

## **THE DANGER'S OF SILICONE IMPLANTS AND IMMUNE DISEASE**

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Silicone Immune Disease can occur when silicone gel leaks outside the Silastic shell of breast implants. The disorder stems from the effects of free silicon, as well as the chemicals used in the manufacturing process, acting on the various systems of the body. Patients can present more than twenty symptoms, many of them vague, like muscle aches, chronic fatigue and brain fog. The illness progresses slowly over a number of years and can be difficult to diagnose. Nonspecific diagnoses of arthritis, chronic fatigue syndrome and fibromyalgia are common. Women often don't connect their symptoms with their implants and even if they do, their physicians may tell them their implants cannot possibly be causing their illnesses.

Once the silicone gel leaks out of the Silastic shell, either as a result of the body's lipolysis reaction (the attempt to break down the implant casing, gradually weakening the shell and allowing the silicone to slowly seep out) or to an actual rupture of the shell, the problems caused by free silicone in a woman's body are obviously not limited to the chest wall, even though implant companies and plastic surgeons often tell her they are. When the silicone leaks from the casing, it migrates throughout the body, affecting every organ and system of the body. As early as 1956, researchers at Dow Chemical had established that liquid silicone injected into animals migrated to all the major organs and affected the brain, heart, lungs and spleen.

In 1970, research at both Dow Corning and Dow Chemical again confirmed that silicone migrates to all parts of the body, finding evidence of silicone in bone marrow and noting a reduction in brain weight in the animals they studied. In 1998, research scientists at Baylor College of Medicine found that silicone injected into mice migrated to ten different organs. In 1999, researchers reported that silicone injections in mice resulted in fatal liver and lung damage.

When breast implants rupture or leak, the silicone released into the human body has the same effect as silicone injections. According to professors at the University of Tennessee, "There is little if any difference between the effects of direct injections of silicone and the effects of gel-filled devices (implants). A

number of studies have shown that silicone implants are likely to leak within ten years of surgical placement, releasing free silicone into the body. In 1995, FDA Commissioner David Kessler estimated that the rupture rate of silicone implants ranges between 5% and 51%. Dr. Lu-Jean Feng, a plastic surgeon at Mt. Sinai Medical Center, presented evidence to the Plaintiff's Steering committee for the National Breast Implant Litigation which indicated that the rupture rate of implants which have been in the body for less than seven years is 11% while the rupture rate of implants in the body for longer than seven years is 61%.

From the study of the literature, we have learned that scavenger cells called macrophages pick up the free silicone and carry it into the lymphatic system where it gains access to the rest of the body. The silicone and chemicals in the gel are toxic to the macrophages, and digestion of these materials by the macrophages is not possible. Therefore, the macrophages discharge the materials elsewhere in the body where it is picked up by other macrophages. This process leads to an increase in the release of cytokines or inflammatory intermediates, which promote local inflammation and pain. This is why I experience, as did most of my patients, a burning sensation in the tissues around the leaking implant when the Silastic shell of the implant was no longer functioning to keep the silicone gel and the associated chemicals inside the shell. This burning in my chest wall gradually increased and eventually affected my left arm, as that was the side on which my implant was leaking. Some women experience a burning sensation equally on both sides of their chest with the sensation traveling down their arm as their illness progresses.

The department of Radiology Sciences at UCLA published an abstract entitled "Compromising Abnormalities of the Brachial Plexus as Displayed by Magnetic Resonance Imaging" by Collins, Shaver, Disher and Miller". Nerve conduction testing and neurological exam later confirmed the diagnosis as thoracic outlet syndrome, as well as conduction delays along the median nerve associated with sensory and motor deficits.

Because of the dysfunction of the lymphatic drainage of the arm when silicone clogs up the lymphatic channels in the axilla, many patients experience swelling of the extremities, and many underwent carpal tunnel release as the median nerve became entrapped at the wrist due to this swelling. Unfortunately, some women also had an entrapment due to the silicone around the brachial plexus

(large nerves) in their axilla armpit), and when the median nerve scarred to the tissues near the wrist after the carpal tunnel surgery, they experiences neurological problems when they extended their arm, due to stretching of the nerves between these two fixed points.

## Silicone Disease and Surgery

It became clear that surgical removal of the silicone was mostly achieved only in the chest wall and in the lymph nodes close to the chest wall where most of the silicone was entrapped. Removal of these larger infected and inflamed lymph nodes was advisable, especially as that the majority of breast implant patients dying were dying of lymphoma.

Chemicals in the silicone gel that had reached these lymph nodes were known to be carcinogens as well as neurotoxins. Concern about anaplastic large-cell lymphoma developing in this patient population had been expressed in a communication to JAMA IN November of 2008.

Although it was not advisable to remove multiple lymph nodes, especially if they were not enlarged or firm clinically, by removing the abnormal lymph nodes aided in the recovery of neurological function on the side from which the lymph nodes were removed.

In order to remove the majority of the silicone gel in the chest wall without spilling the contents of the implants into the breast or chest wall, doctors routinely remove the scar capsule surrounding the implant one piece of “en bloc”. This helps prevent the escape of the silicone gel, which can be either firm or runny, but in either case is difficult to remove from the tissues once it has escaped the capsule. In the early 1990’s, plastic surgeons were not routinely removing the scar capsules, as there was a misconception that the scar capsule would dissolve once the implant was removed.

Pathological examination of the capsules showed foreign body granulomatous reaction, a response to the silicone within the scar capsule. In this type of reaction, the body recognizes the silicone as “not self” walls it off with scar tissue and surrounds it with inflammatory cells. Later, articles in the plastic surgery literature indicated that if the capsules were not removed, there was a greater

risk of postoperative complications including infection and fluid collections called seromas.

In some cases, the silicone gel already traveled beyond the capsule and was forming granulomas or hard tender nodules within the muscles or the breast tissue wall muscle due to involvement of the muscle with a large silicone granulomas.

Many patients have had the release of the pectoralis muscle insertion during the surgery to place the implants, especially if large implants were inserted. It is important to reattach these muscle insertions if possible in order to avoid chest wall deformities. Patients with multiple surgeries are especially at risk for removal of the chest wall muscles, either because these are incorporated with the capsule or because surgeons who do not realize how difficult the dissection is between the capsule and the chest wall muscles remove them inadvertently.

If a surgeon tells a patient that he or she is able to remove the implants and capsules in one to two hours, the surgeon is likely speaking from inexperience. The more tissue removed, the more likely the patient is to have a permanent chest wall deformity. Tissue that is incorporated in the capsule or within a silicone granulomas must be removed in order to avoid post-operative problems.

Explanation surgery is much more difficult than implantation, so it is important to find a qualified surgeon. If a surgeon does not believe implants are associated with health problems, he or she is less likely to spend the time necessary to remove the entire capsule. Retained capsules are associated with problems such as seromas formation, infection and problems with imaging for cancer screening in the future.

## Chemical Soup

Further evaluation of the chemical makeup of silicone gel may explain why systemic illness can occur after it leaks into the body. According to Truth About Implants, a group providing support for women affected by breast implants, information reported from the manufacturers and the court documents indicate that thirty-seven chemicals are used in making silicone implant gel. The groups' website lists the following chemicals as ingredients:

1. Methyl ethyl ketone (neurotoxin)
2. Cyclohexanone (Neurotoxin)
3. Dentured Alcohol
4. Acetone (neurotoxin)
5. Urethane
6. Polyvinyl chloride (neurotoxin)
7. Isopropyl alcohol
8. Amine
9. Toluene (neurotoxin/carcinogen)
10. Dichloromethane (carcinogen)
11. Chloromethane
12. Ethyl acetate (neurotoxin)
13. Silicone
14. Sodium fluoride
15. Lead based solder
16. Formaldehyde
17. Talcum powder
18. Oakite (cleaning solvent)
19. Methyl 2-cyanoscrylates
20. Ethylene oxide (carcinogen)
21. Xylene (neurotoxin)
22. Hexon
23. 2-Hexanone
24. Thixon OSN-2
25. Stearic acid
26. Zinc oxide
27. Naptha (rubber solvent)
28. Phenol (neurotoxin)
29. Benzene (carcinogen/neurotoxin)
30. Lacquer thinner
31. Epoxy resin
32. Epoxy hardener 10 and 11
33. Printing ink
34. Metal cleaning acid
35. Color pigments as release agents
36. Heavy metals such as aluminum and platinum

### 37. Silica

Any plastic surgeon reviewing this list of chemicals should be able to understand why after approximately eight to ten years, silicone patients may present with symptoms of a progressive illness with features of immune, neurological and endocrine problems. Indeed, despite the Institute of Medicine's conclusion that there was insufficient evidence to establish that either or both types of breast implants cause systemic health effects, such as autoimmune disease, Douglas R. Shanklin, M.D., professor of pathology and of obstetrics and gynecology at the University of Tennessee in Memphis, believes that there is a relationship. His extensive research involving implant patients demonstrates that "immune processing and inflammatory cell responses are commonplace in the tissues surrounding silicone mammary implants. Dr. Shanklin concludes that the cellular conditions he has observed can be attributed to a new form of autoimmunity. He reports: there is growing evidence of progression into plasma cell myeloma, an usual malignancy of the immune system and certain precursor disorders".

***Sadly, evidence has now begun to accumulate that children born after a woman has these devices implanted are likely to be in poor health. The children show lymphocyte sensitization indices at about half the maternal levels, indicating an impaired immune system. Children born to the same women before they received implants had normal health and showed normal growth and development.***

Dr. Shanklin once said that his best chemical analysis of the breast implants was that they were a "bag full of silicone garbage." Since it is well known that chemicals can trigger autoimmune disease, it should not be a surprise to anyone that once these chemicals leak into the body, an autoimmune disease results.

Any physician who has studied the patient population at risk has seen a variety of autoimmune problems, the majority of which do not fall into any known disease category. Some patients have symptoms similar to patients with scleroderma, rheumatoid arthritis, lupus, and multiple sclerosis, but the most common diagnosis is atypical connective tissue disease and atypical neurological disease.

It becomes clear why the early epidemiological studies done at Harvard, Duke, and Mayo clinic failed to show a correlation between known autoimmune

diseases and silicone gel implants. It is not possible to perform an epidemiological study on a disease that has not yet been characterized. While it is true that silicone breast implants do not cause the autoimmune diseases listed in these studies, it is not true that they are not the root cause of the patients' symptoms. Since these patients do not have scleroderma, rheumatoid arthritis, lupus or multiple sclerosis, it is not difficult to show a lack of correlation between their symptoms and these illnesses. Instead, these patients are suffering from silicone immune disease, a new illness that has not been identified or characterized and for which laboratory tests confirming their diagnosis do not exist. Instead of using science to develop and treat their conditions, medical science is being used in the service of corporate interests to disprove their conditions.

### "The Ethical Irony"

It is a common practice for the institutions conducting the research into the safety of breast implants to receive endowments from Dow Corning, Dow Chemical or other interested corporate concerns. This practice, in and of itself, can be considered a conflict of interest and raises questions about the possibility of scientific bias in the research.

## SYMPTOMS OF SILICONE IMPLANT DISEASE

### ENDOCRINE SYSTEM:

#### Thyroid:

- Hair Loss
- Constipation
- Weight Gain
- Dry Skin
- Low Basal Metabolic Temperature

#### ADH:

- Dry Mouth
- Excessive thirst
- Shocks from static electricity
- Frequent urination

#### Adrenal:

Low Blood Pressure

Dizziness

Passing out, especially with standing up quickly (orthostatic Hypotension)

Feeling as if you are dying

#### Sex Hormones:

Irregular or lack of menses

PMS

Low Sex Drive

#### NEUROLOGICAL SYSTEM:

Arrhythmias

Cognitive Dysfunction

Memory Lane

Difficulty with Concentration

Brain Fog

Abnormal Brain MRI or Spectra Scan of the Brain

Blurred Vision

Sensory Loss

Tingling

Burning Pain of Extremities

Muscle Weakness

Balance Disturbance

Burning Pain of the Chest Wall, Breast or Axilla

Headaches

Tremors

Seizures

#### IMMUNE SYSTEM

Viral Infection

Mouth Ulcers

Herpes Simplex



## Fungal Infections

- Chronic Urinary Tract Infections
- Mouth Ulcers
- Shortness of Breath
- Depression
- Fungal Rashes

## Bacterial Infection

- Chronic Urinary Tract Infections
- Low Grade fever
- Night Sweats
- Bronchitis
- Sinusitis
- Colitis
- Periodontal Disease

## Autoimmune Disease (intracellular bacteria)

(less common in biotoxin patients)

- Rashes
- Joint Aches and Swelling
- Raynaud's Disease
- Dry Eyes
- Dry Mouth
- Difficulty Swallowing (less common than in silicone patients)
- Photosensitivity
- Difficulty Swallowing
- Abnormal Blood Clotting

## Other Symptoms

- Restrictive Lung Disease
- Pericarditis
- Muscle Aches
- Chronic Fatigue
- Lymph Node Enlargement

Mal-absorption syndrome  
Food Allergies  
Multiple Lipomas (platinum Exposure)  
New Onset Asthma (Platinum Exposure)

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