Infectious complications in implant based breast surgery and implications for plastic surgeons

Infektiöse Komplikationen bei alloplastischen Brustoperationen und Implikationen für Plastische Chirurgen

Abstract

Implantation of breast prosthesis is still one of the most frequently performed breast reconstructing or contouring procedures. Infectious complications and capsular contracture are inherent problems that may have different causes which are not clearly defined yet in terms of pathophysiology. Recent findings showed bacterial contamination as a major cause of implant failure. Since this has direct implications for the surgical management we report on biofilm development on alloplastic breast prostheses, characteristics and effects after implantation of medical devices in general. This article gives a review of the current literature and discusses possible issues to solve the problem of infection after implantation of breast prosthesis.

In conclusion the reinsertion of single-use devices should not be recommended and should be strictly avoided when a device related infection has occurred. According to current knowledge contaminated implants should be removed, the infection then be cured and if necessary, a new prosthesis may be implanted after a regeneration period. Alternatively a change in therapy towards autologous tissue reconstruction should be considered if previous attempts with alloplastic prostheses have failed and if radiation therapy has worsened the local tissue situation in the recipient area.

Zusammenfassung


Introduction

In recent literature there is a growing body of scientific evidence that bacteriae could be a major cause for implant failure [1], [2]. We have previously reviewed the biofilm problem with regard to late seroma and revisional breast surgery [3] and want to highlight this issue because not only in aesthetic procedures but also in breast reconstruction implants still play a considerable role [4]. In contrast to this procedure, usually no long term infectious problems are seen when restoring the breast mound with the patient’s own tissue. Through an increased standardization of autologous breast reconstruction surgery this alternative has become a routine procedure in the hands of experienced reconstructive surgeons and it is available to many patients in Europe when amputation of the breast or partial loss of breast tissue as a consequence of cancer therapy is experienced. In addition, when performed in high volume centers, free microsurgical transplantation of suitable tissue has been optimized rendering reliable results with a high rate of safety, even in previously irradiated patients [5], [6], [7]. Other future options, such as creating replacement tissue by means of tissue engineering and regenerative medicine seem highly promising but are not clinically available yet [8], [9], [10], [11], [12], [13], [14], [15], [16], [17]. Nevertheless on a worldwide perspective implant based alloplastic breast reconstructions with or without skin expansion is believed to account for the majority of procedures to restore breast shape and volume. Moreover despite the undeniable benefits of autologous breast repair authors have even proclaimed a shift of paradigm towards increasing alloplastic reconstructions recently [18].

Breast implants are also used for aesthetic reasons, malformation of the breast, expanders followed by definitive implants in reconstructive surgery, prophylactic mastectomy due to BRCA 1 mutations. After skin sparing mastectomy (with still approximately 5% of remaining breast tissue) often a critical perfusion of the skin envelope is experienced. In these patients it is questionable if less perfused tissue may present a sufficient mechanical barrier against microorganisms. If the skin is irradiated this problem might become even more significant. Patients who had radiotherapy have a significantly higher incidence of subclinical infection than patients who did not [19]. Oposite after a risk-reducing mastectomy with still approximately 5% of remaining breast tissue a robust skin envelope remains that could act as a good mechanical barrier of microorganisms. Among other well known side effects of breast implants, such as displacement, double bubble deformity, undue scarring, implant rupture, systemic spreading of silicone into the body [20] etc., the event of a capsular contracture remains an unsolved but serious clinical problem [21], [22], [23], [24], [25]. Up to now numerous attempts to prevent capsular contracture failed and did not achieve a reliable effect for clinical use [23], [26]. Following the so called PIP scandal numerous questions were brought up again whether we do know enough about the material properties and longevity of alloplastic breast implants, the mechanisms of capsular contracture [27], and the involvement of subclinical infectious processes, long term side effects such as the occurrence of anaplastic large cell lymphoma cells in the periprosthetic fluid etc. [28], [29], [30], [31], [32], [33], [34], [35], [36].

Anecdotally it has been reported that bacterial colonization was detected in the seroma fluid of patients with capsular contracture [37], [38], but even when infection was clinically seen bacterial counts were not positive in all cases [1], [2], [39], [40], [41], [42], [43]. Researchers removed breast prostheses from capsular contracture grade III and IV, and sonication detected bacteria in 41% of removed breast implants. The identified bacteria belonged to normal skin flora [2]. Although further investigations will be needed to determine a true causal relation between biofilms and capsular fibrosis, the infectious hypothesis has gained widespread acceptance as one major cause of capsular contracture [1], [44]. According to Jacobs et al. this is based on both clinical and research studies that have shown an association between the presence of bacteria and high grade capsular contracture [45]. With a better understanding of the complex interactions of planktonic bacteria in biofilms [46] an increasing number of publications now focuses on the problems of bacterial contamination of chronic wounds and infected implants of any type [47]. Knowledge about the behavior of various bacteria within biofilms, their diagnosis and treatment options in dental medicine and in microbiology is constantly growing, but data on biofilms in breast implants are still scarce [47], [48], [49], [50], [51], [52], [53], [54], [55], [56]. In the literature there is no clear description of a correlation of the grade of capsular contractions and microbiological structures found in biofilms so far.

Biofilm development on devices

The detrimental effects of bacterial biofilms on medical devices have been established within the scientific literature to be responsible for persisting infections in concerned implants and recently have been shown to be responsible for non-healing chronic wounds too. Electron microscopy of biopsies from chronic wounds found that 60% of the specimens contained biofilm structures in comparison with only 6% of biopsies from acute wounds. According to Philips et al. [57] biofilms are complex microbial communities that contain bacteria and fungi. The microorganisms synthesize and secrete a protective matrix that attaches the biofilm firmly to a vital or non-vital surface. Bacteria within biofilms interact with each other and exchange signals. This phenomenon has been termed “quorum sensing”. Cell-to-cell communication is pivotal to the development and maintenance of biofilm structures [45]. This system confers several advantages to these microorganisms, including protection from the host immune system and antibiotic treatment. Biofilms are considered to be dynamic heterogeneous
Biofilm formation is a very complex, multistep process with microorganisms attraction and adhesion, with pluri-stratification of bacteria onto the artificial surface as the first and decisive step to a given surface [53] (Figure 1). The first step requires the mediation of bacterial surface proteins, in which the main bacterium is S. aureus autolysin [38]. Free-floating microorganisms are attracted to dirty, wet surfaces and initially adhere to these surfaces using weak intermolecular van der Waals forces. If not physically separated from the surface immediately, these microorganisms “permanently” attach to such surfaces using cell adhesion molecules such as pili. Water coated surfaces provide better attachment conditions than dry surfaces. As the biofilm begins to form, an increasing number of microorganisms is attracted to cell adhesion sites [56], [57].

The second step is dominated by the growth period. As the biofilm grows, the structure is held together and protected by an excreted EPS (extracellular polymeric substance). As already mentioned biofilm molecules, often consist of many different Bacteria, and they communicate with one another using “quorum sensing” [56]. Quorum sensing, an interbacterial communication mechanism itself is dependent on population densit. The EPS protects the microorganisms living within and provides pathways for efficient communication between cells and microorganisms also undergo a genetic change when living within biofilms [57]. Several studies suggest that some cells such as E. coli become virtually immune to antibiotics due to a low level of metabolic activity. In their study from 2001 Stewart and Costerton have estimated that antibiotic resistance of sessile bacteria living within biofilms can be 1000 fold greater than that of free-floating planktonic bacteria [63]. The biofilm matrix forms both mechanical stability and the possibility that the individual organisms build synergistic interactions among themselves, to survive periods of starvation and remain extracellular enzymes get into the mucus layer [38], [66]. The third phase is characterized by detachment. This is seen when biofilms grow into large macroscopic three-dimensional structures. This is when shear forces may cause large sections of the biofilm to detach – releasing millions of organisms [57], [67].
Infectious complications after breast implants and biofilms

Infection after breast implant surgery occurs in 1.1% to 2.5% of procedures performed for augmentation and up to 35% of procedures performed for reconstruction after mastectomy. Most infections result from skin organisms and occur in the immediate postoperative period, although infections can occasionally present after many years [72]. Many product recalls and product contamination issues are caused by biofilm detachment. Generally there is a consensus that despite all safety measures local complications cannot be completely avoided after breast implant surgery. Devices such as sterile funnels to prevent skin contact during insertion of breast prostheses have been developed for this reason. Similar to infections of other medical devices the removal of the potentially contaminated implant is the cornerstone of treatment. Bacterial cells which detach from these biofilms can enter the circulatory system. This can lead to severe systemic side effects such as sepsis. For instance, in patients with catheter sepsis, sepsis has been described to occur in 6%, and endocarditis in 1% [73]. In general, in current reviews any device in place is considered to be bacterially contaminated during its life span in around 7% [74].

For any exposed or infected implant the main aim is to cure the infection in the first step before reinsertion of another implant can be considered. A time frame of 3–6 months is generally accepted to be sufficient before repeating the device implantation [75], [76], [77], [78]. Failed post cancer breast reconstructions frequently are converted into autologous reconstructive procedures [79], [80], [81], [82] to get rid of the alloplastic material. Only within the last years the impact of bacterial biofilms on the pathogenesis and maintenance of chronic inflammation processes could be shown as the most frequent reason for implant failure, which is why the strict removal of potentially infected breast prosthesis is essential [83].
In contrast to the scientific aspects especially for Plastic Surgeons the legal aspects have to be taken into consideration when dealing with one way products and devices. Due to economic needs in modern medicine the repeated use or “re-use” of single-use products has become an increasingly contentious issue. Obviously this is not primarily a pure medical problem. But if surgeons deviate from the standard regulations concerning medical devices lawful they take over the responsibility of delivering a certified product. This usually would be the task of the manufacturer who has to oblige certain laws and regulations in order to get permission to distribute medical devices for implantation into a human body which have been shown to cause no harm. There has been considerable debate if medical devices that are intended for single use may be recycled or not. In Germany the Robert Koch Institute and the Association of Scientific Medical Societies (AWMF) have issued a consensus statement that covers also the handling of silicone implants for breast surgery [66].

European Union member states have propagated certain steps to tighten regulatory controls over medical devices and technologies in the wave of revelations that French breast implant manufacturer Poly Implant Prothèse Company (PIP) used non-medical-grade silicone in its products. Coordinated efforts have been initiated at national levels to ensure full implementation and enforcement of existing medical device legislation to guarantee safety and improve patient confidence in the EU regulatory system. On a regulatory level verification of notified body designations needs to be evaluated whether these entities are truly designated only for assessment of medical devices and technologies, as well as making sure that Notified Bodies fully leverage their authority being laid out in conformity assessments, including their power to conduct unannounced inspections. In any respect it seems advisable for Plastic Surgeons to be informed about the legal implications of deviating from common standards and how to perform safely during revisional breast implant surgery. Infections after breast implants and the role of potential biofilms are a common cause for legal cases. As long as the microscopically thin biofilms containing bacteria or fungi are not visible by pure inspection an implant that may look otherwise intact the implant should be considered to be potentially afflicted with biofilm once it has been exposed. It should be clear that washing breast implants in bactericidal solutions or in antibiotics intra-operatively in order to get rid of biofilm is not sufficient to ensure product safety. Given the complex 3D surface structure of breast prosthesis (Figure 2, Figure 3) it can easily be perceived that a full penetration of any antimicrobial agent into the deepest holes and spaces of the surface is almost impossible. Case reports in the literature about successful retention of exposed silicone breast implants were based on clinical experience and did not discuss the removal of a biofilm or the problems of incomplete microbicidal action and penetration into the structure [20], [73], preventing complete removal of the biofilm [74]. Furthermore on it has been suggested that aggressive biocides may well alter the surface of a silicone implant and could lead to implant failure by destroying the original material properties of the membrane. Testing potential side effects of antimicrobial agents and various disinfectants on the material properties of breast implants is necessary and is currently envisioned by researchers to clarify these questions.
Conclusion

In conclusion our current knowledge about biofilms and breast implants implicate that a reliable elimination of biofilm on breast implants during operative revisions is not safely possible so far. Moreover, exposed prostheses need to be replaced by new ones to make sure that any risk of persisting biofilm is excluded. It seems obvious and is highly advisable to not reuse single-use products when an infection might have occurred. The safest resolution is first of all to remove the implant, then cure the infect and either come back to reinsert another prosthesis or change the procedure to an autologous reconstruction.

Notes

Competing interests

The authors declare that they have no competing interests.

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Please cite as

This article is freely available from http://www.ejgms.de/en/journals/gpras/2013-3-gpras000014.shtml

Published: 2013-07-04

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