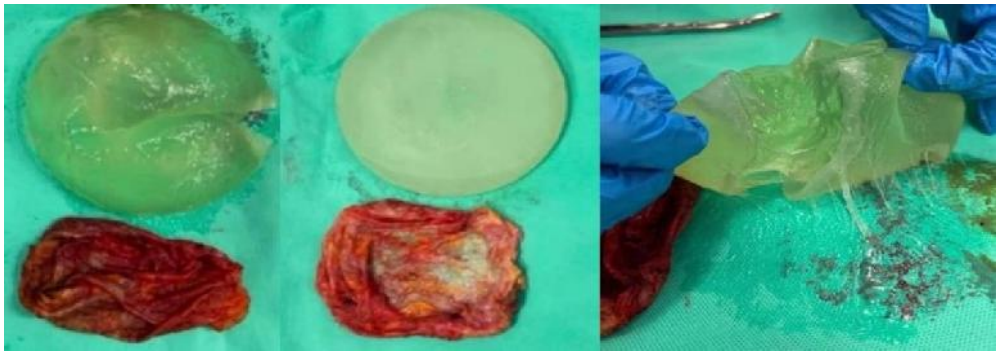
[1] FDA David Kessler https://www.youtube.com/watch?v=3uToeeUw7nY&t=114s April 1992
[2] FDA Tells Firm to Open Data on Breast Implants https://www.latimes.com/archives/la-xpm-1992-01-19-mn-914-story.html
[3] Silicone Breast Implant Litigation https://journalofethics.ama-assn.org/article/silicone-breast-implant-litigation/2010-05
[4] Breast Implants: A Research and Regulatory Summary https://www.center4research.org/breast-implants-research-regulatory-summary/

Marga van Amersfoort

MEDICAL DEVICES (breast implants) containing fumed nano silica



…….but below accurate representations of reality



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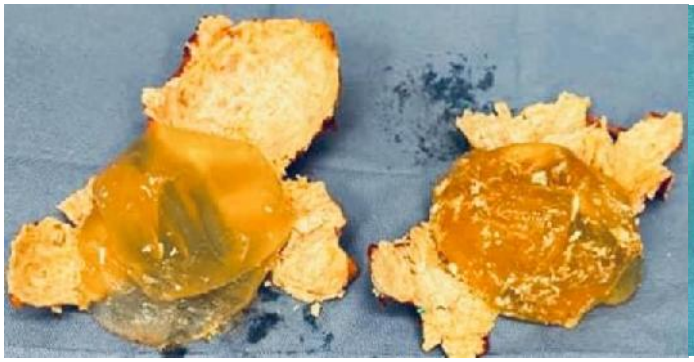
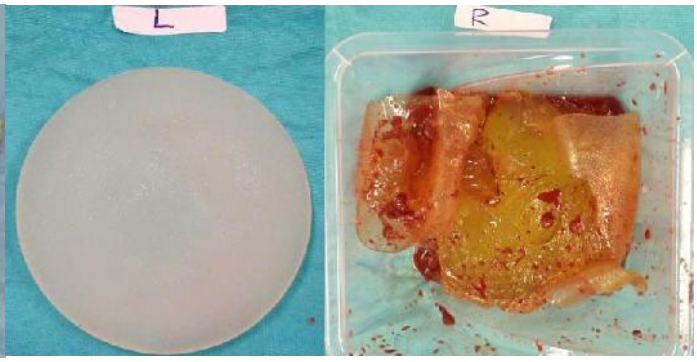
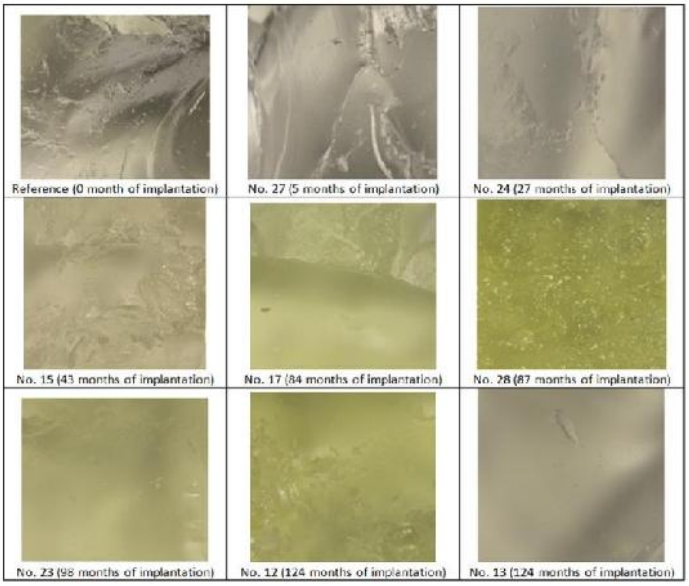


Capsular contraction/ fibrosis



Unilateral rupture

After implantation, the degradation process begins. The following research shows that the implants degradates.



Aging of retrieved gel breast implants :

https://pubmed.ncbi.nlm.nih.gov/25746931/

3.2.6. *Shell thickness*

The shell thickness of each implant is presented in Table 3. Globally, for round style implants, a decrease in thickness could be observed especially after 51 months of implantation. The average decreasing rate was 16%. On the contrary, with respect to anatomical implants, the thickness varied less over the implantation time. The average decreasing rate was 8%. Moreover, one observes in Fig. 7 that the shell thickness on the patch side was greater than on the opposite side for the anatomic implant (around 8% difference).

Go to study

After 51 months of implantation decrease of the shell/envelop thickness for round style implants average rate was 16% and for anatomical 8%.

Chemicals in breast implants

Almost all chemicals used in manufacturing have already been covered in the literature. Some substances are still debatable, such as the low-molecular siloxanes, but one substance is quite remarkable.

Few seem to know that this substance is in the shell of the implants.[1]

A substance mentioned inconspicuously in the Summary of safety and effectiveness data of the implants[2] [3] [4] namely silica.

5. Silica Filler

X-ray diffraction studies on the elastomer shell confirmed that the silica used as reinforcing filler material is in the amorphous form.

Exactly the same paragraph for all major American brands.
No information on the type of silica and whether it is treated or not (hydrophilic or hydrophobic).
To find out which type is used in implants, we then searched the IOM study "Safety of silicone breast implants"[5] where the chemical composition was discussed in detail.

Reading the executive Summary (page 22 PDF) it becomes clear that little/no research has been done on the silica

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Since the evidence is lacking or flawed that amorphous silica in breast implant shells is available to, or found in tissues of experimental animals or humans, or that crystalline silica is formed or present at any time in women with implants, the toxicology of silica has not been reviewed, although literature on silica is included in the references.

More quotes from the "Safety of silicone breast implants"

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The filler treatment involves silica aerogel filler. This filler, whose manufacture is outlined, is amorphous silica with a surface high in silanol groups. In a nonpolar environment such as silicone gum, these silanols tend to bond between filler particles, causing aggregation. Although the primary particle size is ca. 5–7 nm (LeVier et al., 1993), this aggregation can form long chains and/or agglomerates of filler particles. The agglom-

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SILICONE CHEMISTRY 49

TABLE 2-3 Silicone Adhesive to Seal Injections Sites, RTV Cure

No.	Chemical Name	Function	Q7-2198 (%)
DC-200	Hexamethyldisiloxane)	Solvent	40.31
DS Polymer	HO-terminated PDMS	Reactive polymer	48
R-972	Me_3Si-treated aerogel	Treated silica	8.23
ETS-900	Methyltriacetoxysilane and ethyltriacetoxysilane, 1:1	Cross-linker Cross-linker	1.72 1.72
Sn oleate	Tin oleate	Catalyst	0.038

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No.		Function	MDF-0372 (%)	MDF-0070 (%)	MDF-0009 Patches (%)
SGM-11	Vi-terminated Me_2-*co*-MeVi siloxane	Reactive	65.5	66.81	64.3
MS-75D	Silica aerogel	Filler	26.85	24.05	26.36
PA Fluid	HO-terminated PDMS	Process aid	6.55	7.18	6.47
$(Cl_2BzCOO)_2$	Bis(2,4-dichlorobenzoyl) peroxide	Cross-linker	1.1	1.96	2.92

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High-molecular-weight, viscous silicone gums filled with amorphous silica (Cab-O-Sil or Aerosil) are mixed with process aids and with peroxides such as 2,4-dichlorobenzoyl peroxide and cured under heat and pres-

or 0.50 mm, thick. The fumed silica or silica aerogel content of these elastomers varied from about 24 to 37%.

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IMPLANT SHELL CHARACTERISTICS

Implant shells are made of silicone rubber, that is, elastomer with a filler. They vary in the composition and characteristics of the elastomer (e.g., approximately 21–27% amorphous silica filler in the elastomer for the shell and in shell patches, and 16.5% in barrier coats according to Dow Corning). Specifications of other manufacturers may vary. Amorphous silica is different in its physicochemical properties and in its biologic effects from crystalline silica, which is reported not to be present in measurable amounts in implant shells or gels (see Chapter 2; see also IARC, 1997; Iler, 1981). Shell thickness also varies, ranging from 0.13 to 0.75 mm, or 0.005 to 0.030 inch. Some shells have been even thicker, and areas of some implant shells lie outside this range (J. Curtis, Dow Corning, personal communication, February 17, 1998; P. Klein, Dow Corning, personal communication, August 10, 1998; Z.F.Twardochleb, McGhan Medical, personal communication, July 7, 1998). Most shells have had smooth elastomer rubber, but increasingly, some are textured with different surface features or shell projections of varying coarseness, depending on the manufacturer.

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The committee included citations on the toxicology of silica in the reference list of this report, because there has been considerable mention of silica as a component of breast implant elastomers. However, the toxicology of silica is not reviewed here because the committee found no valid scientific evidence for the presence of or exposure to silica in tissues of women with breast implants. Some compounds not found in breast im-

Types of silica according to the Safety of silicone breast implants

Fumed silica from Evonik

1.1. Product identifier

Trade name	AEROSIL® R 972 V
Chemical Name	Silane, dichlorodimethyl-, reaction products with silica
CAS-No.	68611-44-9

8.1. Control parameters

• **Silicon dioxide, chemically prepared**		
CAS-No.	112945-52-5 7631-86-9	
Control parameters	6 mg/m3	Recommended exposure limit (REL):(NIOSH)

CAB-O-SIL® MS-75D FUMED SILICA

Chemical name	CAS No	weight-%	Trade secret
Synthetic Amorphous, Pyrogenic Silica	112945-52-5	> 99.9	-

Silica info-card according REACH/ ECHA [6]

AMORPHOUS SILICA

Regulatory process names 2 IUPAC names 43 Other names 7 Other identifiers 2

Substance identity

EC / List no.: 601-216-3

CAS no.: 112945-52-5

Mol. formula: O2Si

O=Si=O

Hazard classification & labelling

Danger! According to the classification provided by companies to ECHA in **CLP notifications** this substance may cause cancer, causes serious eye irritation, causes skin irritation and may cause respiratory irritation.

Properties of concern

C — Some data submitters indicate they consider this substance as Carcinogenic

More details

Nanomaterial form

Substance is known to be on the EEA market in nanomaterial form.

about INFOCARD - Last updated: 06/05/2022

Another fact

The same amorphous pyrogenic silica trimethyl silyl treated is also used as a biocide in the EU[7]

Studies that already sounded the alarm about the toxicity of silica at the time (1991)

There were a number of studies that very clearly showed a T-cell response already (Shanklin and Smalley[8] [9] [10] [11] [12]) *(I have the book/PDF (Immunology of silicones)* , but this was hardly discussed. It seems like they assumed amorphous silica couldn't be toxic at all. There was also speculation at the time about silicone possibly degrading to crystalline silica, which was dismissed also.
Two studies which already showed a reactive cellular response:

- Analysis of the soft-tissue response to components used in the manufacture of breast implants: rat animal model[13]
- Investigation of silicone oil and fumed silica in an adjuvant animal model.[14]

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[1] https://pubmed.ncbi.nlm.nih.gov/21964678/ Breast implants: the good, the bad and the ugly. Can nanotechnology improve implants?
[2] SUMMARY OF SAFETY AND EFFECTIVENESS DATA Mentor https://www.accessdata.fda.gov/cdrh_docs/pdf3/p030053b.pdf
[3] SUMMARY OF SAFETY AND EFFECTIVENESS DATA Allergan https://www.accessdata.fda.gov/cdrh_docs/pdf2/p020056b.pdf
[4] SUMMARY OF SAFETY AND EFFECTIVENESS DATA Sientra https://www.accessdata.fda.gov/cdrh_docs/pdf7/p070004b.pdf
[5] Safety of silicone breast implants IOM https://www.ncbi.nlm.nih.gov/books/NBK44792/
[6] Echa https://echa.europa.eu/nl/substance-information/-/substanceinfo/100.118.670
[7] https://echa.europa.eu/documents/10162/2977f64b-a27c-fab4-c69b-1cd1234792dd
[8] Chapter T Cell-Mediated Immune Response to Silica (..)https://link.springer.com/chapter/10.1007/978-3-642-85226-8_22
[9]Immunologic stimulation of T lymphocytes by silica after use of silicone mammary implants https://pubmed.ncbi.nlm.nih.gov/7896014/
[10] Microscopic techniques and histologic findings in silicone mammary implant capsules and regional paranodal tissues https://pubmed.ncbi.nlm.nih.gov/8565564/
[11] Lymphocyte response to silica among offspring of silicone breast implant recipients https://pubmed.ncbi.nlm.nih.gov/9145333/
[12] The immunopathology of siliconosis. History, clinical presentation, and relation to silicosis and the chemistry of silicon and silicone https://pubmed.ncbi.nlm.nih.gov/9951648/
[13] https://pubmed.ncbi.nlm.nih.gov/1847746/
[14] https://pubmed.ncbi.nlm.nih.gov/9283562/