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Evaluation of the Oncologic Outcomes of Breast Cancer According to the Smooth Implants Versus Textured Implants: A Systematic Review and Meta-analysis

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ABSTRACT

Background and aim: Concerns about the potential carcinogenic effects of breast implants, particularly those with textured surfaces, have recently been raised by an increasing number of reports of anaplastic large cell lymphoma associated with breast implants. The present study was conducted to evaluate oncologic outcomes of breast cancer according to the smooth implants vs. textured implants.

Material and methods: For this systematic review and meta-analysis study, international databases such as MEDLINE (PubMed and Ovid), Web of Science, and Scopus were searched until July 2024 using keywords relevant to the study objectives. Cohort studies published in English that investigated the oncologic outcomes of breast cancer according to the surface type of implants were included in the study. STATA/MP. v17 software was used to analyze data.

Results: Six studies were reviewed. The use of a textured implant vs smooth implant was associated with a significantly lower DFS (HR, 2.88; 95% CI, 1.71-4.04) vs (HR, 2.96; 95% CI, 1.57-4.35), ($p<0.01$).

Conclusions: According to the results of the present meta-analysis, breast cancer recurrence may be related to the type of surface implant used for reconstruction.

1. Introduction

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) has been documented in additional studies since the first case was documented in 1997.[1] The condition's exact cause is still unknown, but a textured implant is a possible risk factor.[2-4] Breast implant safety has become a hot topic with many unanswered questions and the need for reevaluation since this serious and unexpected complication's sudden appearance is likely related to the texture of the implant surface.[5] In addition, there is growing concern about the possibility of additional unforeseen negative effects related to the surface structure or the breast implant itself, such as the occurrence or recurrence of other types of cancer.[6] Breast cancer survivors who have had their breasts rebuilt with implants, particularly textured implants, may need to be particularly concerned. Patients who have visited clinics for consultation or inquired about implant removal have expressed concerns not only about the possibility of developing BIA-ALCL but also about the possibility that textured implants may be associated with the recurrence of their original cancer.[7] A smooth or textured implant should not alter the biological behavior of tumors since, from a technical and surgical point of view, prostheses are traditionally placed in the subpectoral space for breast reconstruction, which is isolated from the region where breast cancer usually arises. Based on this reasonable assumption, numerous surgeons have helped their patients feel less anxious by explaining that the breast cancer results most likely had nothing to do with the implants inserted. Regarding the periprosthetic space, it is known that textured implants, in contrast to smooth implants, can be more prone to the formation of biofilms and chronic inflammation.[8-11] Persistent inflammation around the implant can continuously stimulate the host's immune system and lead to lymphoma, a suspected mechanism for developing BIA-ALCL.[12] Chronic inflammation induced by a structured implant may, in a similar situation, activate dormant

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cancer cells or cause them to migrate through the systemic circulation of substances, potentiallyaltering the risk of breast cancer recurrence. Several experimental and clinical studies have shown that inflammation caused by postoperative complications can affect dormant or localized tumor cells containing inflammatory mediators or cytokines, potentially leading to tumor metastasis and regrowth. Aside from these conflicting beliefs and concerns, no research has examined the possibility that the type of implant surface used for reconstruction may be associated with breast cancer recurrence.[13-15] The research found that the type of implant surface had no effect on breast cancer outcomes and that there was no difference in oncologic outcomes between patients with smooth and textured implants. Little evidence on this issue is available at present; this study was conducted to evaluate oncologic outcomes of breast cancer according to smooth implants vs. textured implants.

2. Material and methods

Search strategy and Information sources

Until July 2024, the international databases MEDLINE (PubMed and Ovid), Embase and Cochrane were searched for scientific evidence to evaluate the oncologic outcomes of breast cancer according to smooth implants vs. textured implants using relevant keywords (Table 1). Scopus Wiley Online Library, Web of Science, Cochrane Central Register of Controlled Trials, EBSCO, ISI, Elsevier and the Google Scholar search engine were also used. The present study is based on the 27-point checklist PRISMA 2020.[16]

Selection criteria

Inclusion criteria for studies in this research were articles published in English. The answers to the questions in the current study were based on the PICOS strategy; Population (P): Breast cancer patients; Intervention (I): textured implant; Comparison (C): smooth implant; Outcome (O): disease-free survival, survival rate and oncologic outcome. Study design(s): randomized controlled trial (RCT), cohort studies. Review studies and books, qualitative studies, laboratory studies, animal studies, studies without comprehensive and relevant data, and Data not reported on breast cancer were excluded from the study.

Table 1. The search strategy used for each database.

NO	Search Terms
	The search strategy used in MEDLINE (via PubMed)
1	("Breast"[Mesh]) OR ("Breast Implants"[Mesh] OR "Breast Neoplasms"[Mesh] OR "Breast Cancer Lymphedema"[Mesh] OR "Inflammatory Breast Neoplasms"[Mesh] OR "Breast Implantation"[Mesh]).
2	((("Breast Neoplasms/surgery"[Mesh] OR "Breast Neoplasms/therapy"[Mesh])) OR ("Breast Implants/adverse effects"[Mesh] OR "Breast Implants/standards"[Mesh] OR "Breast Implants/statistics and numerical data"[Mesh] OR "Breast Implants/trends"[Mesh])) OR ("Breast Implantation/adverse effects"[Mesh] OR "Breast Implantation/instrumentation"[Mesh] OR "Breast Implantation/methods"[Mesh] OR "Breast Implantation/standards"[Mesh] OR "Breast Implantation/statistics and numerical data"[Mesh]).
3	Breast Implantations; Implantation, Breast; Implantations, Breast; Breast Prosthesis Implantation; Breast Prosthesis Implantations; Implantation, Breast Prosthesis; Implantations, Breast Prosthesis; Prosthesis Implantation, Breast; Prosthesis Implantations, Breast.
4	Implants, Breast; Breast Implant; Implant, Breast; Breast Prosthesis, Internal; Breast Prostheses, Internal; Internal Breast Prostheses; Internal Breast Prosthesis; Prostheses, Internal Breast; Prosthesis, Internal Breast.
5	("Disease-Free Survival"[Mesh]) AND ("Survival"[Mesh] OR "Mortality"[Mesh] OR "Survival Rate"[Mesh]).
	The search strategy used by Cochrane
1	Breast OR Breast Implants OR Breast Neoplasms OR Inflammatory Breast Neoplasms OR Breast Implantation.
2	Breast Implantations OR Implantation OR Breast OR Breast Prosthesis Implantation OR Breast Prosthesis Implantations OR Breast Prosthesis OR Prosthesis Implantation.
3	smooth implant AND textured implant.
4	Disease-Free Survival AND Survival AND Survival Rate AND Mortality.
5	Oncologic events.
	The search strategy used in Embase
1	(Breast) OR (Breast Implants) OR (Breast Neoplasms) OR (Inflammatory Breast Neoplasms) OR (Breast Implantation): ab,ti,kw.
2	Breast Implantations' Implantation' Breast' Breast Prosthesis Implantation' Breast Prosthesis Implantations' Breast Prosthesis':ti,ab,kw.
3	smooth implant AND textured implant;: ti,ab.
4	Disease-Free Survival' Survival' Survival Rate' Mortality: ab,ti,kw.
5	chapter' OR 'conference abstract' OR 'conference paper' OR 'conference review' OR 'editorial' OR 'erratum' OR 'letter' OR 'note' OR 'preprint' OR 'short survey'/it (Filter).

The process of selection and data collection

Two researchers separately collected data from subjects using a standard data collection form designed in advance to reduce reporting, data collection errors, and omissions. The research team created the original form, which included the following information: the author's name, year of publication, Number of patients in each group, mean of age, kinds of implant used, oncologic outcomes and mortality.

Methodological quality

The risk of bias in the reviewed articles was assessed using the Cochrane Risk of Bias tool.[17] Seven components are used: random sequence generation, allocation concealment, participant blinding, outcome blinding, incomplete outcome data, selective outcome reporting, and other risk of bias assessment tools. Two researchers independently rated each article using a seven-point scoring table to determine the risk of bias. In the event of a disagreement, an external researcher reviewed the article. The included cohort studies were assessed for methodological quality using the Newcastle-Ottawa Scale (NOS).[18] Each study received a maximum of nine stars on this scale. Research was considered high quality if it received seven or more stars; if not, it was considered inferior.

Heterogeneity and publication bias

The heterogeneity across studies was examined using the Chi-square ($\chi 2$) test and quantified by the I^2 statistic. According to the I^2 value, heterogeneity was classified as low (less than 50%), between 50 and 74% means moderate heterogeneity, and above 75% is considered high heterogeneity. The Egger and Begg tests explored the possibility of publication bias and funnel plot.

Certainty of evidence

The grading of the Recommendations, Assessment, Development and Evaluation (GRADE) framework was applied to determine the level of certainty of the evidence for each primary outcome. When creating the GRADE criteria, the following six factors were considered: publication bias, risk of bias, precision, consistency and study design. Clear evidence was used to initiate RCTs. Five elements could reduce the evidence's certainty level: publication bias, indirectness, inconsistency, risk of bias and imprecision. Based on these standards, we divided the evidence of each outcome into four categories (high, moderate, low, or very low).

Data analysis

The effect measure of choice was the Hazard Ratios with 95% confidence intervals. The results were reported based on a Fixed-effects model with inverse variance. The data were analyzed at a significance level 0.05 using Stata software (version 17).

3. Results

Description of studies

The initial search found 281 articles. In the first phase, based on the article titles, 79 articles were deleted due to duplicate records. In the second step, studies that did not meet the inclusion criteria were excluded by examining the abstract of 186 articles (n=152). In the third step, 28 articles with incomplete data or non-compliance with the inclusion and exclusion criteria were eliminated by examining the full text of 34 articles. Finally, six articles were used in the present study (Fig. 1 and Table 2).

Study characteristics

In the present study, 2648 patients were included in the textured implant group and 1855 patients in the smooth implant group. Table 2 provides a summary of study characteristics.

Bias Assessments

According to the GRADE assessment, the meta-analysis using Disease-free survival rates demonstrated high certainty of evidence (Table 3). The risk of bias in cohort studies was low (Table 4).

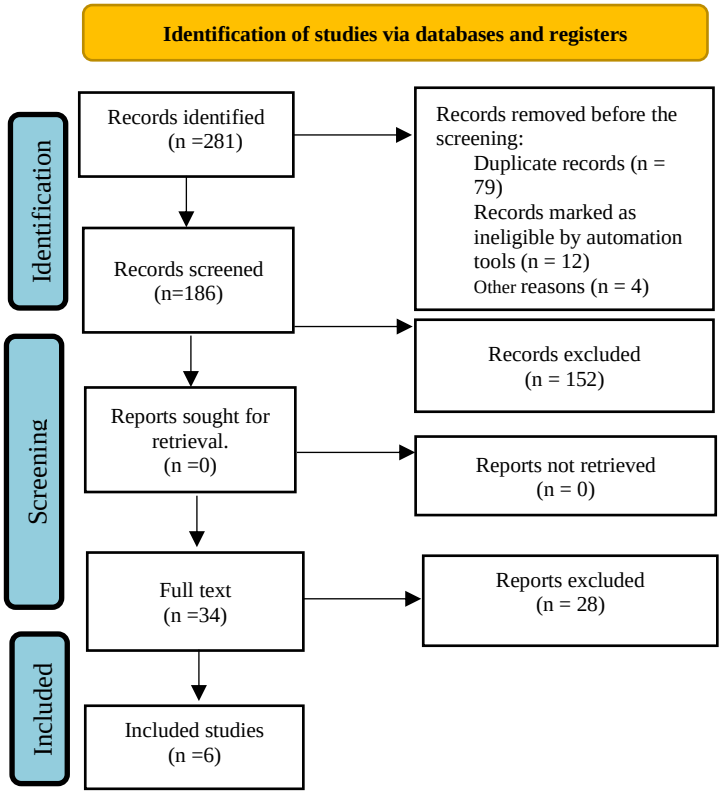

Fig. 1. PRISMA 2020 Checklist.

Table 2. Summary characteristics of studies.

Study. Years	Study Design	Mean [SD] Age	Number of Patients		Kinds of Implant Used		Oncologic Outcomes							
							TI				SI			
			TI	SI	TI	SI	LR	LN	DR	O	LR	LN	DR	O
Spoor et al., 2024[19]	Cohort Study	43	1187	1206	NR	NR	NR				NR			
Huang et al., 2023[20]	Cohort Study	41	15	8	NR	NR	24	8	-	-	19	4	-	-
Ha et al., 2023[21]	Cohort Study	45.0 [8.0]	636	212	Polytech, BT, MMG,	MMG, BS	43				43			
Wu et al., 2022[22]	Cohort Study	41	276	138	NR	NR	32	11	11	21	15	7	5	8
Wu et al., 2021[23]	Cohort Study	40	121	17	NR	NR	NR				NR			
Lee et al., 2020[7]	Cohort Study	43.5 [7.4]	413	274	ANS110, ANS410, MMG, BT	ANS10, MMG, BS	7	4	10	23	4	1	0	5

TI: Textured implant; SI: Smooth implant; ANS: Allergan Natrelle style; MMG: Mentor MemoryGel, BS: Bellagel Smooth; O: Other; LR: Local recurrence; LN: LN recurrence; DR: Distant recurrence; BT; Bellagel Textured.

Table 3. Certainty of the evidence (GRADE).

Outcomes	Included Studies (Participants)	Factors that Downgrade the Certainty of the Evidence					Certainty of the Evidence
		Risk of Bias	Indirectness	Inconsistency	Imprecision	Publication Bias	
DFS	6	Not downgraded	Not downgraded	Not downgraded	Not downgraded	Not downgraded	⊕⊕⊕⊕/A
LRRFS	6	Not downgraded	Not downgraded	Downgraded	Not downgraded	Not downgraded	⊕⊕⊕⊖/B
SO	6	Not downgraded	Not downgraded	Not downgraded	Not downgraded	Not downgraded	⊕⊕⊕⊕/A

A: refers to a high certainty of evidence; B: refers to a moderate certainty of evidence.

Table 4. Newcastle-Ottawa Scale (NOS) for cohort study.

Study	Item & Score								Total Scores
	The exposed cohort（1）	Selection of the non（1）	Ascertainment of exposure（1）	Demonstration that outcome of interest was not present at the start of the study（1）	Compare the ability of cohorts based on the design or analysis.（2）	Assessment of outcome（1）	Was follow-up long enough for outcomes to occur（1）	Adequacy of follow-up of cohorts（1）	
Spoor et al., 2024[19]	*	*	*	*	*	*	*	*	8/9
Huang et al., 2023[20]	*	*	*	*	*	*	*	*	8/9
Ha et al., 2023[21]	*	*	*	*	**	*	*	*	9/9
Wu et al., 2022[22]	*	*	*	*	**	*	*	*	9/9
Wu et al., 2021[23]	*	*	*	*	**	*	*	*	9/9
Lee et al., 2020[7]	*	*	*	*	*	*	*	*	8/9

Disease-free survival (DFS) rates

The use of a textured implant vs a smooth implant was associated with a significantly lower DFS (HR, 2.88; 95% CI, 1.71-4.04) vs. (HR, 2.96; 95% CI, 1.57-4.35), ($p<0.01$) (Figs. 2 and 3). The heterogeneity was low ($I^2 = 0\%$, $p = 0.98$ and $p=0.94$).

local and regional recurrence-free survival

The LRRFS rate was lower in the textured group (94% vs. 97%) compared to the smooth group (Figs. 4 and 5). The LRRFS did not vary between the textured and smooth implant groups based on the type of implant surface ($p>0.05$). The heterogeneity was low ($I^2 = 0\%$, $p = 1.00$).

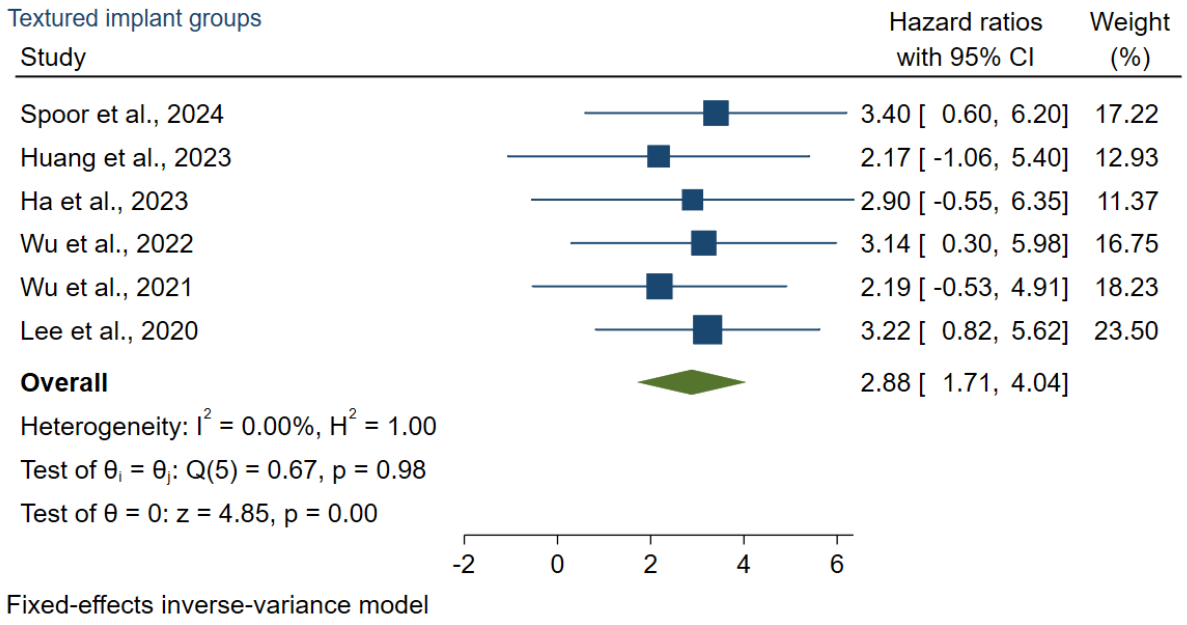

Fig. 2. Forest plot showing the disease-free survival rates of a textured implant used.

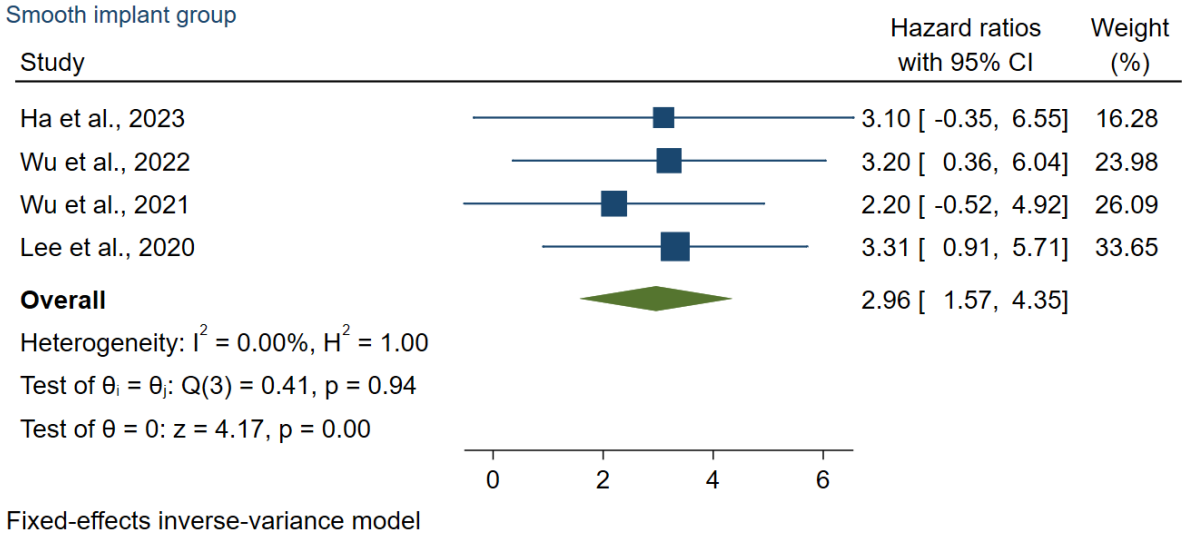

Fig. 3. Forest plot showing the disease-free survival rates of a smooth implant used.

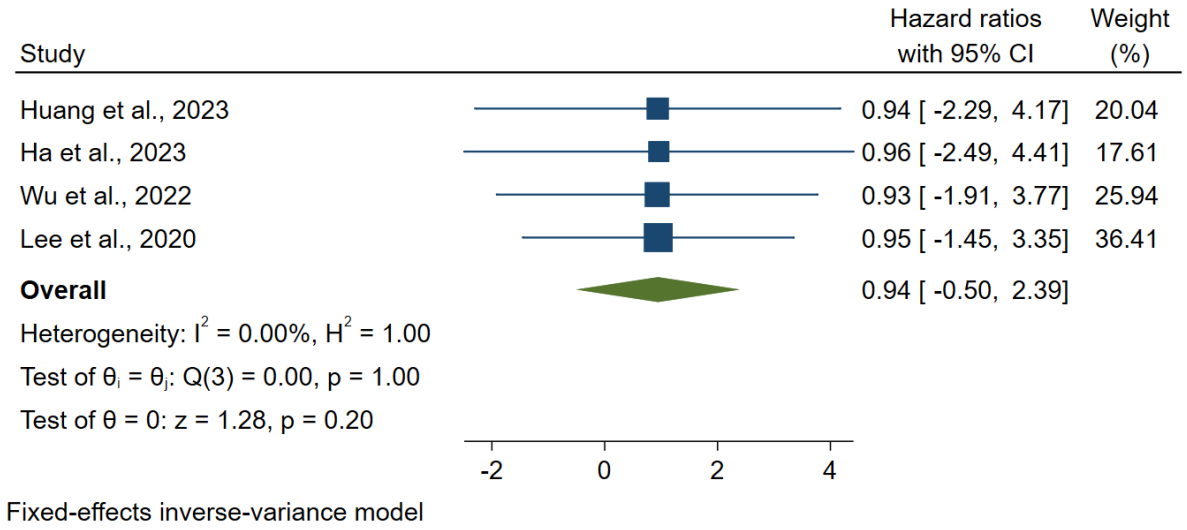

Fig. 4. Forest plot showing the local and regional recurrence-free survival in the textured implant group.

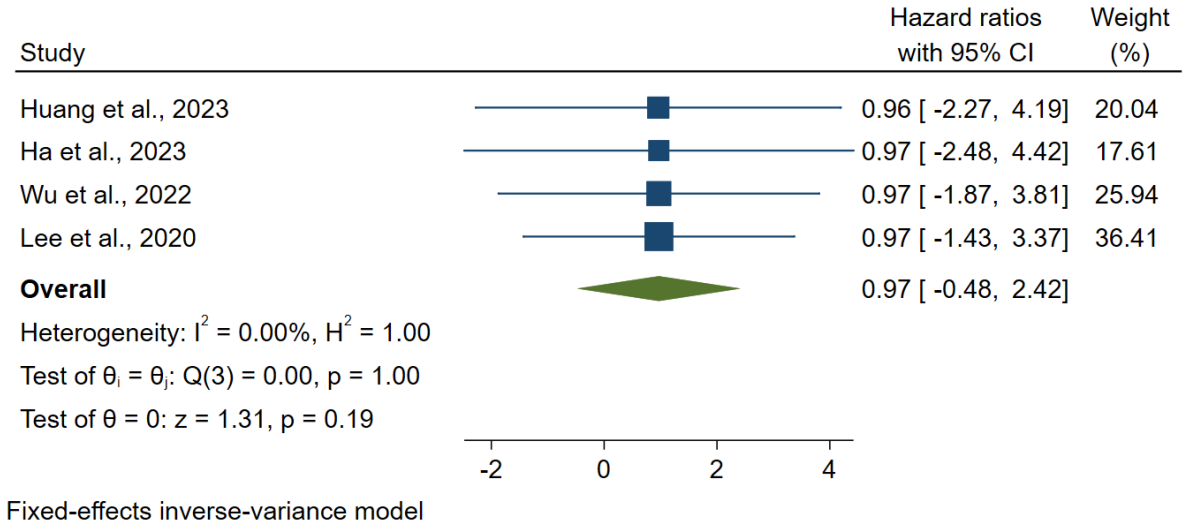

Fig. 5. Forest plot showing the local and regional recurrence-free survival in the smooth implant group.

4. Discussion

Previous implant surface-type studies have been highly concerned about their possible impact on postoperative complications, such as B. capsular contracture. The current systematic review and meta-analysis study is the first to examine the association between implant surface type and patient survival in breast cancer patients. According to the current meta-analysis, the use of textured implants was found to be statistically significantly associated with lower DFS and a higher risk of recurrence. Compared to the smooth group, the DFS of the textured implant group was significantly lower. These results suggest that the type of implant may have an independent influence on breast cancer progression and that using a textured implant as opposed to a smooth implant may increase the risk of recurrence. The current study needs more information to explain the exact mechanism underlying this unexpected finding. The risk of breast cancer recurrence is higher when textured implants are used for reconstruction, and this association is most likely due to chronic inflammation, according to the results of previous relevant studies. In vitro studies with structured implants, in contrast to smooth implants, showed an increased rate of biofilm formation.[9, 11, 24, 25] Biofilm formation activates the host's immune system, leading to a sustained inflammatory response.[26, 27] In addition to localized inflammation in the periprosthetic capsule, a systemic inflammatory reaction has also been associated with breast implant placement in certain clinical studies.[24, 28] In a prospective controlled study, Silva et al., 2011 found that patients who underwent augmentation mammoplasty with textured silicone implants had higher C-reactive protein levels at two months postoperatively than their preoperative six months values.[29]

According to this research, textured silicone implants could lead to an inflammatory response throughout the body.[29] Additionally, ample data supports the connection between inflammation and breast cancer recurrence. After controlling for other variables, patients with elevated C-reactive protein levels had, according to a cohort study by Pierce et al., 2009 significantly lower overall survival and DFS.[30] According to these findings, systemic inflammation may have a separate impact on breast cancer survival. Two limitations of the present study were the small sample size and the lack of studies comparing smooth implants vs. textured implants. Although the follow-up period in this study was five years and was the same in all studies, the follow-up periods in the other studies also differed. A follow-up period of

less than four years after implant insertion is not enough, especially for Estrogen receptor-positive breast cancer. Larger-scale and multi-institutional studies would be required.

5. Conclusion

According to the results of the present meta-analysis, breast cancer recurrence may be related to the type of surface implant used for reconstruction. Compared to smooth implants, using textured implants may result in lower DFS and a higher risk of recurrence. This correlation could hold regardless of other variables, such as tumor stage and ER status. Additional research needs to confirm these results.

Conflict of Interest

The authors declared that there is no conflict of interest.

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