

MANAGEMENT OF COMPLICATIONS IN RECONSTRUCTIVE MAMMOPLASTIES WITH PROSTHESES: SYSTEMATIC REVIEW

Conduas em complicações de mastectomias reconstruídas com próteses: revisão sistemática

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ABSTRACT

Objective: The aims of this study were to determine the main managements of surgical complications in reconstructive mammoplasties with prostheses through a systematic literature review, and to evaluate the effectiveness in preserving the reconstruction. The secondary objective was to analyze factors regarding prosthetic loss. **Methods:** We used the MedLine database through the following expressions: “breast cancer” or “breast neoplasm” or “breast and neoplasm” or “breast and cancer” and “implants complications” or “implants and complications”. The reference period for these studies comprised January 2000 to July 2016. **Results:** Of the 856 articles found, seven were included to analyze the applied protocols. The rate of saved prostheses after stratification of complications and use of managements varied from 45 to 100%, depending on the degree of complication. Other 12 articles that evaluated the factors associated with prosthetic loss were secondarily chosen. Radiotherapy was considered the most frequent factor and was found in seven studies. The number of lost prostheses varied from 0.9 to 22.7% in such studies. **Conclusion:** There is still no agreement on how to manage complications of reconstructive mammoplasties with prostheses. The decision remains a challenge, and therefore surgeons need to know the possible conducts in order to establish the most appropriate treatment.

KEYWORDS: Breast cancer; mastectomy; mammoplasty; breast implantation.

RESUMO

Objetivos: O objetivo principal deste estudo foi determinar, por meio de revisão sistemática da literatura, as principais condutas nas complicações cirúrgicas de mastectomias reconstruídas com próteses, bem como avaliar a eficácia em preservar a reconstrução. O objetivo secundário foi analisar fatores relacionados à perda da prótese. **Métodos:** Foi empregado o banco de dados do MedLine, utilizando as expressões: *breast cancer*, *ou breast neoplasm ou breast and neoplasm ou breast and cancer e implants complications ou implants and complications*. O período de referência desses estudos foi de janeiro de 2000 até julho de 2016. **Resultados:** Dos 856 artigos encontrados, 7 foram incluídos para análise dos protocolos de condutas aplicados. A taxa de próteses salvas após estratificação das complicações e aplicação das condutas variou de 45 a 100%, a depender do grau de complexidade. Foram selecionados, secundariamente, outros 12 artigos que avaliaram fatores associados à perda da prótese. A mais frequente foi a radioterapia com 7 estudos. O número de próteses perdidas variou entre 0,9 e 22,7% nesses estudos. **Conclusão:** Ainda não existe unanimidade no manejo das complicações de mastectomias reconstruídas com próteses. Portanto, a decisão permanece desafiadora e o cirurgião necessita conhecer as possíveis condutas para definir a mais apropriada.

PALAVRAS-CHAVE: Câncer de mama; mastectomia; reconstrução da mama; implante de mama.

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INTRODUCTION

Breast cancer surgical treatment is divided into two great groups: conservative surgeries and mastectomies. Both of them have similar and well-established oncological safety defined in medical literature^{1,2}. The improvement of reconstructive techniques, concomitant to the technological prosthetic evolution, enabled less morbid surgeries, without changing survival³⁻⁶. The choice for mastectomies became more popular in the last decades because they have been assuming a less damaging character throughout time⁷.

The cosmetic advantages of reconstruction with prosthesis provide the patient a positive impact on psychosocial aspects, organ functionality, and quality of life^{8,9}. They explain the increasing number of indications, even after the increased costs attributed to post-mastectomy reconstruction^{10,11}.

Although patients' satisfaction is above 85% in reconstructive surgeries with implants¹², no managements protocols regarding its complications have been established yet. Understanding the mechanisms associated with reconstructive failures and establishing criteria may lead to better cosmetic results.

The main purpose of this study was to review, in the medical literature, the protocols of managements of surgical complications in reconstructive mammoplasties with permanent implants and/or tissue expanders.

METHODS

The study evaluated, through the literature systematic review, women who underwent reconstructive mastectomy with temporary or permanent implants. The two authors selected the studies in MedLine database. The terms used were:

1. "breast cancer" or "breast neoplasm" or "breast and neoplasm" or "breast and cancer"; and
2. "implants complications" or "implants and complications".

Inclusion criteria were:

- studies presenting their own results;
- patients who underwent mastectomy and reconstructive surgery with implants;
- papers published between January 2000 to July 2016;
- investigations carried out only in humans;
- female participants;
- 18 years old or older; and
- papers written in English.

The preliminary research was carried out in July 2016 and resulted in 854 articles. After applying the inclusion criteria, only 330 articles were left for title evaluation. Papers with disagreement between the authors were separated for discussion until a consensus was achieved, which was divided into refusal or inclusion. Then, irrelevant or doubled articles were excluded,

resulting in 62 studies for complete text analysis. From then on, the studies were separated into three groups:

1. excluded: if it did not approach the complications and losses of prostheses;
2. data direct extraction: if it presents management protocols for treatment of reconstructions complications and prosthesis outcomes;
3. data indirect analysis: if it did not satisfy any of the two previous criteria.

Forty-five studies were excluded, in which 6 were chosen for data direct analysis and 11 for data indirect extraction. A study that was mentioned in the reviewed studies was later included in the direct analysis group due to its relevance for the theme, resulting in 7 papers for direct analysis and 11 papers for indirect ones.

RESULTS

Seven studies had their management protocols evaluated on different kinds of complications, mainly prosthesis infection and exposure. Published between 2003 and 2013, they were all retrospective studies. The isolation of *staphylococcus* and *streptococcus* cultures in breast wounds was the most common factor found in prosthetic complications. This fact was associated with surgical failure in three of seven studies and then with radiotherapy (two studies). The classification of the infection degree was performed in all seven studies; and even though this stratification was not uniform, the advanced level was among the main causes of prosthetic loss. In four studies, the severity of infection implicated in removal of the prosthesis and late reconstruction, in case the patient desired so¹³⁻¹⁹. The rate of saved prostheses after stratification of complications — including the use of the same prosthesis or its replacement by another device — varied from 45 to 100%. Differences in complications' stratification are included in Table 1. The suggested managements and rates of "saved" prostheses are seen in Table 2.

The eleven studies chosen for indirect analysis did not present a specific management protocol for patients with surgical complications; however, they evaluated the relation between surgical complication and prosthetic loss. Two of these studies were prospective and assessed complications during a six-week period of follow-up while the others evaluated from postoperative 30 days to 3 years. The total "n" of patients who underwent a reconstructive surgery, either with prosthesis or expander, in the indirect analysis studies was 15,353. The main factors associated with prosthetic loss were:

- radiotherapy (7 studies);
- lymph node condition (2 studies); and
- surgeon's experience (2 studies).

The number of prostheses lost ranged between 0.9 and 22.7% in the studies (Table 3)²⁰⁻³⁰.

DISCUSSION

Mastectomies reconstructed with prostheses preserve the patients' quality of life. However, we need to understand the mechanisms associated with reconstruction failures in order to increase the number of excellent results³¹. The main kinds of early complications include infection, exposure, and extrusion.

Their consequences vary from simple local dressings to the need of antibiotic administration, hospitalization or even prosthetic removal, compromising the expected result and afflictions due to an additional morbidity to the previous oncological disease. The threshold separating several managements in these situations is not unanimous, considering it is very influenced by their complication degree and the experience of each surgeon¹².

Spear et al.¹⁸ have created a management protocol divided according to the kind of complication. In 2010, the same authors published an update with a larger number of cases¹⁷. In both

Table 1. Stratification of complications.

First author, reference, and year of publication*	Title	Study type	Review period	Stratification of complications
Reish ¹³ , 2013	Infection following implant-based reconstruction in 1952 consecutive breast reconstructions: salvage rates and predictors of success.	Retrospective	2004 to 2010	Clinical opinion on the infection degree (erythema, fever degree, leukocytes, and use of acellular matrix), of the quality of remaining flap and patient's desire.
Peled ¹⁴ , 2012	Long-term reconstructive outcomes after expander-implant breast reconstruction with serious infectious or wound-healing complications.	Retrospective	2005 to 2007	Infection regardless the level of any healing problem of the operative wound that requires unplanned surgical intervention.
Prince ¹⁵ , 2012	Prosthesis salvage in breast reconstruction patients with periprosthetic infection and exposure	Retrospective	2002 to 2008	Severe infection (free pus with bad smell or signs and symptoms of local or systemic severe inflammation) versus without severe infection. Exposed prostheses were analyzed according to the infection degree or associated contamination.
Bennett ¹⁶ , 2011	Management of exposed, infected implant-based breast reconstruction and strategies for salvage	Retrospective	1989 to 2009	Severe infection (edema, heat and erythema and progressive systemic signals or culture microorganisms); versus mild infection. The exposure condition was classified in intact skin, exposure risk, and exposed implant.
Spear ¹⁷ , 2010	Management of the infected or exposed breast prosthesis: a single surgeon's 15-year experience with 69 patients	Retrospective	1993 to 2008	Division into 7 groups: G1. Mild infection (edema, heat and cellulitis, without pus drainage and with antibiotic response); G2. Severe infection (edema, heat and cellulitis that do not respond to antibiotics, pus drainage, positive culture or severe systemic signs); G3. Exposure threat; G4. Exposure threat with mild infection; G5. Exposure threat with severe infection; G6. Exposed prosthesis with or without mild infection. G7. Exposed prosthesis and severe infection.
Spear ¹⁸ , 2004	The infected or exposed breast implant: management and treatment strategies.	Retrospective	1990 to 2002	Division into 7 groups: G1. Mild infection (edema, heat and cellulitis, without pus drainage and with antibiotic response); G2. Severe infection (edema, heat and cellulitis that do not respond to antibiotics, pus drainage, positive culture or severe systemic signs); G3. Threat exposure; G4. Threat exposure with mild infection; G5. Threat exposure with severe infection; G6. Exposed prosthesis with or without mild infection. G7. Exposed prosthesis and severe infection.
Yii ¹⁹ , 2003	Salvage of infected expander prostheses in breast reconstruction.	Retrospective	1995 to 2000	Implant infection of was defined as the presence of purulent secretion around the prosthesis and/or bacteria growth in wound cultures. All the suspected cases underwent antibiotic therapy with exclusion of those with improvement.

*Associated with recurrent infection; G: Degree.

studies, the complications were divided into seven groups based on the infection severity and the degree of prosthetic exposure. It presented the most precise management criteria of the reviewed studies. Stratification began with mild infection without prosthetic exposure and evolved to severe infection with exposed prosthetic, which was the only situation resulting in immediate removal of the device and reconstruction postponing. The use of specific management protocol by these authors was able to save the prostheses in 76.9% of the cases in the first publication and 64.4% in the second one. However, the case selection of authors included breast enlargement (aesthetics) surgeries, performed in the majority

of the population in both studies, and the reconstruction with prosthesis (repair). It is known that complication incidences are different between these two kinds of surgery. Breast reconstructive surgeries with prosthesis have higher rates of complications (around 21%)³² if compared with breast enlargement surgeries of purely aesthetical nature, in which the rates vary from 1 to 2%^{33,34}. The study's "n" was not enough for a significant statistical analysis and varied from 1 to 8 patients per analyzed subgroup, with a total of 26 patients in the first study and 87 in the following one.

Reish et al.¹³ have developed the study with the largest selection of cases, in which 1,952 patients who had their breasts

Table 2. Synthesis of management protocols.

First author, reference, and year of publication*	Therapeutic Plan	Rate of saved implants	Factors associated with failure (p<0.05)
Reish ¹³ , 2013	If the quality of the remaining skin was poor, then the prosthesis was removed, the infection was controlled, and late reconstruction was performed. Managements to save the prosthesis include washing with antibiotics, capsulectomy, change of device, and primary or combined closure with muscular flap.	13 (72.2%)	Leukocytosis during admission and cultures with methicillin-resistant <i>Staphylococcus Aureus</i>
Peled ¹⁴ , 2012	All the patients were candidate to one or more attempts of salvage implants, unless they refused	15 (62%)	Radiotherapy
Prince ¹⁵ , 2012	In patients with severe infection, the implant was removed. In patients without severe infection, attempts of saving the implant: antibiotics, cultures, prosthetic removal, capsule curettage, site washing with 3 liters of physiological solution and 3 liters containing antibiotics, placement of new prostheses and drain, removal of the inviable skin and closure according to each type of incision.	33 (76.7%)	<i>Staphylococcus Epidermidis</i>
Bennett ¹⁶ , 2011	In patients with severe infection, the implant was removed. In other situations, we tried to save the implant, which was divided into four possible approaches: 1. Change of implant and primary suture; 2. Change for a smaller implant and primary suture; 3. Development of thoracoabdominal skin and change of implant; 4. Great dorsal flat and implant change.	9 (45%)	No factors associated with failure were seen.
Spear ¹⁷ , 2010	G1: Antibiotic; G2: Antibiotic, capsulectomy, device modification with possible site change; G3: Antibiotic, coating with local tissues; G4: Antibiotics, capsulectomy, debridement, washing, change of device, primary closure and/or local flaps; G5: Antibiotics, in case of improvements, G4 managements, in case of no improvements, prosthesis removal; G6: Antibiotics, capsulectomy, debridement, washing, change of device, primary closure and/or with local flaps or implant removal; G7: Antibiotics, implant removal and late reconstruction assessment.	G1=34 (100%), G2=8 (30.8%); G3=6 (100%); G4=2 (66.7%); G5=2 (40%); G6=4 (66.7%); G7=0 (0%)	<i>Staphylococcus Aureus</i> in cultures and radiotherapy*
Spear ¹⁸ , 2004	G1: Antibiotic; G2: Antibiotic, capsulectomy, change of device with possible site change; G3: Antibiotic, coating with local tissues; G4: Antibiotics, capsulectomy, debridement, washing, change of device, primary closure and/or local flaps; G5: Antibiotics, in case of improvements, G4 managements, in case of no improvements, prosthesis removal; G6: Antibiotics, capsulectomy, debridement, washing, change of device, primary closure and/or with local flaps or implant removal; G7: Antibiotics, implant removal and late reconstruction assessment.	G1=8 (100%), G2=2 (50%); G3=3 (100%); G4=3 (100%); G5=0 (0%); G6=4 (80%); G7=0 (0%)	Severe infection
Yii ¹⁹ , 2003	All the patients with suspicion of periprostheses infection who did not get better after using antibiotics were candidates to attempting to use salvage implants, unless they refused to.	9 (64%)	<i>Staphylococcus Aureus</i> in cultures.

*Associated with recurrent infection; G: Degree.

Table 3. Indirect data on complication stratification and prosthetic loss factors.

First author and reference	Year	Study type	Review period	Amount of patients reconstructed with implant or expander	Evaluated complications	Number of lost prosthesis (%)	Factors associated with prosthesis loss (p<0.05)
Jagsi ²⁰	2016	Retrospective	1998 to 2007	3007	New hospitalization in 30 days, operative wound complications and infection.	442 (14.7%)	Radiotherapy
Wang ²¹	2016	Retrospective	2006 to 2013	489	Operative wound dehiscence that required surgical intervention; infection was divided into those needing oral, intravenous antibiotics or surgery; exposure of expander/implant; expander/implant removal.	33 (4.3%)	Radiotherapy and axillary emptying
Kearney ²²	2015	Retrospective	2007 to 2013	210	Complications of greater impacts including implant/expander removal; hematoma or seroma with the need of surgery; cellulitis with the need of antibiotics; expander/implant removal (without placement of a new device).	26 (9.8%)	Radiotherapy
Anker ²³	2015	Retrospective	1998 to 2009	218	Any complications requiring surgical intervention: asymmetry, poor cosmetic result and contracture; pain; necrosis; dehiscence and extrusion; infection; seroma or hematoma; papillary problems; and disease recurrence.	20 (9%)*	Radiotherapy
Cordeiro ²⁴	2014	Retrospective	1998 to 2010	1415	Any complications resulting in implant loss: infection, extrusion, contracture, seroma, deflation, cosmesis, asymmetry and rippling.	160 (7.5%)**	Radiotherapy
Fischer ²⁵	2013	Retrospective	2005 to 2010	9305	Perioperative complications (30 days); dehiscence, infection (superficial or deep)	85 (0.9%)	Severe infection
Petersen ²⁶	2012	Retrospective	2002 to 2009	141	Epidermolysis (skin superficial necrosis), skin necrosis (reaches the entire thickness), infection (clinical diagnosis), prosthetic removal.	26 (12.5%)	Age >44 years old and smoking
Kobraei ²⁷	2012	Retrospective	2005 to 2010	102	Greater complications (requiring hospitalization or return to the operating room); smaller complications: flap necrosis, hematoma, seroma, healing issues, and infection.	22 (14%)	Radiotherapy
Cowen ²⁸	2010	Prospective	1998 to 2006	141	Any complications requiring other surgical intervention.	32 (22.7%)	Smoking, initial size of the tumor and lymph node condition
Radovanovic ²⁹	2010	Prospective	2004 to 2008	205	Greater complications: necrosis of flap larger than 2 cm, infection requiring intravenous antibiotics; lower complications: necrosis of flap smaller than 2 cm, infection that may be treated with oral antibiotics.	12 (5.6%)	Experience of surgeons
Woerdeman ³⁰	2006	Retrospective	1996 to 2000	120	Seroma, hematoma, skin issue or infection. Divided into greater (in case of prosthesis loss) or smaller complications.	19 (11%)	Experience of surgeons

*Data taken after analysis of the article; **Data regarding the period before the expander change.

reconstructed with prosthesis were retrospectively evaluated. The progression of complications followed the:

- clinical opinion on the infection severity;
- evaluation of the remaining tissue; and
- patient's desire on trying to keep their prosthesis.

Based on the conducts outlined in the study (Table 1), only if the skin quality remained poor, the prosthesis would not be saved. The rate of overall complication of this study was 5.1%. There has been success among the attempts to preserve the implants in 72.2% of the complicated cases.

Peled et al.¹⁴ defined the complications of patients as any infection or problem in the operative wound which required surgical intervention. Based on this situation, the initial management plan was to try and save the prosthesis in all the cases, provided the patient would not refuse it. Of the 29 patients presenting complications with indication for surgical intervention, 5 underwent a reconstructive surgery with abdominal flap, and only 24 cases had the intent to save the prosthesis; of which 15 were successful (62.5%). Yii and Khoo¹⁹ applied similar criteria in 17 cases, of which 3 patients refused the conduct and 14 were approached with the objective of saving the prosthesis; 9 of them (64%) were successful. Although the rates of saved prostheses in these two studies were lower than those of other ones, the complication criterion was more restricted and only the most severe patients were chosen, considering that cases with conservative management did not enter the selection. The managements established by these authors are simple, considering that all the cases are indicative of saved prosthesis. Therefore, they are objective and have great reproducibility, in addition to being challenging, once that for several decades, on an imminent risk situation, the irrefutable procedure was to remove the prosthesis³⁵.

For Prince et al.¹⁵, cases of severe infection (pus associated with signs of local or systemic severe inflammation) consisted in the only situation where there was not an attempt of saving the prosthesis. Among the 60 patients with complications and indication of surgical approach, 43 received recommendations for trying to save the prosthesis. Success was achieved in 76.7% of these cases. Indications for surgical intervention were similar to those presented in the study of Peled et al.¹⁴. However, in Prince et al.¹⁵, removing the most severe cases presented higher rates of saved prostheses. Stratification of postoperative complications, in Bennet et al.¹⁶, is similar to Prince et al.¹⁵ and Peled et al.¹⁴, in which the management of severe infection cases consisted in

prosthetic removal and late reconstruction. In the other cases, there was an attempt to save the prostheses, with or without the support of myocutaneous flaps, depending on the quality of the remaining skin. Of the 68 patients with complications, 45 of them underwent immediate removal of the prosthesis, 3 underwent immediate reconstructive surgery with autologous tissue, and 20 underwent an attempt to save the implant, of which only 9 (45%) cases were successful. The rates of saved prostheses showed in these seven studies do not allow establishing means or comparative analyses, considering they refer to different stratifications of specific complications and managements of each team.

Three of the seven studies with direct data presented positive Gram-bacteria of the skin as a statistically significant factor of non-success among the attempts of saving the prostheses^{13,15,19}, and *Staphylococcus Aureus* was the most responsible one for it. Radiotherapy appears in second place as the cause of implant loss. Spear and Seruya¹⁷ concluded that both the presence of *S. Aureus* in wound culture and radiotherapy were associated with recurrent infection and prosthetic exposure, without impact on the rate of saved prostheses. Agreement on the adversities of reconstruction with prostheses has not yet been achieved, whether due to the heterogeneity of managements, whether by the selection of cases; therefore, we need prospective studies with higher "n", as well as uniform and reproducible managements.

Reconstruction of breasts that had undergone radiotherapy still remains a great challenge. Among the studies with indirect data analysis, radiotherapy was the main factor associated with implant loss, which was shown in seven papers^{20-24,27,30}. According to a metaanalysis published in 2015, the relative risk of reconstructive surgery failure in irradiated patients is 2.58 (95% confidence interval – 95%CI 1.86–3.57). The main management to minimize this situation is the reconstructive surgery with autologous tissue alone or together with prosthesis, thus decreasing such risk in 92 and 72%, respectively³⁶.

CONCLUSION

Breast reconstructions with the use of prostheses have high rates of complications and therefore increase the relevance of researches that might help defining and improving managements in these situations. Among the several existing management protocols, there is not an agreement between the authors; therefore, the choice for the most adequate procedure remains a challenge.

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