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## Safety & imaging of modern silicone breast implants

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# CHAPTER 2

A History of Silicone Breast Implants  
through the eyes of PubMed



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## ABSTRACT

**BACKGROUND:** Silicone breast implants have been subject of debate and controversy since their introduction. This debate has been covered by both medical publications and lay media. General public opinion and safety issues covered by media have influenced development and innovations of implants and their legislation. This historical review aimed to investigate the influence of lay media on the number of silicone breast implant related publications in PubMed during the past 50 years.

**METHODS:** A PubMed search was performed and all articles on “silicone breast implants” were categorised according to subtopic. The archives of The New York Times were searched for headlines on the same subject and popularity and subtopics in both an example of lay news coverage and peer reviewed medical journals were compared.

**RESULTS:** 2665 articles were found in medical journals and most frequent topics were silicone breast implants in general, complications, surgical techniques, imaging and legislation. Our results suggest that lay media and medical journals show corresponding popularity and subtopics in their timelines as medical articles and research seem to follow coverage in mainstream media.

**CONCLUSIONS:** This study illustrates that the number of silicone breast implant related publications increased significantly following news headline stories and important historical events in their legislation. Let us not wait until the next news event and instead produce well-designed prospective studies on results and complications.

## BACKGROUND

Silicone breast implants have been subject of international debate in medical literature since their introduction to the market by Cronin and Gerow in 1962.<sup>1</sup> Recently, we celebrated their 50<sup>th</sup> anniversary and the authors felt this to be the perfect moment to evaluate the turbulent history of these medical devices by looking at the sort and frequency of medical literature published on the subject. There have been a few historical articles describing the legislation and safety issues of silicone implants over time, but none has done so by evaluating published medical articles.<sup>2,3</sup>

Regular media is known to influence the general public opinion about health issues. Examples of large scale media impact on women's health issues in the past include Premenstrual Syndrome (PMS) and pregnancy related publications.<sup>4,5</sup> We believe that an increase in general media attention might also influence the number of medical publications on a particular subject and vice versa. Regarding silicone breast implants, this influence of media and general public opinion has led to the introduction of new legislation, increasing the amount

of research performed and stimulated innovations. The authors hypothesized that the quantity of medical articles on the subject of silicone breast implants increased whenever important

**Table 1. Medical publications about silicone breast implants categorized on subtopic based on the title and the number of articles found since 1962 until 2013**

General	452
Systemic complications	445
<i>auto-immunity (n=213)</i>	
<i>cancer (n=126)</i>	
<i>Anaplastic Large Cell Lymphoma (n=18)</i>	
<i>lymphoma (n=9)</i>	
<i>breast cancer (n=43)</i>	
<i>interference with breast cancer detection (n=13)</i>	
<i>other (n=43)</i>	
<i>undefined auto-immune diseases (n=17)</i>	
<i>allergy (n= 16)</i>	
<i>neurological complications (n=6)</i>	
<i>other (n=67)</i>	
Local complications	389
<i>capsular contraction (n=155)</i>	
<i>rupture (n=84)</i>	
<i>infection (n=38)</i>	
<i>lymphadenopathy (n=28)</i>	
<i>malformation (n=14)</i>	
<i>hematoma (n=10)</i>	
<i>pain (n=6)</i>	
<i>other (n=54)</i>	
Indications	243
Other (non-SBI topics)	213
Radiology	201
Tissue and serum research	184
Surgical and operation techniques	113
Complications general & Safety	93
Regulation/Legislation/Juridical	64
Design and innovations	59
Psychosocial	52
History and society	50
Silicone found elsewhere	38
Offspring effect & breastfeeding	36
Follow-up	27
Complication management	4
Introduction	2
<b>Total</b>	<b>2665</b>

legislation and safety reports on the subject were published in regular media, creating identifiable spikes and trends in subtopics. We therefore came to the idea of describing the history of silicone breast implants through the eyes of published medical articles and lay media and to evaluate the impact of lay media publications on the number of scientific publications about silicone implants.

Moreover, negative media attention also influences patients' opinions regarding their implants.<sup>6</sup> Television and newspapers showed to have the biggest impact; television far more than other media.<sup>6</sup> News media therefore does not only influence individual health behavior, but also the public officials responsible for public health policy. News media strongly influence public opinion, while medical articles give insight from a professional viewpoint. Their subtopics reveal the development, innovations and history of the positive and negative outcomes of the technical use and clinical implications of silicone breast implants. By critically looking at the interactions between these two factors we could perhaps learn lessons how to interpret media coverage around the recent PIP crisis<sup>7</sup>, which led to the recall of more than 500.000 women with silicone breast implants.

## METHODS

A systemic search in the electronic database PubMed was conducted on 30 may 2013. The search terms included ("silicones"[MeSH Terms] OR "silicones"[All Fields] OR "silicone"[All Fields]) AND ("breast implants"[MeSH Terms] OR ("breast"[All Fields] AND "implants"[All Fields]) OR "breast implants"[All Fields] OR ("breast"[All Fields] AND "implant"[All Fields]) OR "breast implant"[All Fields] OR "breast implantation"[MeSH Terms] OR ("breast"[All Fields] AND "implantation"[All Fields]) OR "breast implantation"[All Fields] OR ("breast"[All Fields] AND "implant"[All Fields])) OR (("silicones"[MeSH Terms] OR "silicones"[All Fields] OR "silicone"[All Fields]) AND ("breast"[MeSH Terms] OR "breast"[All Fields]) AND ("protheses and implants"[MeSH Terms] OR ("protheses"[All Fields] AND "implants"[All Fields]) OR "protheses and implants"[All Fields] OR "protheses"[All Fields])). After a search in the Cochrane library no additional articles were identified.

Based on titles the authors categorized all articles manually into different groups of subtopics. For the present study only one subtopic per article was chosen. The quantity of publications each year was calculated and a graph was formed. The archives of The New York Times were searched on headlines involving silicone breast implants, to compare the above mentioned graph of published medical articles with legislation and safety news trends in the regular media.

The New York Times was chosen because of the unique availability of free accessible online data on historical headlines. The Daily Mail for example has only online historical headlines dating back to the year 2000. Still the authors decided to include these headlines as an example of European news coverage on the recent PIP recall, which received less media attention in the US than in Europe.

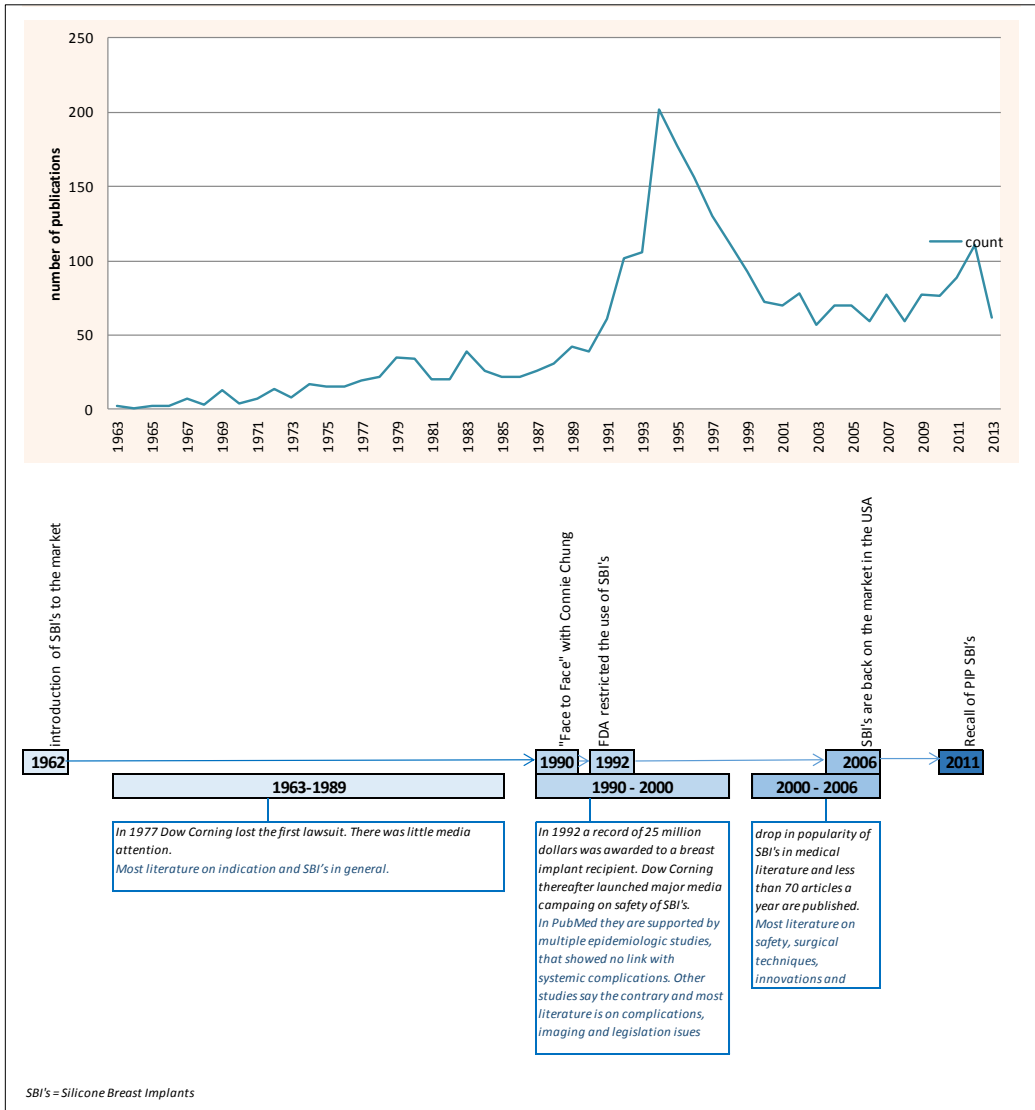
## RESULTS

### Medical Literature on Silicone Breast Implants

The literature search in PubMed on 30 May 2012 provided 2665 titles. Literature found was in English or French, but also Chinese, Danish, Swedish and Spanish literature was seen. Most literature was published in plastic, reconstructive surgery and aesthetic surgery journals or internal medicine/ immunology journals. All articles were categorized in subtopics based solely on the titles and Table 1 contains an overview of the quantity of articles per specific subject. The subtopics most popular in silicone breast implant medical literature found were: silicone breast implants in general, indications, complications (local and systemic), radiology or imaging and safety. There were 64 titles covering regulation, legislation and/or juridical issues and another 50 about the history and society aspects of the matter. Surprisingly few articles focus on complication management and satisfaction or quality of life of the patients who benefited from silicone breast implants. Figure 1 illustrates the popularity of silicone breast implants in medical literature in the past 50 years. The first medical literature on silicone breast implants was published shortly after their introduction to the US market.

In the early 60's most literature about silicone breast implants described indications for their use and the first general and clinical experiences, operation techniques and innovations.<sup>8</sup> The first described complications of silicone breast implants were published in 1968 and included a local infection, hematoma, rupture and a case of breast cancer after prophylactic mastectomies, reconstructed with silicone implants.<sup>9-11</sup> More than 10 years later the first systemic complications were described.<sup>12,13</sup> In the early 80's capsular contraction<sup>14</sup> and silicone migration<sup>15</sup> became more popular subjects as well as innovations and design. In the late 80's local and systemic complaints have been more frequently described.<sup>16</sup>

Figure 1 shows that less than 20 articles a year were published on silicone breast implants until the 90's. After 1990 a steep increase in medical articles published on silicone breast implants was seen with a peak of 200 articles a year in 1994, mainly on systemic and local complications.<sup>17,18</sup> Also papers on imaging techniques,<sup>19</sup> tissue and serum studies on immunologic factors<sup>20</sup> and of course legislation and court room science<sup>21</sup> were found. After 1994 the popularity of silicone breast implants as a subject of medical articles decreases fast and the number of publications by 2000 has dropped significantly compared to the 1990 level. Publications after 1994 cover immunologic research, complications and imaging studies.<sup>22-25</sup> Also the first studies on patient satisfaction and positive effects of silicone breast implants<sup>26,27</sup> and the first long term explantation studies were published.<sup>28,29</sup> From 2000 until 2010 around 70 new medical publications a year were written on mainly complications,<sup>30</sup> legislation, innovations, operation and imaging techniques. Very recently, a new spike is seen as over a 100 articles a year have been published in 2012 on complications and rupture of in particular the infamous PIP implants as well as the economic and social implications of their recall.<sup>7,31</sup>



**Figure 4.** The number of publications on Silicone Breast Implants in PubMed from 1962 until now, related to a timeline of historical events and subtopics

### Headlines in lay media

The headlines in the archives of The New York Times are used only as an illustrative example of lay media coverage of silicone breast implants of which most are stated in Table 2. We did not aim to be complete, but did notice a similar peak in popularity on the subject of silicone breast implants in the years from 1990 to 2000, just as we saw in medical articles.

**Table 2. Headlines concerning silicone breast implants in The New York Times from 1962 to 2009**

Timeline	Date	Headline
'62-'90	13/4/1969	More and more "average "Americans are visiting plastic surgeons in search of the body beautiful
	15/7/1974	Silicone infections traced to Tijuana; amputation often required small amounts, rigidly controlled
	9/12/1976	After mastectomy: The options for breast reconstruction
	24/11/1988	Panel calls for review of breast implants safety
	5/12/1988	Silicone implants: No cause for concern
	25/7/1989	Data suggest that implants may pose risk of later harm
'90-'99	19/12/1990	U.S. to begin regulation of breast implants in '91
	1/8/1991	Doctors urged to be frank on breast implant risk
	21/10/1991	Under pressure, U.S. weighs ban on use of breast implants
	4/11/1991	No evidence for breast-implant cancer
	7/1/1992	F.D.A. seeks halt in breast implants made of silicone
	19/1/1992	As silicone issue grows, women take agony and anger to court
	22/2/1992	Breast-implant plan upsets surgeons
	20/2/1994	Breast implant makers agree to pay \$3.7 billion
	16/6/1994	Study finds no implant-disease links
	13/12/1994	Ethics issue over doctors as legal consultant
	16/5/1995	Dow Corning in bankruptcy over lawsuits
	16/5/1995	Legal system and science come to different conclusions on silicone
	22/6/1995	New study finds no link between implants and illness
	28/2/1996	Study reports a small risk, if any, from breast implants
	6/3/1997	Many who get breast implants are found to need more surgery
	15/7/1998	British panel disputes risks of implants using silicone
	21/7/1998	Cosmetic breast enlargements are making a comeback
2/12/1998	Panel can't link breast implants to any diseases	
'00-'09	15/10/2003	F.D.A. panel reconsiders silicone implants
	16/10/2003	F.D.A. panel backs breast implants made of silicone
	7/4/2005	High rate of failure estimated for silicone breast implants
	18/11/2006	F.D.A. will allow breast implants made of silicone
	24/5/2007	Implants are back, and so is debate
	17/1/2008	Do my breast implants have a warranty?
	15/1/2009	Seeking self-esteem through surgery
<i>The above list of articles is not complete, but illustrates the topics covered in lay media on the subject of silicone breast implants and its popularity in the news at certain moments in time, the most recent spike in figure 1 is not included in this table 2</i>		

The subtopics popular in news coverage are safety issues, legislation and court cases. Of the safety issues especially systemic complications were mentioned and their association with silicone breast implants has been suggested as well as rejected. Local complications are hardly ever described in lay media as well as innovations and imaging. The reason the New York Times was used as an example is that most large European news journals lack free online historical data on cover headlines. The Daily Mail has an online register dating back only to 2000, but the headlines on silicone breast implants are included in Table 3. One can see that besides some headlines on EU guidelines in 2001 the topic had not been in the headlines until the PIP recall in 2011.



**Table 3. Headlines concerning silicone breast implants in the Daily Mail from 2001 up to date, illustrating the popularity of the topic from December 2011**

11/12/2013	Founder of PIP breast implant company is jailed for four years in France after being found guilty of aggravated fraud
15/11/2013	It hurts so much I can't sit down': The dangerous practice of butt implants that is ruining women's lives across Venezuela
14/11/2013	British women among 1,700 in line for minimum of £2,500 compensation after PIP breast implant court ruling
5/6/2013	Sweden orders all women with PIP implants to get them removed as fresh tests show they could harm babies in womb
9/5/2013	Chemical in faulty breast implants used by 47,000 women in UK 'causes damage to unborn babies'
8/4/2013	Hundreds of women with faulty breast implants jeer French businessman as he goes on trial for making millions 'selling leaky PIP silicone'
7/4/2013	Top doctors call for removal of every breast implant given to 50,000 British women
18/11/2012	Faulty breast implant firm plunges into bankruptcy... to avoid paying millions to 1,700 victims
27/1/2012	Frenchman behind breast implant scandal charged with 'unintentional wounding'
27/1/2012	Breast implant 'butcher' at centre of PIP silicone scandal charged with 'unintentional harming'
14/1/2012	'Replace our toxic timebombs for free!' Dozens of women march on Harley Street clinics demanding 'dangerous' breast implants are replaced
13/1/2012	Buy one, get one free: The French firms cashing in on toxic implants scandal
12/2/2012	Free surgery for implant victims... if you live in Wales: English patients will still face bill
7/1/2012	NHS to offer 3,000 British women implant replacement following scare but private patients are told not to worry
6/1/2012	Psychologically frail women are trying to make money out of me, says Frenchman behind PIP breast implant scandal
2/1/2012	Revealed: The 'near criminal' mix of chemicals used in the dodgy breast implants affecting 50,000 UK women
1/1/2012	3,000 women in UK at risk from faulty breast implants as Government finally orders review of risks of ruptures from cheap silicone
31/12/2011	The breast implant butcher: The terrifying story of how former French butcher earned millions selling implants made from mattress filling
30/12/2011	Tycoon behind breast implants scandal to 'reopen business under new name and perform 60,000 operations a year'
29/12/2011	Tycoon behind breast implants scandal admits he KNEW they were not approved for use
25/12/2011	Interpol launches manhunt for breast implant 'butcher'
22/12/2011	At least 250 women to sue British clinics over silicone breast implants involved in cancer scare
22/6/2011	Bad news for Heidi and Pam! FDA rules breast implants are safe - but you can't keep them for more than eight to ten years
15/11/2001	New checks on breast implants
21/2/2001	New guidelines for breast implants revealed

## DISCUSSION

To provide an historical overview of silicone breast implants the authors studied medical literature and an example of lay media on the subject of silicone breast implants. A relation was found between the two forms of media, as we saw the popularity of the topics on silicone breast implants increase simultaneously in the 90's, when huge law suits and legislation issues dominated the silicone breast implant debate.<sup>32</sup> We observed the same pattern just recently when Jean Claude Mas, the former director of the French silicone breast implant factory Poly Implant Prothèse (PIP), went to trial for fraud just after a huge number of women in Europe were recalled

to have their PIP implants explanted. The clear correlation between popularity (either in a positive or negative sense) of silicone breast implants in lay media and medical literature is not new. Media watchers even credited (or blamed) the Connie Chung program in 1990 with setting off a chain reaction of similar shows, a national panic, and ultimately, lawsuits settled for millions of dollars. We do acknowledge the fact that our PubMed search might not have been complete and that the historical headlines of The New York Time is just an example of one media source. Nevertheless it was not our aim to be conclusive, but rather to get a representable body of the most important trends in medical literature on silicone breast implants and to correlate these findings to the actual legislation and coverage of lay media on silicone breast implants.

Figure 1 showed us the popularity of silicone breast implants over time and in the timeline thereunder we related the spikes in popularity to historical events regarding legislation and safety (text figure1). One can see a clear peak of popularity of silicone breast implants from 1990 to 2000, a few years before and up to 7 years after the FDA's decision of the moratorium on silicone breast implants.<sup>33</sup> The same popularity peak is seen in the headlines of The New York Times (Table 2). During the years before the moratorium conflicting research results have reported an alleged link or lack of this link between silicone breast implants and systemic disease, such as autoimmune diseases and other general complaints. In the years following the moratorium, well respected and highly rated medical journals such as the New England Journal of Medicine published large epidemiological studies that rejected any association.<sup>22</sup> Meanwhile other authors reported case series with women and systemic complaints.<sup>34,35</sup> A prestigious medical journal editor and researcher was criticized for a conflict of interest because the researcher was also a consultant for a manufacturer and had rejected the publication of articles indicating that implants injured health. Thereafter, more and more women with silicone breast implants and vague complaints registered in the huge class action lawsuits against silicone breast manufacturers. We see a drop in media attention in both medical journals and lay media after Dow Corning Wright Company, the largest manufacturer of breast implants in the US, filed for bankruptcy and large settlements were reached.

While The New York Times thereafter mainly covered the court cases and legislation issues the medical journals continued to investigate associations between silicone breast implants and systemic diseases and most found none. These results were supported by the Institute of Medicine (IOM) in 1999.<sup>36</sup> In the medical literature the focus shifted from systemic to local complaints like rupture and capsular contracture, which often lead to re-operations.<sup>37</sup> Many articles described innovations and imaging techniques to cope with these complications. Although more popular than before the moratorium, the media attention of silicone breast implants in both medical journals and lay media settled down. After convincing evidence on the safety of silicone breast implants the FDA lifted the moratorium in 2006<sup>38</sup>. Since then we see an increase in long term follow up studies in medical literature, of which most are financed by breast implant manufacturers in the process of getting FDA approval to market their newer modern high cohesive silicone gel filled implants.<sup>39-43</sup>

The recent media attention of fraudulent silicone breast implants from the French manufacturer Poly Implant Prothèse (PIP) generated the most recent spike in figure 1. Over 50 articles were published in the last years about a fraudulent manufacturer, which was far from a monopoly position. During the same time less than 30 titles appeared on large FDA approved manufacturers Mentor and Allergan. The PIP debacle got more media coverage in Europe than in the US and we see a similar peak of popularity very recently, illustrated by the headlines in the Daily Mail (Table3). Authors concluded that the quantity of articles on a specific subject or aspect of silicone breast implants does not necessary reflect its clinical or medical significance. This however can be very confusing to lay audience, who are confronted with this imbalance in medical literature.

Marketing uses the principle that whatever is in your face, on your radio, television or facebook page long enough and often enough will eventually be most frequently included in your life. Washing powder commercials are the typical example that either negative or positive emotions at media attention both equally contribute to brand awareness. Whether you like or hate the commercial, we most likely tend to buy the brand we encounter the most in our lives. The same is true for silicone breast implants, because despite all negative lay media attention recently, silicone breast implants are more popular than ever. In the US alone in 2011 307.180 women underwent breast augmentation with silicone breast implants and 96.277 women were reconstructed with silicone breast implants after breast cancer.<sup>44</sup> Since the reintroduction of silicone breast implants in 2006 breast augmentation has been the top cosmetic surgical procedure. The positive aspects of a medical device so frequently used as silicone breast implants could be more often emphasized in both medical literature as lay media. We should not wait until the next media peak in the history of silicone breast implants with dedicated long follow-up prospective research on their results and complications.

## CONCLUSIONS

We present a historical overview of silicone breast implants based on the subtopics and popularity in both PubMed and lay media. Media interest leads reactively to publications in the medical literature. Plastic surgeons should be aware of the historical context of breast implants, which will place the recent PIP recall in a certain perspective. The lack of research has been a reason for the FDA to ban silicone breast implants from the market. There is a need for plastic surgeons to be proactive, let us not wait for the next media circus but instead produce well designed prospective studies and breast implant registries, with audit outcomes and hard data.

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