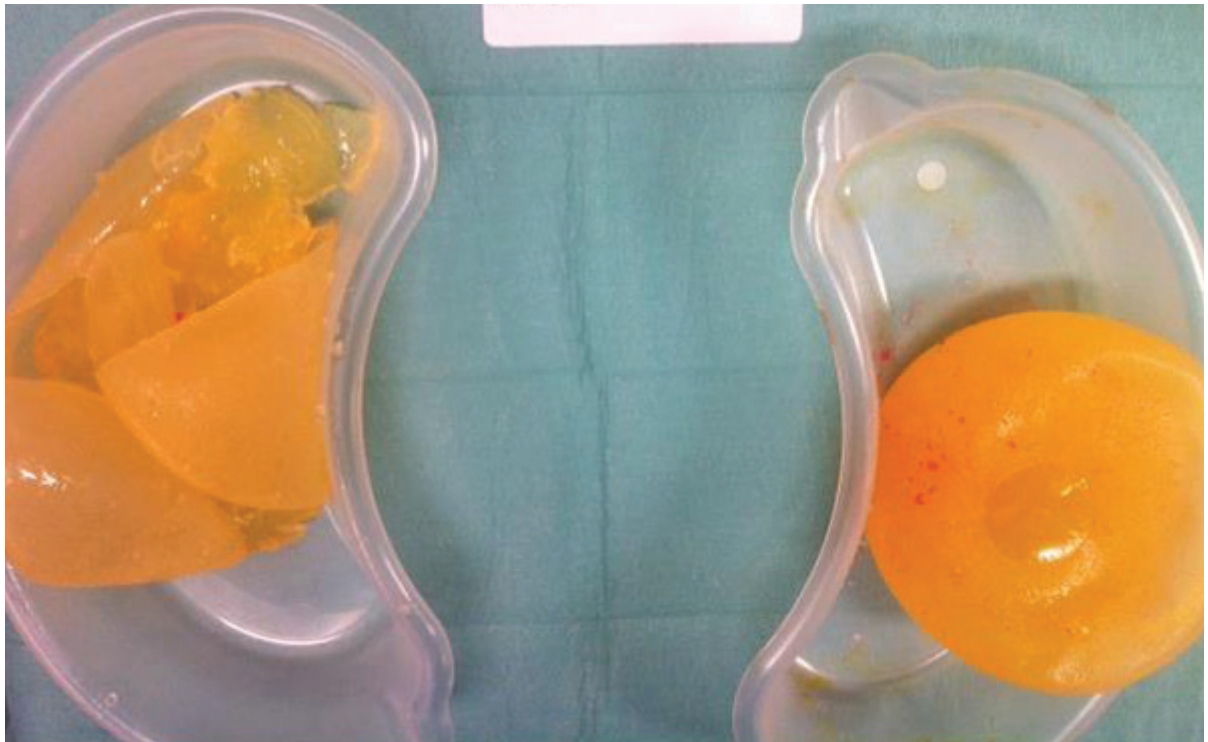


This **Literature Review** has been reproduced to inform Physicians caring for victims of the P.I.P Health Fraud

THE LITERATURE REVIEW • JUNE 2013

P.I.P. Breast Implants

The Literature Review June 2013



This **Literature Review** has been reproduced to inform Physicians caring for victims of the P.I.P Health Fraud

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Peer Reviewed Literature

A staggering 47,000 British women are thought to have been exposed to massive regulatory failures in medical devices, and affected by the largest medical fraud in history. In January 2013, 13 months after the fraud was first reported in the British press, the Department of Health published figures showing that only 431¹ women, of almost 8,000 referred to the NHS for treatment by private healthcare providers, had undergone P.I.P. implant removal surgery.

As more women are presenting for treatment at GPs surgeries and specialist consultations and more details are available to help understand the effects and dangers patients are facing, it is vital that all the emerging literature is reviewed. In a fast-moving health crisis where there are so many uncertainties this dissemination of information and scientific and medical evidence improves the quality of care and treatment all patients receive.

Unlike women in other European countries, including France, Germany, Belgium and most recently Sweden (4 June 2013), the Health Authorities and Public Safety Regulator (MHRA) in Britain expect women to wait for clinical signs of rupture before they are able to access NHS healthcare. This policy poses additional risks for women. As emerging evidence reveals new concerns over women's fertility and children's health associated with P.I.P breast implants, there is enormous fear that vital testing

is not undertaken and knowledge is not being shared, even though British experts are actively contributing to the mounting evidence with their findings. **The lack of information sharing and dissemination amongst healthcare professionals, by the British Health Authorities is adding to the difficulties British women are experiencing accessing the care, treatment and future monitoring they need.**

As part of an information sharing programme established by British victims of P.I.P fraud, here is the literature for your review.

All studies have been reproduced in brief, please use the web links to access the full article.

June 2013

1; <http://webarchive.nationalarchives.gov.uk/20130402145952/http://transparency.dh.gov.uk/2012/07/05/pip-breast-implants-published-data/>

The world is a dangerous place to live; not because of the people who are evil,
but because of the people who don't do anything about it.

Albert Einstein

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Figure 4. FDA Medical Device Safety Communication: Reports of Anaplastic Large Cell Lymphoma (ALCL) in Women with Breast Implants

1. Chemical & biochemical composition of late periprosthetic fluids from women after explantation of ruptured Poly Implant Prothèse (PIP) breast prostheses

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Abstract (excerpts)

In this study we have analysed the chemical composition of the silicone extracted from two explanted intact PIP breast prostheses and of breast late periprosthetic fluid (LPF) samples from n = 4 patients with ruptured PIP implants.

...

To the best of our knowledge, the profile of the major constituents in PIP-induced LPF have been unequivocally characterised for the first time in this work. Further studies will be needed to evaluate the biological consequences of the current results. The potential toxicological implications of the results are discussed in the light of the current literature on the health effects of PIP implants.

...

CONCLUSION (excerpt)

The combination of our results with those reported by other research groups suggest that the particles produced by the emulsification process are small enough in diameter to be drained by the breast lymphatic system through deep, superficial and capillary lymph collecting vessels and transported to the axillary lymph nodes and/or the skin. In the light of these results, we believe that urgent further

investigations are needed to understand the toxicological consequences (in particular for the lymphatic/lymphoid systems) of silicone conversion into such small, emulsified and mobile particles into the periprosthetic capsule, breast tissue and into other excitable organs or body regions (i.e. lungs and thoracic cavity). However, above all, **we believe that the results of this study confirm the conclusion that was underlying our previous investigation [see 7), still in line with the position declared by the International Confederation for Plastic and Reconstructive Surgery (IPRAS) on its website at the beginning of 2012: "There is no further room for discussion. It is mandatory to recommend the explantation of PIP (...) implants"**

Read the full article here:

<http://www.ncbi.nlm.nih.gov/pubmed/23835059>

2. Poly Implant Prothèse (PIP) breast implants: Our experience.

Chummun S, McLean NR.

Department of Plastic Surgery, Frenchay Hospital, Frenchay Park Road, Bristol BS16 1LE, UK. Electronic address: shaheelchummun@hotmail.com.

Abstract

INTRODUCTION:

This study describes our experience on the management of patients with PIP (Poly Implant Prothèse) breast implants between 2000 and 2008.

MATERIALS AND METHODS:

The medical records of patients were reviewed. Data was collected on clinical presentation, investigations, management and outcome.

RESULTS:

44 patients, with bilateral breast implants, and a median age of 33 years (18-54 years), were reviewed, and of these, 31 patients were asymptomatic. Symptoms at presentation included lymphadenopathy, capsule formation, breast lump, seroma and breast pain. Patients underwent mammography, ultrasound and MRI scanning of the breasts as part of the imaging investigations. 5 patients declined explantation. Reasons for explantation included patient anxiety, silent rupture, aesthetic breast change, palpable nodes and breast lump. 17 out of a total of 78 implants (21.8%) were noted to have ruptured; 2 had a simple tear and 15 were totally disintegrated. 1 patient underwent removal of the implants, 18 underwent exchange of implants, and 20 patients had a capsulotomy and exchange of implants. Postoperative complications included wound infection, seroma, axillary

lymphadenopathy, hypersensitive scar and overgranulation of the wound.

CONCLUSION:

Our series confirms the high rate of PIP implant rupture (21.8%), the majority of which were asymptomatic. The main reasons for explantation were patient anxiety and silent rupture of implants. It is imperative that patients should be appropriately counseled, prior to surgery with regards to removal of the implants, given the increased rupture rates noted.

<http://www.ncbi.nlm.nih.gov/pubmed/23499229>

3. Bilateral supraclavicular swelling: an unusual presentation of ruptured Poly Implant Prothese (PIP) breast implants.

Manickavasagar T, Morritt AN, Offer GJ.

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Abstract

Breast implants manufactured by the French company Poly Implant Prothese (PIP) have gained notoriety in the International media since the realisation that industrial grade silicone was used in their manufacture with consequent increased risk of implant rupture. At present, it is estimated that there are estimated to be over 40,000 women in the UK with PIP implants. **We report an unusual presentation of PIP breast implant rupture as swelling in the supraclavicular fossae. This has not previously been reported in the literature.**

<http://www.ncbi.nlm.nih.gov/pubmed/22836112>

4. Breast implant (PIP), chronic inflammation and cancer: is there a connection?

Case report.

Gubitosi A, Docimo G, Ruggiero R, Esposito A, Esposito E, Foroni F.

Abstract

The “PIP problem”, in the field of the breast augmentation, represents today a surgical epidemiological emergency. The massive media coverage produced a kind of mass fear and many women are asking for explantations. A 47 y.o. female, breasts implanted with PIP devices for breast augmentation in 1998, came to our clinic asking for explantation and excisional biopsy of a 2.5 cm nodule adjacent to the upper side of the breast implant capsule. The outcome of the pathologic examination of the excised nodule was: ductal infiltrating carcinoma of the breast, medium degree of differentiation. After 7 days from the first operation the patient underwent a skin-sparing mastectomy with axillary lymphadenectomy and immediate reconstruction by a submuscular placement of implant.

The surgical specimen sent for pathologic examination revealed: “granulomatous inflammation by giant cells around extraneous material, lymph nodes, negative for cancer, showed extensive accumulation of foamy macrophages containing extraneous material”. The findings of foreign material in granulomas and macrophages that are the primary inflammation body defense, suggest that the chronic inflammation, coming from mammary implants subject to leakage or/and osmotic shift, increase the risk of breast cancer. We therefore suggest improving the explantation/replacement of old implants.

KEY WORDS: Breast cancer, Extraneous material, Immediate breast reconstruction, Inflammation, Pip Implant.

<http://www.ncbi.nlm.nih.gov/pubmed/23075481>

5. Ruptured (PIP) breast implant after aesthetic breast augmentation: diagnosis, case management & histologic evaluation.

Dieterich M, Stubert J, Stachs A, Radke A, Reimer T, Gerber B.

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Abstract

Since the scandal of the poly-implant protheses (PIP) breast implants, all patients with PIP are advised to have their implants removed. With approximately 400,000 PIP implants sold worldwide breast, surgeons will be confronted with these patients. Histologic examination in the reported case showed silicone infiltration into fatty tissue and breast tissue without signs of malignancy. A general histologic analysis for the rare event of an anaplastic large T cell lymphoma is not advised. **The malignant potential of PIP implants currently is uncertain, and further investigation is required.**

Level of Evidence V This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

<http://www.ncbi.nlm.nih.gov/pubmed/23288097>

6. Silicone lymphadenopathy after breast augmentation: case reports, review of the literature, and current thoughts.

Zambacos GJ, Molnar C, Mandrekas AD.

Artion Plastic Surgery Center, Athens, Greece, gz@aestheticsurgery.gr.

Abstract

BACKGROUND:

Silicone lymphadenopathy after implantation of silicone breast implants is a foreign body reaction due to the release or migration of silicone into the tissues surrounding the breast implant.

METHODS:

For the study, 14 cases of silicone lymphadenopathy were identified from the authors' files. Four patients had been implanted before 2000 and had various types of implants. The remaining 10 patients all were implanted between 2006 and 2009, and all had Poly Implant Prothèse (PIP) implants. In addition to an analysis of the authors' own cases, a thorough bibliographic search was initiated to identify all reports of lymphadenopathy related to silicone breast implants.

RESULTS:

The implant age of the four patients implanted before 2000 was 12-34 years (mean, 17.25 years). The implant age of the 10 patients implanted after 2000 was 2-6 years (mean 3.45 years). The literature search identified 29 papers with case reports of silicone lymphadenopathy published between 1978 and 2012, with a total of 175 cases. Usable data were extracted from 164 of the 175 cases. Of these patients, 159 were implanted before (and including) the year 2000 and had a mean age of 11 years at presentation or explantation, and 5 of these patients were implanted after the year 2000 and had a mean age of 4.6 years at

presentation or explantation. After inclusion of the authors' own cases, the mean age of the implants at presentation or explantation was 10.56 years in a total of 178 cases. Of these patients, 163 were implanted before (and including) the year 2000 and had a mean age of 11.16 years at presentation or explantation, and 15 of these patients were implanted after the year 2000 and had a mean age of 4.06 years at presentation or explantation.

CONCLUSIONS:

Current breast implant technology has minimized the release of silicone gel due to rupture or bleeding of silicone and its migration into the surrounding tissues, thus reducing the rate of silicone lymphadenopathy in the last 10 years. **The PIP implant scandal highlights the fact that disregard for the implant manufacturing technologies and standards in favor of higher profits increased rupture rates and gel diffusion, leading to increased local complication rates. Silicone lymphadenopathy is a foreign body reaction that does not warrant treatment unless it is symptomatic or interferes with breast cancer detection.**

LEVEL OF EVIDENCE III: This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

<http://www.ncbi.nlm.nih.gov/pubmed/23354761>

7. Chemical and physicochemical properties of the high cohesive silicone gel from Poly Implant Prothèse (PIP) breast prostheses after explantation: A preliminary, comparative analytical investigation.

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Abstract

Aim of this work was to gain a deeper insight into the analytical profile of the macromolecular and LMW fractions of polymeric silicones present in breast implants. The study was conducted on silicone gel samples from (i) breast prostheses (Poly Implant Prothèse, PIP) explanted from a patient that needed their therapeutical removal, (ii) from a virgin Mc Ghan 410 MX prosthesis and (iii) from a sample of technical-grade non-cohesive silicone. The gels were analysed using rheological techniques, attenuated total reflectance infrared spectroscopy (ATR-FT-IR), nuclear magnetic resonance (¹H NMR), gas chromatography coupled to mass spectrometry (GC-MS) and flow injection electrospray mass spectrometry (FI-ESI-MS). **Our results demonstrate that, compared to the virgin McGhan gel, the silicone present in the PIP prostheses lacks a significant part of the cross-linking sites necessary for the high-cohesive properties of the gel, significant amounts of cholesterol have been absorbed from the breast tissue by the silicone material, demonstrating the lack of impermeability of its elastomer shell. The potential implications and consequences of these analytical results are discussed.**

<http://www.ncbi.nlm.nih.gov/pubmed/23454600>

8. [Breast augmentation by Poly Implant Prothèses silicone implants: retrospective study about 99 patients. Rupture analysis and management].

Aktouf A, Auquit-Auckbur I, Coquerel-Beghin D, Delpierre V, Milliez PY.

Service de chirurgie plastique, reconstructrice et esthétique, SOS mains, CHU Charles-Nicolle, Rouen, France. ghaniaktouf@hotmail.com [Article in French]

Abstract

BACKGROUND:

Breast augmentation is one of the most frequent intervention in plastic surgery. In March 2010, the Afssaps has withdrawn from the market all the Poly Implant Prothèses (PIP) silicone implants, the authors report a retrospective study of 99 patients who had breast augmentation by PIP implants. The aims of this work are to evaluate the ruptures observed with these implants and to propose a management.

CONCLUSION:

Given our results, it seems reasonable to withdraw all the PIP silicone breast implants.

<http://www.ncbi.nlm.nih.gov/pubmed/22651997>

METHODS:

We included in the study 99 patients and 192 silicone gel implants. The interventions were performed between 2005 and 2010. On 192 implants, 184 had a textured surface and eight a smooth one. According to the latest recommendations from the Afssaps, all patients had a clinical examination and an ultrasonography looking for rupture signs. MRI was performed in case of doubt.

RESULTS:

We found 23 ruptured implants: 18 intracapsular and five extracapsular ruptures, involving 17 patients. We also found 28 patients with axillary lymphadenopathy and eight patients with locoregional silicone spread. Finally, we found that 35 patients had chronic breast pains.

9. Surface and mechanical analysis of explanted Poly Implant Prosthèse silicone breast implants.

Yildirimer L, Seifalian AM, Butler PE.

Department of Plastic and Reconstructive Surgery, Royal Free Hospital Hampstead NHS Trust, and University College London (UCL) Centre for Nanotechnology and Regenerative Medicine, UCL Division of Surgery and Interventional Science, UCL, London, UK.

Abstract

BACKGROUND:

The recent events surrounding Poly Implant Prosthèse (PIP) breast implants have renewed the debate about the safety profile of silicone implants. The intentional use of industrial-grade instead of certified medical-grade silicone is thought to be responsible for reportedly higher frequencies of implant rupture in vivo. The differences in mechanical and viscoelastic properties between PIP and medical-grade silicone implant shells were investigated. Surface characterization of shells and gels was carried out to determine structural changes occurring after implantation.

METHODS:

Breast implants were obtained from women at the Royal Free Hospital (London, UK). PIP implants were compared with medical-grade control silicone implants. Tensile strength, tear resistance and elongation at break were assessed using a tensile tester. Surfaces were analysed using attenuated total reflectance-Fourier transform infrared (ATR-FTIR) spectroscopy. Spearman correlation analyses and Kruskal-Wallis one-way statistical tests were performed for mechanical data.

RESULTS:

There were 18 PIP and four medical-grade silicone implants. PIP silicone shells had significantly weaker mechanical strength than control shells ($P < 0.009$). There were negative correlations between mechanical

properties of PIP shells and implantation times, indicative of deterioration of PIP shells over time in vivo ($r_s = -0.75$, $P = 0.009$ for tensile strength; $r_s = -0.76$, $P = 0.001$ for maximal strain). **Comparison of ATR-FTIR spectra of PIP and control silicones demonstrated changes in material characteristics during the period of implantation suggestive of time-dependent bond breakage and degradation of the material.**

CONCLUSION:

This study demonstrated an increased weakness of PIP shells with time and therefore supports the argument for prophylactic removal of PIP breast implants.

<http://www.ncbi.nlm.nih.gov/pubmed/23475661>

10. The Psychological Impact of the PIP Breast Implants Scandal on a Cohort of UK Women.

Segaren, Nicholas MD; Taylor, James MD; Gilleard, Onur MD; Shanmugarajah, Kumaran MD; Segaren, Neil MD; Markar, Sheraz MD

INTRODUCTION:

It has been reported that 400,000 women worldwide received PIP implants consisting of non-manufacture grade silicone. The associations of this prosthesis with high rupture rates and cancers such as anaplastic large cell lymphoma have the potential to inflict serious psychological trauma on a cohort of women who are already vulnerable following a diagnosis of breast cancer.

Objective:

In the UK there was a huge amount of media publicity following the outbreak of the scandal that led to thousands of women demanding information from the medical community. This study was undertaken to assess the risk of developing psychological disorders in a susceptible group of women.

METHODS:

100 breast cancer patients who received implants for reconstructive purposes were asked to complete the Impact of Event Scale (IES) questionnaire. The IES consists of 15 short questions that give a total score out of 75. This numerical score can then be used to quantify how stressful an event has been. The questionnaire can identify less intense forms of stress right through to Post Traumatic Stress Disorder.

RESULTS:

92% of the women surveyed reported a score that impacted on their life in some way. 31% had a score that equated to the event having a powerful impact on their life and 9% produced a score that when interpreted meant that the event had a severe impact on their life and was thus capable of altering their ability to function.

CONCLUSION:

The reported costs of the scandal to the British government could run to over £150 million. The cost to the mental health of all who have been involved is impossible to calculate. **The medical community has a responsibility to limit the psychological impacts of this traumatic event by arranging appropriate counselling and timely intervention to support these women.**

http://journals.lww.com/plasreconsurg/Fulltext/2012/11001/The_Psychological_Impact_of_the_PIP_Breast.143.aspx

11. Rupture of poly implant prothèse silicone breast implants: an implant retrieval study.

Swarts E, Kop AM, Nilasaroya A, Keogh CV, Cooper T.

Perth and Nedlands, Western Australia, Australia From the Department of Medical Engineering and Physics, Royal Perth Hospital, and the Rodin Clinic.

Abstract

BACKGROUND:

: Poly Implant Prothèse implants were recalled in Australia in April of 2010 following concerns of higher than expected rupture rates and the use of unauthorized industrial grade silicone as a filler material. Although subsequent investigations found that the gel filler material does not pose a threat to human health, the important question of what caused a relatively modern breast implant to have such a poor outcome compared with contemporary silicone breast implants is yet to be addressed.

METHODS:

: From a cohort of 27 patients, 19 ruptured Poly Implant Prothèse breast implants were subjected to a range of mechanical tests and microscopic/macroscopic investigations to evaluate possible changes in properties as a result of implantation. New Poly Implant Prothèse implants were used as controls.

RESULTS:

: All samples, explanted and controls, complied with the requirements for shell integrity as specified in the International Organization for Standardization 14607. Compression testing revealed rupture rates similar to those reported in the literature. Shell thickness was highly variable, with most shells having regions below the minimum thickness of 0.57 mm that was specified by the manufacturer.

Potential regions of stress concentration were observed on the smooth inner surfaces and outer textured surfaces.

CONCLUSIONS:

: **The high incidence of Poly Implant Prothèse shell rupture is most likely a result of inadequate quality control, with contributory factors being shell thickness variation and manufacturing defects on both inner and outer surfaces of the shell.** No evidence of shell degradation with implantation time was determined.

<http://www.ncbi.nlm.nih.gov/pubmed/23249979>

12. Breast cancer detection and survival among women with cosmetic breast implants: systematic review and meta-analysis of observational studies.

Eric Lavigne, epidemiologist, **Eric J Holowaty**, adjunct professor, **Sai Yi Pan**, epidemiologist, **Paul J Villeneuve**, senior research scientist, **Kenneth C Johnson**, adjunct professor, **Dean A Fergusson**, senior scientist and director, **Howard Morrison**, director, **Jacques Brisson**, full professor

Abstract

Objectives

To evaluate whether the stage distribution among women diagnosed as having breast cancer differs between those who have received breast implants for cosmetic purposes and those with no implants and to evaluate whether cosmetic breast augmentation before the detection of breast cancer is a predictor of post-diagnosis survival.

Design Systematic review of observational studies with two meta-analyses.

Data sources Systematic search of the literature published before September 2012 conducted in Medline, Embase, Global health, CINAHL, IPAB, and PsycINFO.

Study selection

Eligible publications were those that included women diagnosed as having breast cancer and who had had augmentation mammoplasty for cosmetic purposes. **Results** The overall odds ratio of the first meta-analysis based on 12 studies was 1.26 (95% confidence interval 0.99 to 1.60; $P=0.058$; $I^2=35.6\%$) for a non-localized stage of breast cancer at diagnosis comparing women with implants who had breast cancer and women without implants who had breast cancer. The second meta-analysis, based on five studies, evaluated the relation between cosmetic breast implantation and survival.

This meta-analysis showed reduced survival after breast cancer among women who had implants compared with those who did not (overall hazard ratio for breast cancer specific mortality 1.38, 95% confidence interval 1.08 to 1.75).

Conclusions

The research published to date suggests that cosmetic breast augmentation adversely affects the survival of women who are subsequently diagnosed as having breast cancer. These findings should be interpreted with caution, as some studies included in the meta-analysis on survival did not adjust for potential confounders. **Further investigations are warranted regarding diagnosis and prognosis of breast cancer among women with breast implants.**

Author Affiliations

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<http://www.bmj.com/content/346/bmj.f2399>

13. Public health implications of differences in U.S. & European Union regulatory policies for breast implants.

Zuckerman D, Booker N, Nagda S.

National Research Center for Women & Families, Washington, DC, USA.
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Abstract

The recall of tens of thousands of defective breast implants in Europe in 2011-12 as well as new data on risks have raised questions about regulatory standards for these and other medical implants in the United States (U.S.) and European Union (EU). In the U.S., breast implants are regulated as high-risk medical devices that must be proven reasonably safe and effective in clinical trials and subject to government inspection before they can be sold. In contrast, clinical trials and inspections have not been required for breast implants or other implanted devices in the EU; approval is based on other information. **As a result of these differing standards, the PIP breast implants that were recalled across Europe had been removed from the market years earlier in the U.S. than in the EU, a decision U.S. government health agencies can point to with pride.** Nevertheless, the FDA track record on post-marketing breast implant research indicates poorly implemented studies and little meaningful enforcement to ensure that studies have been conducted correctly or findings reported accurately or acted upon. **In sum, neither the EU nor the US has used their regulatory authority to ensure the long-term safety of breast implants.** However, in 2012 the EU announced regulatory changes that could improve that situation.

<http://www.ncbi.nlm.nih.gov/pubmed/23245415>

14. Axillary lipogranuloma mimicking carcinoma metastasis after silicone breast implant rupture: a case report.

Gundeslioglu AO, Hakverdi S, Erdem O, Ozen EC, Inan I, Emlik D.

Necmettin Erbakan University, Department of Plastic, Aesthetic and Reconstructive Surgery, Akyokus, Meram, 42080 Konya, Turkey. ozlemgundes@hotmail.com

Abstract

Silicone-gel-filled breast implants have been widely used for breast augmentation and reconstruction after mastectomy. However, silicone implants have some well-known complications, such as implant rupture, which requires surgical intervention. Dissemination of silicone particles out of the implant causes a granulomatous reaction, a phenomenon known as silicone granuloma, in breast parenchyma as well as axillary, breast and chest wall lymph nodes, which mimics breast cancer metastasis. However, lipogranuloma after silicone breast implant rupture has not been reported in the literature, although it is a common complication after mineral oil or liquid silicone injection. **We present a case report of an axillary lymphadenopathy resulting from lipogranuloma after silicone-gel-filled implant rupture. Review of the literature suggests that this is the first report of a lipogranuloma resulting from implant rupture.**

See Figure: 1

<http://www.ncbi.nlm.nih.gov/pubmed/23245917>

15. Prediction of human genes and diseases targeted by xenobiotics using predictive toxicogenomic-derived models (PTDMs).

Cheng F, Li W, Zhou Y, Li J, Shen J, Lee PW, Tang Y.

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ytang234@ecust.edu.cn.

Abstract

New technologies for systems-level determinants of human exposure to drugs, industrial chemicals, pesticides, and other environmental agents provide an invaluable opportunity to extend the understanding of human health and potential environmental hazards. We report here the development of a new computational-systems toxicology framework, called predictive toxicogenomics-derived models (PTDMs). PTDMs integrate three networks of chemical-gene interactions (CGIs), chemical-disease associations (CDAs) and gene-disease associations (GDAs) to infer chemical hazard profiles, identify exposure data gaps and to incorporate genes and disease networks into chemical safety evaluations. Three comprehensive networks addressing CGI, CDA and GDA extracted from the comparative toxicogenomics database (CTD) were constructed. The areas under the receiver operating characteristics curve ranged from 0.85 to 0.97 and were yielded using our methodology using a 10-fold cross validation by a simulation carried out 100 times. As the illustrated examples show, we predicted new potential target genes and diseases for bisphenol A and aspirin. The molecular hypothesis and experimental evidence from published literature for these predictions were provided. **The results demonstrated that our method has potential applications for chemical profiling in human health exposure and environmental hazard assessment.**

<http://www.ncbi.nlm.nih.gov/pubmed/23455869>

16. The PIP scandal: an analysis of the process of quality control that failed to safeguard women from the health risks.

Victoria Martindale, Andre Menache

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Introduction

<http://jrs.sagepub.com/content/106/5/173>

Plastic surgery is a sector of medicine that continues to show strong trends in growth. In 2011, women accounted for 90% of all procedures, with breast augmentation being the most common. There are estimated to be a total of 130,000 women in the UK who have received breast implants and around 47,000 of these were silicone implants manufactured by the French-based company Poly Implant Prothèse (PIP). **Following the misuse by PIP of industrial grade silicone, an expert panel, chaired by Sir Bruce Keogh, was appointed by the Department of Health to investigate the consequences of this scandal. They concluded in their final report of June 2012 that 'PIP implants have not shown any evidence of significant risk to human health'.**

We disagree with their conclusion. Here we aim to share our concerns on the regulatory and quality control procedures that failed to safeguard thousands of women from the health risks associated with PIP breast implants. In light of the current ongoing review into cosmetic surgery which is also being led by Sir Bruce Keogh, it is vital that such failings are identified and tightened to ensure such a scandal is not repeated.

Read Full Article: Journal of the Royal Society of Medicine

17. Anaplastic large cell lymphoma in the setting of textured breast implant: a call for patients and physicians education.

Zakhary JM, Hamidian Jahromi A, Chaudhery S, Kim M.

Department of Surgery, Louisiana State University Health Sciences Center, Shreveport, USA.

Abstract

An anaplastic large cell lymphoma (ALCL) arising from the breast tissue is an extremely rare cancer possibly associated with breast implants. According to the FDA database, there are only approximately 60 reported cases of ALCLs in women with breast implants worldwide, and there is the possibility that some of those are duplicate reports of a single case. Here, we present a case of ALCL in a woman who had breast implants for more than 10 years. We discuss preoperative imaging and intraoperative findings, along with the histopathology features and the postoperative management. We suggest that the possibility of late presentation of ALCL be discussed with the patients when we offer and consent them for implant reconstructions following breast surgeries. **Increased awareness of the patients and the physicians would make the diagnosis of this entity less of a challenge.**

<http://www.ncbi.nlm.nih.gov/pubmed/23550394>

18. Ruptured poly-implant protheses breast implant after aesthetic breast augmentation: diagnosis, case management, and histologic evaluation.

Dieterich M, Stubert J, Stachs A, Radke A, Reimer T, Gerber B.

Breast Unit, Department of Obstetrics and Gynecology, University of Rostock, Suedring 81, 18059, Rostock, Germany. max.dieterich@uni-rostock.de

Abstract

Since the scandal of the poly-implant protheses (PIP) breast implants, all patients with PIP are advised to have their implants removed. With approximately 400,000 PIP implants sold worldwide breast surgeons will be confronted with these patients. Histologic examination in the reported case showed silicone infiltration into fatty tissue and breast tissue without signs of malignancy. A general histologic analysis for the rare event of an anaplastic large T cell lymphoma is not advised. The malignant potential of PIP implants currently is uncertain, and further investigation is required.

Level of Evidence V This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

<http://www.ncbi.nlm.nih.gov/pubmed/23288097>

19. Importance of histological analysis of seroma fluid.

Murphy S, Carroll S.

Abstract

The recent observation of anaplastic large cell lymphoma (ALCL) in association with breast implants has initiated a large amount of literature recently, particularly in light of the issues with Poly Implant Prosthese implants. There are now approximately 35-50 reports of this lymphoma associated with breast implants. **One of the presenting signs with this lymphoma is a late perimplant seroma.** Given Kim et al's recommendations for seroma fluid to be analysed, **we suggest that all late seromas should be considered for analysis for the possible presence of a causative ALCL pathology, and add to the data currently available on this association.**

LEVEL OF EVIDENCE V: This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors <http://www.springer.com/00266>.

<http://www.ncbi.nlm.nih.gov/pubmed/23288102>

20. [About two cases of lymphoma in implant capsule: A difficult diagnosis, an unknown pathology.]

Ivaldi C, Perchenet AS, Jallut Y, Casanova D.

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Abstract

The anaplastic large cell lymphoma (ALCL) is a rare disease, its incidence in the United States is one case per 500,000 women and three for 100 million patients for breast single location. Forty-six cases have been reported in the literature. They can grow on any type of implant: expander prosthesis silicone and saline, smooth or textured envelope. Currently, the consensus process includes capsulectomy, removal of the implant, chemotherapy and radiotherapy. However, some authors classify under indolent disease, but **we believe that some cases may escape any therapeutic and become very aggressive forms. It is therefore important to make an early diagnosis and start treatment urgently. Severity and suspicion of iatrogenic nature of ALCL have an obligation to inform future with implants.**

<http://www.ncbi.nlm.nih.gov/pubmed/23707084>

21. Anaplastic large cell lymphoma of the breast arising around mammary implant capsule: an Italian report.

Farace F, Bulla A, Marongiu F, Campus GV, Tanda F, Lissia A, Cossu A, Fozza C, Rubino C.

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Abstract

Anaplastic large cell lymphoma (ALCL) of the breast is a very rare nonepithelial neoplasm. In the literature, this tumor has sometimes been described in proximity of breast implants (60 implant-related ALCL reported). In 2010, a patient who had undergone a right mastectomy and tissue expander/implant reconstruction for a “ductal” carcinoma 10 years before was referred to our unit for evaluation. On examination, an enlarged reconstructed right breast was found. The reconstructed breast did not show tenderness or signs of infection, ulceration, or breakdown. Mammograms and ultrasound scan did not suggest the presence of recurrent cancer, infection, deflation of the implant, or severe capsule contracture. The patient underwent mammary implant replacement. About 3 weeks after surgery, the patient came back to our unit for a new mild enlargement of the operated breast and the implant was removed. Three months later, the patient returned with a skin lesion in the right parasternal region. A radical excisional biopsy was performed under local anesthesia and the diagnosis of ALK-1-negative ALCL was finally made. **The clinical and histological diagnosis of this disease is difficult as it can often be mistaken for a simple seroma (breast enlargement), an infection, or an unspecific reaction to silicone (redness and/or tension of the skin, itching, and fever). We strongly**

suggest considering ALCL in any patient with a spontaneous breast seroma lasting more than 6 months after mammary prosthesis implantation. The suspicion of ALCL must be suggested to the pathologist immediately.

LEVEL OF EVIDENCE V: This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors
www.springer.com/00266 .

<http://www.ncbi.nlm.nih.gov/pubmed/23620008>

22. PIP silicone breast implants: Rupture rates based on the explantation of 676 implants in a single surgeon series.

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Summary

Introduction

To determine the true rupture rates of PIP implants from a large single surgeon cohort and to assess whether rupture rates varied depending on time of implant insertion. In addition, the efficacy of ultra sound scanning (USS) in determining rupture is examined.

Design

Predominantly prospectively based analysis of patient records, investigations and surgical findings.

Participants

338 patients (676 implants) were included in the study and they all had removal of their implants. The senior author operated on all patients at some stage of their treatment. 160 patients were imaged pre-operatively with USS. Patients had implants inserted between 1999 and 2007 for cosmetic breast augmentation.

Results

A total of 144 ruptured implants were removed from 119 patients, giving a rupture rate of 35.2% per patient and 21.3% per implant over a mean implantation period of 7.8 years. A statistical difference ($P < 0.001$) in rupture rates between implants inserted prior to 2003 and those inserted from 2003 was demonstrated, with higher failure rates in the latter group. There was a significant difference in rupture rates depending on pocket placement of

the implants. The sensitivity and specificity of USS at detecting rupture was 90.6% and 98.3% respectively. A proportion of patients (29.4%) demonstrated loco-regional spread of silicone to the axilla on scanning.

Conclusions

Our paper has confirmed high rates of PIP implant failure in the largest published series to date. The significant difference in rupture rates between implants inserted prior to 2003 and those after this time supports the view that industrial silicone was used in the devices after 2003. **Implants are more likely to rupture if inserted in the sub muscular plane compared to the sub glandular plane.** USS is highly effective at detecting rupture in PIP implants and loco-regional spread is high compared to other devices. **We believe this paper provides hard data enabling more informed decision making for patients, clinicians and providers in what remains an active issue affecting thousands of women.**

[http://www.jprasurg.com/article/S1748-6815\(13\)00278-7/abstract](http://www.jprasurg.com/article/S1748-6815(13)00278-7/abstract)

23. A single surgeon's experience of the PIP breast implant "saga": Indications for surgery & treatment options.

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Cambridge University Hospitals NHS Foundation Trust, UK
Cambridge Breast Unit, Addenbrooke's Hospital, Cambridge University Hospitals NHS
Foundation Trust, UK
School of Clinical Medicine, University of Cambridge, UK
Department of Plastic & Reconstructive Surgery, Addenbrooke's Hospital, Hills Road,
Cambridge University Hospitals NHS Foundation Trust, UK

Results

Presentation

The average age of the six patients was 42.5 years (range 34e59) and median duration of PIP implant being in-situ was just over five years (range 2e11). All primary procedures had been performed in cosmetic clinics in the UK by practitioners who were not plastic surgery accredited. All patients had at least two of the following five features: (i) breast discomfort (ii) axillary discomfort, (iii) breast swelling (iv) axillary swelling, or (v) change in breast consistency.

...

Discussion

All patients presented with pain or discomfort, swelling or changes in appearance of their breasts and axillae. Almost all required further investigations prior to corrective surgery. Investigations confirmed ruptured implants and silicone granulomas in the breast and axilla.

Surgery was necessarily more complicated than a typical revision requiring a total capsulectomies and replacement of the implants with pocket change or mastopexy to ensure acceptable cosmesis.

Additional procedures included local granuloma excision, resection of clinically enlarged silicone-filled lymph nodes and wash-outs of extravasated silicone. The operations were therefore prolonged and technically challenging, while patients were required to stay in hospital for at least 48 h with drains in-situ. The cost to the patient rose in parallel with this degree of surgical complexity.

Read Full article:

[http://www.jprasurg.com/article/S1748-6815\(13\)00051-X/abstract](http://www.jprasurg.com/article/S1748-6815(13)00051-X/abstract)

24. The clinical and diagnostic consequences of Poly Implant Prothèse silicone breast implants, recalled from the European market in 2010.

Maijers MC, Niessen FB.

Department of Surgical Oncology, Erasmus Medical Center/Daniel den Hoed Cancer Center, Amsterdam, the Netherlands.

Abstract

BACKGROUND:

Recently, Poly Implant Prothèse silicone breast implants were recalled from the European market. The authors studied 112 women and previously published data on rupture prevalence. Women are presenting with symptoms they feel may be a result of ruptured implants. The authors' aim was to study the clinical consequences of Poly Implant Prothèse implants.

METHODS:

One hundred twelve women with 224 proven Poly Implant Prothèse implants after 10 years of implantation were enrolled in this study. All women underwent physical examination and magnetic resonance imaging and were interviewed regarding symptoms. Details of the explantations of 35 women with at least one ruptured implant were documented. Tissue from 10 women was sent for pathologic investigation.

RESULTS:

Of 112 women, 34 (30.4 percent) had symptoms attributable to their implants. Physical examination showed that 12 of the 121 women (10.7 percent) had findings suggestive of rupture, most commonly pain. Three had lymphadenopathy that seemed to correlate with implant rupture or excessive "gel bleed." Pathologic findings showed no malignancies. Eight women who underwent explantation had no

implant rupture. **Excessive gel bleed was documented in half of them.**

CONCLUSIONS:

Clinical consequences of women with Poly Implant Prothèse implants are comparable to those reported in the literature of other manufacturers. Neither complaints nor findings at physical examination had a significant correlation with implant rupture at explantation. **Magnetic resonance imaging is still the preferred method compared with physical examination for diagnosing rupture.** The low specificity was probably caused by the difficulty in differentiating between rupture and excessive gel bleed in these implants.

<http://www.ncbi.nlm.nih.gov/pubmed/23446590>

25. Implant-Associated Anaplastic Large Cell Lymphoma: Beyond Breast Prostheses.

Kellogg BC, Hiro ME, Payne WG.

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Abstract

OBJECTIVE:

Anaplastic large cell lymphoma (ALCL) is a rare form of non-Hodgkin T-cell lymphoma potentially associated with silicone-shelled breast implants. The low incidence of ALCL has prevented establishment of causality. Many implantable devices are constructed with biomaterials similar to those used in breast prostheses. The purpose of this paper is to identify reports of ALCL in association with other types of implantable devices.

<http://www.ncbi.nlm.nih.gov/pubmed/23722577>

METHODS:

A literature review was conducted using PubMed to identify reports of non-Hodgkin lymphoma in association with various implantable devices.

RESULTS:

One case of ALCL was identified in association with a stainless steel internal fixation plate. Diffuse large B-cell lymphoma was widely reported in association with various implantable biomaterials and chronic inflammation.

CONCLUSION:

The neoplastic response associated with breast prostheses appears substantively different from other implantable devices. Physicians caring for patients with silicone elastomer-containing implants should have increased suspicion for implant-associated ALCL and report all pertinent cases in the literature.

26. Breast implant associated Anaplastic Large Cell Lymphoma: A case report and reconstructive option.

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Abstract

Since 1995, the association between Anaplastic Large Cell Lymphoma (ALCL) and breast implant capsules has been of increasing concern. Up to 40 cases have been reported worldwide. The majority of cases favour an indolent course, similar to that of primary cutaneous ALCL, with a 10-year survival rate of greater than 90%. Many recommendations have been made for diagnosis, treatment and adjuvant therapy but the issue of reconstruction post capsulectomy and removal of implants has not yet been addressed. We present a case report and management option.

<http://www.ncbi.nlm.nih.gov/pubmed/23751975>

27. Poly implant breast implants (PIP) and the rupture risk in asymptomatic patients: a warning for greater clinician suspicion in assessment & counselling.

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Discussion (excerpt)

Although it was not clear whether this patient had PIP implants, this clinical scenario is becoming a more common phenomenon facing GP's, breast and plastic surgeons. Where there is doubt with regards to the nature of the breast implant, clinical diligence and patient anxiety demands they are assumed to be PIP and so have a potentially increased risk of leakage. The final UK department of health report on PIP implants concluded that they are twice as likely to rupture as other implants with a rate of 6–12% at 5 years and 15–30% at 10 years [3]. In addition, it has been recognized that most implant ruptures do not produce any symptoms and signs. This silent rupture does produce limitations in providing a true rupture rate as only those women seeking imaging will be diagnosed. PIP implants though are more likely than other implants to produce symptoms with the rate of explants with signs of 0.7 at 5 years and 1.9% at 10 years [4].

The evidence available with regards to PIP implants will continue to evolve with time, but current UK recommendations and guidance on risk and assessment of rupture may underestimate and miss patients with subclinical implant ruptures

as highlighted in this case. Although PIP implants have no quality data to compare the rupture rates compared with other contemporary implants, possibly due to under reporting, the trend suggests that they are at an increased risk of rupture. It is also suggestive that upon rupture they are more likely to spread locally and generate a greater inflammatory response. This case highlights the possibility of widespread implant rupture in an asymptomatic patient and hence the need to consider radiological assessment in all patients to complement the clinical assessment by breast and plastic surgery specialists.

See Figure: 2

<http://jscr.oxfordjournals.org/content/2013/2/rjs044.full>

28. Complications of Poly Implant Prothèse breast implants: the current discussion.

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Department of Hand, Plastic and Reconstructive Surgery, Burn Care Unit, University of Heidelberg, BG Trauma Center Ludwigshafen, Ludwig-Guttman-Strasse 13, 67071 Ludwigshafen, Germany.

Against the background of the current discussion about Poly Implant Prothèse (PIP, Seyne-sur-mer, France) breast implants, we want to present a case demonstrating the complications such as implant rupture, silicone dissemination and level III silicone lymphadenopathy.

A 29-year-old woman with cosmetic breast augmentation with PIP implants 5 years previously showed a sensitive swelling in her right axilla and neck region.

All tests to detect an infectious or lymphomatous lymphadenopathy were negative. After ultrasound and MRI, rupture of the right implant was assumed and multiple pathologically enlarged lymph nodes up to supraclavicular region were shown.

An excision biopsy of one axillary lymph node was performed; the histological examination detected a strong silicone lymphadenopathy. Surgical removal of both implants as well as capsulectomy was performed and 14 axillary lymph nodes up to level II were resected. Histologic evaluation confirmed the previous results.

Our case underlines the actual discussion concerning increased rupture rate and massive silicone lymphadenopathy by PIP implants.

The Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) recommends clinical and ultrasound examination every 6 months for women with PIP implants. Any rupture, suspected

rupture or leakage of prosthesis should lead to its explantation as well as that of the contralateral implant.

In cases of unusual signs of inflammation, histological and immunohistochemical samples are to be taken.

<http://www.ncbi.nlm.nih.gov/pubmed/23480085>

29. Clinical Radiology:

The ruptured PIP breast implant

V. Helyar, C. Burke, S. McWilliams

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Abstract

Public concern erupted about the safety of Poly Implant Prothèse (PIP) breast implants when it was revealed in 2011 that they contained an inferior, unlicensed industrial-grade silicone associated with a high rate of rupture. **There followed national guidance for UK clinicians, which led to a considerable increase in referrals of asymptomatic women for breast implant assessment.**

In this review we discuss possible approaches to screening the PIP cohort and the salient characteristics of a ruptured implant.

See full article here:

<http://www.sciencedirect.com/science/article/pii/S0009926013001190>

Figure : 1

1. Chemical & biochemical composition of late periprosthetic fluids from women after explantation of ruptured Poly Implant Prothèse (PIP) breast prostheses

Optical microscopical examination of (20× magnification) of the PF from (A) patients 1 and (B) patient 2.

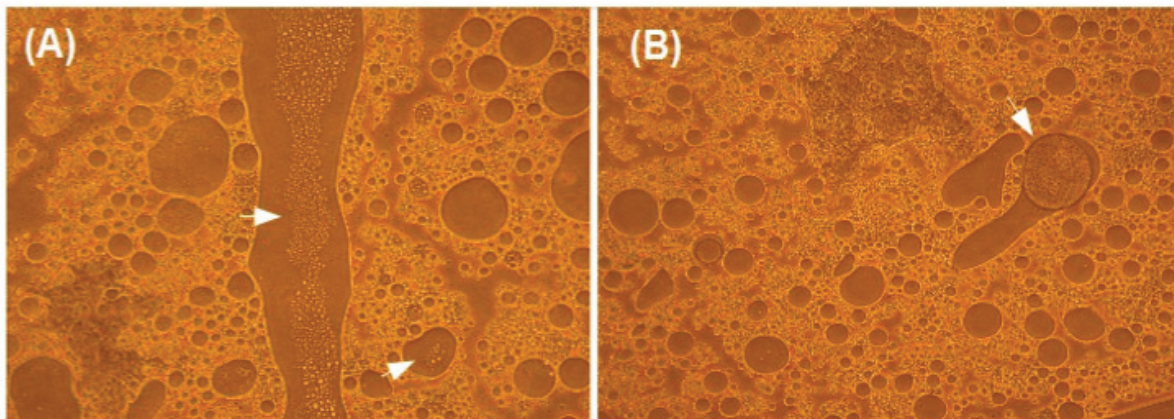
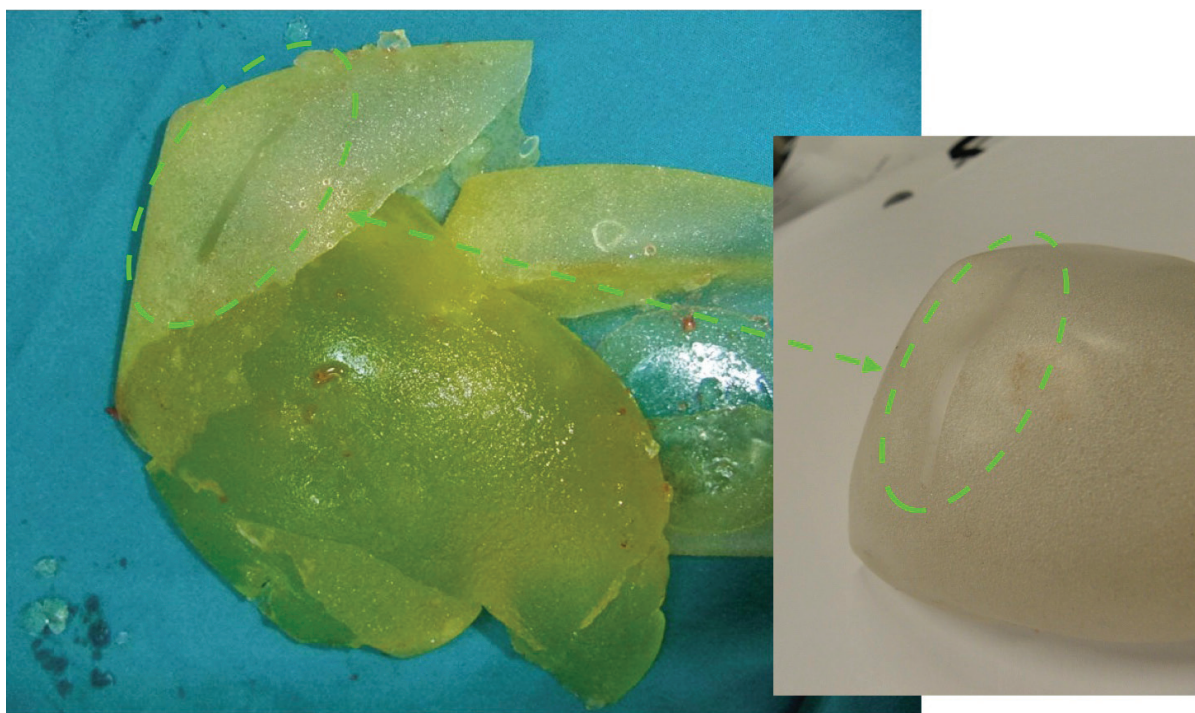


Figure : 2

14. Axillary lipogranuloma mimicking carcinoma metastasis after silicone breast implant rupture: a case report.



Round, textured implant explanted in Turkey with total disintegration of implant shell.
According to the authors, the implant lacked any manufacturer identifier.

From: A. Ozlem Gundeslioglu, Sibel Hakverdib, Ozlem Erdemc, E. Cigdem Ozena, Irfan Inana, Dilek Emlikd. Axillary lipogranuloma mimicking carcinoma metastasis after silicone breast implant rupture: A case report. Journal of Plastic, Reconstructive & Aesthetic Surgery. Volume 66, Issue 3, March 2013, Pages e72–e75.

New, empty PIP implant shell from the PIP factory in La Syne Sur Mer - cedex (francia).

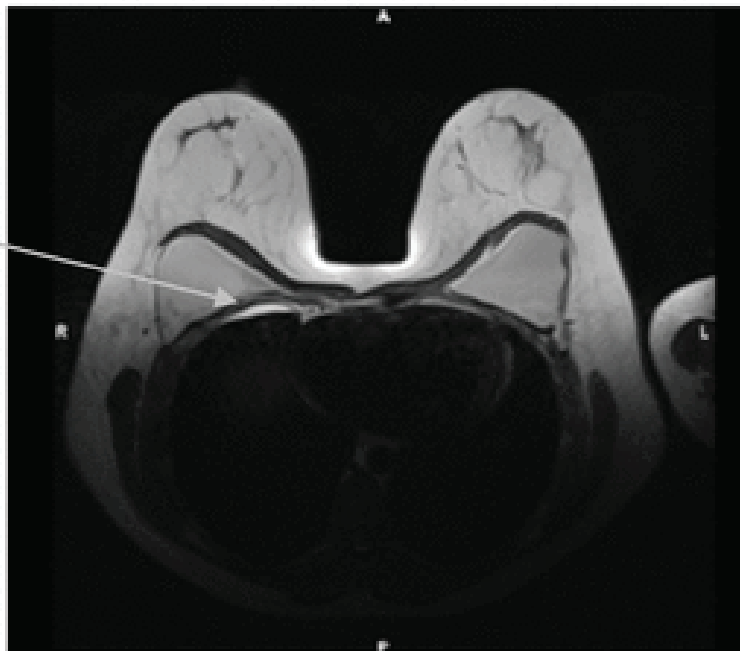
Both specimen share the same texturisation defect (or hidden identifier sign ?!).

Figure : 3

27. Poly implant breast implants (PIP) and the rupture risk in asymptomatic patients: a warning for greater clinician suspicion in assessment & counselling.

(a)

Intrathoracic
silicone



(b)

Intrathoracic
silicone

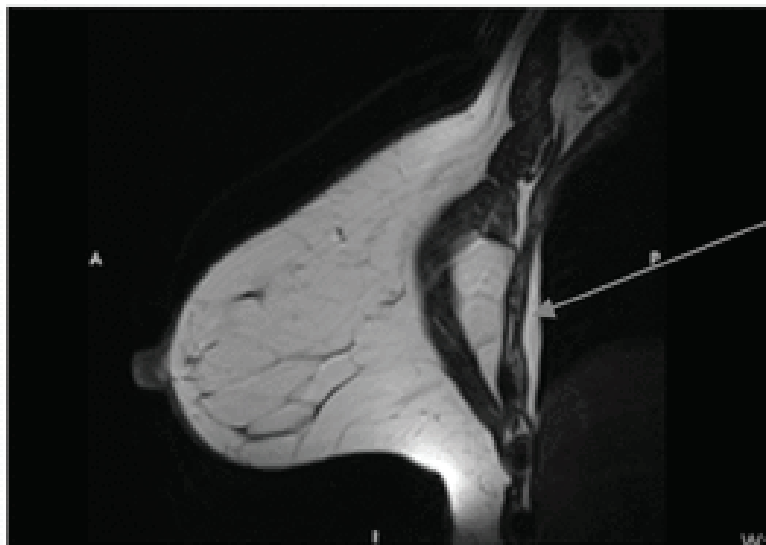
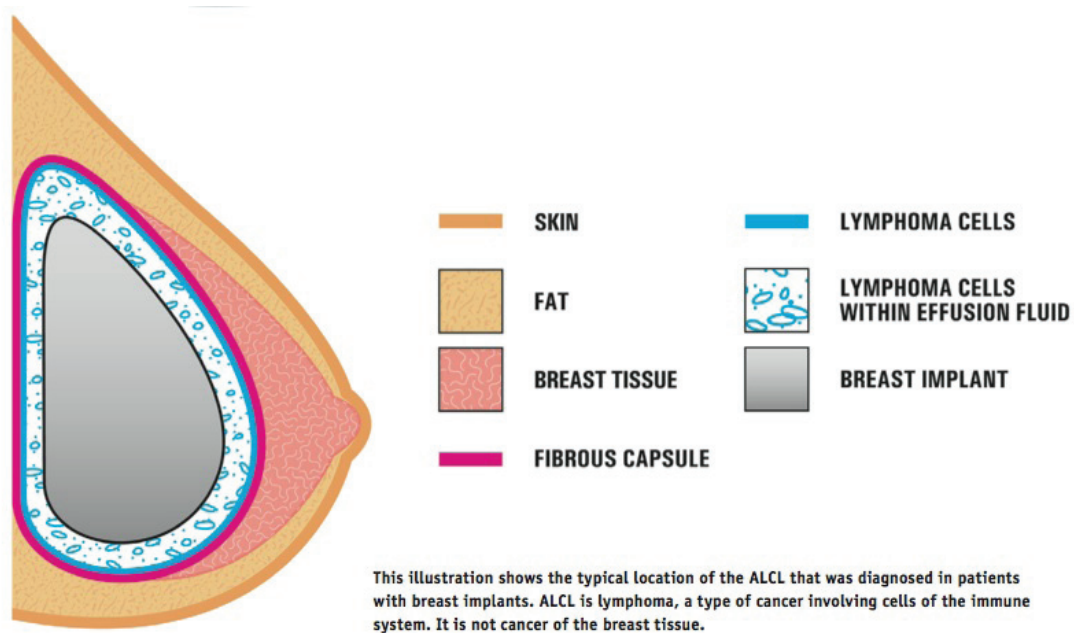


Figure: 4

FDA **Medical Device Safety Communication:** Reports of Anaplastic Large Cell Lymphoma (ALCL) in Women with Breast Implants

Updated: 20 November 2012

Most patients were diagnosed when they sought medical treatment for implant-related symptoms such as pain, lumps, swelling, or asymmetry that developed after their initial surgical sites were fully healed. These symptoms were due to collection of fluid (persistent seroma), hardening of breast area around the implant (capsular contracture), or masses surrounding the breast implant. Examination of the fluid and capsule surrounding the breast implant led to the ALCL diagnosis.



<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm240000.htm>

No problem can be solved from the same level of consciousness that created it.

Albert Einstein