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LONG-TERM RESULTS IN POSTMASTECTOMY BREAST RECONSTRUCTION WITH POLYURETHANE-COATED IMPLANTS

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Summary

Background. Breast reconstruction after mastectomy supports physical and psychological recovery in breast cancer patients. While implant-based procedures are common, capsular contracture (CC) remains frequent, causing firmness, pain, and aesthetic problems. Polyurethane-coated implants were introduced to reduce CC risk by minimizing fibrous capsule formation. This retrospective study examines CC incidence in patients reconstructed with polyurethane-coated implants, with a minimum of five years' follow-up.

Methods. A retrospective study was conducted on patients who underwent breast reconstruction using polyurethane-coated implants from 2013 to 2018. Thirty-seven reconstructions were included, with follow-up durations ranging from 6 to 11 years (mean 8.5 years). Patients underwent either prepectoral or submuscular implant placement. Additionally, the impact of postmastectomy radiation therapy (PMRT) on CC incidence was assessed by comparing irradiated and non-irradiated cases.

Results. The overall incidence of CC was 35.1%. Stratification revealed higher rates in irradiated patients (75%) compared to non-irradiated patients (25%) [p = 0.001762]. Submuscular placement showed a lower incidence of CC (23.8%) compared to prepectoral placement (37%) [p = 0.007433]. Most cases of CC were classified as Baker grades II and III, indicating mild to moderate severity.

Conclusions. Polyurethane-coated implants are associated with a reduced incidence of capsular contracture in the initial years following surgery. However, as the polyurethane coating degrades, the risk of CC increases, potentially reaching levels comparable to other implant types. Further long-term studies are necessary to validate these findings and to explore strategies for sustaining the benefits of polyurethane coatings in breast reconstruction.

Key words: breast reconstruction, polyurethane-coated implants, capsular contracture, submuscular placement, prepectoral reconstruction, postmastectomy radiation therapy, long-term outcomes, implant degradation

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INTRODUCTION

Breast reconstruction following mastectomy plays a pivotal role in the physical and psychological rehabilitation of women undergoing breast cancer treatment. Among the reconstruction techniques, alloplastic reconstruction using breast implants is the most frequently employed. Capsular contracture (CC) is one of the most common complications associated with breast implants. It occurs when the immune system reacts to a foreign body, forming a fibrous capsule around the implant, which can become thickened and contract, causing firmness, pain, and aesthetic deformities [1]. The Baker classification system is commonly used to assess the severity of CC, with grades III and IV indicating significant firmness and visible deformities. Various factors contribute to the development of CC, including the implant surface texture, placement, surgical technique, and whether the patient underwent postmastectomy radiation therapy (PMRT) [2-4].

Polyurethane-coated implants were introduced to reduce the risk of CC compared to traditional smooth and textured implants [5]. The polyurethane coating creates a sponge-like structure that interacts with the surrounding tissue, leading to more random collagen fibril organization, which is believed to reduce the likelihood of capsular formation and contraction. However, concerns have been raised about the long-term efficacy of polyurethane-coated implants as the coating degrades over time, potentially diminishing the protective effect against CC [6].

This retrospective observational study aims to evaluate the incidence of capsular contracture in patients undergoing breast reconstruction with polyurethane-coated implants, with a minimum follow-up of 5 years. The findings are compared with published data on textured implants with longer follow-up durations, providing insights into the long-term behavior of polyurethane implants and their implications for patient outcomes.

MATERIALS AND METHODS

Study design and population

The study is a retrospective analysis of patients who underwent breast reconstruction between 2013 and 2018 using polyurethane-coated implants. A total of 147 patients were initially reviewed, and 37 reconstructions were ultimately included in the analysis. Patients were followed for an average of 8 years and 6 months, with follow-up durations ranging from 6 to 11 years. Follow-up evaluations were performed by two independent surgical teams, which helped ensure a more comprehensive assessment of outcomes.

Surgical techniques

Patients underwent various surgical approaches, including both prepectoral and retropectoral (submuscular) placements of the implants. The selection of the surgical technique was based on patient-specific factors such as anatomy, prior surgical history, and the presence of PMRT. Nine patients underwent prepectoral reconstruction, while 28 had retropectoral placement. Additionally, five cases involved direct-to-implant (DTI) procedures, and the remaining 33 were staged reconstructions with tissue expanders followed by implant placement.

Radiation therapy

Postmastectomy radiation therapy (PMRT) is known to increase the risk of capsular contracture due to its effects on the healing process and tissue fibrosis. In this study, nine patients received PMRT, with irradiated and non-irradiated cases analyzed separately to evaluate the impact of radiation on CC incidence. The inclusion of both irradiated and non-irradiated patients allowed for a comparison of outcomes in different risk groups [2,7].

RESULTS

Incidence of capsular contracture

The overall incidence of capsular contracture (grades II and III) in the study cohort was 35.1%. When stratifying the data, the incidence was markedly higher in patients who underwent radiation therapy (Fig. 1), with a 75% rate of contracture in the irradiated group. In contrast, the rate dropped to 24.1% in non-irradiated patients (Fig. 2), demonstrating a significant reduction in risk when radiation was not a factor. Furthermore, the incidence of CC was even lower in submuscular reconstructions, with a rate of 23.8%, corroborating evidence from meta-analyses indicating that subpectoral positioning is associated with fewer capsular complications [8]. Conversely, the rate of capsular contracture increased in prepectoral reconstructions to 37% (Fig. 3), indicating a modestly higher risk compared to submuscular placement [7] (Tab. I). The differences in capsular contracture rates between irradiated (Fig. 4) and non-irradiated patients, as well as between submuscular and prepectoral reconstructions, were statistically significant, with p-values of 0.001762 and 0.007433, respectively.

In terms of severity, most cases fell into the Baker II and III categories, with grade III being more common in the irradiated group (30.7 *vs* 7.7%). The breakdown of contracture rates by surgical technique showed significant difference between prepectoral and retropectoral placements, indicating that the placement approach influenced the risk of CC in this cohort.

Comparison with historical data

The incidence of capsular contracture observed in this study was lower than that reported in some previous studies involving textured implants. For example, Japanese studies have noted a 28,9% CC rate for textured submuscular implants not undergone PMRT with follow-up periods exceeding 10 years [9]. In contrast, our study found a 23,8% CC rate after approximately 8.5 years of follow-up in the group of patients with the same characteristics. Although the incidence was lower in our cohort, the shorter follow-up period suggests that the long-term outcomes for polyurethane-coated implants may approach those of textured implants [6].

Impact of polyurethane degradation

Polyurethane-coated implants are known to undergo gradual degradation, with the outer coating typically resorbing almost two years after post-implantation [10].Our study's results suggest that after the polyurethane degrades, the implants' behavior may become similar to that of other implant types regarding CC incidence. As noted in previous studies, the initial reduction in CC risk afforded by the polyurethane coating diminishes over time, potentially leading to comparable contracture rates in the long term [6].

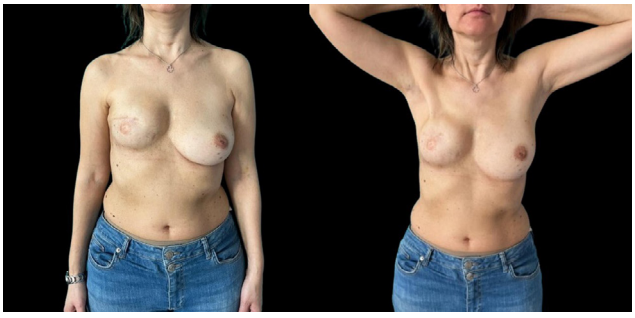

Figure 1. Right submuscular breast reconstruction – radiotreated patient – Grade III contracture – 7 years post-treatment.

Figure 2. Right submuscular breast reconstruction – non-radiotreated patient – Grade III contracture – 7 years post-treatment.

DISCUSSION

The findings of this study indicate that polyurethane-coated implants offer a reduced incidence of capsular contracture in the short to medium term compared to historical data for other implant types. However, this advantage appears to diminish over time, particularly in patients with risk factors such as radiation therapy. The similarity in long-term outcomes between polyurethane-coated and textured implants may be explained by the degradation of the polyurethane coating, which results in a loss of its protective effect against capsule formation.

Factors influencing capsular contracture

Several factors are known to contribute to the development of capsular contracture, including implant surface texture, surgical technique, pocket placement, and radiation therapy. The submuscular position not only offers enhanced soft tissue coverage but also limits the implant's direct interaction with the mastectomy flap, potentially reducing fibrosis. However, pre-pectoral reconstructions, despite showing slightly higher contracture rates, have gained popularity due to their lower incidence of animation deformity and improved patient satisfaction in terms of aesthetics [8]. This study's findings corroborate the notion that PMRT significantly increases the risk of CC, likely due to the fibrotic changes induced by radiation. The fact that CC rates were different across different surgical

Table I. Results by groups: RT: patients received post mastectomy radiotherapy; NRT:patients not subject to radiotherapy; CC: capsular contracture.

Cases	CC	Percentage	Technique (two stages)	Technique (direct to implant)
OVERALL	37	35.1%	28	9
RT	8	75%	5	3
NRT	29	24%	23	6
SUBMUSCOLAR NO RT	21	23.8%	17	4
PREPECTORAL NO RT	8	25%	6	2

Figure 3. Bilateral prepectoral breast reconstruction – non-radiotreated patient – Grade I contracture – 6 years post-treatment.

Figure 4. Left submuscular breast reconstruction – radiotreated patient – Grade II contracture – 8 years post-treatment.

techniques suggests that both the surface characteristics of the implant and pocket placement could play an important role in determining the likelihood of contracture [7]. Regarding severity, most cases were classified as Baker II and III, with grade III occurring more frequently in the irradiated group than in those not irradiated, suggesting that while polyurethane-coated implants may initially mitigate the extent of contracture, their protective effect appears less pronounced in the presence of external factors such as radiation. It must be specified, however, that these polyurethane-coated prepectoral implants (with an average follow-up of 8 years and 6 months) represent the initial experience with this kind of breast reconstruction, and this factor may have influenced the outcome.

Association between polyurethane and BIA-ALCL

Recent reports implicate polyurethane-coated breast implants in the development of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) [11]. Although the overall incidence remains low, studies have suggested that because of their unique structural features and higher degree of texturing, polyurethane surfaces may predispose patients to a heightened inflammatory response compared to other types of implants [12]. Chronic inflammation, in particular due to bacterial biofilm formation on the textured surface, is considered a key driver for oncogenesis [13]. Variations among different manufacturers and implant models have resulted in different risk profiles, with some regulatory bodies taking steps to restrict or withdraw certain polyurethane implants from the market [14]. Consequently, it is crucial that both the patient and surgeon be aware of these risks and take great care in the selection of implant devices, with postoperative vigilance for early detection and intervention if BIA-ALCL develops.

Comparison with previous studies

Our findings are consistent with those of other studies that report lower capsular contracture rates for polyurethane-coated implants in the short term. For instance, a meta-analysis showed that polyurethane implants had an incidence of 0.4-1% at six years, which was significantly lower than textured silicone implants, which had rates of 10-15% [15]. However, our study suggests that as follow-up periods extend, the incidence of CC in polyurethane-coated implants increases, supporting the hypothesis that the protective effect wanes as the polyurethane degrades [6].
A study involving a 30-year follow-up of polyurethane implants also reported an increase in contracture rates over time, with most cases appearing after the polyurethane had degraded [6]. The degradation process affects the organization of collagen fibrils, leading to a more structured capsule and increased likelihood of contracture. Thus, while polyurethane implants provide early benefits, long-term results may mirror those of other implant types [16]. Another study comparing immediate breast reconstruction with polyurethane and textured implants reported a lower CC incidence for polyurethane implants, with a rate of 8.1% over a median follow-up of 2.3 years. 2 Although this suggests an advantage of polyurethane implants in reducing CC, the relatively short follow-up period limits the ability to draw long-term conclusions. As the follow-up duration was shorter than in other studies reporting higher CC rates, the observed low incidence may reflect early postoperative benefits rather than sustained long-term outcomes.

Limitations

The limitations of this study include its retrospective nature, relatively small sample size, and variability in follow-up duration and furthermore it's a case series study presenting the lack of a control group. Although the inclusion of patients treated at two centers improves generalizability, the findings should be interpreted cautiously due to potential selection bias and variations in clinical practices. Additionally, the lack of a standardized

protocol for assessing capsular contracture may have introduced variability in outcome reporting. This is a preliminary report of a larger study involving the inclusion of a homogeneous control group consisting of patients undergoing breast reconstruction with textured implants.

CONCLUSIONS

This retrospective analysis indicates that polyurethane-coated implants are associated with a reduced incidence of capsular contracture compared to historical data on textured implants. However, this advantage appears to decrease over time, likely due to the degradation of the polyurethane coating. The findings suggest that after the polyurethane layer resorbs, the long-term risk of CC may be similar to that associated with other types of implants. Further research is needed to confirm these results and explore strategies for optimizing the long-term outcomes of breast reconstruction with polyurethane-coated implants.

Conflict of interest statement
The author declare no conflict of interest.

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Author contributions
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AP, DM: D, S
DA: W

Abbreviations
A: conceived and designed the analysis
D: collected the data
DT: contributed data or analysis tool
S: performed the analysis
W: wrote the paper

Ethical consideration
Not applicable.

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