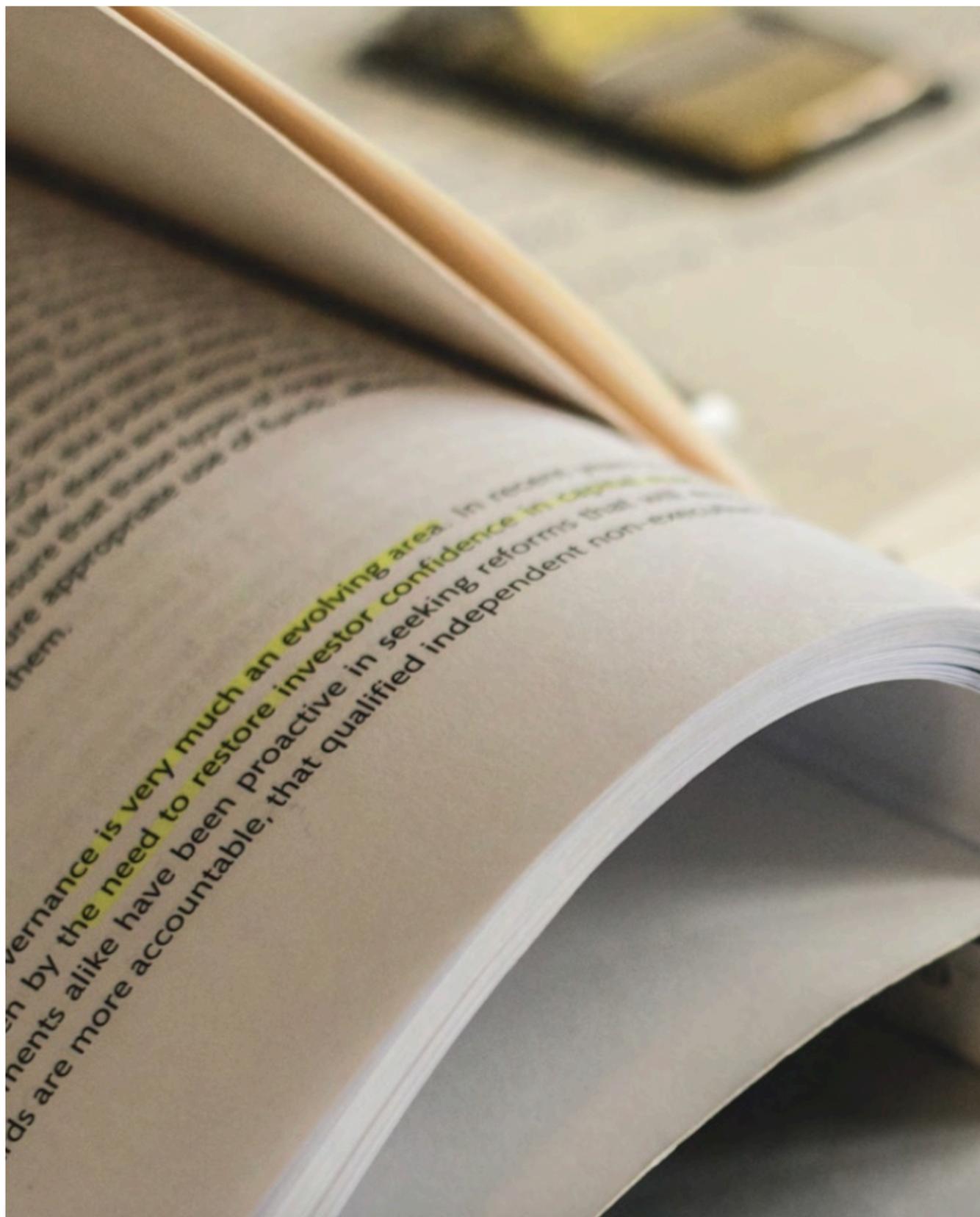


# PUBLIKATIONEN



# Capsular contracture in implant based breast reconstruction—the effect of porcine acellular dermal matrix

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**Background:** Irradiation of implant-based breast reconstructions (BR) is known to increase capsular contracture (CC) rates on average by 4-fold over non-irradiated reconstructions. The use of acellular dermal matrix (ADM) has been associated with lower CC rates in non-irradiated reconstructions (0-3%). Experimental and clinical studies suggest that ADM may also reduce CC rates in irradiated breasts. The aim of this study was to evaluate CC rates in non-irradiated and irradiated one- and two-stage BRs performed with the assistance of porcine ADM (PADM).

**Methods:** A single centre, retrospective, cohort study was designed from December 2008 to October 2012. A total of 200 immediate implant-based BRs were performed using PADM for inferior pole reinforcement. We included non-irradiated BR with a minimum follow up of 6 month from primary surgery (one stage) or from explantation of expander and implantation of the definitive implant (two stage). Of the postoperatively irradiated BR we included patients with 1 year or more follow up time from termination of radiotherapy. CC was graded using the conventional Spear-Baker classification and modified version for irradiated BR. According to the literature Grade III and IV CC were defined as clinically significant CC.

**Results:** Of 200 BRs with PADM, 122 were included in this study (84 non-irradiated and 38 irradiated). Sixty-five BR were one stage and 57 were two stage BR. Grade III/IV CC was remarkable low in non-irradiated (6%) and irradiated BR (13%). There was a non-significant trend to increased Grade III and IV CC in irradiated BR *vs.* non-irradiated BR (13% *vs.* 6%,  $P=0.216$ ). In this study follow up time ( $P<0.001$ ) and the stage of ADM reconstruction (two *vs.* one stage,  $P=0.022$ ) were significant risk factors for occurrence of grade III/IV CC on univariate analysis and remained significant for the follow up time ( $P=0.013$ ) and remarkable for the stages ( $P=0.093$ ) in multivariate analysis.

**Conclusions:** Our data support the current clinical evidence that ADM use in implant-based BR is associated with a reduced risk of CC when compared to the standard submuscular techniques in literature. The reduced risk is maintained in the setting of radiotherapy. Two stage procedures in our study population showed increased grade III/IV CC compared to one stage procedures with or without exposure to radiation.

**Keywords:** Breast; acellular dermis; implant reconstruction

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## Introduction

Acellular dermal matrices (ADMs) are increasingly used in immediate implant-based breast reconstruction (BR) (1). Although originally intended to provide support and coverage of the breast lower pole, growing evidence suggests that ADM use may also mitigate the risk of capsular contracture (CC) (2-5).

CC is a significant complication in implant-based reconstructions, with a cumulative incidence of 6–18%, over a 3–6-year period reported in core clinical studies of implant manufacturers (6-8). In contrast, ADM-assisted reconstructions have consistently been associated with CC rates of <5%, albeit a shorter follow-up period of 0.6–2.4-year (9-15) is reported. Mechanistic studies in animal models as well as human histopathologic studies suggest a reduction or delay in capsule formation in the presence of ADM as a possible explanation for the reduced occurrence of CC (5,16-18).

External beam radiotherapy (EBRT) is a recognised risk factor for CC and CC rates of 15–50% have been reported in standard submuscular reconstructions without the use of ADM (19-24). Given the rising trend of immediate implant-based BR following mastectomy before the need for radiotherapy is fully determined, there is an increasing need for novel measures to reduce CC risk in this patient group. Because ADMs appear to mitigate the risk of CC, the natural question is whether these matrices also reduce the risk in the setting of radiotherapy. Data on the incidence of CC in the setting of radiotherapy in ADM-assisted reconstructions are, however, limited with short follow up times (9,12,13,18,24-28). Salzberg recently published a long-term follow-up (13 years) with low CC rate even after radiotherapy (1.9%) when ADM is used in one-stage implant based BR (28). The purpose of this study was to compare CC rates in non-irradiated and irradiated porcine acellular dermal matrix (PADM)-assisted one- and two-stage immediate implant-based BR.

## Methods

This is a retrospective cohort study performed from December 2008 to October 2012 at Guy's and St Thomas's Hospitals, London. During this period, 149 patients (200 reconstructions) who underwent immediate, implant-based BR with the assistance of PADM with or without radiotherapy were identified.

Our operative technique of using PADM (Strattice™, LifeCell Corporation, Branchburg, NJ, USA) has been

previously described (29). Briefly, mastectomy was performed via a skin-sparing or nipple-sparing approach by breast surgeons in attendance of the plastic surgeon. Following mastectomy, the pectoralis major muscle was elevated and a subpectoral pocket was created using standard techniques. PADM was rinsed in antibiotic solution prior to insertion. The inferior border of PADM was sutured to the chest wall along the inframammary fold, extending medially and laterally. A silicone cohesive gel implant (one stage) or tissue expander (two stage) was placed into the pocket and the upper border of PADM was sutured to the inferior border of the freed pectoralis muscle in a sublay technique resulting in closure of the pocket. Extra care was taken to avoid creases or folds of the PADM and dead space between the PADM and host tissue. Two drains were placed, one in the pocket and the other subcutaneously along the inframammary fold. If axillary clearance was performed, a third drain was placed in the axilla. All drains were removed after drainage was reduced to <30 mL over 24 h. Typically, prophylactic intravenous antibiotics were commenced 30 min prior to surgery, which was followed by 3 additional intravenous doses and then switched to oral antibiotics, which were continued for 5 days.

In one stage procedures, a definitive implant was placed at the same operative step as mastectomy was performed. In the two stage procedures, an expander was placed at first step (critical skin flap perfusion, surgeons' preference, patients wish for larger breast size), followed by weeks of expansion to the desired breast size.

Adjuvant anthracycline or anthracycline/taxane based chemotherapy given over 6–8 cycles generally started 4 weeks postoperatively (one stage) or after completion of expansion (two stage) when no wound healing problems were present. In a neoadjuvant chemotherapy setting a time slot of 3–6 weeks was maintained before mastectomy and reconstruction. Adjuvant radiotherapy was initiated at a minimum of 3 weeks following completion of chemotherapy or surgery. External beam irradiation to the chest wall comprised 40 Gy in 15 fractions delivered using tangential 6 and/or 10MV photon beams. In two stage procedures EBRT and chemotherapy were started after completion of expansion and the exchange for the definitive implant was performed after completion of chemo/radiotherapy in all cases.

We included patients with a minimum postoperative follow up of 6 months after insertion of implant in one-stage procedures and after exchange of expander for definitive implant in two-stage procedures in non-irradiated

**Table 1** Patient demographics and clinical characteristics

Variables	Data
Patients	96
Breast reconstructions (BR)	122
Follow up, median [range] (months)	26.5 [6–51]
Age, mean $\pm$ SD (years)	47.5 $\pm$ 11.4
BMI, mean $\pm$ SD (kg/m <sup>2</sup> )	25.4 $\pm$ 4.4
Mastectomy	
Breast weight available	91
Breast weight >600 g (% of BR)	31 (34.0)
Current tobacco use (% of patients)	12 (12.5)
Diabetes (% of patients)	2 (2.2)
Neoadjuvant chemotherapy (% of patients)	12 (12.5)
Adjuvant chemotherapy (% of patients)	35 (36.5)
Chemotherapy for contralateral breast cancer (% of patients)	3 (3.2)
Irradiation (% of BR)	38 (31.5)
No Irradiation (% of BR)	84 (68.9)

BR. Irradiated BR were included with a minimum follow up time of one year from completion of radiotherapy.

### Data collection and analysis

Patient demographic data including age, body mass index, diabetes, current tobacco use, chemotherapy (neoadjuvant or adjuvant) and radiotherapy use were collected from hospital records. Clinical examination and classification of CC was performed in the outpatient clinic by the first author only (AML who was not involved in the surgery). CC was graded using the conventional Spear-Baker classification for non-irradiated breasts (30). A modified version of this classification in irradiated breasts (26). Grade III and IV CC were determined as clinically significant CC according to the literature.

All complications occurring during the follow-up period specified above were recorded. Complications and Grade III/IV CC rates were analysed using a Generalized Estimating Equations (GEE) model (31). This model accounts for potential inpatient correlation of results. If due to low cell sizes a GEE model could not be fitted rates were compared using Fisher's exact test. Exact confidence

intervals for rates and rate differences were calculated assuming a binomial distribution. A value of  $P < 0.05$  was considered significant.

### Results

Over a 4-year period, 149 patients underwent 200 PADM-assisted immediate implant-based BR. A total of 177 reconstructions met our inclusion criteria (>6-month follow-up after the last procedure in non-irradiated breasts and >1-year follow-up after radiotherapy in irradiated breasts). Of the 177 reconstructions, 55 were excluded because 28 were switched to autologous reconstruction or had implant loss (infections, skin flap necrosis, patients wish) and 27 were lost to follow up. The remaining 122 reconstructions were included in this study. Eighty mastectomies were performed for oncological reason, 42 were risk-reducing mastectomies in BRCA positive patients. Sixty-five were one-stage (direct to implant) and 57 two-stage procedures. In 84 BR, no radiotherapy had to be administered, 38 BR underwent postoperative radiotherapy. Patient demographics are summarized in *Table 1*.

Patients were followed for a median of 26.5 months (range, 6–51 months). During this time, complications occurred in 32 breasts for a total complication rate of 26%. Complications included, 14 seromas (11.5%), 6 haematomas (7.3%), and 10 grade III/IV CC (8.2%) and 3 others (2.4%) (1 small skin necrosis, 1 implant rotation, 1 moderate wound healing problem).

When stratified by radiotherapy use, total complication rate and CC rate was numerically higher 12 (31.6%) *vs.* 20 (23.8%), but not significantly higher ( $P=0.535$ ), in irradiated breasts (*Table 2*). Patient demographics (age) and clinical characteristics (BMI, tobacco use, diabetes, breast weight) were similar between the irradiated and non-irradiated groups (*Table 3*). Mean follow up was significantly longer (31.8 months) in irradiated versus non-irradiated breasts (22.2 months) due to the inclusion criteria (follow up time in irradiated BR at least >1 year of termination of radiotherapy, compared to minimum 6 months postoperative in non-irradiated BR). A significantly higher percentage of breasts in the irradiated group had mastectomy weights >600 g. Treatment with neoadjuvant and adjuvant chemotherapy was also significantly higher in irradiated breasts (*Table 3*).

When stratified by one- *vs.* two-stage procedures, overall complications were similar between the groups while seroma and hematoma were numerically higher and

**Table 2** Complications in irradiated versus non-irradiated breasts

Complication	Non-irradiated breasts (n=84) (%)	Irradiated breasts (n=38) (%)	P value (univariate GEE model)
Total complication	20 (23.8)	12* (31.6)	0.535
Seroma	10 (11.9)	4 (10.5)	0.689
Haematoma	4 (4.8)	2 (5.3)	0.903
CC (grade III/IV)	5 (6.0)	5 (13.2)	0.216
Other	2 (2.4)	1 (2.6)	0.553

\*, haematoma and seroma occurred in one breast. CC, capsular contracture.

**Table 3** Patient demographics and clinical characteristics stratified by radiotherapy use

Demographics, clinical characteristics	Non-irradiated (patients =58; breasts =84)	Irradiated (patients =38; breasts =38)	P value
Follow up, median [range] (months)	21.0 [6–51]	33.3 [12–47]	<0.001*
Age, mean $\pm$ SD (years)	48.7 $\pm$ 11.9	46.7 $\pm$ 10.5	0.208**
BMI, mean $\pm$ SD (kg/m <sup>2</sup> )	24.9 $\pm$ 3.2	26.1 $\pm$ 5.5	0.221**
Mastectomy			
Breast weight available	64	27	
Breast weight >600 g (% of breasts)	17 (26.6)	14 (51.9)	0.029***
Current tobacco use (% of patients)	6 (10.3)	6 (15.6)	0.534***
Diabetes (% of patients)	1 (1.7)	1 (2.6)	1.000***
Neoadjuvant chemotherapy (% of patients)	1 (1.7)	11 (29.0)	<0.001***
Adjuvant chemotherapy (% of patients)	13 (22.4)	22 (57.9)	<0.001***

\*, Wilcoxon rank sum test; \*\*, *t*-test; \*\*\*, Fisher's exact test.

**Table 4** Complications in one versus two-stage procedures

Complication	One stage breasts (n=65) (%)	Two stage breasts (n=57) (%)	P value (univariate GEE model)
Total complication	17 (26.2)	15* (26.3)	0.837
Seroma	10 (15.4)	4 (7.0)	0.179
Haematoma	4 (6.2)	2 (3.5)	0.501
CC (grade III/IV)	1 (1.5)	9 (15.8)	0.022
Other	2 (3.1)	1 (1.8)	0.924

\*, haematoma and seroma occurred in one breast. CC, capsular contracture.

CC significantly lower in one-stage procedures (1.5% vs. 15.8%,  $P=0.022$ ) (Table 4). There was no difference in patient demographics and clinical characteristics between the two groups, except for adjuvant chemotherapy and adjuvant radiotherapy use, which was significantly higher

in two-stage procedures (Table 5). Average follow-up was significantly longer in two-stage procedures (31.0 vs. 21.6 months,  $P<0.001$ ) because of increasing numbers of one-stage procedures toward the end of the study period. The higher rate of CC in two-stage procedures was seen in

**Table 5** Patient demographics and clinical characteristics stratified by one- versus two-stage procedures

Demographics, clinical characteristics	One stage (breasts =65; patients =46)	Two stage (breasts =57; patients =50)	P value
Follow up, median [range] (months)	21.6 [7–51]	31.0 [6–47]	<0.001*
Age, mean ± SD (years)	47.6±10.9	47.4±12.0	0.922**
BMI, mean ± SD (kg/m <sup>2</sup> )	24.7±3.3	26.0±5.0	0.173**
Mastectomy			0.081***
Breast weight available	50	41	
Breast weight >600 g (% of breasts)	13 (26.0)	18 (43.9)	
Current tobacco use (% of patients)	5 (10.9)	7 (14.0)	0.762***
Diabetes (% of patients)	0	2 (4.0)	0.496***
Neoadjuvant chemotherapy (% of patients)	5 (10.9)	7 (14.0)	0.762***
Adjuvant chemotherapy (% of patients)	11 (23.9)	24 (48.0)	0.020**
Adjuvant radiotherapy	11 (23.9)	27 (54.0)	0.003***

\*, Wilcoxon rank sum test; \*\*, *t*-test; \*\*\*, Fisher's exact test.

**Table 6** Grade III/IV capsular contracture stratified by irradiation and stage

Statistics	Nonirradiated		Irradiated	
	One stage	Two stage	One stage	Two stage
Breast	54	30	11	27
Rate of CC (%)	1.9	13.3	0.0	18.5
95% CI (%)	0.0–9.9	3.8–30.7	0.0–28.5	6.3–38.1
P value	0.070*		0.295**	

\*, GEE model; \*\*, Fisher's exact test.

**Table 7** Exploration of risk factors for the occurrence of grade III/IV capsular contracture (grade III/IV) using univariate GEE model analyses

Risk factor	Odds Ratio	95% CI	P value
Stage (two vs. one stage)	11.74	1.43–96.12	0.022
Irradiation (yes vs. no)	2.29	0.62–8.49	0.216
Chemotherapy (yes vs. no)	2.00	0.53–7.51	0.304
Follow-up	1.11	1.05–1.17	<0.001
Age	1.02	0.97–1.07	0.471
BMI	1.11	0.96–1.27	0.145
Breast weight	1.001	0.999–1.003	0.265
Smoker (yes vs. no)	0.91	0.11–7.72	0.927

**Table 8** Exploration of risk factors for the occurrence of grade III/IV capsular contracture (grade III/IV) using multivariate GEE model analyses for factors significant in univariate models

Risk factor	Odds ratio	95% CI	P value
Stage (two vs. one stage)	6.55	0.73–58.52	0.093
Follow-up	1.10	1.02–1.18	0.013

both irradiated and non-irradiated breasts (*Table 6*).

The univariate analysis for exploration of risk factors of the occurrence of clinical CC (Grade III/IV) showed two significant risk factors in this study: follow up time ( $P<0.001$ ) and stages ( $P=0.022$ ) (*Table 7*). Irradiation and chemotherapy did not point out as significant risk factors, neither BMI, age, breast size or smoking.

On the multivariate analysis combining follow up time and the stages (*Table 8*), the follow up time kept a significant ( $P=0.013$ ) influence on occurrence of CC in this study. The two-stage procedure remained a strong risk factor for development of CC ( $P=0.093$ )

## Discussion

CC is a significant complication of implant-based, BR with unpredictable occurrence and recurrence despite treatment. The aetiology of CC remains unclear but recent evidence suggests a bacterial infection trigger for

the inflammatory response that characterizes CC (32). There are no known specific preventive measures for CC but technical considerations such as antibiotic breast pocket irrigation (33), use of textured implants (34), and subpectoral placement of implants (35) have all been shown to reduce the risk of contracture. A growing body of evidence indicates that the use of ADM may provide another means to reduce the risk of CC (2-5,9-15).

Radiotherapy is considered as one of the most important factors that augment the risk of CC. In the absence of radiotherapy, the rate of clinically significant CC (Grade III/IV) varies from 0–20% in standard submuscular BR without the use of ADM. In the presence of radiotherapy, the rate increases to 15–50%, which is an approximately 4-fold increase (19-24). The need for subsequent irradiation is, thus, often considered as a relative contraindication for implant-based BR. Radiation-induced CC is undoubtedly detrimental to the aesthetic appearance of the implant-enhanced breast.

Data on the rate of CC in ADM-assisted reconstructions in the setting of radiotherapy are limited. In the published studies the contracture rate varied between 0–60% (9,12,13,18,24-28) and 0–3% for non-irradiated breasts (12,25,26).

In the present study using PADM for lower pole reinforcement, we found a low rate of clinically significant CC (grade III/IV) in both non-irradiated (6%) and irradiated (13%) immediate implant-based BR, although the rate was 2-fold higher in the irradiated group. The median follow up was almost 2 years in the non-irradiated group and almost 3 years in the irradiated group, suggesting that the low risk of CC with ADM use is at least maintained over medium term.

The findings of this study have been attenuated by the fact that the longer follow up time after primary surgery (one stage) or after exchange of the expander for definitive implant (two stage) the higher risk for occurrence of high grade CC was found. This fact suggests a further increase in CC in long term. On the other hand, Salzberg in his recent study found CC, when ADM was used, did appear during the first 2 years postoperatively and was described as an early event in ADM based reconstructions (28). Nevertheless, there is a need for more large series with long follow up times and comparison to non-ADM reconstructions to strengthen the findings.

Regardless a significant increase in occurrence of CC was found in expander based traditional (two stage) procedures compared to direct to implant (one stage) reconstructions ( $P=0.022$ ). In the multivariate analysis, this trend was maintained after clearing for the effect

of follow up time ( $P=0.093$ ) and hasn't been described in literature to our knowledge. Two-stage procedures provide the opportunity to perform capsulectomy at the time of exchange of the expander (which eventually also was exposed to chemo/radiotherapy) for the definitive implant. Therefore, it is generally believed that two stage procedures are associated with a lower incidence of CC. Our results seem to contradict these general expectations. It is imaginable that tissue expansion in itself increases scar tissue/capsule formation similar to callus formation during healing of fractures. The repetitive trauma of expansion, tension and weakening of the skin flap may have created an environment for an exaggerated tissue response to the implant, which may explain the higher rate of contracture in our series.

This study is limited by its retrospective nature, the small number of reconstructions in the irradiated group, and the absence of a non-ADM group and the relatively short follow up times. Nevertheless, compared to published CC rates with similar follow up times, our rates are substantially lower, suggesting that PADM use is associated with a reduced or delayed risk for CC and could tribute to longevity of the reconstruction result. In addition, this study points out the importance of follow up times concerning occurrence of CC and suspects expansion to trigger CC.

## Conclusions

Our data support the current clinical evidence that ADM use in implant-based BR is associated with a reduced risk of CC when compared to the standard submuscular techniques in literature. The reduced risk is maintained in the setting of radiotherapy. Two stage procedures in our study population showed increased grade III/IV CC compared to one stage procedures with or without exposure to radiation.

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## Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

*Ethical Statement:* Statement of institutional review board approval and/or statement of conforming to the

Declaration of Helsinki. This study was approved by the local Institutional Review Board.

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