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REVIEW BREAST SURGERY

Controllable Factors to Reduce the Rate of Complications in Primary Breast Augmentation: A Review of the Literature

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Abstract
Background Aesthetic augmentation mammoplasties are one of the most demanded procedures performed in the aesthetic surgical sector. Because of the high epidemiological impact, the evaluation of measures to reduce the risk of complications is highly needed. The goal of this review is to evaluate the current literature for successful actions to reduce the risk of complications in aesthetic breast augmentation.
Methods We searched Medline-listed journals for "complications primary breast augmentation" and defined surgeon-dependent and patient-dependent factors within those.
Results Most of the strategies to reduce the risk of any complication are based on meticulous hygienic precautions and adequate training of the surgeon. The current literature suggests complications such as capsular contracture, infection and BIA-ALCL are closely linked with bacterial contamination and therefore can be avoided with different hygienic measures.
Level of Evidence III 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 Augmentation · Complications · Breast · Implant · ALCL

Background

Augmentation mammoplasty is one of the most demanded and performed aesthetic surgical procedures. In 2017, over 300,000 primary breast augmentations were performed in the USA with an increase of 41% since the year 2000 [1]. In spite of a low relative number of complications, their absolute number due to the high caseload represents an important issue that every plastic surgeon has to face on a regular basis.

One of the major and most frequent complications is capsular contracture. According to the literature, it occurs in 2.54–14% of patients undergoing aesthetic breast augmentation, depending on multiple factors [2–4]. Almost half of capsular contractures occur within the first 2 years of implantation and 80% within the first 5 years [4]. With a complication-related reoperation rate of up to 15% within the first year, strategies to prevent complications in primary breast augmentation are of utmost importance [5]. Moreover, the recent inception of associated anaplastic large cell lymphoma (BIA-ALCL) has added a lot to the ongoing discussion about safety of this procedure [6–9].

The aim of this study was to look for scientific evidence that might link complications to patient- and surgeon-related factors, in an attempt to reduce their risk after primary breast augmentation.

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Methods

We searched Medline-listed journals for "complications primary breast augmentation" released until May 6, 2019, and sorted different aspects discussed in the 179 articles found. We separated these points into patient-dependent factors and surgeon-dependent factors. From those 179 articles, only 74 articles met the criteria of not being case reports, letters, editorial comments or opinions. Patient numbers and percentages were included accordingly.

Patient-Dependent Factors

BMI

The odds ratio to experience minor and major complications in body contouring surgery is reported to be between 5.54 and 19.8 in obese patients [10]. Similarly, several studies are available suggesting a higher incidence of complications after primary breast augmentation in patients with an increased BMI [11]. Of note, a recent study with 2565 patients comparing BMI above/under 21 has found no difference in the incidence of capsular contracture after primary breast augmentation [4]. Other studies do not report any impact of the BMI on the rate of complications [12]. A recent study showed a trend that did not reach statistical significance between BMI and risk of rotation of anatomical implants [13].

Age

One study analyzing the correlation between capsular contracture and risk factors showed that age seems to play no crucial role in the incidence of complications in primary breast augmentation [4]. However, it has been shown that advanced age may correlate with delayed wound healing in general [14]. The tight cellular orchestration of wound healing is impaired in aged skin in all four phases of wound healing (hemostasis, inflammation, proliferation and remodeling) which may lead to a higher risk of infection, delayed wound healing, necrosis and bad scarring [15].

Preoperative Breast Volume

Besides studies have shown that breasts with more existing tissue have a higher risk of developing breast cancer [16], there is evidence that larger breast size also correlates with a higher rate of implant rotation in breast augmentation reported in a cohort of 531 patients [17]. This has to be included into the consent discussion as implant-based augmentation can alter the validity of a breast cancer screening [18, 19].

Smoking

A study conducted on 906 patients (of whom 103 were smokers) who underwent aesthetic breast augmentation showed a significantly higher incidence of seroma when the patient was a smoker [20]. Interestingly, patients with history of smoking were also found to more likely request an implant size change in the absence of any complication [20]. In breast reduction surgery, history of smoking increases the risk of complication by 100% [21]. No other correlation was found in combination with aesthetic breast augmentation. In an analysis of 129,007 patients with cosmetic surgeries, smokers showed an increased risk of surgical site infections (0.6% vs 0.5%). Body procedures lead to an increase in complications from 1.0 to 2.9% in smokers. Taken together, this study found a relative risk of surgical site infections of 1.61 for smokers compared to non-smokers [22]. Smoking implicates a transient effect on tissue microenvironment, leading to delayed healing and complications. Smoking cessation restores the tissue microenvironment rapidly and the inflammatory cellular functions within 4 weeks, while the proliferative response remains impaired [23]. In the USA, patients are requested to stop smoking prior to elective plastic surgery procedures. A mortality and societal cost analysis showed that between May 2008 and May 2013, 7867 patients quit smoking prior to their aesthetic surgical procedure. Though the recidivism is around 68%, smoke cessation before elective aesthetic surgery is associated with a lifetime saving on societal costs of over $524 million and it is estimated to save 429 lives over a 5-year period [24].

Medications

At least 50 percent of patients undergoing surgery (seen in a cohort of 1025 patients) take medications on a regular basis [25]. However, while this study only represents general surgery patients, another study showed that only 11% of the patients demanding a primary breast augmentation are taking medications (excluding oral contraceptives) on a regular basis [20]. Of all patients undergoing primary breast augmentation, 25% of the patients are taking oral contraceptives [20]. But there was no association shown between a higher incidence of complications and the intake of regular medications or oral contraceptives [20].

Surgeon-Dependent Factors

Incision

The location of the incision that provides access to the mammary pocket has been postulated as potential risk factor for capsular contracture. According to a retrospective study on 183 patients by Jacobson et al., transaxillary incisions significantly result in the highest number of capsular contracture cases (6.4%) followed by periareolar (2.4%) and inframammary (0.5%) approaches [26]. Similar results were obtained by Wiener et al. [27] suggesting the lowest capsular contracture rates in inframammary incisions (total of 420 patients). However, another study performed by Stutman et al. [28] on 619 patients showed no difference in complications between all three incision sites. A recent meta-analysis conducted by Li et al. [29] including the three mentioned studies (Wiener et al., Jacobsen et al. and Stutman et al.) reported the periareolar incision to be associated with higher capsular contracture rates compared to the inframammary incision.

Additionally, in one review including 4412 patients periareolar (n = 981) and transaxillary incisions (n = 132) have higher rates of malpositioning of the implant and a higher incidence of corrective procedures compared to an inframammary incision (n = 7526) [30].

Capsular contracture's rate is significantly reduced when the implant is placed subpectoral compared to subglandular reporting OR between 3 and 7.8 (studies with over 4000 patients cumulative) [30–32]. A small study with subfascial placement (25 patients) showed similar risks compared to the other pocket locations but has a higher patient satisfaction [33]. The complication of implant rotation is reduced (0/410) by subfascial placement in another study including 410 implants [33].

Implant Texture

A review including 4412 patients has shown that the risk of capsular contracture (OR 0.16–0.42), secondary procedures (OR 0.48) and malpositioning (OR 0.29) is reduced with textured surface devices [30]. One meta-analysis showed a difference in the occurrence of capsular contracture between 3.80% in imprinted textured implants and 15.56% in smooth implants [31]. Macrotextured implants have been shown to reduce the risk of capsular contracture by factor 3–4. Also the rate of rippling (fivefold) and malrotation is reduced in macrotextured implants compared to implants with microtexturation [32]. Furthermore, the use of macrotextured implants may improve patient's satisfaction significantly [32]. However, another study showed in a series of 310 patients with macrotextured implants a seroma rate of 0.3% and double capsulas in 1.3% which is comparable to the rates of non-macrotextured implants [34].

As of July 2019, the FDA received a total of 573 medical devices reports of breast implants (BIA-ALCL). Thirty-three patients died of BIA-ALCL and its consequences. The median age at time of diagnosis was 52 years with the earliest diagnosis with 37 years. The median time between the last implant to diagnosis of BIA-ALCL was 9–11 years with a range from 0 to 34 years [35, 36]. Similar data are available from Australia with a mean age of diagnosis with 47 years and median implant exposure of 7.5 years. One study including 55 BIA-ALCL patients from Australia and New Zealand concluded a significant increase in BIA-ALCL occurring in higher-surface-area textured implants (14.11 times higher with Biocell textured implants and 10.84 higher with polyurethane-textured implants compared with Siltex textured implants) [37]. The incidence varies on geographical and ethnical distribution. The lowest rates of incidence are found in the Eurozone, China and Brazil, while the highest incidence is found in New Zealand and Australia [38]. BIA-ALCL is found to be relatively rare in people of Asian, African and Native American descent [38].

While most patients demonstrate seroma (58–86%), breast swelling (30%) or capsular contracture (15%), the anaplastic lymphoma kinase status is negative (all tested specimens) while the CD30 status is positive (all tested specimens) [35, 36].

One disadvantage and topic of ongoing discussion is the association between macrotextured implants and the occurrence of BIA-ALCL. In a study, macrotextured implants were found in 23 of 28 patients with BIA-ALCL for whom the type of breast implant was known. Relative risk of BIA-ALCL in women with breast implants was 421.8 and absolute cumulative risk was 29 per million at age 50 years and 82 per million at age 70 years. [9]. Another study reports the estimated relative risk with 1 in between 3817 and 30,000 women with textured breast implants [8, 9]. A recent review shows a higher incidence of 1 in 2832 due to increasing awareness on this topic and higher numbers of patients consulting their doctor with symptoms [38]. Importantly, FDA demonstrated 26 cases of BIA-ALCL with smooth implants compared to 385 with textured implants—showing a strong trend but no exclusivity for BIA-ALCL to textured implants. In the 26 cases of smooth implants, 12 have unknown prior history of implants, 7 have a history of textured implants and 7 have a history of prior implants with an unknown texture [35]. More recent studies include a new approach to classify the surface of the implants into four surface types: polyurethane, Biocell/gas diffusion, salt loss/imprinting and smooth. The highest incidence for BIA-ALCL is given

implant based in Biocell (1/3817), followed by polyurethane (1/7788) and Siltex implants (1/60,631) similar findings to the mentioned study with patients from Australia and New Zealand [37, 39]. The relative risk of BIA-ALCL compared to Siltex implants regarding the surface grade is 16.5 in surface grade 3 and 23.4 in surface grade 4 [38]. The relative risk to develop BIA-ALCL is 67.6 times compared to primary ALCL [38]. Another study reports a relative risk of BIA-ALCL according to ISO 14607 category of "microtexture" breast implants of 0.0012% including 656 patients with BIA-ALCL worldwide [40].

There is also a broad scientific discussion on the association between the biofilm and the occurrence of BIA-ALCL. Several studies confirm a higher rate of biofilm formation in textured implants [39]. A bacterial load on contaminated implants directly correlates with the activation of CD4 + T cells, the origin of BIA-ALCL. One study showed that non-tumor capsule specimens as well as BIA-ALCL yield a high number of bacteria. Interestingly, the microbiome diverges greatly between both samples: While breast implant associated BIA-ALCL specimen showed a greater proportion of *Ralstonia* spp., non-tumor capsule specimens have a higher number of *Staphylococcus* spp. [41]. The association of a certain microbiome on breast implants underlines the importance of utterly hygienic conditions preoperatively in implant-based aesthetic surgery. A study including 21,650 patients with a meticulous antibacterial handling showed no cases of BIA-ALCL [6].

Another upcoming technology not only to reduce the bacterial contamination of the implants but also to facilitate tissue integration is the use of nanotechnology surfaces. The aim of this technology is to move from a "foreign body reaction" to a guided interaction [42].

Implant Shape

There is still little consensus for choosing the shape of an implant. The rate of bottoming out is significantly higher in round implants (implant number 1200) [13]. Overall, round implants do have a higher cumulative risk in developing capsular contracture (3.4% vs. 11.3%) as well as implant rupture in primary augmentation and have a higher infection risk in primary reconstruction (1.6% vs. 6.2%) compared to shaped implants [13, 43, 44]. There are still an ongoing debate and no consensus on which implant shape is favorable in primary breast augmentation [44]. In any given situation, the choice should be determined by the patient's physical characteristics, available implant types and the surgeon's experience while taking into account patient's wishes and expectations [13].

There is little evidence that larger implants (> 355 ml vs. < 355 ml) lead to a lower rate of capsular contracture in a study with 2565 patients (OR 1.4) [4].

Operational Procedure

Usage of prophylactic antibiotics (750 mg cefuroxime) during anesthetic induction showed no superiority in terms of capsular contracture or infection [45, 46]. However, intravenous antibiotic prophylaxis at the induction of anesthesia is recommended in the 14-point plan to reduce device-associated infection [6].

In a study, specifically for breast augmentation the use of propyl alcohol for preparation of the operational field with 4% chlorhexidine and 4% chlorhexidine alone has higher rates of infection (OR 2.099 and 1.156, respectively) compared to povidone–iodine as prep solution. There was a decreased rate of infection for 2% chlorhexidine gluconate in 70% isopropyl alcohol alone compared to povidone–iodine (OR 0.554). None of these reached statistical significance [11]. Larger trials, although not specific for breast augmentation, showed how chlorhexidine–alcohol is superior to povidone–iodine when prepping the patient, in terms of reduction of surgical site infections [47, 48]. Currently, there seems to be no clear statement on the preference of a specific surgical site preparation solution.

There is an ongoing scientific discussion about the irrigation of the pocket with antibiotic solutions. Some studies favor the use of antibiotic pocket irrigation before inserting the implant and report lower rates of infections [49, 50]. Another meta-analysis favors the combination of antibiotics and povidone–iodine [51]. However, one other study showed pocket irrigation with antibiotics (OR 1.6) leads to a significantly higher rate of capsular contracture [4]. Taken together, there is not a unanimous consensus on whether irrigation of the pocket with antibiotics is beneficial. Nonetheless, a majority of the studies show a benefit by means of irrigation [6, 52, 53].

In a meta-analysis, Yalanis et al. reported that povidone–iodine irrigation of the pocket before insertion decreases Baker III/IV class capsular contracture significantly with an odds ratio of 0.30. Another study suggested antibiotic irrigation reduces capsular contracture tenfold [2]. The clinical benefit of a proposed triple antibiotic breast irrigation to reduce the risk of capsular contracture is still topic of ongoing scientific discussion [54, 55].

Biofilm formation and its subsequent pocket contamination are one of the causes of capsular contracture [56]. One strategy to overcome this issue is the reduction in bacterial contamination through decreasing the contact between the implant and the patients skin as well as the surgeons gloves [56]. In 2009, the Keller Funnel (Keller Medical Inc., Stuart, FL)—an insertion funnel constructed of polymeric vinyl—was introduced. It allows a reduction in skin contact and thus potential contamination by 27-fold in a cadaveric model [57]. A recent study was able to show a significant reduction in the incidence of reoperations due

to capsular contracture within 12 months of primary breast augmentation when the Funnel device was used (1177 patients without Funnel versus 1620 patients with Funnel) [58]. A major advantage of the Keller Funnel is the reduction in the scar length and a reduced time of implant insertion which, in turn, might potentially reduce contamination of the device (50 patients with Keller Funnel and 50 without) [59].

It was found that the usage of drains increases the risk of infection by 2.4-fold [11]. Interestingly, drains did not prevent seroma formation in the groups where drains were used (56 patients versus 56 patients) [60]. Taken together, the usage of drains in aesthetic breast augmentation is not favorable.

The use of nipple shields has shown to reduce a potential risk of implant contamination and therefore may play a role in development of capsular contracture. Based on the cultures from nipples and nipple shields in a study from Wixtrom et al. of 63 consecutive breast augmentation patients, the baseline risk of implant contamination from nipple bacteria was found to be 34.9% [61]. Collis et al. [62] showed in 25 patients a significant reduction in bacterial contamination at the operation site by nipple shields. The usage of nipple shields to avoid contamination from the mammilla advised.

Change or cleaning of all surgical instruments, drapes and gloves before opening the implant reduces bacterial contamination [63].

A prolonged duration of the surgery may also increase the rate of infections [11]. Therefore, an efficient planning of the surgery by an experienced surgeon is advised to minimize operation time.

Postoperative Care

The occurrence of hematoma or seroma increases the risk of capsular contracture by 3.9 [4]. Some surgeons recommend massaging of the breast in the healing phase. This may, however, lead to a higher rate of capsular contracture (OR 2.0) [4]. One study recently showed the usage of a surgical bra may increase the risk of capsular contracture by factor 2.5. However, this is still topic of ongoing scientific discussion [4, 64].

A study with over 1600 patients showed no indication for postoperative antibiotics in terms of reduction in superficial or periprosthetic infections [46].

There are no scientifically validated data on when patients can resume exercises and sportive activities after the operation.

Discussion

In aesthetic medicine, primary augmentation mammoplasty is the most performed procedure. With the high number of cases, strategies to reduce the risk of complications must be optimized. We were able to summarize risk factors and ways to potentially overcome some of them.

A meticulous aseptic working environment has a tremendous effect on the reduction in complications such as capsular contracture. The literature presents a highly significant correlation between implant contamination and capsular contracture but also with the occurrence of BIA-ALCL. BIA-ALCL seems to have a strong correlation with certain bacterial strains [41]. Moreover, elaborated protocols such as the 14-point plan and standards for aseptic and antiseptic work are shown to reduce the incidence of capsular contracture and might decrease the risk of developing BIA-ALCL [2, 6]. Nonetheless, there is only little solid knowledge about ways to reduce BIA-ALCL. There are many indications for a potential reduction in the risk of developing BIA-ALCL by meticulous aseptic work, but most studies only present epidemiological correlations but no causal context.

The effect of the interaction between the implant and tissue is also manifested in the increased risk of capsular contracture, secondary procedures and malpositioning in devices without textured surface. Additionally, cases of BIA-ALCL were almost exclusively linked to macrotextured surfaces. The current literature does not provide a guideline about the implant choice. In the end, the choice of the implant has to be a combined patient and surgeon decision on the basis of clinical experience, patients wish, medical circumstances and aesthetic goal of the procedure.

To reduce the risk of bacterial contamination, some strategies are shown to be advantageous: certain combinations of prep solutions, usage of nipple shields, change of instruments and gloves before opening the implant, irrigation of the pocket, soaking the implant in antibiotic solution before insertion and using an insertion sleeve. The 14-point plan gives a rough guideline to implement all of those precautions [6]. Still, the scientific basis of each point is not solid. For example, there is no evidence that nipple shields reduce the implant contamination—it only reduces the surgical site contamination. Secondly, a variety of prep solution for primary breast augmentation is used, but none of them demonstrated clinical superiority. Taken together, this 14-point plan gives a scaffold for the general microbial safety of the procedure but scientific work is required to elaborate this plan in more details, e.g., to provide the ideal prep solution and irrigation of the implant, to evaluate whether nipple shields are beneficial and not only theoretical.

The incision site should be determined for every single case—however, studies show a high evidence for the inframammary incision to have the lowest rates of complications in terms of infection, malpositioning and development of capsular contracture. The transaxillary and periareolar approach provide a higher rate of infections probably due to a more contaminated area around the incision. Subsequently, this could lead to a higher rate of capsular contracture. However, this assumption is based on epidemiological findings again and does not provide a solid causal context. The clear approach through the inframammary fold also allows a better positioning of the implant into the pocket, which is more difficult via the transaxillary and periareolar incision.

The rate of bottoming out is significantly higher in round implants. However, the indication for the implant shape is based on the patient specific physique and has to be decided on a case-by-case basis.

While age and intake of medications do not seem to play a crucial role in the patient-dependent circumstances in primary breast augmentation, active smoking increases the rate of seromas and the request for a larger implant in the absence of any medical complications. The BMI is correlating in some studies with a higher frequency of certain complications. Therefore, patients demanding a primary breast augmentation should be advised to reduce their weight if the BMI is extranormal high and quit smoking to reduce the risk of complications.

A study by Calobrace et al. showed the following circumstances (with decreasing importance) around an aesthetic breast augmentation as risk factors for capsular contracture: subglandular placement (OR 4.6), smooth surface (OR 4.5), hematoma/seroma before capsular contracture (OR 3.7), surgical bra used (2.5), periareolar incision site (OR 2.2), antibiotic pocket irrigation (OR 1.6) and the device size < 355 cc (OR 1.4).

Conclusion

Taken together, we have summarized patient- and surgeon-dependent risk factors in primary breast augmentation, which are associated with a higher rate of complications. Most of the strategies to reduce the risk of any complication are based on meticulous hygienic precautions. Nonetheless, a solid scientific basis must be created to further support these precautions. Furthermore, history of smoking and a high BMI do bear the risk of complications and therefore should be included in every medical consultation. Smoking cessation and normalizing the BMI should be advised before primary breast augmentation.

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Compliance with Ethical Standards

Conflict of interest Dr. Montemurro is a consultant and speaker for Allergan, Inc. (Irvine, CA). Dr. Hedén is a consultant and speaker for Allergan, Inc., Establishment Labs Co, G&G Medical, GC Aesthetics, Johnsson & Johnsson (Irvine, Calif.) and an unpaid consultant for Canfield Scientific (Fairfield, N.J.). The other authors declared no potential conflicts of interest with respect to the research, authorship and publication of this article.

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent For this type of study, informed consent is not required.

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