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Implant salvage in post-mastectomy reconstruction complicated with infection: molecular diagnosis and negative-pressure wound therapy combined with expander

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Abstract

Breast implant infections are a critical concern in post-reconstructive surgery, often requiring implant removal and delayed reconstruction. To address this challenge, we implemented a "fast-track protocol" integrating rapid molecular diagnostics with advanced surgical techniques to salvage the implant and reduce patient morbidity. A case series of 11 patients treated with this brand-new protocol at our Institution from January 2023 to October 2024 was collected. Each patient underwent preoperative screening and, upon signs of infection, received immediate analysis of periprosthetic fluid using the FilmArray™ PCR system. This approach enabled the rapid identification of pathogens and the initiation of targeted antibiotic therapy within 24 h after implant removal. The surgical intervention included debridement, Negative-Pressure Wound Therapy with saline instillation, and the use

of a tissue expander to maintain pocket integrity and width. The integration of the FilmArray™ PCR system and Negative-Pressure Wound Therapy with instillation resulted in successful salvage of breast reconstructions in 11 out of 11 cases within a medium ten-day timeframe. This series underscores the potential of combining rapid molecular diagnostics with tailored surgical strategies to enhance outcomes in breast implant infections.

Keywords: Breast implant infection, molecular diagnosis, fast-track protocol, FilmArray™ PCR, negative-pressure therapy, targeted antibiotic therapy, breast reconstruction, implant salvage

INTRODUCTION

Breast implant infections pose a significant challenge in reconstructive surgery, presenting a range of complications that often necessitate the removal of the implant and a delayed approach to reconstruction[1,2]. Traditional management of these infections has involved extensive courses of antibiotics, multiple surgical interventions, and prolonged recovery periods. Moreover, reconstructive loss was commonly described[3,4].

Historically, standard treatment involved removing the infected implant, followed by antibiotics and multiple surgeries, including tissue debridement and staged reconstructions[1,2,5]. This approach led to extended recovery times and significant patient discomfort. Delayed reconstruction or conversion to autologous used to be the standard of care[1,6-9].

In recent years, advancements in infection management have prompted new approaches aimed at preserving the implant and reducing patient impact[10-12]. Rapid molecular diagnostics and wound care technologies have emerged as key components of infection management, improving outcomes[5,11,13-15].

Our institution has pioneered a "fast-track protocol" that represents a significant departure from traditional practices[16]. This protocol integrates advanced molecular diagnostics with cutting-edge surgical techniques, specifically focusing on the use of tissue expanders and Negative-Pressure Wound Therapy with instillation (NPWT-i)[15]. By leveraging these innovations, we aim to streamline the infection management process, reduce recovery times, and enhance the overall efficacy of treatment.

The "fast-track protocol" incorporates rapid molecular diagnostics to provide timely and accurate identification of pathogens[17]. Traditional microbiological cultures, which can take several days to yield results, often delay the initiation of appropriate treatment and prolong the infection management process[5]. In contrast, the rapid molecular diagnostics employed in our protocol, such as the FilmArray™ PCR system, offer results within hours. This enables the rapid removal of the implant and prompt initiation of targeted antibiotic therapy, which is crucial for effectively addressing the infection and minimizing its impact on the patient[17].

In addition to advanced diagnostics, our protocol integrates the use of tissue expanders and NPWT-i[18-21]. Tissue expanders, which have long been a staple in breast reconstruction, are employed as an interim solution between the removal of the infected implant and the placement of a permanent implant. They provide essential support to the breast pocket, helping to maintain its structure and prevent collapse or retraction. This is particularly important in ensuring a successful reconstruction and achieving desirable aesthetic outcomes[6].

NPWT-i complements the use of tissue expanders by addressing the immediate challenges of wound management[19,21]. It involves the application of controlled vacuum pressure to the wound area, facilitating the removal of infectious material, necrotic tissue, and excess fluid. This approach promotes a cleaner wound environment and accelerates the healing process, preparing the breast pocket for subsequent reconstruction. By preserving the integrity of the breast pocket and reducing the risk of further complications, NPWT-i plays a critical role in optimizing the overall outcome of the infection management process[15,18-21].

This Technical Note details our experience with the fast-track protocol from the moment we started to apply it, that is, from January 2023, through a case series of 11 patients. Our aim is to illustrate the effectiveness of our innovative combined approach in managing breast implant infections and preserving breast reconstructions.

MATERIALS AND METHODS

Population

A prospective cohort study was conducted between January 2023 and October 2024, including all patients who underwent alloplastic breast reconstruction and subsequently tested positive on culture of the periprosthetic fluid following symptoms suggestive of implant infection.

Preoperative screening

Preoperative screening is a critical component of infection prevention. At our institution, since the new protocol took place (January 2023), all patients scheduled for implant-based breast reconstruction undergo thorough screening to identify potential pathogens. Nasal swabs are collected to detect Staphylococcus aureus, and rectal swabs are taken to screen for Pseudomonas aeruginosa. For methicillin-resistant *S. aureus* (MRSA), the treatment involves mupirocin nasal ointment and chlorhexidine skin washes for 7 days, with a follow-up nasal swab to confirm eradication. If MRSA persists, treatment repeats with the addition of doxycycline and rifampicin for 7 days, followed by another nasal swab to confirm pathogen clearance. For positive rectal swabs for resistant bacteria such as *P. aeruginosa*, an infectious disease consultation determines the appropriate prophylaxis regimen. This approach is crucial for patients in preoperative chemotherapy, emphasizing targeted antibiotic prophylaxis[16]. In case of a positive result, site decontamination and preoperative administration of targeted antibiotics are required to reduce the risk of postoperative infections, otherwise standardized antibiotic prophylaxis with Cefazoline 2 gr is administered[22,23].

Fast-track protocol

The fast-track protocol, recently published by the first author[16], involves several key steps, each designed to address infection promptly and effectively:

· Sample Collection and Rapid Diagnostics. Upon presentation with symptoms suggestive of infection, such as erythema, elevated inflammatory markers, and systemic symptoms, periprosthetic fluid is aspirated and analyzed using the FilmArray™ PCR system (Joint Infection Panel, 91.7% sensitivity and 99.8% specificity)[24-26]. This molecular diagnostic tool provides rapid pathogen identification, typically within 24 hours for positive results and within a few hours for negative results. This allows for timely initiation of targeted antibiotic therapy[17].

· Surgical Debridement. Immediate surgical intervention is performed upon confirmation of infection by a positive molecular test. The debridement procedure includes the removal of the infected implant and

thorough cleansing of the pocket with Betadine Triple solution[27]. Multiple tissue samples from the pocket are collected during surgery, before debridement and washing - two for traditional cultures and one for molecular analysis. The goal is to ensure comprehensive pathogen identification and optimize treatment.

· NPWT-i and Tissue Expander: Negative-pressure Wound therapy with saline instillation (NPWT-i) is applied to the breast pocket to enhance cleaning and maintain pocket integrity. The therapy involves applying a vacuum pressure (-70 mmHg) to the pocket, which helps to remove debris and promote healing. To maintain the width of the implant pocket, a tissue expander surrounded by a polyurethane sponge is inserted into the pocket. The expander maintains skin expansion, preventing collapse under pressure and supporting proper reconstruction[21]. The dressing change, performed in the aforementioned manner, is scheduled every 3-5 days until the intraoperative samples are taken for the FilmArray™ PCR system and the cultural microbiological assay result is negative. This process is shown in Supplementary Video 1.

· Antibiotic Therapy: Based on the rapid molecular diagnostics results, targeted antibiotic therapy is initiated. The choice of antibiotics is tailored to the identified pathogens, ensuring effective treatment. Antibiotic therapy is adjusted as necessary based on further microbiological results and the patient's clinical response[5,24].

RESULTS

From January 2023 to October 2024, 11 breast implant infections were recorded among patients who were submitted to heterologous reconstruction after mastectomy. Patient characteristics and surgical details are summarized in Table 1.

The patients presented with common infection symptoms, including localized tenderness, erythema, fever, and elevated inflammatory markers [Figure 1].

The patient cohort included individuals with diverse backgrounds and histories of heterologous breast reconstruction. The average time from symptom onset to intervention was 1.5 days. All patients underwent thorough preoperative screening and were treated according to the fast-track protocol.

The FilmArray™ PCR system identified pathogens in 11 out of 11 cases, which were confirmed by the microbiological culture in 100% of cases. Methicillin-sensitive Staphylococcus aureus (MSSA) was the most common pathogen detected, with other Gram-positive and Gram-negative organisms present in a minority of cases [Table 2].

Rapid results enabled timely targeted antibiotic administration. Surgical debridement, NPWT-i, and tissue expander insertion were successfully performed in all cases. The association of tissue expander and NPWT-i facilitated the preservation of breast reconstructions in all 11 patients within 10 days on average.

At the medium follow-up of six months, all the patients had stable reconstructions with no recurrence of infection [Figure 2].

DISCUSSION

The approach to managing breast implant infections has undergone significant transformation. Historically, culture-based diagnosis, followed by implant removal upon confirmation of infection and delayed reconstruction, was the only course of action. This often necessitated a period of up to six months without

Table 1. Patient characteristics and surgical details

Patients, *n*	11	
Follow-up, months, median (IQR)	5	(3-11)
BMI, kg/m', median (IQR)	23	(21-25)
Active smoking, *n* (%)	1	(9.1)
Comorbidity, *n* (%)		
Hypertension	3	(27.3)
Diabetes	1	(9.1)
Removed breast tissue, g, median (IQR)	264.5	(178-366)
Plane of reconstruction, *n* (%)		
Prepectoral	9	(81.8)
Subpectoral	2	(18.2)
Dual-plane	0	(0)
Mastectomy procedure, *n* (%)		
Nipple-sparing	9	(81.8)
Skin-sparing	2	(18.2)
Breast reconstruction side, *n* (%)		
Right	6	(54.5)
Left	5	(45.5)
Chemotherapy, n (%)	8	(72.7)
Radiotherapy, *n* (%)	3	(27.3)
Drain duration, days, median (IQR)	13	(10-15)

IQR: Interquartile range.

Table 2. Germs isolated by standard cultures and Film Array tests

Germs isolated	Standard culture	Film Array
Methicillin-sensitive staphylococcus aureus	4	4
Methicillin-resistant staphylococcus aureus	1	1
Pseudomonas aeruginosa	3	3
Candida spp.	1	1
Streptococcus agalactiae	1	1
Serratia marcescens	1	1

breast reconstruction or, alternatively, a transition to autologous reconstruction[1,2,6,28]. Spear *et al.*, in 2004, were the first to propose a method to save implants when possible[3,4].

Multiple advancements have emerged from this now obsolete protocol, particularly in terms of infection prevention. The increasing prevalence of antibiotic resistance has rendered cefazolin prophylaxis, once commonly employed, less suitable[29]. Furthermore, gram-negative bacteria, which are not susceptible to cefazolin, have become more frequent in cases of implant-associated infections[2,30].

Regarding diagnostic methods, traditional culture-based approaches - currently considered the gold standard - pose limitations due to delayed results, typically requiring 4-5 days to yield findings[5]. This delay constitutes a critical “dead period”, which can now be circumvented with advanced molecular diagnostic techniques[31].

Figure 1. Breast infection 4 months after nipple-sparing mastectomy and breast reconstruction with prepectoral implant. Erythema and swelling characterized the rapid onset of the infection; moreover, yellowish periprosthetic fluid was collected with US-guided needle aspiration.

Figure 2. Four months postoperatively after administration of the Fast-track protocol.

Surgical intervention remains essential, with a focus on prompt implant removal and extensive debridement of the implant pocket. In this process, NPWT with instillation, enabling continuous lavage of the pocket, has proven invaluable[15,18,19,21]. To counteract the natural tendency for skin contraction during this phase, we have implemented the use of a tissue expander within the sponge to preserve volume, facilitating early replacement with a new implant. The full protocol, from first consultation to discharge, typically spans a period of 7-10 days.

The integration of NPWT-i and tissue expanders in our fast-track protocol has demonstrated substantial benefits in managing breast implant infections, enabling the rapid salvage of most reconstructions. This combined approach has been instrumental in improving outcomes, preserving breast reconstructions, and reducing patient morbidity. NPWT-i has proven to be a cornerstone of effective infection management. In the context of breast implant infections, the application of controlled vacuum pressure within the breast pocket serves multiple functions[18,21]. It assists in the rapid removal of infectious material, necrotic tissue, and excess fluid, which are key contributors to prolonged infection and delayed healing. By drawing out these contaminants, NPWT-i helps to create a cleaner wound environment, thus minimizing the risk of further infection and facilitating a more efficient healing process. Moreover, NPWT-i plays a significant role in maintaining the structural integrity of the breast pocket[15,18,19,21]. Following the removal of an infected implant and debridement of the affected tissue, the breast pocket can be susceptible to collapse or retraction. This risk is particularly pronounced when dealing with significant tissue loss or damage[15,20].

The use of tissue expanders in conjunction with NPWT-i with the aim of volume preservation in this setting has not been extensively studied, and our findings, though promising, are based on a limited cohort. Tissue expanders are designed to gradually stretch the overlying skin and underlying tissue, creating an optimal environment for the placement of a permanent implant[32]. In the context of infection management, tissue expanders offer several advantages. They provide a means to support and maintain the shape of the breast pocket, reducing the likelihood of skin retraction and pocket collapse. By maintaining the structural integrity of the pocket, tissue expanders help to ensure a better fit for the final implant, thus reducing the need for additional corrective surgeries[33].

The combination of NPWT-i and tissue expanders also contributes to a more streamlined reconstruction process. Traditional methods of managing breast implant infections often involve multiple stages of surgery and extended recovery periods. These methods can be both time-consuming and physically demanding for patients. In contrast, our fast-track protocol, which incorporates both NPWT-i and tissue expanders, allows for a more efficient and expedited approach to infection management and reconstruction. The rapid identification of pathogens through molecular diagnostics further complements this approach, enabling the timely initiation of targeted antibiotic therapy.

Molecular diagnostics, such as the FilmArray™ PCR system, have revolutionized the management of breast implant infections by providing rapid and accurate pathogen identification. This advancement enables the prompt initiation of targeted antibiotic therapy, which is crucial for effective treatment[17,31]. Traditional microbiological cultures, which typically require several days to yield results, often delay the start of appropriate treatment. In contrast, molecular diagnostics offer results within a matter of hours, facilitating immediate and precise antibiotic adjustments. This rapid response enhances the effectiveness of treatment and contributes to a reduction in the overall duration of infection management. In our case series, there was a 100% match between the Film Array and classical culture test, which allows us to consider the result obtained with the molecular test reliable. The limit of this new method is represented in case there is an infection caused by germs not tested in the panel; for this reason, at present, we continue with the execution of both tests: we consider the time advantage that the molecular test allows us to have in early diagnosis essential information to initiate a targeted antibiotic therapy as soon as possible.

The successful outcomes observed in our case series underscore the potential benefits of combining NPWT-i and tissue expanders. However, we acknowledge that our study is limited by the small sample size (11 patients), which may affect the generalizability of our results. Larger, controlled studies are needed to validate these findings and further establish the role of this protocol in clinical practice. In our cohort of 11

Figure 3. Preoperative and 6-month postoperative view of a BRCA-1 patient who underwent bilateral mastectomy (risk-reducing on the right side and skin-sparing on the left). An infection caused by S. Aureus occurred on the 34th postoperative day on the left side. The patient was promptly enrolled in the fast-track protocol, which successfully preserved the reconstruction.

Figure 4. Preoperative and 8-month postoperative view of a patient who underwent a right skin-reducing mastectomy and contralateral breast reduction. An infection caused by *Streptococcus Agalactiae* occurred on the 23rd postoperative day. The patient was promptly treated using the fast-track protocol, enabling preservation of the reconstruction.

patients, the fast-track protocol enabled the preservation of breast reconstructions in all cases, demonstrating the efficacy of this approach in managing complex infections. The ability to maintain the structural integrity of the breast pocket and achieve satisfactory reconstruction outcomes with minimal additional interventions highlights the advantages of this protocol over traditional methods [Figures 3 and 4].

However, it is important to acknowledge that the use of the FilmArray™ PCR system for breast implant infections remains off-label. While the rapid results provided by this system are invaluable, further validation through larger studies is necessary to establish its role and optimize its application in this context.

Additionally, patient-specific factors must be considered when tailoring the protocol. Each patient's unique medical history, infection severity, and response to treatment can impact the effectiveness of the protocol and should be taken into account when planning and implementing the treatment strategy. As we continue to refine and validate this protocol, it is essential to consider both the benefits and limitations, ensuring that the approach is optimized for each individual patient. The promising results observed in our case series provide a strong foundation for further research and development in this area, with the potential to improve patient care and outcomes in breast reconstruction.

CONCLUSION

The fast-track protocol, characterized by early diagnosis, surgical debridement, and application of NPWT-i and tissue expanders, offers a promising approach to managing breast implant infections. This strategy enables the preservation of breast reconstructions, enhances patient outcomes, and minimizes overall morbidity. Ongoing evaluation and refinement of this protocol will be essential for further improving infection management in breast reconstruction.

DECLARATIONS

Authors' contributions

Made substantial contributions to the conception and design of the study and performed data analysis and interpretation: Caputo GG, Weitgasser L, Schoeller T

Performed data acquisition, as well as providing administrative, technical, and material support: Scarabosio A, Ferrari A, Mahrhofer M, Pagotto A

Availability of data and materials

Not applicable.

Financial support and sponsorship

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Conflicts of interest

All authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

Informed consent to participate in the study was obtained from all participants in accordance with the Declaration of Helsinki. The study was approved by the Institutional Review Board of the Department of Medicine of the University of Udine (Prot IRB: 103/2024).

Consent for publication

A written informed consent for publication was obtained.

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