

# Study of Infections in Breast Augmentation Surgery with Implants in 9,691 Patients over 5 Years

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**Background:** This study presents a review of a single retrospective cohort of patients who underwent surgery for breast augmentation with implants, during a period of 5 years, aged 17–60 years (mean 32 years), in a single institution, IQ Interquiroyanos, a private clinic in the city of Medellín, Colombia.

**Method:** A single retrospective cohort study was carried out, in which the database of patients who underwent breast augmentation with implants during 5 years was analyzed.

**Results:** In this period of time, 9,691 female patients and a total of 19,382 breast implants implanted by 66 plastic surgeons underwent breast augmentation surgery. All the breast prostheses used were round, made of silicone gel in all cases and textured in most of them. 37 patients presented infection at the surgical site, 33 were unilateral and four bilateral, with an incidence of 0.38% per patient. The form of presentation was cellulitis in 46% of the cases, followed by seroma and hematoma in 25%. It was found that there is no difference in the incidence of infection between patients with breast augmentation for the first time and implant replacement due to different causes (OR 1.25, 95% CI 0.66–2.3,  $P = 0.49$ ). One of the surgeons was associated with 37.8% of the infections and was found to be an asymptomatic carrier of *Staphylococcus aureus*, requiring medical treatment. The relationship of the infection with the treating surgeons was also analyzed and it was found that there is an association between these two variables. The infection appeared in the first 2 weeks after surgery in 92.7% of the cases. The main isolated germ was *Staphylococcus aureus*, followed by *Pseudomonas aeruginosa*, *Staphylococcus epidermidis*, *Serratia marcescens*, *Candida parapsilosis*, *Enterobacter cloacae*, and a patient with *Mycobacterium fortuitum* in both breasts. Of the 37 patients with infection, six breast implants were required to be explanted in five patients, who were repositioned 3–6 months later without complications.

**Conclusions:** Incidence of infection in augmentation mammoplasty with implants was 0.38% in patients infected in one or both breasts, during 5 years. There is a relationship between the presence of breast infection and the surgeon who performed the intervention. The most frequent germs found in breast implant infections continue to be *Staphylococcus aureus* followed by *Pseudomonas aeruginosa*. (*Plast Reconstr Surg Glob Open* 2021;9:e3752; doi: 10.1097/GOX.0000000000003752; Published online 10 August 2021.)

## INTRODUCTION

Breast augmentation surgery with prostheses is the most frequent surgical intervention in plastic surgery reported worldwide in the latest studies published by the International Society of Aesthetic Plastic Surgery in 2018.

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Colombia is the seventh country with the most augmentation mammoplasty surgeries in the world ranking.

In breast surgery, the use of implants is widely used to improve the shape and volume of the breasts, either to solve congenital problems (asymmetries and hypoplasia) or acquired.<sup>1</sup> The type of breast implants can be silicone gel or saline and smooth or textured. Augmentation for cosmetic purposes is usually performed through an inframammary or periareolar incision with placement of the implant in either the subglandular, submuscular, or dual position.<sup>1</sup> One of the main complications that can occur in this surgery is infection, which produces great physical, mental, professional, and economic problems for patients, medical institutions, and treating physicians.<sup>1–3</sup>

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Risk factors for surgical site infection (SSI) include preoperative, intraoperative, and postoperative factors. Preoperative factors associated with increased risk of SSI common to all breast surgeries include elevated body mass index, diabetes, smoking, and prior breast operation. Intraoperative factors include duration of the operation, lymph node dissection, higher amount of blood loss or tissue ischemia, and postoperative factors associated with increased risk include elevated serum glucose, seroma, or hematoma formation and surgical drains.<sup>1,4-7</sup> Perioperative antimicrobial prophylaxis and appropriate skin antiseptics are associated with decreased SSI risk.<sup>4</sup>

Infection is the leading cause of morbidity that occurs after breast implantation and complicates 0.27%–2.5% of interventions in most case series.<sup>1,2,4,6-10</sup> In a worldwide survey conducted in 1970, the incidences of early and late onset infections in 10,941 women who underwent breast augmentation were 1.7% and 0.8%, respectively.<sup>9</sup>

Patients with early onset infections typically present with breast pain, swelling, and erythema, with or without fever. Late infection (more than 6 weeks to months after surgery) usually results from secondary bacteremia or an invasive procedure at a location other than breasts.<sup>3,11-13</sup>

Gram-positive organisms, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, beta hemolytic Streptococci, coagulase negative *Staphylococcus*, and *Propionibacterium acnes* are the usual pathogens associated with early postimplant infections isolated from the breast. Other skin flora frequently isolated from the breast includes *Diphtheroids*, *Enterococcus*, *Lactobacilli*, and *Bacillus* species.<sup>5,7,8,10,11</sup> In a single-center, retrospective review conducted at a referral center in south France, gram-negative bacilli, *Pseudomonas aeruginosa* in particular, were noted to be the second leading cause of microbiologically confirmed breast implant infections after *Staphylococcus aureus*.<sup>7</sup>

Nontuberculous mycobacterial (NTM) implant infections are being reported with increasing frequency. Clinically, NTM infections may present as acute, subacute, or late infections and they have been reported both as sporadic cases and outbreaks. *Mycobacterium fortuitum* is the most common NTM species associated with breast implant infection, but multiple other species of NTM have been described. These include *Mycobacterium avium*, *Mycobacterium abscessus*, *Mycobacterium conceptio-nense*, *Mycobacterium thermoresistibile*, and *Mycobacterium chelonae*.<sup>1,12-14</sup>

Knowing the possible causes of the infection and the risk factors, and studying the variables that may influence this disease give us clarity to improve the protocols for surgical management and health personnel, to reduce this complication.<sup>3</sup>

## MATERIALS AND METHODS

A single retrospective cohort study was carried out, in which the database of patients who underwent breast augmentation with implants during a period of 5 years, between January 1, 2012 and December 31, 2016, in a single institution was analyzed: IQ Interquirofanos, a private clinic that, during that time, concentrated the

largest number of plastic surgeons in the city of Medellín, Colombia.

All breast surgeries during that time where breast implants were used were analyzed and tabulated, and whether those surgeries were done for breast augmentation for the first time or whether breast implants were changed for different causes, such as contracture, rupture, or desire to change the shape or size of the breast, and whether the implant was removed, were also recorded.

Male breast augmentation patients (seven patients), or breast reconstruction patients with postoncological or prophylactic mastectomy implants were not included in the study, due to their different behavior and higher infection rate. Patients who had breast implants removed for any reason and underwent implant-free mammoplasty were also not included.

All patients complied with an antibiotic prophylaxis protocol with cefazolin 2 gr IV between 30 minutes and 1 hour before the intervention began, and the dose was repeated if the surgery lasted more than 4 hours. In patients allergic to cefazolin or in the procedures of different surgeries, ciprofloxacin, clindamycin, or sulfamicylin were used according to the protocols. In addition, they continued with oral antibiotics for 5–7 days if their treating physician considered it.

Every patient who undergoes cosmetic surgery at the clinic must take out mandatory medical insurance that covers any complications that may arise. This is how the information of the patients reported with infections was taken: from the insurance policy and from the database of the IQ Interquirofanos infection committee (the entity that registers all patients infected by any procedure in this institution). Finally, they collated the data and analyzed it. With this double check, the bias of unreported patients was reduced.

After applying the inclusion and exclusion criteria previously described, the results were taken and tabulated with the epidemiology and biostatistics group of IQ Interquirofanos and the CES University. For statistical analysis, the  $\chi^2$  test was used, with the Fisher exact test if applied according to the sample size.

## DISCUSSION

The results that are presented in this study are very important to know the behavior of the different variables in breast augmentation surgeries, including the infection rates in our institution, IQ Interquirofanos. Also, our institution's high casuistry and the large number of surgeons involved in the work (66) make this study a benchmark for our specialty. If we take into account that Colombia and the city of Medellín is a benchmark in plastic surgery for medical tourism, comparing our results of incidence of infection in patients with breast implant surgery of 0.381% against those reported in the largest study published in the literature makes us a very safe plastic surgery clinic. The studies by Brand in 54,661 implantations for 73 plastic surgeons, with 60 infections and a rate infection of 0.27%, and by Cholnoky of 10,941 women who underwent breast augmentation with 1.7% early rate infection,<sup>4,7-10</sup>

and other studies that report up to 2.5% place us with a very low infection rate worldwide.<sup>1,2,6,11</sup>

Saline solution prostheses were not placed; so it cannot be established if the type of prosthesis is related to the appearance of infections. The most commonly used implants were textured and some were smooth. The amount of micro or macrot textured implants could not be established among textured implants because these data were not described in the clinical history. However, some authors have published that there does not appear to be a difference in infection rates between silicone and saline implants, or the surgical procedure seems to have a significant influence on the timing of infection.<sup>4,5,12,13</sup> Brand in his publication says that the smooth-textured and polyurethane-coated implants had similar infection rates<sup>8</sup>; so the absence of these data in the medical records are not considered to modify the results of this study.

An important finding is that the ratio of first-time surgeries and implant changes in the period studied had an important variation because in 2012, there were quality problems with PIP brand prostheses, which led to many patients and surgeons deciding to change the implants. This event modified the first time / implant change ratio to more than double in favor of the change (0.48). In the following years, the average ratio was 1.48 in the institution where the study was carried out.

Other authors have reported that there may be an increased risk of infection with a periareolar or transareolar approach, likely related to potential contamination of the implant by the endogenous flora of the nipple or breast ducts.<sup>5,6</sup> But in our study the comparison of the approaches in the breasts, periareolar or transareolar and the submammary were not tabulated due to insufficient data being found in the evaluated medical records. However, there was no statistically significant difference between the first-time group vs the change group, where more transmammary approaches were used, and in this group the mastopexy technique was used more, despite that there was no more infection in the second group.<sup>4,6,8,10</sup>

When evaluating the results of the habits and diseases of the patients who were infected, no relevant antecedents were found that would justify making a comparison with the rest of the group. Only three patients were active smokers and a case of hypertension, hypothyroidism, and takayasu arteritis was found. This finding agrees with what has been published in the literature, where smoking, obesity, and diabetes did not significantly predispose to infection.<sup>8</sup>

It should be mentioned that in our environment we do not use shrouds for implant placement and it is extremely rare to use drains in breast surgery for cosmetic reasons of augmentation or mastopexy unless there is bleeding during the surgery that warrants it, other than breast reconstruction cases where drains are used.

In reference to the germs reported in our study, we did not find any significant difference with other authors, *Staphylococcus aureus* being the most frequent germ, followed by *Pseudomonas aeruginosa*.<sup>5,7,10-14</sup> The rest of the

germs can vary according to the hospitals, and this is evidenced in what is reported in the literature.<sup>4,5,7,10,11</sup>

The appearance of the signs and symptoms of the infection in the breasts occurred in 92.7% of the cases in the first 2 weeks with an average of 10–12 days, with the appearance of erythema, heat, and redness of the breast, which caused some of the surgeons to start antibiotic therapy empirically without being able to isolate any germ. They were isolated only in those patients that the infection did not respond to the initial treatment and would be those that were finally reported in this study.

An important fact to mention is that only five cases of the 37 infected required explantation, which corresponds to 13.5% of those infected. If we evaluate the germs of the patients that required explantation, we find two cases with *Staphylococcus aureus*, out of four isolates among all infected patients, which would give us 50% of the cases that ended in explantation due to this germ. However in the breasts with infection by *Pseudomonas aeruginosa* and *Mycobacterium fortuitum*, all ended in explantation. The bilateral infection by *Mycobacterium fortuitum* of a patient in our study corresponds to the *Mycobacterium* most frequently isolated in published works, with this being one of rapid growth.<sup>12-14</sup>

In relation to the antibiotic protocol that was used and is still being used at the moment in IQ Interquirofanos, it is the same as that reported in the majority of the published works, and with the result that we obtained, we consider that the use of cephalexin 2gr IV 30 to 60 minutes before surgical insertion is an adequate and current treatment.<sup>3</sup>

A relevant finding was that the surgeon could be associated with the appearance of infection, and this is a topic that can be studied more extensively in future studies, as it has a direct relationship with the infection, as found in this work. In our study, one surgeon presented 37.8% of the total infections; he was studied and was diagnosed as a carrier of *Staphylococcus aureus* with his subsequent medical treatment. It is important to mention that after medical treatment, the number of infections of this surgeon decreased considerably.

If the information obtained from this work is compared with others, it should be mentioned that since it is in the same surgical center and is tabulated by third parties, in addition to the infection committee and the complications policy, it makes it very pragmatic. In other studies reported in the literature, the information is provided by different medical centers that may have different germs, and the data collection in some publications is provided by each surgeon, which may lead to a bias in the data provided on the infection of their patients.<sup>15</sup>

## RESULTS

The review of the database from January 1, 2012 to December 31, 2016 revealed 9,691 female patients who underwent nononcological breast surgery. The average age of the patients was 32 years ( $\pm 9.84$ ) with an age range of 17–60 years.

It was found that 4,995 patients (51.54%) underwent breast augmentation for the first time and 4,696 (48.46%)

had an implant change. The relationship of first-time and exchange patients was 1.06 in the total of 5 years, but in 2012 a large number of patients changed their implants because they were PIP brand. For this reason, during this year the relationship was reversed due to presenting more changes than new implants, as shown in Table 1.

The mammary prostheses used were round and made of silicone gel in all cases; no saline solution was used. Most of the prostheses were textured; the medical records reviewed did not detail whether they were micro or macro textured. Drains were not used in any surgery, nor were sleeves used for implant placement. All the breast implants used had the approval of the country's regulatory body, which in this case was INVIMA.

The average number of patients operated on per year was 1938. However, there was a peak of interventions in 2012, associated with patients requesting a change of PIP implants. The number of patients operated on per year is detailed in Table 2.

Most infections were diagnosed in the first 2 weeks, with an average of 10–12 days in 92.7% of cases (38/41), and 7.3% (3/41) were diagnosed between the fourth and sixth week after surgery.

Counting the number of breast implant infections that occurred in the 9,691 patients, 41 cases of implants associated with infection were found in 37 patients, distributed in unilateral or bilateral breast infections (Tables 3 and 4).

Of the four patients who presented bilateral infections, these were presented with four different surgeons and all occurred in patients with implantation for the first time. In one of them, the infection by *Mycobacterium fortuitum* was present. The form of presentation of the infection was mainly cellulitis in 46% of cases; followed by seroma and hematoma in 25%; fever, pain, and wound dehiscence in 12.5% of patients.

The number of plastic surgeons who performed surgeries during these 5 years was 66; with a variable volume of patients, infections were only reported in 15 surgeons. The distribution of how many infections occurred per surgeon is presented in Table 5. However, if we evaluate the number of infections associated with each surgeon in relation to the number of patients who intervened during the period studied, we find that the relationship changes significantly, finding a higher percentage of infection in some surgeons who operated on less patients and a lower percentage of infection in those who operated on more (Table 6).

It was found that when comparing the incidence of infections by each of the surgeons evaluated in this period of time, there was a statistically significant difference ( $P = 0.0105$ ), which shows that who performs the surgery

**Table 1. First-time Implant/Replacement Ratio**

Year	First Time	Change	Relationship to First Time/Replacement
2012	930	1930	0.48
2013	1027	807	1.27
2014	927	585	1.58
2015	1044	642	1.62
2016	1067	732	1.46

**Table 2. Distribution of Patients Operated on during the Five Years**

Year	No Patients
2012	2860
2013	1834
2014	1512
2015	1686
2016	1799
Total	9691

**Table 3. Place of Infection**

Year	Unilateral	Bilateral
2012	5	1
2013	8	1
2014	5	0
2015	9	1
2016	6	1
Total	33	4 (× 2) = 8

**Table 4. Patients and Implants Incidence of Infections**

Years	Patients	Implants	SSI of		SSI of	
			Implants	Incidence	Patients	Incidence
2012	2860	5720	7	0.122	6	0.209
2013	1834	3668	10	0.273	9	0.491
2014	1512	3024	5	0.165	5	0.331
2015	1686	3372	11	0.326	10	0.593
2016	1799	3598	8	0.222	7	0.389
Total	9691	19382	41	0.212%	37	0.381%

**Table 5. Number of Infections per Surgeon**

	No. of Surgeons	No. of Patients with Infections	% of Total Infections
	1	14	37.8
	1	4	10.8
	1	3	8.1
	4	2	5.4
	8	1	2.7
Total	15	37	100

**Table 6. Percentage of Infections by Number of Surgeries of Each Surgeon**

Surgeons	No. Patients	No. Infections	% of Infections
1	46	2	4.34
2	383	14	3.655
3	97	3	3.09
4	67	2	2.98
5	37	1	2.7
6	122	2	1.64
7	169	2	1.18
8	207	1	0.48
9	906	4	0.44
10	246	1	0.41
11	353	1	0.28
12	400	1	0.25
13	548	1	0.18
14	754	1	0.13
15	908	1	0.11
Total	5.243	37	



could also have relevance in the outcome of the surgery infection.

Infections of patients with breast implant surgery for the first time were 23 out of a total of 4,916 patients, and implant exchange patients were 18 out of a total of 4,775 (Table 7). It was found that there is no greater risk due to the fact that it is an implant change surgery versus placement for the first time, with an OR of 1.24, CI 0.66–2.3,  $P = 0.49$ .

The infection committee studied the surgeon with the highest number of infections (37.8% of the total), with 10 breast implants for the first time (eight unilateral and one bilateral) and four implant replacement (unilateral); it was found that he was a carrier of *Staphylococcus aureus*, requiring therapeutic management by infectology since infections also occurred in other types of surgeries other than those of the breasts.

Of the 37 patients with reported infection, 46% presented as cellulitis where no germ could be isolated as well as in those with hematoma. In the remaining cases with seroma and dehiscence, *Staphylococcus aureus* was isolated in four cases, *Pseudomonas aeruginosa* in two cases, one case of *Staphylococcus epidermidis*, one case of *Serratia marcescens*, one case of *Candida parapsilosis*, one of *Enterobacter cloacae*, and finally, one patient with *Mycobacterium fortuitum* in both breasts. The other cases were managed medically because there was no material to take gram and culture of any secretion.

In five cases, explantation of the mammary prostheses was required, in four cases a single implant was explanted, and in one patient both implants, with the latter associated with infection by *Mycobacterium fortuitum*. Of the five cases, three were associated with breast augmentation surgery for the first time and the other two in exchange for implants. The surgery times of these five cases were between 1 and 2 hours, except in one case of replacement of implants with mastopexy, which lasted three and a half hours.

The germs that were isolated in the five cases of explantation were three *Staphylococcus aureus*, two *Pseudomonas aeruginosa*, and one *Mycobacterium fortuitum*. All patients were given the same protocol of antibiotic therapy with cefazolin 2 gr, 30 minutes before surgery and continued with outpatient management for 5–7 days with first generation cephalosporin, and after the infection showed up they were managed according to the antibiogram. The removal of the implants took between two and a half weeks and 4 weeks, except in one case where it was removed after 4 months. After removal of the implants, antibiotic therapy was continued as determined by the infectologist, and the breast implants were repositioned between 3 and 6 months without presenting a subsequent complication.

Evaluating the personal history of the infected patients, among the 37 patients, three active smokers and one patient with hypothyroidism, arterial hypertension, and takayasu arteritis were found.

Of the 41 implants associated with infection, 18 were due to change of implants; of these implants that were removed for replacement, 13 were ruptured and five were in good condition. Nine were PIP (eight implants with rupture and one good), three Sebbin (two with rupture and one good), three Mentor (two good and one with rupture), one McGhan (with rupture), one Hans Biomed (with rupture), one CUI (good). After these 18 were removed, they were exchanged for the following implants that became infected: six Mentor, four CUI, three Sebbin, three Arion, and two Natrelle. The number of implants that were infected for the first time was 23: eight from CUI, seven from Mentor, four from Natrelle, two Cereform, and one from Eurosilicone and Sebbin.

The weights of the ruptured prostheses were between 275 cm<sup>3</sup> and 555 cm<sup>3</sup> (average: 380 cm<sup>3</sup>), and those without rupture from 280 cm<sup>3</sup> to 430 cm<sup>3</sup> (average 330 cm<sup>3</sup>).

Another variable that we studied was the use of intra-operative breast sizers, where the relationship of their use with the infection could not be concluded because the two surgeons who usually use them did not specify in their medical records who did it; however, the number of infections associated with these two surgeons were not relevant. No case of death of any patient was presented.

## CONCLUSIONS

The reported incidence of infection of 0.381% in augmentation mammoplasty with implants in patients infected in one or both breasts, during the 5 years, in 9,691 patients operated on by 66 plastic surgeons in the same institution shows that this clinic is a safe place for the practice of our specialty, regardless of whether they were national or international patients, since patients from outside the country may represent a different bacterial flora.

The appearance of the infection occurred in 92.7% of the cases in the first 2 weeks after surgery, making it the most critical period for follow-up. Furthermore, there is no difference in relation to infection between patients who underwent breast augmentation for the first time and those who underwent implant exchange with different surgical approaches.

The PIP phenomenon caused a massive change in these implants that occurred in 2012 and 2013, reversing the ratio of breast implants placed for the first time versus those of implant changes, going from a ratio of 0.48 in 2012 to averages of 1.48 in the following years, which is normal in our institution.

Based on the findings of our study, we consider that there is a relationship between the presence of breast infection and the surgeon who performed the intervention; so each surgeon should review their own statistics. The most frequent germs found in breast implant infections continue to be *Staphylococcus aureus* followed by *Pseudomonas aeruginosa*.

Explantation is rare and only occurred in 13.5% of infected patients (5/37). When the infection is by *Staphylococcus aureus*, the possibility of ending in

**Table 7. Infections of Patients according to the Type of Surgery**

First Time	Implant Change	Total Patients
19	18	37

explantation is 50% of the cases, and if the isolated germ is *Pseudomonas aeruginosa* or *Mycobacterium fortuitum*, the explantation occurs in all cases.

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