



Management of Capsular Contracture in Cases of Silicone Gel Breast Implant Rupture with Use of Pulse Lavage and Open Capsulotomy



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Abstract

Introduction Pulse lavage (PL) irrigation of prosthesis pockets has prior been described for breast implant salvages. However, PL for removal of leaked silicone from prosthesis pockets after implant ruptures has not been studied yet. Since open capsulotomies are regarded as equal treatment of capsular contracture (CC) than capsulectomies, this study analyzed the clinical outcome of PL for silicone removal and subsequent capsulotomy in cases of concurrent CC and breast implant rupture.

Methods Between 2012 and 2017, 55 patients (75 breasts) with suspected silicone implant rupture and CC (Baker grade III/IV), after primary breast augmentation or implant-based breast reconstruction, were included in a retrospective, observational study. Mean patient follow-up was 12.2 ± 3.6 months.

Results In all preoperatively suspected ruptured silicone breast implants, around a quarter were intact. In contrast to previously published data, implant exchanges in cases of implant ruptures did not lead to significantly higher CC recurrence rates (27.6% vs. 22.2% in cases of intact implants, $p = 0.682$), if the prosthesis pockets were treated

with PL irrigation followed by open capsulotomy. PL reduced the amount of encapsulated silicone remnants histologically. The age of patients with CC after failed implant-based reconstruction was significant lower for salvage surgeries with flap reconstruction than for implant exchanges, $p < 0.05$.

Conclusions PL irrigation of prosthesis pockets prior to open capsulotomy is a safe and effective treatment of CC with concurrent silicone leakage. Remaining silicone remnants in breast capsules may affect the development of a recurrent CC. To avoid CC recurrences, patients should consider conversion to autologous tissue.

Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Capsular contracture · Breast implant rupture · Pulse lavage irrigation · Silicone gel leakage · Open capsulotomy

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Introduction

Wound irrigation through pulse lavage (PL), also known as pulsed or pulsatile lavage, is an established method in the treatment of infected or contaminated open wounds as well as implant surgeries, e.g. arthroplasties [1, 2]. Low- and high-pressure PL irrigations have been investigated previously in animal models and in the clinical setting [3]. While high-pressure PL irrigation was superior in removing bacteria, it has also shown a negative biomechanical effect on diaphyseal fracture healing in experimental studies [1, 4]. In a large international, blinded, randomized,

controlled clinical trial, PL irrigation of different pressures has been compared, showing similar clinical outcomes after treatment of open fractures regardless of the irrigation pressure used [5].

Pulse lavage irrigation has shown its applicability in plastic surgery of the breast and has been successfully implemented in the treatment of periprosthetic infections [6]. In the management protocol of persistent infection or breast implant exposure, PL irrigation of the prosthesis pocket after implant removal has shown to be an essential operative step along with subsequent capsulectomy [7]. Despite periprosthetic infections, capsular contracture (CC) remains the leading long-term complication in breast implant surgery [8]. The widely performed treatment of CC includes capsulectomy, breast implant site change from subglandular to subpectoral, and implant exchange. While the etiology of CC is still intensively discussed, one current hypothesis for a possible origin of CC is the theory of a low-grade, subclinical infection, or biofilm formation around breast implants [9]. Therefore, the radical excision of the capsule around the breast implant through capsulectomy was regarded as necessary in order to remove the possible infective tissue. However, a recent review on treatment strategies demonstrates that the clinical evidence behind capsulectomies remains low, with similar CC recurrence rates (0–53%) compared to open capsulotomies alone (0% and 54%) where the capsules are left in the patient [10].

While capsulectomy requires a significantly greater invasive and technically challenging dissection, open capsulotomy reduces the operating time as well as the postoperative recovery time [11]. In contrast, capsulectomy leads to less remaining tissue for implant coverage and greater risk of injury of nerves, the axilla, and the chest wall [12]. Additionally, no harm has been reported for leaving thin and noncalcified capsules in the patient during open capsulotomy [13]. According to several authors, capsulectomy should be reserved for thick and calcified capsules, whereas removal of all calcification is reported to be unnecessary [10, 11, 13].

Silicone bleed after rupture of cohesive gel implants is known to be associated with an increased CC recurrence. In experimental studies, the amount of silicone leakage correlated with the severity of the CC and the capsule thickness in a dose-dependent manner [14, 15]. In concordance, a current retrospective study on patients with Baker III/IV CC reveals significant greater risk of recurrence in cases of ruptured silicone gel implants [11]. However, PL irrigation of breast prosthesis pockets after silicone gel leakage and concurrent CC has not been investigated yet. The clinical outcome of PL irrigation of breast prosthesis pockets after explantation of the ruptured implants with subsequent open capsulotomy was analyzed in a 5-year retrospective,

observational study, and a treatment algorithm for the salvage of simultaneous CC and breast implant rupture proposed. Furthermore, the effects of PL irrigation on the breast implant capsule were assessed histologically.

Material and Methods

From 2012 to 2017, a chart review was performed of patients admitted to the Division of Plastic, Reconstructive and Aesthetic Surgery of the University Hospital Bonn with suspected implant ruptures based on magnetic resonance imaging (MRI) or ultrasound (US), and concurrent CC (Baker grade III/IV). In a retrospective, observational study design, 55 patients after primary breast augmentation or implant-based breast reconstruction (75 breast implants) fulfilled the above-mentioned criteria. Patients receiving capsulectomies were not included in the study. Indications for performing a capsulectomy instead of a capsulotomy were calcified capsule or suspected carcinoma. During follow-up, Baker grade 1 or 2 capsules were defined as contracture-free, while Baker grade 3 and 4 capsules were counted as CC recurrence. The hospital records of the included patients were examined, and data on demographics, postoperative complications, and dates of CC recurrence were collected.

Treatment Algorithm

All included patients underwent preoperative examination and received informed consent for PL irrigation of the breast pocket in case of implant rupture, open capsulotomy, subpectoral site change, implant removal, implant exchange, implant exchange with fat grafting, autologous breast reconstruction with fat grafting only, or flap reconstruction of the affected breast. Patients without implant rupture were all treated by open capsulotomy and subsequent implant exchange, without prior PL. In cases of ruptured implants in subglandular pockets, subpectoral site changes were performed after PL irrigation of the old prosthesis pockets.

Surgical Technique

All patients underwent surgery using total intravenous anesthesia and received cefuroxime 1.5 g IV perioperatively. Access to the breast pocket was either over an inframammary incision along the original scar in patients after primary aesthetic breast augmentation, or over the original mastectomy incision in patients after implant-based breast reconstruction. Implant status was then classified as ruptured or intact, followed by explantation of the breast implant. All intraoperatively observed implant

ruptures were intracapsular. In cases of present implant ruptures, PL irrigation of the breast prosthesis pocket with a 3-L bag of normal saline solution was performed using a PL device (InterPulse Irrigation System, Stryker Instruments, Kalamazoo, Michigan, USA). The PL system was used with the high-flow tip attachment at maximum pressure of 19 psi and maximum flow rate of 1025 mL/min, as previously described [16]. Samples of the capsular tissue were collected prior to PL irrigation of the breast pockets as well as after PL irrigation. Subsequently, open capsulotomy was carried out as previously described with minor modifications by semicircular incision of the capsule as well as perpendicular incisions using a monopolar electrocautery knife (ERBE Elektromedizin, Tübingen, Germany) [17].

Based on the preoperative informed consent, salvage was achieved either by implant removal without reconstruction, implant exchange with or without fat grafting, fat grafting only, or flap reconstruction. Myocutaneous pedicled flaps (latissimus dorsi flap, LD, and transverse rectus abdominis myocutaneous flap, TRAM) as well as fasciocutaneous free flaps (deep inferior epigastric artery flap, DIEP, and transverse upper gracilis flap, TUG) were performed in cases of failed implant-based breast reconstruction only. One LD flap was combined with an additional implant, two TRAM flaps were inserted as deepithelialized flaps, and the skin island of one DIEP flap was first remained as monitoring skin island and removed after 3 months. Autologous fat grafting was performed as described previously [18]. Conversion of failed implant reconstruction to autologous tissue will be termed as tertiary breast reconstruction as previously described [19, 20].

Histology Analysis of Capsular Tissue

For histological analysis, specimens of breast capsules prior and after PL irrigation of breast pockets were collected and fixed in 4% formaldehyde, embedded in paraffin, and cut into 4- μ m-thick sections at the Institute of Pathology, University Hospital Bonn. The sections were then stained with hematoxylin and eosin, examined by light microscopy as well as under polarized light, and digitalized for further histopathological image analysis using Pannoramic Viewer (3DHISTECH Ltd., Budapest, Hungary).

Statistics

Data were collected using a Excel spreadsheet (Microsoft Corporation, Redmond, WA, USA), and GraphPad Prism (Graph Pad Software, Inc., San Diego, CA, USA) was used for data analysis. The Chi-square test was used, where applicable to compare categorical data; the *t* test, where applicable for continuous variables. For the comparison of

the CC recurrence over time, we applied the Kaplan–Meier survival analysis with log-rank test and the assumption that when implants had been changed bilaterally each side was analyzed independently in terms of the risk of contracture, as previously described [21]. The statistical significance level was set to $p < 0.05$.

Results

In total, 55 women ($n = 75$ breasts) with present CC (Baker grade III/IV) and suspected implant ruptures were included in this study (see Fig. 1), with mean follow-up time of 12.2 ± 3.6 months. Breast implant ruptures could be confirmed in 76% of all explanted implants ($n = 57$; 43 patients), while 24% were intact and displayed no implant ruptures ($n = 18$; 12 patients). In cases of no implant ruptures, open capsulotomies with subsequent implant exchanges were performed. All breast pockets with silicone leakage were treated with explantation of the ruptured implant and subsequent PL irrigation (see Fig. 2), followed by open capsulotomy (see Fig. 3; $n = 51$; 40 patients), or subpectoral site change in cases of subglandular implant pockets ($n = 6$; 3 patients).

Two patients desired removal of their bilaterally ruptured implants without further reconstruction ($n = 4$ implants, app. 8%). Implant exchanges ($n = 29$; 24 patients) were performed in over 57% of cases with confirmed implant ruptures. Among those implant exchanges, additional fat grafting for breast contour improvement was required in 5 breasts (4 patients). In more than one-third (app. 35%) of implant rupture cases, autologous breast reconstruction was achieved with either fat grafting ($n = 8$; 5 patients) or tertiary flap reconstruction ($n = 10$; 9 patients).

In summary, 37 ruptured implants (29 patients) after primary breast augmentation and 10 ruptured implants (7 patients) after implant-based breast reconstruction were exchanged. The mean age of all patients in the study receiving exchanges of ruptured implants was 42.8 ± 14.4 years. The mean age of patients after initial implant-based breast reconstructions needing implant exchanges (60.7 ± 10.9 years), due to CC and concurrent implant rupture, was highly significantly above that of patients after primary cosmetic breast augmentations (38.5 ± 11.6 years), $p < 0.001$. A slightly higher BMI, older implant age, and elevated CC recurrence rate for patients after implant-based breast reconstruction were recorded, that, however, did not reach statistical significance ($p > 0.05$), see Table 1a. All reconstructed breasts among this treatment group received prior postmastectomy radiation therapy.

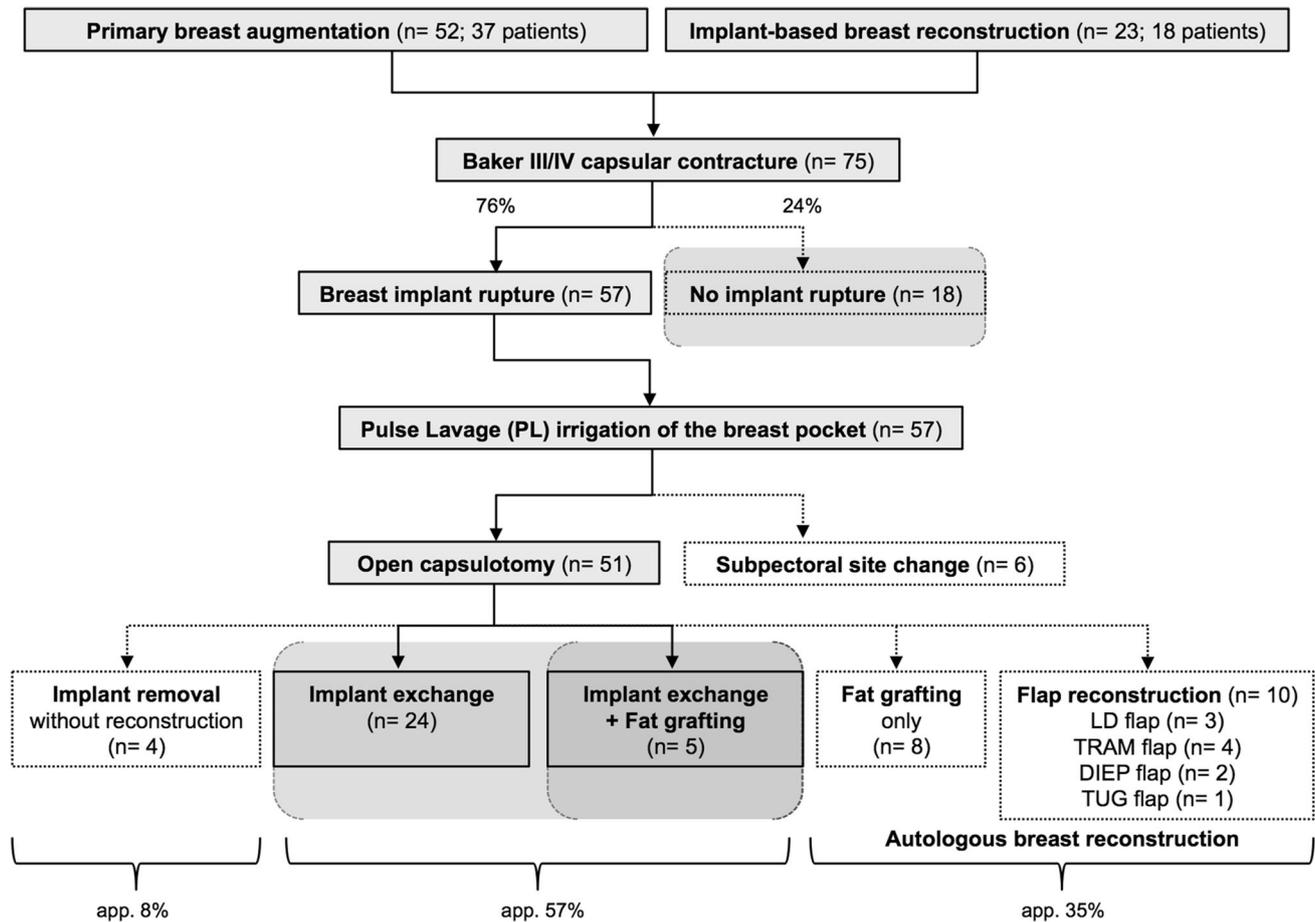


Fig. 1 Study flowchart with treatment algorithm of patients with capsular contracture and suspected breast implant rupture. Treatment (breast implant rupture with PL and open capsulotomy, $n = 29$) and

control (no implant rupture and open capsulotomy only, $n = 18$) groups are gray-shaded and additionally framed

In contrast, the patient demographics in cases of implant ruptures were comparable to cases with intact non-ruptured implants in terms of mean age, BMI, and implant age, see Table 1b. Both infection and seroma were balanced between groups without statistical significant differences found. However, all breasts after infection or seroma developed CC recurrences.

The results reveal that the CC rate of salvages of implant ruptures by PL irrigation, open capsulotomy, and implant exchange is statistical insignificant to salvages in cases of no implant ruptures (27.6% vs. 22.2%, $p > 0.05$).

Six site changes in cases of CC and ruptured silicone implants from subglandular to subpectoral pockets were performed. Equally, PL irrigation of the prosthesis pockets was performed, prior to the preparation of the neopockets. Conversions from subglandular to subpectoral ($n = 6$; 3 patients) were only performed in cases after initial cosmetic subglandular augmentation mammoplasties, as all cases after implant-based breast augmentation had already been in subpectoral plane. One case of unilateral CC

reoccurred 12 months after implant exchange of bilateral ruptured implants during the follow-up of patients receiving subpectoral site changes. In comparison with the other treatment groups, the CC rate after subpectoral site change in cases of ruptured implants was lower (16.7% vs. 25.5% in mean). However, the sample size was too small to reach statistical significance against the other groups, $p > 0.05$.

Histopathological image analyses of the specimens prior to PL irrigation of the breast pockets and directly after removal of the ruptured silicone gel implants of three representative cases of different patients are shown in Fig. 4a, c, e. The specimens present a three-layer composition of the fibrous capsules, as previously described [22]. The internal layer facing the ruptured implant presents multilayers of macrophages and fibroblasts, which is known as a pseudoepithelial cellular layer or a synovia-like metaplasia [22]. The middle layer displays connective tissue formations with infiltration of a great number of mononuclear cells. Within this layer, multiple vacuoles with encapsulated silicone gel can be found. On polarized

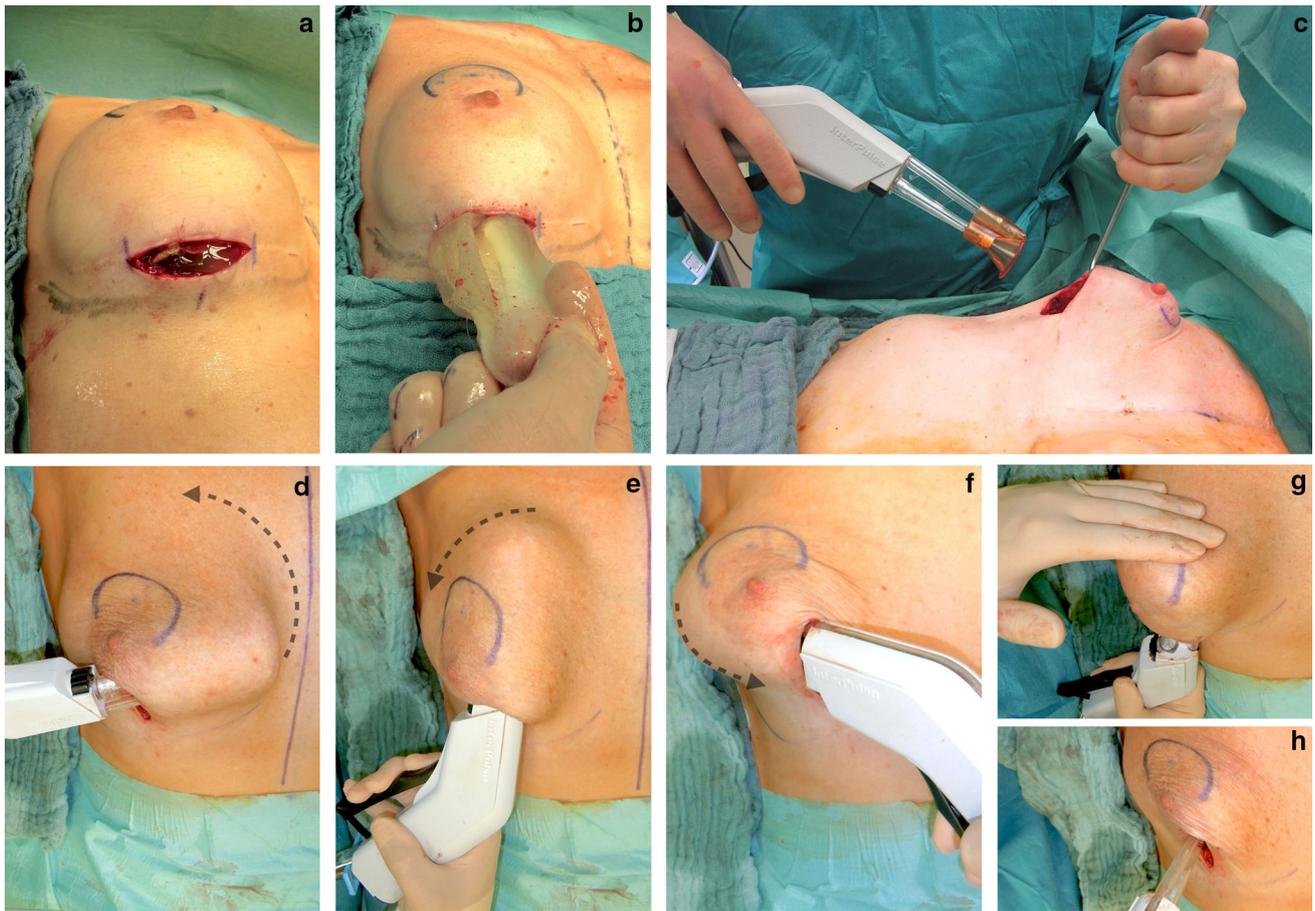


Fig. 2 Demonstration of pulse lavage irrigation. **a** Intraoperative confirmation of silicone breast implant rupture. **b** Explantation of ruptured silicone-filled implant. **c** Preparation of PL irrigation of the

prosthesis pocket with normal saline using a handheld pulse lavage device. **d–h** PL irrigation of the implant pocket in a 360° fashion. Dotted-line arrows indicate the movement of the PL irrigation tip

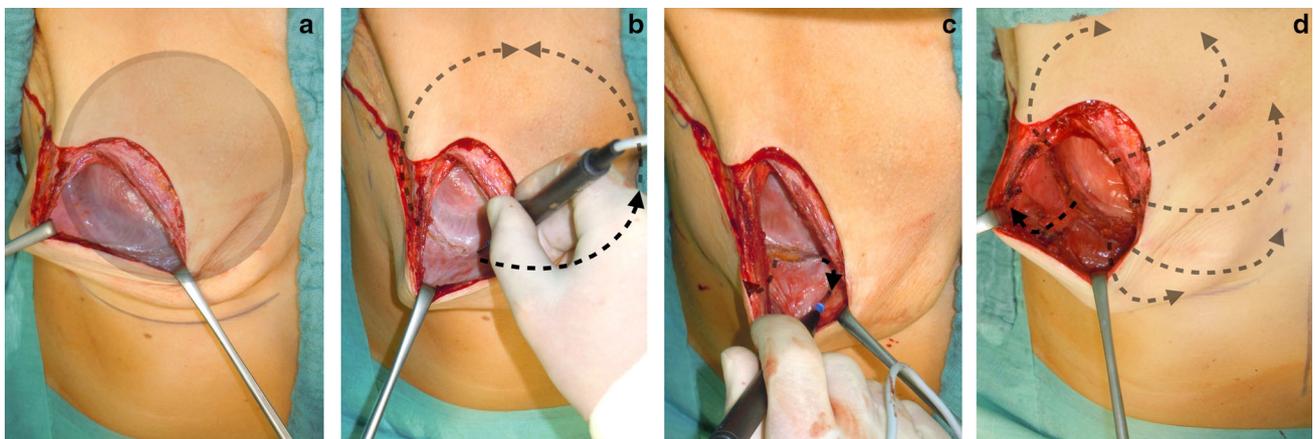


Fig. 3 Demonstration of open capsulotomy. **a** Intraoperative view into the fibrous breast capsule after explantation of a ruptured silicone gel breast implant and prior PL irrigation of the implant pocket. Open

capsulotomy using a monopolar electrocautery knife with circular (**b**) and perpendicular (**c**, **d**) incisions of the fibrous capsule as indicated by dotted-line arrows

light microscopy, the silicone remnants inside these vacuoles displayed the phenomenon of double refraction (data not shown). The effects of PL irrigation on the prosthesis

pockets are depicted in Fig. 4b, d, f, showing the corresponding images of the same patients directly after PL. Pulse lavage irrigation led to disruptions in the internal

Table 1 Comparative analysis of patient demographics, capsular contracture recurrences, infections, and seromas after implant exchange between 2012 and 2017

| | All | Implant exchange after | | | | | |
|---|---------------|-----------------------------|-------------------------------------|-------------------|-----------------|--------------------|----------|
| | | (a) | | | (b) | | |
| | | Primary breast augmentation | Implant-based breast reconstruction | <i>P</i> | Implant rupture | No implant rupture | <i>P</i> |
| Mean age (SD), yr | 42.8 (14.4) | 38.5 (11.6) | 60.7 (10.9) | < 0.001 | 42.0 (14.6) | 44.3 (14.4) | 0.659 |
| Mean BMI (SD), kg/m ² | 22.1 (2.0) | 22.0 (2.1) | 23.2 (0.9) | 0.093 | 22.0 (2.1) | 22.3 (1.8) | 0.622 |
| Implant age (SD), yr | 8.4 (5.7) | 7.6 (5.0) | 11.6 (7.6) | 0.098 | 8.5 (5.2) | 8.0 (6.9) | 0.793 |
| Capsular contracture recurrence (breasts) | 25.5% (12/47) | 21.6% (8/37) | 40.0% (4/10) | 0.237 | 27.6% (8/29) | 22.2% (4/18) | 0.682 |
| Infection (breasts) | 6.4% (3/47) | 5.4% (2/37) | 10.0% (1/10) | 0.598 | 6.9% (2/29) | 5.6% (1/18) | 0.855 |
| Seroma (breasts) | 4.3% (2/47) | 2.7% (1/37) | 10.0% (1/10) | 0.310 | 3.5% (1/29) | 5.6% (1/18) | 0.728 |

SD standard deviation, yr years, BMI body mass index, *P* *p*-value of Chi-square test with significant results in bold

layer of the fibrous capsules, destruction of the architecture in the middle layer, and reduction of the amount of silicone vacuoles within this layer. Additionally, high-pressure irrigation by PL did not lead to further penetration of silicone remnants into the breast tissue. No case of anaplastic large cell lymphoma (ALCL) was found in this study.

Two representative cases of CC Baker grade III/IV with concurrent bilaterally ruptured silicone-filled implants are demonstrated in Fig. 5, showing preoperative conditions and surgical results without CC recurrence at the 12-month follow-up.

The mean time interval between implant exchange and diagnosis of a recurrent CC was 10.7 ± 2.2 months. In cases of implant exchanges after ruptured implants, the recurrences were diagnosed at a mean interval of 10.5 ± 1.9 months, and in cases without implant ruptures at a mean time of 11.0 ± 3.4 months, $p > 0.05$. The risks of CC recurrence after implant exchanges are illustrated in Fig. 6. The Kaplan–Meier analysis showed no statistical difference in contracture recurrence rate between implant exchanges after ruptured or non-ruptured implants, $p > 0.05$.

In our chart review, only patients with implant-based reconstructions were seeking salvage procedures through tertiary breast reconstruction. Additionally, this patient cohort was significantly younger (48.1 ± 9.4 years, $p < 0.05$) than patients receiving implant exchanges after failed implant-based breast reconstruction (60.7 ± 10.9 years). All flaps survived, with one wound dehiscence occurred on the skin island of a latissimus dorsi flap with partial exposure of the implant that was salvaged by a sub-mammary intercostal perforator flap as previously demonstrated [23]. We further observed one partial umbilical necrosis after TRAM flap harvest that healed by

secondary intention, and one case of seroma at the donor site after TUG flap harvest that was remittent after seroma aspiration.

In contrast, autologous fat grafting (with $n = 5$; or without additional implant exchange, $n = 8$) for salvage of ruptured implants and concurrent CC was performed at a mean age of 53.1 ± 11.7 years after both failed primary breast augmentation or failed implant-based breast reconstruction. In cases of fat grafting only, a second lipofilling procedure was performed in 5 of 8 cases (63%), a third procedure in 4 cases (50%), and a fourth procedure in 2 cases (25%).

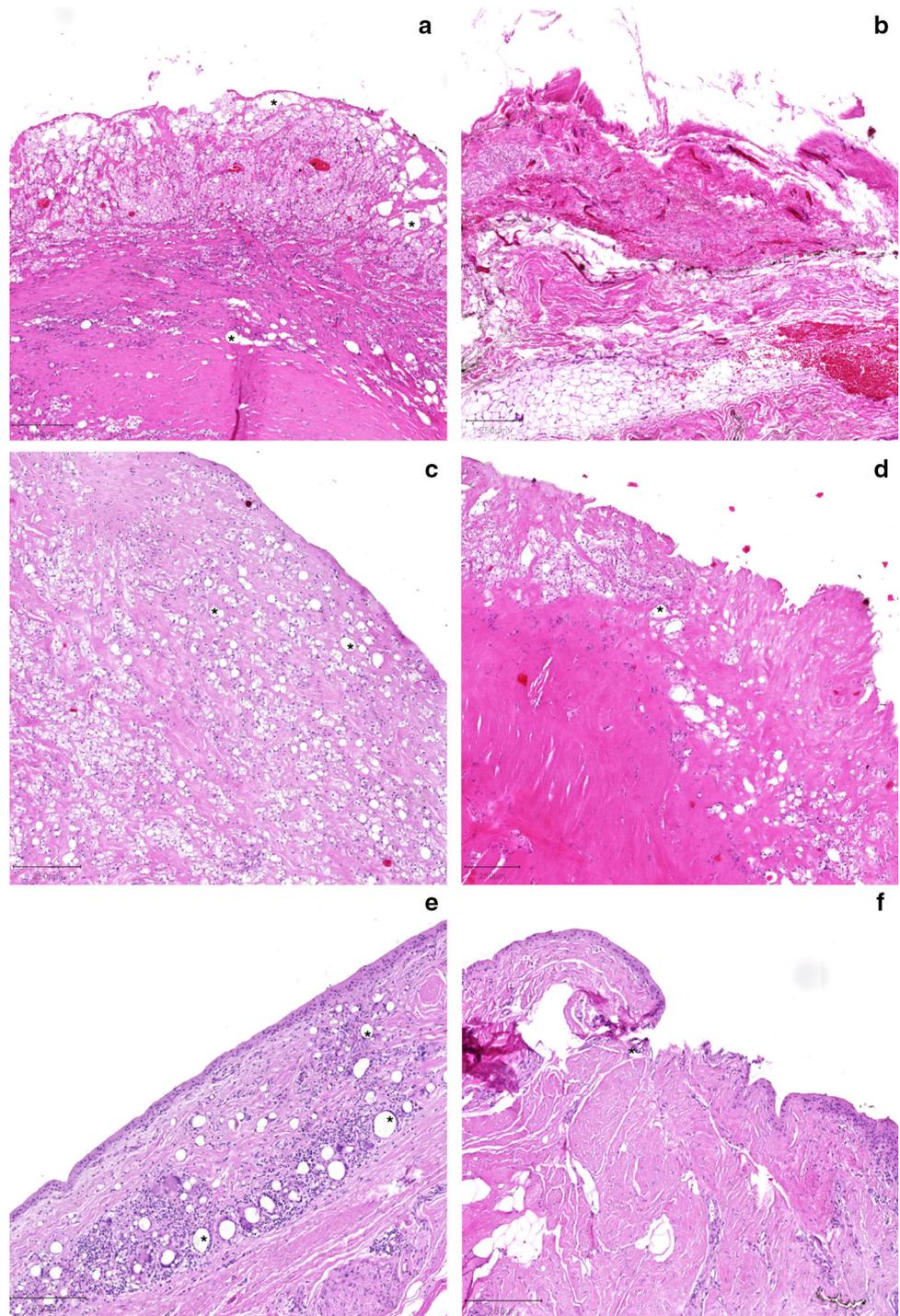
Discussion

Management of Implant Ruptures

According to the literature, this is the first study demonstrating the use of PL irrigation in cases of silicone leakage after primary breast augmentation and implant-based breast reconstruction. Implant ruptures remain a potential complication and a serious concern for patients in aesthetic and reconstructive surgery of the breast. The incidence of rupture is reported to increase with increasing implant age [24, 25], and it is estimated that a minimum of 15% of modern implants rupture between the third and tenth years after implantation [26].

In contrast to the USA, where saline implants have been used since 1992 with continuous popularity, cohesive silicone gel breast implants are preferred in South America and Europe [26]. Whereas ruptures of saline-filled implants become apparent shortly after saline leakage due to absorption of the saline, ruptures of silicone gel implants

Fig. 4 Representative histopathological images of fibrous breast implant capsules before (a, c, e) and after PL irrigation (b, d, f). 25× magnification, bar = 250 μm; *silicone vacuoles in inner and middle layers



can occur unnoticed and often remain undetected as the leaking silicone is encased in the implant pocket [27]. In concordance to previous findings, all cases of the study confirmed typical intracapsular location of ruptured silicone gel-filled implants [28].

Today, five generations of silicone breast implants exist. While the first-generation breast implants were filled with moderately viscous silicone gel, the most recent fifth

generation of implants are filled with highly cohesive gel [15, 27]. Silicone leakage into the implant pocket has shown to cause an inflammatory tissue response that correlates with the severity of the fibrous capsule reaction [14, 29]. Experimental animal studies revealed a dose-dependent relationship between the amount of silicone leakage and the grade of CC that interestingly was independent of the cohesivity of the silicone [15]. The tremendous

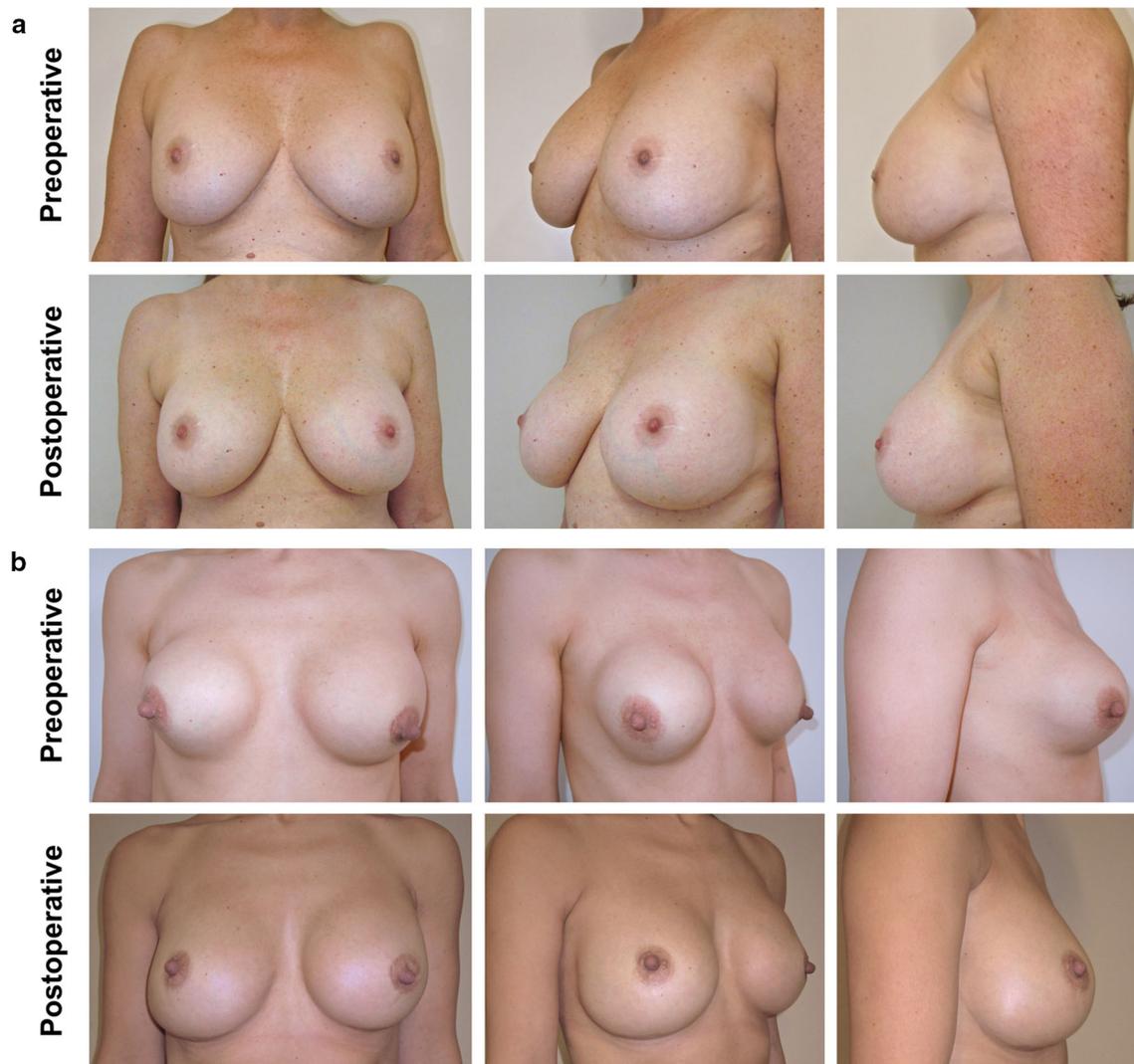


Fig. 5 Preoperative conditions and postoperative 12-month follow-up results after pulse lavage, open capsulotomy, and exchange of bilaterally ruptured implants. Patient **a**: 47-year-old woman with Baker III capsular contracture 12 years after primary breast augmentation using 220-cc round, textured, cohesive silicone gel Polytech implants (Polytech, Dieburg, Germany). Results with 245-cc Motiva Ergonomix round SilkSurface RSD-245 + silicone breast implants with DEMI (moderate) projection (Establishment Labs, Motiva USA,

Miami, FL, USA/ Menke Med GmbH, Feldkirchen, Germany). Patient **b**: 38-year-old woman with Baker IV capsular contracture 11 years after cosmetic augmentation mammoplasty using textured, anatomically shaped silicone gel-filled 245-cc implants (Inamed, Santa Barbara, CA, USA). Results with Natrelle 410 highly cohesive anatomically shaped silicone-filled 420-cc implants with moderate height and full projection (Allergan, Irvine, CA, USA)

impact of leaked silicone has been shown by a recent clinical study reporting a significant higher CC recurrence rate of 69.2% (9 of 13 patients) after open capsulotomy, irrigation with either povidone-iodine or saline solution, and replacement of the ruptured silicone gel implant, while the overall recurrence rate was at 22.7% [11]. In contrast, the presented results of this study base on a larger sample size and in comparison indicate a lower CC recurrence rate of only 27.6% in cases of silicone leakage, if the breast pockets were treated by PL irrigation with normal saline solution prior to open capsulotomy and insertion of the new implant. As control, open capsulotomy and exchange of

intact implants without prior PL showed an insignificant different CC recurrence rate of 22.2%, at an overall CC of 25.5% (12 of 47 patients). In addition, this is the first study evaluating the effect of PL irrigation on breast capsule tissue and providing histological evidence for successful reduction of encapsulated silicone gel remnants after PL irrigation, that potentially leads to interruption of the residual foreign body reaction. The current data reveal that PL irrigation may lower CC rates after ruptured silicone implants, compared to previous reports, by a more efficient mechanical cleansing of the prosthesis pocket.

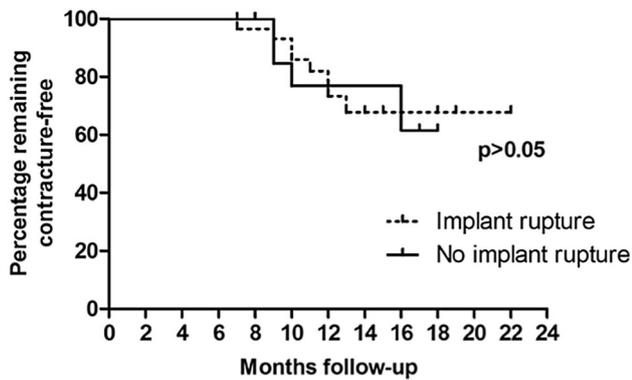


Fig. 6 Kaplan–Meier analysis of capsular contracture over time as a function of implant exchanges after ruptured versus non-ruptured implants

Considerations in Pulse Lavage Irrigation

Prior experimental studies have shown that PL irrigation was more effective and efficient in removing, e.g. bacteria from contaminated wounds, as PL with 3 L of normal saline solution reduced the same amount of bacteria as irrigation with 9 L through a bulb syringe [30]. These findings support the application of PL irrigation for removing of silicone gel remnants because of its efficacy over ordinary irrigation methods. Another study examined the microscopic effect of pulsatile irrigation in case of open fractures and revealed that PL can cause microscopic structural damage to bone architecture [1]. Accordingly, the presented histopathological analyses of fibrous breast capsules after PL in cases of silicone leakage demonstrate structural damage of the tissue architecture as well. More importantly, this study shows that high-pressure pulsatile irrigation of prosthesis pockets with silicone leakage leads to beneficial destructions in the inner layer of the fibrous breast implant capsules and to subsequent reduction of encapsulated silicone remnants in the middle layer, without further penetration of the silicone into profounder layers of the breast tissue.

Nevertheless, harm to bone tissue by PL irrigation in orthopedic surgery is still currently discussed [5]. An early publication investigated high-pressure PL irrigation at 70 psi in a porcine wound model and found superior bacterial removal, while the susceptibility to wound infection increased due to host tissue damage [31]. Yet, this early investigation applied relatively high irrigation pressures. Studies examining the same pressure level indicated delayed fracture healing, and PL over 50 psi still demonstrated inhibition of trabecular fracture healing [32]. The classification of pressure levels in previous studies shows a great variability, whereas more recent studies classified 35 to 70 psi as high pressure and the range of 1 to 30 psi as medium pressure [16]. The recent Fluid Lavage of Open

Wounds (FLOW) trial even distinguished three irrigation pressures: high pressure above 20 psi, low pressure between 5 and 10 psi, and very low pressure of 1 to 2 psi [5]. In addition, several PL devices with different pressure ranges exist. The current study used the Stryker InterPulse lavage system that currently is the most utilized PL device. In consideration with the literature, PL irrigation using a maximum pressure of 19 psi more precisely should be classified as intermediate pressure than high pressure, as discussed previously [16]. The evaluation of postoperative complications of this study revealed that PL irrigation at this intermediate pressure prior to implant exchange did not lead to higher infection, seroma, or CC recurrence rates, which justifies its application in breast implant salvage surgeries.

Postoperative and Subclinical Infections

According to a worldwide study including 10,941 patients, postoperative infections were found in 2.5% of all primary augmentation mammoplasties [33]. The incidence for postoperative infections varies from 0% in some case series up to 53% in cases of immediate breast reconstruction after mastectomy [9]. While overall infection rates and successful salvages after periprosthetic infections are often recorded, postoperative infection rates after surgical revision of CC are scanty [6, 34]. The overall postoperative infection rate in the current study after implant exchange in cases of CC was 6.4%. The presented data reveal that implant exchanges after primary breast augmentation or exchanges of intact implants, display slightly lower infection rates at 5.4% and 5.6%, while implant exchanges after implant-based breast reconstruction or exchanges of ruptured silicone implants demonstrate higher, but insignificant different infection rates (10.0% and 6.9%).

Seroma rates after open capsulotomies have been previously reported at 1.3% among patients with CC following primary cosmetic breast augmentation [11]. Another study investigating recurrent seroma after irradiated breasts leading to implant removals indicated a higher rate of 3.4% [35]. The present study found a total seroma rate of 4.3%. With the same tendency as in the literature, implant exchanges after primary breast augmentation display relatively lower seromas (2.7%) as after implant-based breast reconstruction (10.0%, $p > 0.05$ due to small sample size). However, all patients with complications of postoperative infection or seroma developed a CC recurrence. Consistent with previous findings, seromas or infections are suggested to increase the inflammatory tissue response, and the presence of bacteria, especially *Staphylococcus epidermidis*, has shown to be significantly associated with unsuccessful implant salvages and CC recurrences [6, 36]. With regard to microbial biofilm formation, previous

systemic review and meta-analysis indicated povidone-iodine irrigation for decreasing CC, while another recent meta-analysis concluded that antimicrobial irrigation of implant pockets failed to reduce the propensity for developing CC [37, 38]. Besides the capability of PL irrigation to remove bacterial colonization, PL has also shown to reduce biofilms, even though this may be hindered by implant surfaces, e.g. orthopedic arthroplasty components, where the reduction was less effective or complicated by metal implant material [39]. PL in breast implant surgery has the advantage that the implant can easily be explanted, whether intact or ruptured, allowing pressure irrigation throughout of the prosthesis pocket in a 360° fashion, see Fig. 2. Whether PL irrigation of the breast implant pocket contributes to a biofilm reduction has not been investigated in this study. Despite the intensively discussed difficulties of identifying biofilms in CC [40], further research on the effect of PL and biofilm-related capsular is needed.

Diagnosis of Implant Rupture

The presented data support the remaining discrepancy between suspected silicone implant rupture and surgical findings. Despite preoperative MRI and US, about one-fourth of explanted implants were found intact (24%). In comparison, a previous analysis revealed over one-third of preoperatively suspected ruptured implants as intact (36%), and only 18% of false positive intact implants in cases of prior positive MRI for implant rupture [41]. As consumption, MRI confirmation of suspected implant ruptures should be considered as more sensitive and favored over US only.

Implant Exchange Versus Tertiary Breast Reconstruction

The majority of studies investigating implant salvages are either focusing on primary cosmetic breast augmentations or implant-based breast reconstructions separately [6, 11, 28, 36, 42]. This study proposes a treatment algorithm after CC and concurrent implant rupture for both patient cohorts and found that the chosen salvage procedure varies depending on the age and the initial purpose of implantation. In contrast, groups with and without implant ruptures were well balanced in terms of age, BMI, and implant age.

The data reveal that the patient cohort requiring implant exchanges after primary breast augmentation was significantly younger than patients after implant-based breast reconstruction, which can be explained by the in average younger patient age at implantation for aesthetic augmentation mammoplasties [41]. Implant-reconstructed patients with radiation had an overall higher CC recurrence rate

than patients after primary cosmetic mammoplasties (40.0% vs. 21.6%) that, however, did not reach statistical significance due to small sample size (4/10 vs. 8/37). Nevertheless, this observation is in line with previous findings showing significant higher CC grade III/IV rates in patients after implant reconstruction and postmastectomy radiotherapy [35].

In addition, this study indicates a conversion from implant-based reconstructions to autologous tissue at an earlier patient age. This finding supports previous reports indicating failed implant-based reconstructions were more likely to convert to autologous reconstructions at an earlier stage [43]. In contrast, the mean age of patients desiring fat grafting was in average above that of patients receiving implant exchanges (without statistical significance). Although previous data indicated that age does not necessarily affect microsurgical flap surgery outcomes [44], the current study reveals that the patient desire for fat grafting increases while that for flap reconstruction of the breast declines with rising patient age. The longer operative time for a flap-based tertiary breast reconstruction can also explain why older female patients in this study after implant failure favored implant exchanges or fat grafting over flap surgeries [45].

As previously published, improvements of post-radiation breast skin after fat grafting were also observed [18]. In this study, additional lipofilling was performed in 5 of 29 implant exchanges after implant ruptures and concurrent CC, leading to supplementary correction of breast volume and tissue softness. Unfortunately, this treatment group was too small to allow further analysis. However, evidence on the treatment of CC with autologous fat grafting has been published and discussed showing softer implant capsules after additional lipofilling, potentially through promotion of angiogenesis in the periprosthetic tissue [36, 46].

Open Capsulotomy Versus Capsulectomy and Site Change

Previous analyses of ruptured implants after augmentation mammoplasties suggest full capsulectomies in cases of ruptured liquid gel or soft cohesive gel implants, and capsulotomies only in cases of ruptured high cohesive gel implants [28]. Nonetheless, the clinical evidence behind the surgical management of CC remains limited, without conclusive data indicating the superiority of capsulectomy over open capsulotomy [10]. Open capsulotomy is discussed to restrain the wound area, which in the following limits inflammation and fibroblast activity, as the existing capsule remain [11]. The presented data support open capsulotomies combined with prior PL irrigation as treatment method for silicone leakage, if no capsulectomy is needed, e.g. in cases of thick and calcified capsules, or

suspected carcinomas. In addition, the microscopic effects of high-pressure lavage on fibrous breast capsules could be demonstrated and showed a significant reduction in encapsulated silicone vacuoles. With regard to the equal CC recurrence rates found for implant exchanges after non-ruptured implants versus ruptured implants with additional PL, this study encourages open capsulotomies for the management of CC also in case of silicone leakage. However, we agree that partial or total capsulectomies, which in contrast can be more surgically challenging, invasive, and time consuming [11], should be considered in cases of strong calcification, thick, or granulomatous capsules [10, 47, 48]. Further indications for performing a capsulectomy have been widely discussed previously [12, 49].

Consistent with existing data, we observed that site changes with conversion to subpectoral implant pockets may contribute to a lower risk of CC [10]. Yet in this study, site changes were only performed after primary augmentation and ruptured implants. Larger patient samples are needed to allow further evaluation of the beneficial role of site changes after implant ruptures and silicone leakage.

Limitations of the Study

The study presents a consecutive case series with observational comparison of the clinical outcome after open capsulotomies and implant exchanges of ruptured versus non-ruptured implants in a retrospective study design. Although non-ruptured implants display the control group, the study does not provide a direct control group for PL irrigation in cases of ruptured implants and silicone leakage. In correspondence with the Cosmetic Level of Evidence And Recommendation (CLEAR), the study can be categorized to a Level 4 and a Recommendation C [50]. With regard to the evidence-based medicine approach in plastic surgery, trials comparing the clinical outcome of PL irrigation of prosthesis pockets after silicone leakage versus another irrigation method as control on a larger scale would be a plausible next step. According to a one institutional study, plastic surgeons and patients have strong preferences in surgical decision-making, which may limit the possibility for randomization for practical and also ethical reasons. However, the FLOW trial as a blinded, randomized, and controlled study, investigated the efficacy of PL irrigation with different pressures for the management of open fractures, and demonstrate the feasibility and necessity of such a study design for investigation on that specific irrigation method that overall remains simple and inexpensive [5]. Conversely, the present study did not seek for a comparison of the irrigation pressure, but moreover explored the outcome of PL irrigation at a commonly used intermediate lavage pressure for treatment of silicone

leakage, which has not been investigated beforehand. While the presented data reveal that PL irrigation enables the cleansing of silicone remnants from breast tissue, more studies are needed to elucidate its effect on a potential biofilm reduction in breast implant surgery.

Conclusion

Pulse lavage irrigation of prosthesis pockets prior to open capsulotomy is a safe and effective treatment of CC with concurrent silicone gel implant ruptures. Compared to the existing data, implant exchanges after silicone leakage did not lead to a higher risk of CC recurrence, if PL was performed. Remaining silicone remnants in the inner and middle layers of fibrous implant capsules may affect the development of a recurrent CC. To avoid CC recurrences, patients should consider autologous tissue reconstructions. Younger female patients with failed implant-based reconstructions prefer tertiary breast reconstructions, while fat grafting or implant exchanges are carried out at all ages independently of the purpose of implantation.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval For this type of study, formal consent is not required. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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