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Review of the problem of PIP breast implants

(Revisión del problema de las prótesis PIP)

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Contents

Abstract

In 2010, the European Union decided to suspend all sales and use of PIP prosthesis due to safety concerns that emerged in France and other countries. The decision prompted widespread social alarm, as the prosthesis' relatively low cost resulted in its extensive use in cosmetic surgery. News outlets and social media also increased tension by divulging stories of grim outcomes involving patients who used the implants, which were commercialized in most European countries and in a large portion of Latin America. This study gives a comprehensive review of the actual problems that PIP implants have had in patients in Cantabria and around the world.

En el 2010 la Unión Europea decidió suspender el uso y las ventas de las prótesis PIP debido a advertencias en Francia y otros países, sobre la seguridad en el uso. Como resultado de esto, se produjo una importante alarma social, dada la expansión alcanzada por estos productos en virtud a su relativo bajo coste, especialmente en procedimientos de medicina estética. Dichas prótesis fueron comercializadas en la mayoría de los países europeos y en muchos de América Latina. Las historias de casos muy graves relacionados con estas prótesis fueron exageradas por los medios de comunicación y en las redes sociales. En este estudio hacemos una amplia revisión de los estudios hechos sobre las mismas, para ver los efectos reales en los pacientes que las utilizaron, tanto en Cantabria como alrededor del mundo.

1. Breast Implants

1.1 Characteristics

Breast implants are prosthesis used in plastic, reconstructive and aesthetic surgery for breast reconstruction (for example, to correct congenital malformations, in post-mastectomy reconstruction, or as part of a sex-change operation), and to increase the size of breast (known as augmentation mammoplasty).

There are two main types of breast implants, based on the material with which they are filled: saline solution and silicone gel. They both have an elastomer silicone shell that acts as a capsule to hold the filling material[1]. According to the model used, the shell can either hold a fixed volume of filler or be adjustable. Silicone is a material that is often used in medicine, because of its high thermostability and resistance to chemical attack (for medical devices its most common form is PDMS silicone)[1].

Any medical device should meet certain criteria in order to be considered safe for human use. In the case of breast implants, these are: Security (no link to cancer of the breasts or other locations, autoimmune diseases, connective tissue diseases, etc.), Biocompatibility (that they not generate adverse reactions to tissues in the body, proven by clinical studies), Biodurability (that the body does not alter the conditions of the implant over time), and Percentage of rupture (which should be no higher than ten percent over ten years, and should be proportionate to the time of implantation)[1].

1.2 Mammoplasty

A mammoplasty is a surgical procedure that has the objective of altering the shape or appearance of the breast. This paper will focus on reconstruction and augmentation mammoplasty, for which breast implants are used. It should be noted that of all aesthetic surgeries in Spain[2], breast augmentation surgery is in highest demand, Spain being the 12th country in the world with most demand for this type of surgery[3].

There are different surgical techniques available for breast augmentation or reconstruction, based on the incision type and implant pocket placement. The main types of surgical incisions are: inframammary, periareolar, axillary, transumbilical and transabdominal. As for the implant pocket placement, the two main sites are subglandular (directly behind the mammary glands) and subpectoral (behind the pectoral muscle).

1.3 PIP implants

Poly Implant Prosthèse (PIP) was a French company specialized in the manufacturing of breast implants, which was active from 1991 until 2011[4]. This company was considered the third largest producer by sales volume, producing 100.000 units per year, of which eighty percent were sold outside of France[5]. They were mostly sold in Latin American countries such as Brazil, Argentina and Venezuela (where they were popular for their relatively low cost), as well as in European countries[4].

The problem with the breast implants manufactured by PIP is that they used industrial-grade silicone for their implants (reducing company costs by 90%[4]) instead of the approved medical-grade silicone used for prosthetic devices. Consequentially, the rupture rate of these

implants was much higher (up to 50%[4]) than other implants in the market. The corresponding section addresses these problems in further detail.

2. Complications

2.1 General complications

Breast implants are not lifetime products. Notably, as many as 20 percent of women who had aesthetic breast augmentation, and 50 percent of women with breast reconstruction needed to remove the implants after 10 years[11]. Below is a list of the main complications associated with breast implants, and explanations of their clinical presentation:

a) **Infection, Capsulitis:** As a result of the surgical procedure, the wound site becomes infected, and produces pain and swelling. It must be treated immediately with antibiotics and may lead to the removal of the prosthesis[10].

b) **Capsular contracture:** The body creates a collagen capsule around breast implants, or any foreign object that is inserted into the body (such as pacemakers or orthopedic prosthesis) to isolate the object from the rest of the body. Capsular contracture occurs when this capsule begins to thicken and compress the implants, causing pain and deformities to the patient[10].

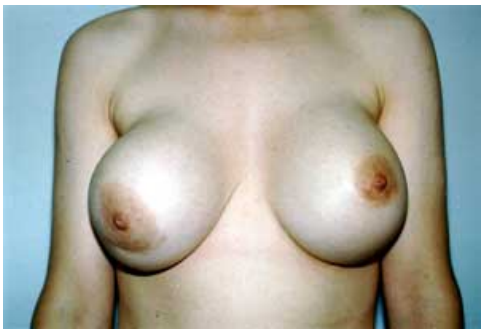

***Image 1**: Deformity of the right breast caused by capsular contracture.*

c) **Position shift:** This happens when the breast implants settle in the wrong place. The most common malposition is that the implants remain too high, although they can also be displaced laterally, medially (Symmastia), or inferiorly[10].

d) **Siliconomes:** Silicone accumulates in surrounding tissues and lymph nodes (especially axillary nodes, but also internal mammary or even supraclavicular nodes). This happens in case of leakage of the filler material. These are relatively frequent, with up to 67% in some cases[6].

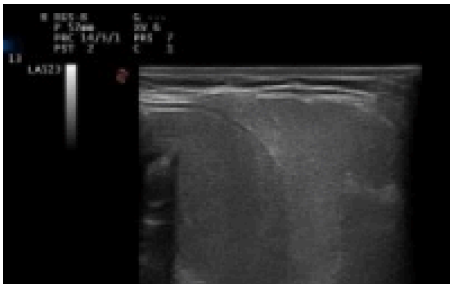

***Image 2**: Siliconome seen with US (note the change of phase in the material)[1].*

e) **Implant rupture or leakage**: Discussed in depth below.

There are other diseases that have been studied in relation to the use of breast implants, such as systemic diseases and cancer. There are reported cases of women with breast implants who have suffered from systemic sclerosis, systemic lupus erythematous, rheumatoid arthritis, and fibromyalgia, although medical research has discredited links between breast implants and these diseases[7,8]. In the case of cancer, numerous statistical studies have found no evidence of increased risk of breast cancer in women with breast implants (neither saline nor silicone)[9,15].

2.2 Implant rupture

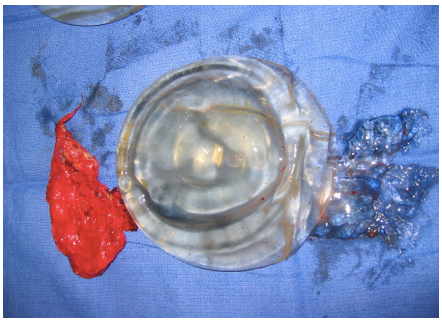

***Image 3**: Implant rupture. The red tissue to the left is the fibrous capsule, in the center the ruptured implant, and to the right the leaked filler silicone material.*

Implant rupture can occur due to damage during the surgical procedure, chemical degradation of the shell, or trauma (blunt, penetrating, or blast trauma). According to the type of filler material, the presentation of the rupture is different. When the shell of a saline implant ruptures, the saline leaks quickly and the implant collapses. Silicone implants do not deflate (although they can alter their shape), instead they leak silicone material to the implant pocket, surrounding tissues and lymph nodes.

The symptoms of implant rupture can include: bumps or inflammation in the breast and/or periareolar area, change in the shape of the breast, collapse of the breast implant, erythema, increased tenderness and swelling of the breasts[1] and lymph node siliconomes.

2.3 Percentage of rupture in PIP vs. other implants

It is difficult to compare the definitive rupture rate of PIP implants against other implants, or in general, between breast implant brands themselves. This is due to the low follow-up rate of the patients after their operations[1], which may be due to the lack of an implant database in Spain and EU countries[37], and also because most patients don't attend checkups unless they experience symptoms. It should be noted that those cases that are reported are mostly in patients who showed complications, which can skew the results.

According to clinical trials, the average rupture rate of breast implants is around 1% over six years[12], giving an industry-standard lifetime of 20-25 years[5]. After this period, the implants should be adjusted or exchanged to be kept in optimal conditions. According to Keogh et al the rupture rate of PIP implants is 6-12% over five years, and 15-30% over ten years[13]: therefore the optimal lifetime of these implants is reduced to only 3 to 5 years[5]. These figures vary by study and country. The following table details results for different countries.

Author	***Journal***	***Years***	***Prosthesis (n)***	***Rupture (%)***	***Time***
Crouzet C Toulouse, France	Ann Chir Plast Esthet 2010		128 Breast Reconstruction	**3,9**	
Maijers MC Amsterdam	Plast Reconstr Surg 2012	2000-2001	224	**24,10** 33	10 years
Berry MG London, UK	JPRAS 2012	2000-2005	194	**15,9** 33,8	59,8 months
Adolf A Rouen, France	Ann Chir Plast Esthet 2012	2005-2010	192	**11,97** 17,17	
Canillon MA Lille, France	Bull Cancer 2012	2006-2010	33	**37,8**	15,35 months
Helver V UK	Breast Cancer Research 2012		290	**15,1** 21	
Blugerman G Buenos Aires Argentina	European Journal of Plastic Surgery 2013	2005-2010	**884** **Implants removed**	**10,6**	
Chummun S Bristol, UK	Surgeon 2013	2006-2008	78	**21,8**	

***Table 1**: Percentage of implant rupture shown in different countries. Note that the number of prosthetic devices analyzed varies[1].*

3. Methods for diagnosis of complications

3.1 Clinical

The manual and clinical examination of breast implants has been shown to be inadequate for the evaluation of implant rupture. In patients with no symptoms, only 1 in 3 patients are accurately diagnosed with clinical examination by an experienced plastic surgeon, whereas up to 86 percent of ruptures are accurately diagnosed with MRI[14].

3.2 Ultrasonography and Mammography

Ultrasonography (US) is more widely available than MRIs and can be an accurate diagnostic method; however, it is a difficult technique to master and therefore the results may vary between operators. We can detect signs of intracapsular (stepladder sign) and extracapsular (snowstorm noise) rupture with US[16], as well as detecting siliconomes, as previously shown. Snowstorm noise is seen as intense and homogeneous echogenicity with a decrease of detail of the posterior silicone[18].

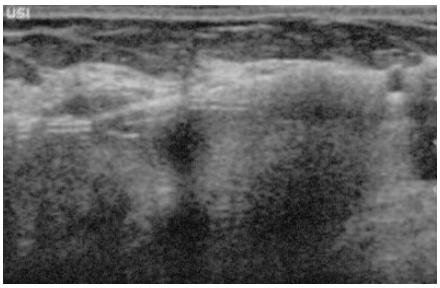

***Image 4**: Snowstorm or hyperechoic noise associated with extracapsular rupture.*

Mammography is a technique widely used for the screening of breast cancer. In the case of women with breast implants, this can also be used to detect signs of implant rupture (such as free extracapsular silicone or opaque lymph nodes). When signs of rupture and extravasation are detected, further studies may not be required. However, mammography alone cannot be the sole method of detection for implant rupture, as it is not sensitive or specific enough[17].

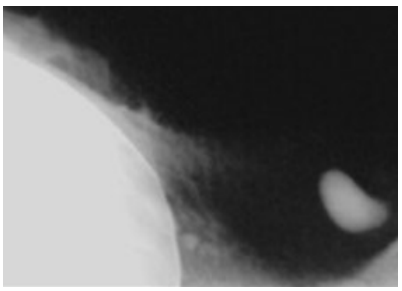

***Image 5**: Extracapsular silicone and opaque lymph node (sign of silicone uptake).*

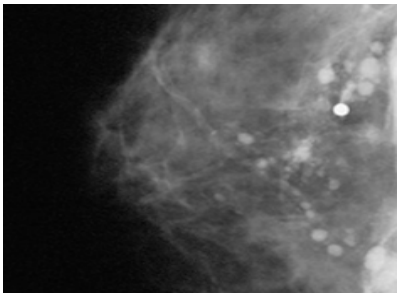

***Image 6**: Free extracapsular silicone around a ruptured breast Implant.*

3.3 MRI

Magnetic Resonance Imaging (MRI) is considered the most accurate method of detection of breast implant rupture[19], or “gold standard”. Unfortunately, the cost and low availability of this method hinder the use of this technique in the screening of implant rupture. It is mainly used in suspicious cases where other techniques are unable to give a conclusive result.

Intracapsular rupture can be seen in MRI as the linguine sign and the keyhole sign. The linguine sign can be seen when the shell of the implant is ruptured and folded inside the implant, floating inside the filler material. This is the most reliable sign of intracapsular rupture[16]. The keyhole sign (also known as teardrop) is seen when silicone is present both inside and outside of the radial fold of an implant.

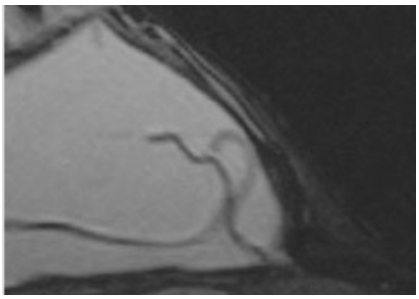

***Image 7**: Linguine sign shown in MRI, consistent with intracapsular rupture.*

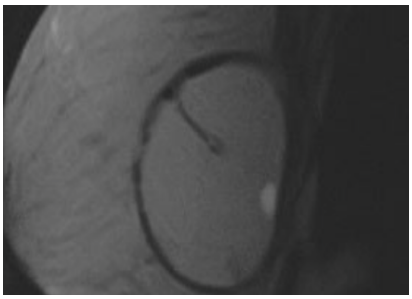

***Image 8**: Keyhole or teardrop sign in MRI, notice the silicone inside the radial fold.*

Extracapsular rupture can be seen in MRI as presence of silicone in the parenchyma, pectoral muscle and surrounding lymph nodes. It should be noted that intracapsular rupture signs might also be present in the same image.

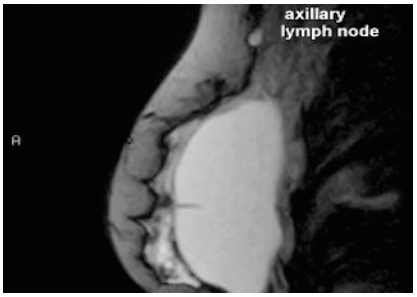

***Image 9**: Extracapsular silicone can be seen surrounding the implant, as well as in the axillary lymph node above.*

4. Problems with PIP implants

4.1 General

As previously stated, the main problem with PIP implants was that they were manufactured using industrial-grade silicone, not fit for human use. PIP implants were made using a combination of an unauthorized in-house manufactured silicone gel (we will call this PIP gel) and an authorized silicone gel (Nusil)[22]. The implants were made with 75% PIP gel and 25% Nusil[22]. It was reported that the silicone found in PIP gel contained the chemicals Baysilone, Silopren and Rhodorsil[20], normally used as fuel additives or in the manufacture of industrial rubber. It should be noted that PIP gel was also used to manufacture gluteal, pectoral and testicle implants for male patients [21].

According to the founder of the company, Jean-Claude Mas, the decision to use lower grade and cheaper silicone was due to economic pressures that the company endured. These constraints included the FDA ruling in 2000 to ban silicone gel breast implants in the U.S.A, which led to loss of market share for the company[22]. In order to gain back the lost business and keep the company viable, Mas decided to severely cut production costs by switching from the authorized Nusil gel (which costs 35 EUR per liter) to the in-house produced PIP gel (which only costs 5 EUR per liter)[22].

Furthermore, the thickness of the elastomer shell of the PIP implants was evaluated to determine whether this was a risk factor for rupture. It was determined that the outer shell of

these implants varied in thickness, with many of them not meeting the minimum requirement of 0,57mm specified in the product description[27]. Additionally, the mechanical resistance of the implant shell was also evaluated and found to be inferior to that of control implants[28]; with a negative correlation between the mechanical properties and the time of implantation[1]. Also, the permeability of the shell was studied, and found to be defective due to the lack of union bridges necessary to maintain the cohesion of the gel[29] – this caused an increased absorption of cholesterol in the implants, which turned them yellow over time[1]. This reinforces the notion that poor quality control was part of the problem in both the product materials and manufacturing.

4.2 Magnitude of the problem

It is estimated that in a twelve-year period, over 300.000 implants were sold in more than 65 countries worldwide[26]. Most of these were destined to European and Latin American markets, mainly because of the relatively low costs of the implants. Unfortunately, due to the poor registry of implantation surgeries and follow-up consultations, the exact number of patients with PIP implants is unknown[5].

4.3 Clinical studies

Numerous studies have been underway since the unraveling of the PIP implant case. The French health and safety agency (AFSSAPS) was the first to study the link between PIP implants and possible cancer or toxic diseases derived from its presence in the body. The first alarm was the case of a woman with PIP implants who had suffered and died from anaplastic large-cell lymphoma (ALCL) in 2010[30]. Since then, cancer has been found in 20 patients with faulty PIP implants, although the AFSSAPS has insisted that no association was found between these cases and the implants[31].

A independent research committee led by the British NHS medical director, Sir Bruce Keogh, was published in June 2012, which found the materials used for PIP implants are not toxic or carcinogenic[13]. The study findings are listed below:

a) Chemical and toxicological analyses have shown no significant health risk, up to this moment.
b) PIP breast implants have a higher risk of rupture than other implants, the difference being detectable after the 5-year mark.
c) In some patients, the rupture or leakage of silicone material has caused local inflammatory reactions.
d) The PIP implants are below required standards of quality, although there is no increased health risk in absence of rupture.

The most recent report on the subject comes from the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), which supports the Keogh report. This report adds that "there is no reliable evidence that ruptured PIP implants create a greater health risk than a ruptured silicone breast implant from another manufacturer"[32].

4.4 Timeline

1991: Poly Implant Prosthèse (PIP) is founded by Jean-Claude Mas[22].
2000: Silicone implant sales are halted in the USA by the FDA[23].

2001: PIP begins to manufacture implants with altered PIP silicone gel[22].

2009: The first reports of an abnormally high rupture rate begin to surface in France.

2010: The French health safety agency (AFSSAPS) recalls PIP implants from the market[4].

March 2010: The Spanish health ministry (AEMPS) issues a warning on PIP implants, highlighting that they may have a higher rupture and inflammation rate. They order the cessation of implantation of these devices in public and private clinics[25].

December 2011: French authorities (AFSSAPS) recommend the preventive removal of PIP Implants, following clinical studies[24].

April 2013: French authorities begin trial against PIP and its founder, with over 5000 litigators[37].

October 2013: SCENIHR preliminarily states that there are no toxicological or carcinogenic risks associated with PIP implants[32].

May 2014: SCENIHR confirms that there is no higher risk of cancer or other diseases associated with PIP implants, and sets out patient-care guidelines[33].

5. Governmental action

5.1 European Union

a) SCENIHR Study and European Commission conclusions.

In their preliminary study (September 2013) the Scientific Committee on Emerging and Newly Identified Health Risks already established that the greatest risk presented by PIP implants is their higher-than-usual rupture rate. Other concerns, like a possible link to breast or other types of cancer have been ruled out by many reports[32]. The use of industrial-grade silicone (PIP gel) in the manufacturing of the implants, which contained elements unauthorized for human use, such as fuel additives and cyclic siloxanes (known as D4, D5, D6) was also of concern. The conclusions of toxicological reports indicated that these chemicals posed no threat to the health of women carrying PIP implants[32].

In their final opinion published in May 2014[33], the SCENIHR reiterated the conclusions given in the previous report about the safety concerns of PIP implants. They also published the recommended guidelines of care for patients with implants. These patients with PIP implants should be have regular clinical examinations and imaging with ultrasonography and MRI, if deemed necessary, to determine the integrity of the implants. Implants should only be removed if there is evidence of rupture, which is standard procedure with other types of implants as well. They may also be removed if they are cause of significant anxiety for the patient. If the implants are intact they should not be removed, as there is no medical or toxicological justification for their removal[33].

b) Criminal investigations into PIP

The founder of PIP, Jean-Claude Mas, is being investigated by French authorities for charges of manslaughter and unintentional injury. A second case of aggravated deception is also under investigation[22]. Several organizations of patients with PIP implants[34] have been formed in the affected countries, in order to formulate a lawsuit against the company and its founder. More than 5000 women claimed compensation for the removal and replacement of the breast implants, and well as for the emotional stress caused[37]. According to the latest information, Mas paid a 100,000-euro bail and would face up to 4 years in prison[35].

TÜV Rheinland, a German quality-control company, gave quality certificates of the production process used by PIP until March 2010. These certificates did not apply to the type of silicone being used. No investigation was opened against TÜV Rheinland in connection to the PIP case. However, many of the patient platforms involved in the case against PIP demand that TÜV Rheinland should be included as a responsible part in the case[37].

5.2 Spanish Government

The Spanish government, through the health ministry and AEMPS, has followed the recommendations set out first by the French authorities (AFSSAPS), and later by the European Commission[36]. The AEMPS gave regular security notes about PIP implants, as scientific reports became available[25]. As of today, the Spanish protocol of care for patients with PIP implants is based on the SCENIHR recommendations[34]. Patients who were given PIP implants due to breast reconstruction surgery done by the public health system (SNS) could choose to have the implants removed and replaced by another type of implant or opt for breast remodelation [1, 36]. Those patients who had the PIP implants inserted in private clinics would have the right to get them removed in the SNS, but they would not be replaced[1].

6. Experience in Cantabria and Spain

6.1 Cantabria

In Cantabria, 28 patients were implanted with PIP prosthesis, 7 of these in Hospital Universitario Marques de Valdecilla (HUMV) and 21 in private clinics. In the HUMV, most recipients of prosthesis had breast cancer previously, but some had benign lesions, or mammary hypoplasia. In the private clinics, all patients were implanted with the PIP prosthesis for aesthetic reasons[1]. It should be noted that 11 of the 21 patients who were not operated in the HUMV were originally from Colombia. This would explain the fact that patients who had implants placed in private clinics always had two implants placed, hence double the number of prosthesis than patients.

Centre	*Patients*	*Oncologic (RM)*	*Benign disease*	*Mammary hypoplasia*	*Aesthetic augmentation*
HUMV	7	4	2	1	0
Other centers	21	0	0	0	21

Table 2: *Reasons for breast reconstruction in HUMV and private clinics in Cantabria[1].*

Situation	*Patients*	*Observations*
Operated	18	13 prosthesis implantation and 5 remodelations
Following	6 3*	*Unknown
Wait list	1	Intact prosthesis

Table 3: *Patient situation in the HUMV[1].*

Centre	*Patients*	*Prosthesis*
HUMV	7	10
Other centers	21	42

Table 4: *Patients and number of prosthesis used[1].*

Patients in HUMV were cared for following the patient protocol given by the AEMPS[36]. As of now, eighteen patients have been operated by the service, thirteen of whom were reimplanted with other prosthesis and five of who had breast remodelation. There are currently nine patients being followed by the medical team, although three of them have not returned to the practice. There is one patient on the waitlist due to delays in the consultation system, or because it was determined that their implants were intact[1].

	Operated	***Total***
Patients	18	28
Bilateral (n prosthesis)	14 (28)	24 (48)
Unilateral	4	4
Ruptured prosthesis	14	14
Total prosthesis	32	52
Percentage of rupture (%)	**43,8**	**26,9**

Table 5: *Percentage of implant rupture in Cantabria[1].*

The percentage of PIP implant rupture in Cantabria was found to be 43,8% of the implants that were removed, and 26,9% if we consider all the patients, including those who were not operated. These figures are above the average of implant rupture in other countries (see Table 1), although they may not be comparable considering the small pool of patients in Cantabria compared to other regions.

6.2 Spain

It is estimated that 18500 patients were affected by the implantation of PIP prothesis[37]. Of these patients, only about 4,2% were given in the public health system. According to PIP patient associations in Spain, the protocol for PIP implants was not fully implemented in all regions, and many patients had to jump many hurdles in order to receive the care promised by the government[37]. Most of these patients paid for the removal of the implants themselves, due to the long waiting lists and prerequisites demanded by the public health system[37].

7. Experience in México and Latin America

7.1 México

During a personal experience in the ERASMUS Exchange program to San Luis Potosi (Mexico) this last semester I procured information on the effects of PIP implants in Mexican patients and how they were managed. According to the Mexican Association of Plastic Surgery (AMCPER), about 5,000 women were implanted with PIP prosthesis[37]. The Mexican government banned PIP implants in March 2010[37]. The cost of removal and medical treatment for patients with PIP implants was not covered by the public health insurance.

According to testimony given by gynecological and plastic surgeons in the Hospital Central de San Luis de Potosi, PIP implants had a lesser impact on Mexico than the rest of Latin America. This may be because the implants were not as cheap to import and utilize as in other

Latin American countries; and due to the NAFTA free commerce agreement with the US and Canada, where most of the brands used were not made in Europe. Of the physicians interviewed, none had used PIP implants either in the public health system, or in their private practices.

7.2 Latin America

As Latin America was one of the regions most affected by the PIP implants, it is interesting to see the effects it had on the region, and the different responses given by the governments. Latin America was the destination for up to 59% of implants produced by PIP in 2007[39]. The countries most affected were Brazil (25,000 implants), Colombia (14,000 implants), and Argentina (13,500 implants), along with Venezuela, Chile and Paraguay. In most countries, the health ministries banned the commercialization of PIP implants starting in March 2010. However, like in Mexico, the cost of removal of the implants would be in the hands of the patients themselves, with the exception of Argentina. In Argentina, the federal government passed a law that ensured that all women who would like their PIP implants removed could do so in public hospitals free of charge[39]; although the government will not cover the implantation of a new prosthesis. Many patient associations were formed in order to pursue legal action against PIP and claim a compensatory fund for the removal of the implants, especially in countries where the government did not provide this service[40]. In Venezuela, more than 1500 victims filed a lawsuit against the local distributor of PIP prosthesis[40].

8. Conclusion

After the review of the problem of PIP implants, the following conclusions may be reached:

- PIP implants were made using industrial-grade silicone instead of the PDMS silicone approved for human use. The manufacturing process of the implants was flawed, as it was reported that they did not meet the minimum criteria of capsule width and strength.
- The principal problems associated with PIP implants were implant rupture, inflammation of connective tissue due to silicone leaks, and siliconomes. It was reported that the lifetime of the implants is significantly less than conventional breast implants.
- There was no proven connection between PIP implants and their complications with systemic diseases, cancer, or toxicological reactions.
- In Cantabria there were 28 patients treated by the HUMV service to remove the PIP implants. The total rupture percentage was 26,9%, which is slightly higher than that found in other hospitals and countries around the world, although this could be due to the small number of patients treated.
- PIP as a company and its founder acted in a deceitful and criminal way in the manufacturing of their silicone implants. They put many people in danger and produced both physical and psychological struggles to the victims.
- The responsibility does not lie solely on PIP, as any medical device should follow strict quality and safety controls by both certifying companies (TÜV Rheinland) and government agencies.
- As a result of this case, the European Commission has put in place new safety protocols to monitor the manufacturing of medical devices. They have also included breast and other implants in the category of medical device, so that they would follow a stricter qualifying process before being commercialized.
- Even though serious problems have been found, especially for safety protocols to protect patients, the scandal was made worse by the sizeable exposure in the media. These reports often portray inaccurate information about the case triggering more psychological damage to the patients that were affected, and leaving a bad reputation for the medical industry in general.

Annex: Case reports

Case 1: 943637 (Explantation and remodeling of intact prosthesis)

- 42 y.o. patient from Colombia.
- Bilateral implants placed in 2008 for aesthetic augmentation.
- Ultrasound showed intact implants.
- Explantation and breast remodeling.

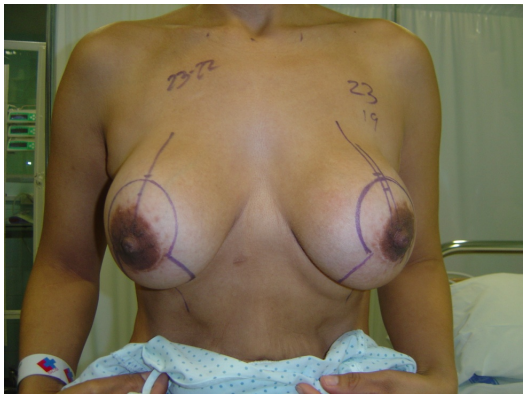

***Image 10**: Pre-operative picture.*

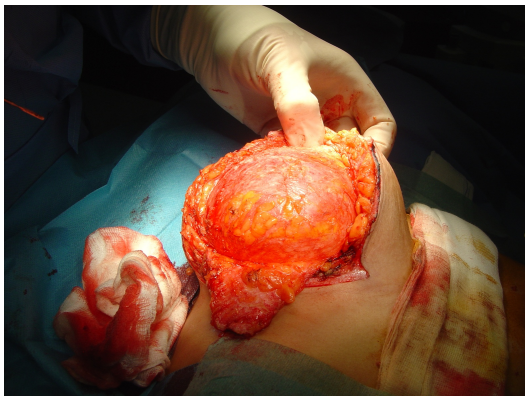

***Image 11**: Intraoperative view of prosthesis and capsule.*

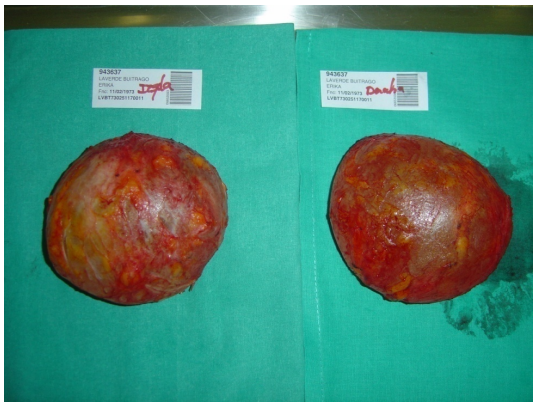

***Image 12**: Prosthesis with capsules.*

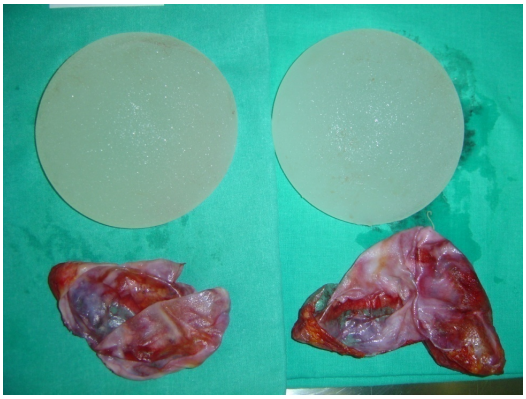

***Image 13**: Capsulectomy and intact prosthesis.*

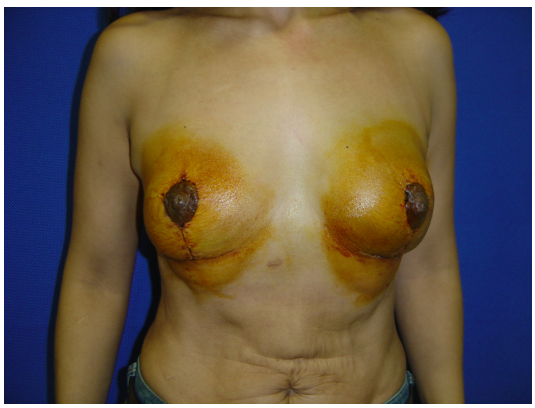

***Image 14**: Post-operative picture, with breast reconstruction.*

946914 (Explantation and remodeling with rupture of right prosthesis)

- 43 y.o. patient from Valencia.
- Bilateral implants placed for aesthetic augmentation.
- Ultrasound and MRI showed rupture of the right prosthesis, and siliconome in the internal mammary lymph nodes.
- Explantation and breast remodeling.

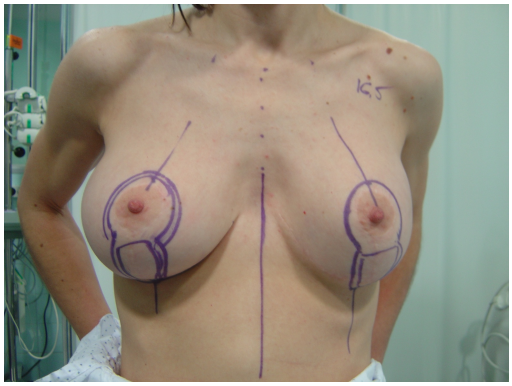

***Image 15**: Pre-operative picture, notice deformity of the right breast, due to Implant rupture.*

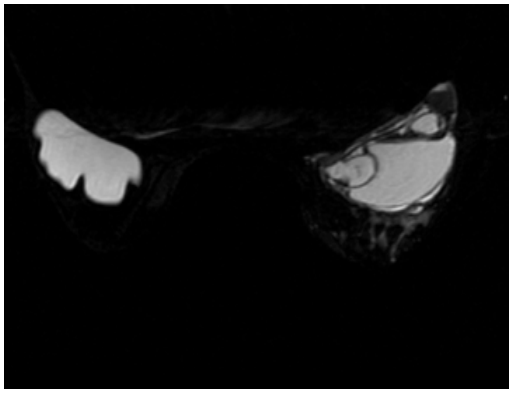

***Image 16**: MRI showing Implant rupture signs.*

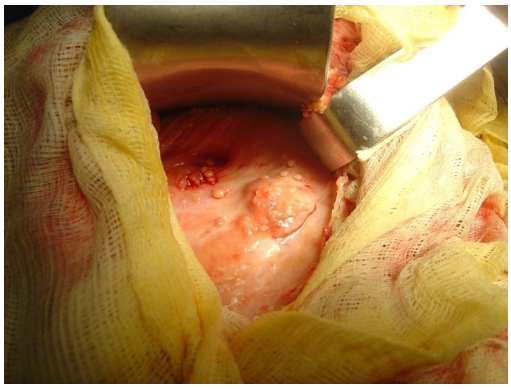

***Image 17**: Intraoperative view of ruptured PIP Implant.*

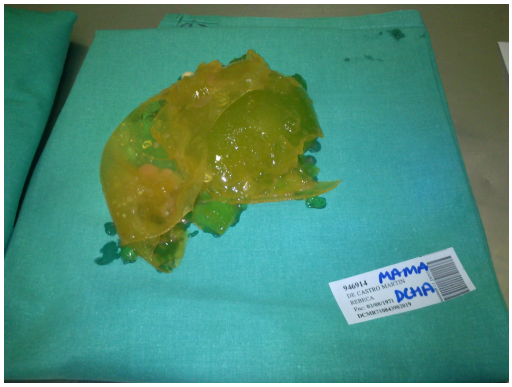

***Image 18**: Ruptured implant after explantation.*

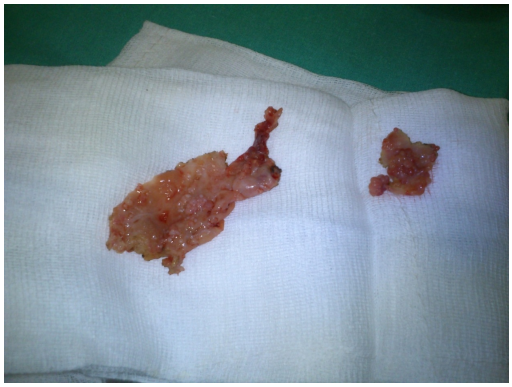

***Image 19**: Surgical piece, which was informed by pathology as: Synovial metaplasia, fibrosis, Xanto-granulomatous reaction. Due to leaked silicone from implants.*

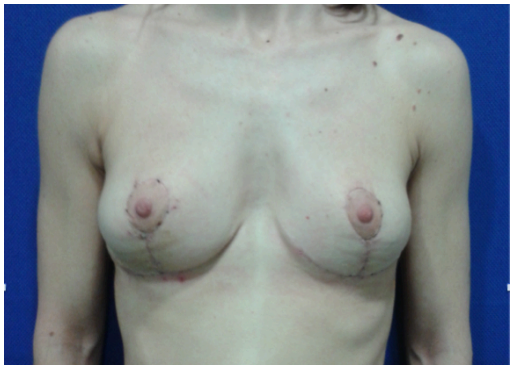

***Image 20**: Post-operative picture, with breast reconstruction.*

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