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Breast Cancer Local Recurrence Risk in Implant-Based Breast Reconstruction with Macrotexturized and Microtexturized Prosthesis: A Multicentric Retrospective Cohort Study

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Abstract

Background Nowadays, implant-based breast reconstruction is a common technique after mastectomy. The widespread use of implant employment is prompting significant concerns regarding the oncological safety of prostheses and the potential impact of surface texture on the recurrence of local breast cancer. This article examines the oncological outcomes associated with postmastectomy breast reconstructions using micro- and macrotexturized implants, focusing on the incidence and relative risk (RR).

Methods A retrospective cohort study was conducted on patients admitted to Multimedica group (IRCCS, San Giovanni Hospital, Milan) and ICH groups (Humanitas Clinical Institute, Milan) between January 2003 and September 2020. Minimum follow-up considered was of 1 year.

Patients submitted to either complete or nipple-spearing mastectomy, who underwent breast reconstruction with macrotexturized or microtexturized prosthesis, were included in group A and B, respectively.

Results A total of 646 patients met the basic inclusion and exclusion criteria. Group A included 410 (63.5%) patients and group B included 236 (36.5%). Cancer recurrence absolute risk in group A was $5.6 \pm 2.2\%$ and in group B was of $2.1 \pm 1.8\%$. RR for breast cancer recurrence in group A compared to group B was of 2.65; confidence interval 95% (1.02; 6.87). Statistical analysis identified a higher local recurrence risk in patients reconstructed with macrotexturized prosthesis (p-value 0.036).

Keywords
- breast reconstruction
- macrotexturized implants
- microtexturized implants
- breast cancer recurrence

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Conclusion This study detected a higher risk for local breast cancer recurrence associated to macrotexturized breast implants employment. Further investigations are required to verify these outcomes.

Introduction

Breast cancer is the most common noncutaneous malignancy in female counting over 2.3 million new cases in 2020 worldwide.[1] Recently, a rise in breast cancer incidence has been detected with an associated decrease in mortality rate.[2,3] Mass screening, improved women awareness, and early treatment protocols have contributed to this trend.[4] Currently, advancements in demolitive techniques have made it possible to carry out breast surgery with predictable results and minimized damage to the surrounding tissue.[5,6] As a result, the number of women eligible and willing to be submitted to breast reconstruction (BR) is constantly increasing.[7] The increased number of patients seeking breast surgery and their higher expectations have diminished the tolerance for aesthetic compromises, highlighting the significance of breast restoration in surgical planning.[8]

Over the years, an extensive array of BR techniques have been described.[9] Currently, implant-based BR is the prevailing method adopted by plastic surgeons.[10] Implant-based BR can be achieved with prosthesis placement in the submuscular or prepectoral plane and scheduled as an one- or two-stage procedure according to patient's characteristics.[11] The two-stage implant-based approach, in which an initial surgery is required for expander placement, is actually the most commonly performed.[10] Expander employments provide optimal outcomes, although contralateral mastoplasty is often needed to improve symmetry.[12]

Breast prosthesis may be categorized into smooth and texturized implants according to prosthesis surface; the latter subdivided into microtexturized and macrotexturized.

The predominant breast implants-related complications are capsular contracture, seroma formation, and implant malposition which can occur in all type of implant-based reconstruction.[13] Given that implant texture is identified as an independent risk factor for oncological outcomes such as breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), it might also have implications for breast cancer recurrence (CR).[14,15]

In order to enhance our knowledge in this domain, we carried out a multicentric retrospective comparative study. The aim was to analyze and report the risk of local CR in patients who underwent BR using macrotexturized and microtexturized implants.

Materials and Methods

Medical records of patients which have been submitted to mastectomy between January 2003 and September 2020 were retrospectively analyzed.

Patients were admitted to Multimedica group (Institute of Recovery and Care, San Giovanni Hospital, Milan) and ICH groups (Humanitas Clinical Institute, Milan). All patients included in this study were 18 years old or older women with diagnosed breast cancer and indication to surgical treatment. Minimum follow-up considered was of 1 year. Patients with high oncologic risk due to familiarity or BRCA1 and BRCA2 mutations were excluded from this study. Patients who encountered significant complications resulting in the postponement or adjustment of their oncological treatment were excluded from the study. Patients with incomplete two-stage reconstruction were not considered.

Texturized prostheses can be distinguished according to the surface concavities diameter into microtexturized (10–50 µm) and macrotexturized ($>$ 50 µm) consistently with the International Organization for Standardization classification system.[16] Mentor microtexturized implants (CPG Mentor, Breast Implants, Santa Barbara, California, United States) (30–35 µm poration diameter) were employed in this study. Allergan macrotexturized implants (Allergan, Inc., Irvine, California, United States) (600–800 µm poration diameter) were utilized.

Patients were divided into two groups according to the BR technique. Group A consisted of patients who underwent immediate or two-stage BR with macrotexturized prosthesis. Group B included patients reconstructed with microtexturized implants.

Preoperative and postoperative data were collected during medical examinations. All participants included in the study underwent weekly follow-up during the initial postoperative month, followed by additional visits scheduled at 3 months, 6 months, and annually following the final surgery.

In order to maintain consistency in the results, we uniformly employed the exclusion criteria for postoperative infection and other significant postoperative complications across both groups. Breast cancer molecular phenotype, grade, and postoperative TNM stage were recorded. Statistical analysis was performed with chi-squared test and two-sample *t*-test, according to data distribution. Significant *p*-values were considered as less than 0.05.

Surgical Technique

Immediate (direct to implant) or two-stage was considered after mastectomy for each patient. Surgical technique selection was based upon patients' individual characteristics. Age, body mass index, breast size and ptosis, diabetes, smoke

habit, patients demand, and intraoperative assessments were evaluated.

Oncological surgery consisted of total, skin-reducing, skin-sparing, or nipple-sparing mastectomy performed through an inframammary incision, periareolar, omega, or lateral S-shaped incision. In cases where a two-stage BR was deemed the most appropriate technique, a tissue expander was positioned within a fully submuscular plane through the elevation of the fascia of the pectoralis major and serratus anterior muscles. Second-stage or immediate BR was performed with microtexturized Mentor and macrotexturized Allergan prosthesis positioning. No acellular dermal matrices or meshes have been adopted. Mean time between first and second BR stage was 8.7 months (range 3–74 months) once complete expansion was achieved. Vacuum drains were inserted in the submuscular pocket and subcutaneous plane. Patients underwent preoperative intravenous antibiotic prophylaxis with 2 g cefazolin or 600 mg clindamycin in allergic patients. Prophylactic therapy was sustained until drains removal with oral 400 mg cefixime or 150 mg clindamycin. All surgeries were performed by a panel of expert plastic surgeons, part of the plastic and reconstructive unit, in collaboration with the breast unit of their respective hospital departments, between 2003 and 2020. Only locoregional and distant breast CRs were reported and no cases of BIA-ALCL were documented. Patients with recurrence were identified based on imaging follow-up and were treated according to the location and size of recurrence and comorbidities with different protocols combining chemotherapy and radiotherapy after multidisciplinary consultation between the breast unit surgeons, oncologist, and radiotherapist.

Results

Retrospective research identified 1,398 patients who underwent monolateral or bilateral mastectomy after breast cancer diagnosis.

From January 2003 to September 2020, 646 patients met the basic inclusion and exclusion criteria. Comprehensively, 491 patients were admitted to Humanitas group and 155 patients to Multimedica group.

Group A included 410 (63.5%) patients who underwent BR with macrotexturized implants. Group B included 236 (36.5%) patients with microtexturized prosthesis.

A total of 334 (51.7%) patients had undergone total mastectomy, specifically, 220 (66%) of patients in group A and 114 patients (34%) in group B.

Alternatively, 312 (48.3%) were submitted to nipple-sparing mastectomies, including 162 (52%) of patients in group A and 151 (48%) in group B.

Patients' characteristics are reported in ►**Table 1**. Group A mean age was 49.2 ± 1.3 years and of group B was 49.2 ± 1.3 years. Overall mean age among included patients was 55.0 ± 1.5 years. Mean group A follow-up was 50.53 months (14–158 months) and 54.73 months (12–140 months) for group B.

All patients who underwent BR were submitted to at least one of the following: adjuvant chemotherapy, hormone therapy, immunotherapy, or radiotherapy. Chemotherapy was performed in 194 (47.3%) cases with macrotexturized and in 104 (44.1%) with microtexturized prosthesis. A total of 287 (70.0%) patients with macrotexturized and 171 (72.5%) with microtexturized breast implants underwent hormone therapy. Immunotherapy was carried out in 82 (20.0%) patients with macrotexturized and 44 (18.6%) with

Table 1 Comparison between patients' clinical characteristics

	Group A	Group B	*p*-Value
Patients			
Number of patients	410 (63.5%)	236 (36.5%)	< 0.00001
Mean age (y)	49.2 ± 1.3	49.2 ± 1.3	0.70
Mean follow-up period (mo)	50.53	54.73	0.43
Adjuvant therapies			
Adjuvant chemotherapy	194 (47.3%)	104 (44.1%)	0.43
Adjuvant radiotherapy	112 (27.3%)	51 (21.6%)	0.11
Adjuvant hormone therapy	287 (70.0%)	171 (72.5%)	0.51
Adjuvant immunotherapy	82 (20.0%)	44 (18.6%)	0.68
Molecular phenotypes			
Luminal	292 (73%)	172 (74.5%)	0.39
HER2 positive	88 (22%)	44 (19.0%)	
Triple negative	20 (5%)	15 (6.5%)	
Cancer recurrence			
Cancer recurrence (absolute risk)	23 (5.6 ± 2.2%)	5 (2.1 ± 1.8%)	0.036
Mean time of recurrence (mo)	52.1	52.3	0.34

Table 2 Patients' breast cancer parameters

	Group A	Group B	*p*-Value
			A vs. B
Stage			
pT			
Tis	12 (2.9%)	13 (5.5%)	0.34
T1	190 (46.3%)	110 (46.6%)	
T2	168 (41%)	89 (37.7%)	
T3	30 (7.3%)	17 (7.2%)	
T4	8 (2.0%)	2 (0.8%)	
pN			
N0	183 (44.6%)	86 (36.4%)	0.08
N1	140 (34.1%)	111 (47.0%)	
N2	48 (11.7%)	25 (10.6%)	
N3	34 (8.3%)	10 (4.2%)	
Grade			
G1	26 (6.3%)	11 (4.7%)	0.21
G2	224 (54.6%)	126 (53.4%)	
G3	138 (33.7%)	77 (32.6%)	

microtexturized prosthesis. Radiotherapy was performed in 112 (27.3%) patients with macrotexturized and in 51 (21.6%) with microtexturized breast implants. All radiotherapy treatments were delivered after primary surgery for expander placement, before receiving definitive prosthesis. Mean time of breast CR after initial surgery in group A was 52.1 months and 52.3 months in group B.

Patients' data analysis detected 49 (5.76%) total cancer relapses; 23 (5.61%) in group A and 5 (2.11%) in group B.

Distinct molecular phenotypes were recorded within the various patient groups, revealing a cumulative count of 482 cases classified as luminal A/B, 124 cases identified as HER2 positive, and 40 cases characterized as triple-negative breast cancer. Detailed information is available in ►**Table 1**. Postoperative TNM stage is reported in ►**Table 2**.

Age comparison showed no statistically significant differences between group A and B (0.70 *p*-value).

No statistically significant differences were observed between reconstructed patients who underwent different adjuvant therapies for chemotherapy ($p = 0.43$), hormone therapy ($p = 0.51$), immunotherapy ($p = 0.68$), and radiotherapy ($p = 0.11$).

CR absolute risk in microtexturized prosthesis was of $2.1 \pm 1.8\%$ and for macrotexturized prosthesis the absolute risk was $5.6 \pm 2.2\%$. Relative risk for breast CR in patients who underwent BR with macrotexturized prosthesis compared to microtexturized prosthesis was of 2.65; confidence interval 95% (1.02; 6.87). Comparative data analysis validated a statistically significant difference in CR in group A and B (0.036 *p*-value).

Absolute risk in breast reconstructed patients was of $4.3 \pm 1.5\%$.

Discussion

Breast cancer is the most common noncutaneous cancer worldwide.[1] The constant increase in oncological breast surgery has drawn flourishing attention to BR, emphasizing the role of breast prosthetic restoration in patients' general well-being. Besides the aesthetic and psychological improvements, it is critical to offer the best possible treatment also considering the health status, quality of life, and oncological background.

Radiotherapy, hormonal therapy, and chemotherapy may affect BR which must consider postoperative oncological treatments.[17,18]

BR and breast CR are both object of interest due the associated considerable physiological, psychological, and economic repercussions.[19]

The search for enhanced surgical techniques which balance radicality with patients complications and the introduction of new treatment protocols and target therapy, increased the prevalence of breast cancer patients survivors, indirectly exposing them for the risk of CR.[20,21] According to literature, the recurrence rate of breast cancer ranges from 15 to 30%, with distant metastasis occurring more commonly than locoregional disease.[22,23] Breast CR are reported to occur from 3 months up to 32 years after initial diagnosis and attributed risk factors included initial TNM stage, grade, molecular features of the cancer, and proposed treatment.[20,22,24] Ahmad[25] proposed a distinct recurrence based

on time of recurrence and molecular characteristics. His findings suggest that estrogen receptor (ER)-negative breast cancers carry a heightened risk of recurrence within the initial 5 years postdiagnosis. Following this period, the risk of recurrence gradually increases in ER-positive breast cancers over the subsequent 10 years. By the 15-year mark post-diagnosis, the recurrence risk seems to equalize between both subtypes.

Autologous free flap BR (AFR) has been reported to be a viable reconstructive option.[26–29] There are numerous types of flaps which may be used, each having different complexities and advantages. AFR has been proven to be safe, with no detected difference between AFR and mastectomy alone in CR.[27] At present, implant-based BR is the primary method for BR, emphasizing the importance of investigating potential associations between various types of texturized prostheses and breast CR.[10] Different breast prostheses are available in the health care market. Implants vary in shape, dimensions, material, consistency, and surfaces. Main coating types may be smooth or texturized with the latter further subdivided into micro- or macrotexturized.[30] In this study, macrotexturized breast prosthesis Allergan Biocell (Allergan) and Mentor microtexturized prosthesis (Mentor Worldwide LLC) were analyzed. Allergan macrotexturized breast prosthesis presents unevenly arranged 600 to 800 µm diameters and 150 to 200 µm depths concavities. The surface structure allows the implants to firmly adhere to the sub- or prepectoral plane resulting in a decreased capsular contraction, malposition, rippling, and rotation rates.[31] Nonetheless, macrotexturized implants are characterized by higher risk of double capsule and late seroma.[31] Mentor microtexturized breast prosthesis presents smaller concavities (< 50 µm) and decreased rates of capsular contracture and malposition compared to smooth-surface implants.[32]

The primary objective of BR is to offer the most appropriate and secure means of restoring the breast. In achieving this goal, considerable emphasis is placed on the patient's prompt recovery and remission from cancer.[33] Recently, texturized prostheses have been related to BIA-ALCL with significantly higher risk associated with macrotexturized implants.[16] The identification of a BIA lymphoma further led the attention to breast implants and possible oncological correlation.

Several studies reported positive data regarding oncological safety of implant-based BR.[34,35] Immediate prosthesis BR is a safe, approachable BR technique in selected patients.[34] Combination with radiotherapy is feasible, although an inferior aesthetic result is reported.[34] McCarthy et al[35] detected no difference in locoregional CR in breast cancer patients submitted to two-stage BR when compared with nonreconstructed patients. In addition, breast implants do not hinder the detection of early cancer relapse and treatment of local recurrence does not require the implant removal in most of the patients.[35]

Literature describing interaction between breast implants' surface and CR is not extensive.[14] Lee et al[14] observed a greater risk of CR in texturized implants without defining implant denomination and texture typology. No studies comparing different texturization grades and breast CR are available. The purpose of this study was to evaluate the impact of different implant surfaces in breast CR. According to our research, this is the first paper to analyze the association between microtexturized and macrotexturized breast prosthesis to their respective risk of CR.

Our research identified a higher CR risk in macrotexturized breast implants.

The biological bases on which macrotexturized prosthesis increase the risk of CR are still uncertain. Various hypotheses have been suggested to explore the interaction between texture and the tissue microenvironment.[36,37] Both microtexturized and macrotexturized implants promote the development of an inflammatory environment, potentially elevating the risk of carcinogenesis. The validity of this data is substantiated by the elevated levels of interleukin-10, granulocyte colony-stimulating factor, transforming growth factor-β, and M2-polarized macrophages, indicating a common tissue microenvironment observed in breast cancer.[36,37] Furthermore, numerous studies documented an increase in biofilm formation rate in texturized breast prothesis.[38,39] Danino et al[40] presented a comparative study in which macrotexturized expanders had a greater incidence in biofilm formation than microtexturized implants. The biofilm-induced chronic inflammation has been associated to a periprosthetic immune response related to T cell hyperplasia.[41] In addition, in patients with texturized breast implant, the elevation in inflammatory markers such as C-reactive protein suggests the onset of a systemic inflammatory response.[42] Both local and systemic chronic inflammation may correlate to an increase in the incidence of CR.[43]

A major limitation regarding this study is the absence of data regarding the preoperative estrogen exposure. Similarly, the local lymphovascular and systemic extension of the cancer were not included in the correlation with CR. Breast expander texturization was not reported in the recorded data. Although the interaction time between the tissue expander and the breast is limited, it may be worthwhile to investigate potential associations between expander texture and CR in two-stage BR.

Acknowledging the multicentric nature of this study, we recognize that the substantial number of surgeons and the temporal introduction of microtexturized breast prostheses may have introduced bias in the selection of breast implants.

This research represents one of the initial efforts to present data regarding the impact of macro- and microtexturized implants on breast CR. It highlights the necessity for further exploration in this area. Nevertheless, it is important to acknowledge the limitations posed by the small sample size, emphasizing the need for additional studies to thoroughly assess and validate our observations.

Conclusion

Implant-based BR is a common method of BR. Despite the wide employment of breast prosthesis, only few studies in literature evaluate the impact of implant positioning with local CR. The objective of this study was to examine, offer

initial data, and contrast the risk of CR in individuals undergoing BR with macrotexturized and microtexturized implants. This preliminary investigation underscores the potential association between macrotexturized breast prostheses and increased rates of breast CR.

Conflict of Interest

None declared.

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