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Complications and Cosmesis in Immediate Breast Implant Reconstruction in the Setting of Post Mastectomy Radiation Therapy

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Abstract

Background and objectives: Post mastectomy radiation therapy (PMRT) is integral for oncological safety in patients of high-risk category, and breast reconstruction has posed significant challenges for PMRT planning in these patients. Our study explores the cosmetic outcomes and complications of PMRT on breast implants. We compared patient demographics, tumour characteristics, implants and radiation protocol to identify risks for complications and cosmesis.

Methods: The study was conducted on 86 patients who had undergone nipple/skin sparing mastectomy with immediate implant reconstruction. Cosmesis was evaluated in patient's perspective by using BREAST-Q questionnaire and the complication rates were assessed by rate of hospital admissions and repeat surgeries for implant related issues.

Results: Seroma and capsular contracture were the commonest early and delayed complications respectively. Additional scar boost caused higher rate of necrotic complications and implant loss. Axillary dissection and adjuvant chemotherapy significantly influenced PMRT related implant complications. Cosmetic outcome and patient satisfaction were desirable in over 75% of the patients, affirming the benefits over risks of PMRT.

Conclusion: PMRT related implant complications can be minimised with highly desirable cosmetic outcomes, by proper patient selection, case-by-case tailoring of radiation and good interdisciplinary management.

Keywords: Post mastectomy radiation therapy; Immediate implant reconstruction; Cosmetic outcome; Capsular contracture

Introduction

Breast cancer has become the commonest cancer in females in 2023 with a staggering 12.5% of all new cancers diagnosed worldwide. Until the 1990s, radical mastectomy used to be the only surgical treatment for breast cancer regardless of the age of the patient and stage of the disease. The surgical concepts in mastectomy have come a long way from the radical concept of Halstead to the recent skin sparing and nipple sparing mastectomies which emerged in the 90s [1]. Although breast conserving surgeries have further changed this trend, some patients with locally advanced malignancies or multi-centric disease still end up undergoing total mastectomy. These procedures affect the psycho-social health of the patients creating a huge negative impact.

The attempts to address this important aspect of quality of life by improving the aesthetics of reconstruction were revolutionized by the introduction of implants and tissue expanders [2]. Despite the several advances in the field

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ranging from 250-650 cc. Single negative pressure drain of size 15Fr was placed in the cavity and kept for 2-3 days. The patient was kept on prophylactic antibiotics for 5 days.

All the patients were explained the need for adjuvant radiation therapy based on the initial clinical and pathological criteria. The radiation is started at least 6 weeks after the surgery in case of neoadjuvant chemotherapy given or 4 weeks after the last cycle of chemotherapy where the patient has taken adjuvant treatment. The patients were treated ZLWK D VLQJOH SKDVH PRGLȩHG WDQJHQWLDO 90$7 EDVHG SODQ (Volumetric modulated arc therapy) and treated to a dose of 45-50 Gy in 25 fractions over a period of 5 weeks. Left sided breast cancer patients were treated with gating techniques (Active Breathing Coordinator (ABC gating) or Surface guided Voluntary Breath hold techniques). There was no bolus used. But scar boost in the form of 10 Gy in 8 fractions was planned in patients, either with positive/close margins OHVV WKDQ PP>@UWKRVH ZLWK LQLWLDO VLJQLȩFDQW VNLQ involvement (cT4b) who eventually underwent neoadjuvant chemotherapy and skin sparing mastectomy. The radiation therapy plan assessment was done as per the standard international guidelines to assess VMAT treatment plans. Utmost care was taken to avoid large hotspots (> 1.5 sq.cm) DURXQGWKHLPSODQWFDSVXOHVNLQÀSVDQGWRHQVXUHDGHTXDWH residual breast tissue coverage on a case-to-case basis. No FRQFXUUHQWVVWHPLFWKHUDSLVRuHUHGLQWKHVHSDWLHQWVZKLOH radiation treatment is on, except aromatase inhibitors and single agent Anti Her-2 therapy.

Statistical methods

SPSS v 26.0 (IBM, SPSS Inc.) and MedCalc v 22.0 were used for statistical analysis. Descriptive statistics were used to compute the frequency, percentages for categorical data and mean ± standard deviations for continuous data. Chi-VTXDUH WHVW ZDV XVHG WR DVVHVV WKH VWDWLVWLFDO GLuHUHQFH LQ frequencies for categorical data. Standard t-test and Mann-Whitney test/ Kruskal-Wallis test was used to assess the VWDWLVWLFDO GLuHUHQFH LQ FRQWLQXRXV GDWD DFURVV WKH JURXSV Binary logistics regression was used to compute the odds ratio associated with the outcome. All the tests were two tailed and DSYDOXHZDVFRQVLGHUHGVWDWLVWLFDOOVLJQLȩFDQW

Results

Out of the 171 patients who underwent skin or nipple sparing mastectomy with immediate implant reconstruction in our center during the study period, 122 patients were LGHQWLȩHGVDSWLHQWVZLWKEUHDVWFDQFHU7KHRVH[UHPDLQLQJ were done for prophylaxis in patients with high-risk genetic PXWDWLRQV 2I WKHVH SDWLHQWV ZHUH LGHQWLȩHG DV WKH study population, since they received PMRT to achieve loco regional disease control. The mean age of the study group was 46.3 ± 9.94 (mean ± standard deviation). Table 1 shows the various patient and tumor characteristics along with radiation and adjuvant treatment modalities employed.

The risk factors analyzed that could have a probable impact on the complications are listed in table 2. 29 patients in the study group were diabetic, among which 27.6% developed

Table 1: Patient and tumor characteristics

Patient and tumor factors/ Adjuvant therapy	Number of patients
Diabetes	29 (33.7%)
Hypertension	46 (53.4%)
Obesity	6 (6.97%)
Histological type	
Invasive ductal carcinoma	75 (87.2%)
Invasive lobular carcinoma	7 (8.13%)
Other	4 (4.65%)
Molecular type	
ER/PR +, HER2 -	33 (38.3%)
ER/PR -, HER2 -	21 (24.4%)
HER2 +	32 (37.2%)
Tumor stage	
T1	5 (5.81%)
T2	46 (58.4%)
T3	33 (38.37%)
T4	2 (2.32%)
Implant type	
Smooth	74 (86.0%)
Textured	12 (13.9%)
Implant size	
250-350 cc	7 (8.13%)
350-450 cc	32 (37.2%)
450-550 cc	38 (44.1%)
550+ cc	9 (10.5%)
Nodal management	
Axillary sentinel lymph node biopsy	42 (48.8%)
Axillary clearance	44 (51.2%)
Radiation type	
To chest wall	59 (68.6%)
Chest wall with scar boost	27 (31.4%)
Adjuvant treatment	
Chemotherapy	36 (41.8%)
Immunotherapy	42 (48.8%)
Hormonal therapy	49 (56.9%)

Abbreviations: ER, Estrogen Receptor; PR, Progesterone Receptor; HER2, Human Epidermal growth factor Receptor 2; T, tumor staging; cc, cubic centimeter.

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infection requiring hospitalization and wound dehiscence or nipple necrosis requiring surgical intervention. Most of the study patients underwent reconstruction with smooth silicone implants and only about 14% had textured implants. The complications profile was, however, comparable in both cases. The molecular type of the tumor had no statistically significant effect on the cosmetic outcome. The two important parameters we found to have an impact on the final aesthetic outcome were axillary management and adjuvant chemotherapy (Figure 1). Patients who had undergone axillary dissection followed by PMRT were more susceptible to seromas and in turn, wound dehiscence, skin necrosis and infection (p value 0.015). From our data, we derived that adjuvant chemotherapy had a statistical significance to the occurrence of wound complications and implant failure (p value 0.047).

Association of complications with radiation plan

The analysis of complications was grouped according to radiation protocol used and classified as early and delayed. The early complications were seroma, wound dehiscence, infection, nipple/skin necrosis, and implant loss. These complications typically occurred within the 6 month follow up point post radiation. Only complex or chronic seromas requiring aspiration/ surgical drainage were included. We derived that most patients who developed seroma had taken scar boost (69.2%). The infected patients in the study were only those whose infection was documented by culture positive for pathogenic organisms or patients who required hospitalization for intravenous antibiotic therapy. Wound dehiscence and nipple necrosis were considered significant when the patient was managed surgically. This included procedures like wound resuturing, minor debridement, nipple excision, implant wash and return with wound closure. Implant loss was defined as the removal of implant due to any of the above-mentioned complications. Capsular contracture was considered a delayed complication and was the main contributor for cosmetic dissatisfaction at the end of 2 years. It was graded by Baker classification from grades I to IV, with most patients with grade I-II contracture. Grade III and IV contractures were managed with capsulotomy and implant repositioning. Table 3 shows the percentage of patients who developed complications with radiation to chest wall as compared to those who were given an additional scar boost.

Table 2: Cross tabulation of risk factors and complications.

Complications			
	Yes	**No**	**p value**
Diabetes			
Yes	8 (27.6%)	21 (72.4%)	0.179
No	3 (5.26%)	54 (94.7%)	
Implant type			
Smooth	13 (17.6%)	61 (82.4%)	1
Textured	2 (16.7%)	10 (83.3%)	
Molecular Type			
ER/PR+, HER2-	6 (18.2%)	27 (81.8%)	
ER/PR-, HER2-	3 (18.8%)	18 (81.3%)	0.9
HER2+	6 (14.3%)	26 (85.7%)	
Axillary Surgery			
SLNB	4 (9.5%)	38 (90.5%)	**0.015**
Axillary clearance	18 (40.9%)	26 (59.1%)	
Adjuvant chemotherapy			
Yes	11(30.5%)	25 (69.4%)	**0.047**
No	6 (12.0%)	44 (88.0%)	

Abbreviations: ER, Estrogen Receptor; PR, Progesterone Receptor; HER2, Human Epidermal growth factor Receptor 2; SLNB, Sentinel Lymph Node Biopsy. Bold values are statistically significant p<0.05.

Regression analysis

Logistics regression revealed that patients who had chest wall radiation with a scar boost had higher odds of developing nipple necrosis (OR: 7.84, 95% CI: 1.19- 51.6, p= 0.03), infection (OR: 7.80, 95 % CI: 2.00-30.41, p= 0.003) and implant loss (OR: 23.0, 95 % CI: 2.32-223.8, p= 0.006), as depicted in figure 2. Although seroma was observed more in patients with scar boost and capsular contracture developed more commonly in patients without boost, statistical significance could not be derived from the analysis in our study population.

Logistics regression analysis showing probability of nipple necrosis, infection and implant loss being higher with additional scar boost as compared to radiation to chest wall only.

BREAST-Q scores comparison

The mean Breast-Q score was calculated by adding the scores for each individual patient at 4 points- just before the start of adjuvant radiation, at 6 months, 1 year and 2 years following PMRT and calculating the average. The BREAST-Q scores of the "satisfaction with outcome" domain was used for the study. For age groups ranging from 21-30, the mean score was 56.0 ± 2.82, For 31-40 years, it was 71.62 ± 4.19, and for 41-50 years, it was 76.18 ± 2.90. The ages ranging from 51-60 and 61-70 had significantly higher breast-Q scores (85.93 ± 1.86 and 89.83 ± 2.78 respectively) (Figure 3).

The mean Breast-Q scores of the PMRT group were

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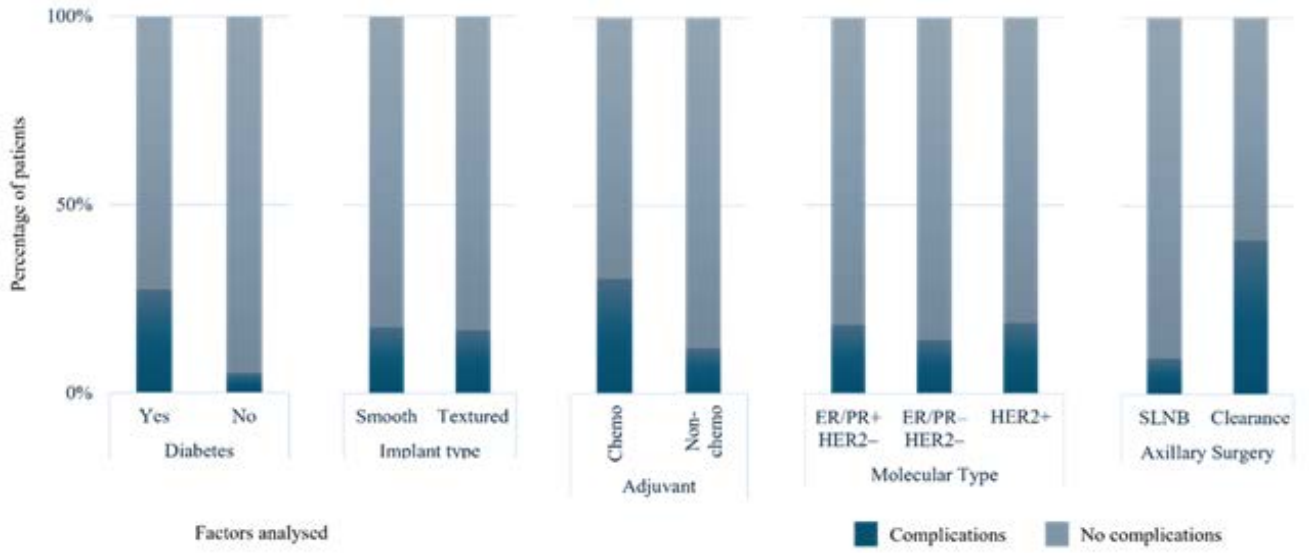

Abbreviations: ER, Estrogen Receptor; PR, Progesterone Receptor; HER2, Human Epidermal growth factor Receptor 2; SLNB, Sentinel Lymph Node Biopsy.

Figure 1: Complications in relation to patient factors, tumor characteristics and management.

Table 3: Type of radiation and complications.

	Type of radiation		
	Chest wall	**Chest wall with scar boost**	**p value**
Capsular contracture	13 (86.7%)	2 (13.3%)	0.162
Wound dehiscence	8 (72.7%)	3 (27.2%)	0.426
Seroma	4 (30.8%)	9 (69.2%)	0.253
Nipple necrosis	2 (40.0%)	3 (60.0%)	**0.041**
Infection	5 (45.5%)	6 (54.5%)	**0.003**
Implant loss	1 (20.0%)	4 (80.0%)	**0.006**

Bold values are statistically significant p<0.05.

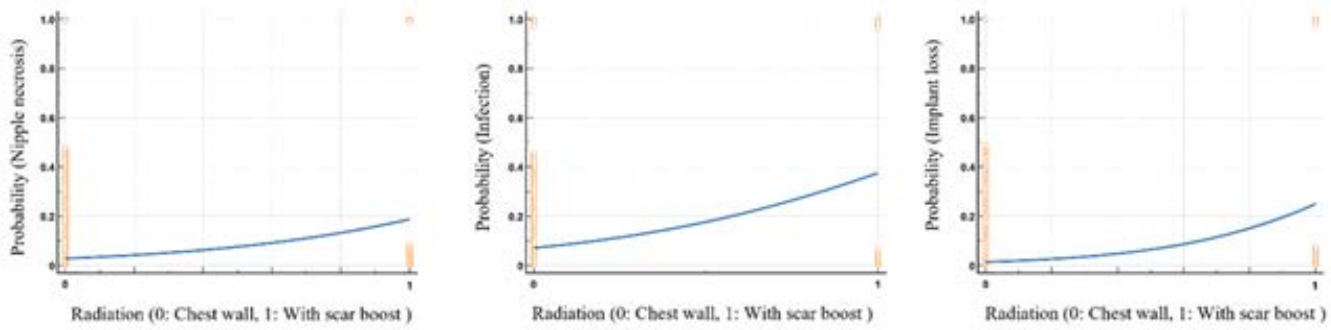

Figure 2: Association of complications with type of radiation.

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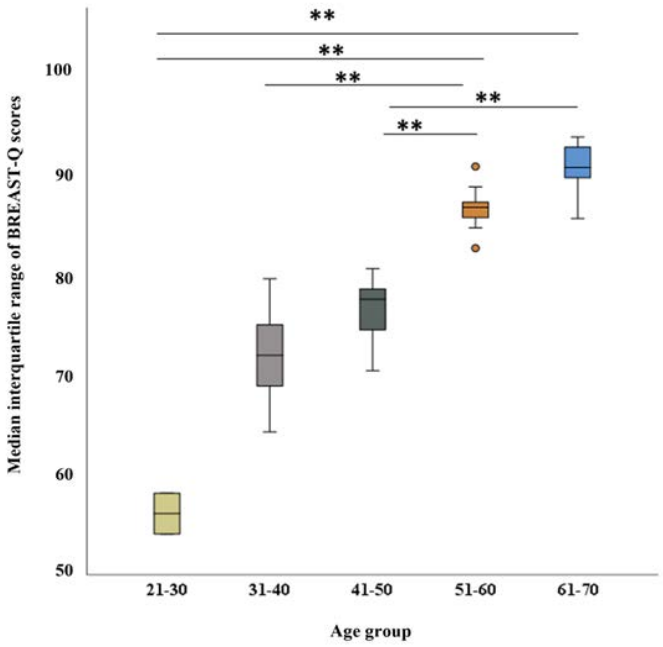
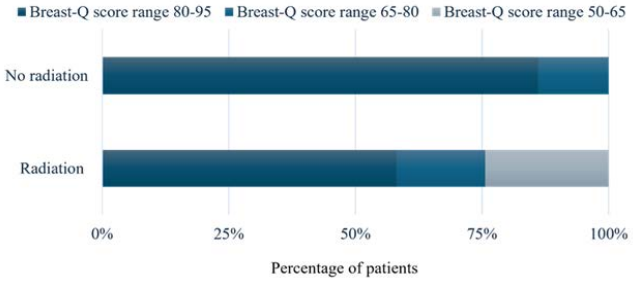


Box whisker plot showing BREAST-Q scores according to different age groups in the study population. ** signifies p-value <0.01.

Figure 3: Comparison of BREAST-Q scores across different age groups.



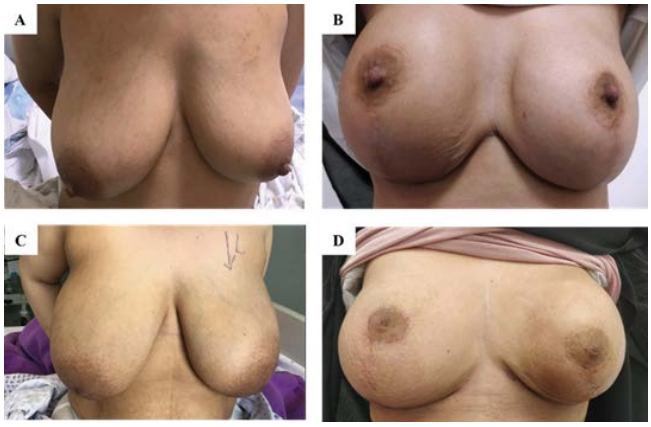
The BREAST-Q score of over 75% of patients in the PMRT group was comparable with those who did not receive any radiation post implant reconstruction.

Figure 4: Comparison of BREAST-Q scores in implant patients in radiation versus non-radiation groups.

compared with the 36 control patients who had not received adjuvant radiation following mastectomy with DTI reconstruction. Figure 4 shows the percentage of patients in the PMRT and non-PMRT groups in various BREAST-Q score ranges. The overall cosmetic outcome and patient satisfaction was comparable in over 75% of the patients, thus affirming that planning PMRT effectively in reconstructed breasts can lead to a decrease in expected complications and promote enhanced cosmetic outcomes. Representative images of our study patients two years post radiation after mastectomy with implant reconstruction are depicted in figure 5.

Discussion

Post-mastectomy breast reconstruction has been up



(A) Before bilateral nipple sparing mastectomy with implant reconstruction. (B) Two years after PMRT - BREAST-Q score over 90. (C) Before left nipple sparing mastectomy with implant reconstruction and symmetrization. (D) Two years after PMRT showing mild capsular contracture - BREAST-Q score between 70 - 80.

Figure 5: Patient images pre and post radiation therapy.

trending in the last two decades. A recent study in the United states has highlighted the increase in reconstruction rates from 14.7% in 2004-2005 to as high as 31.7% in 2012-2014 with an immediate implant based reconstruction of about 12.3% [13]. Another US based study pointed out that as of 2016, 40% of women who underwent mastectomy opted for reconstruction with almost 80% being implant based [14].

On reviewing the regional statistics, breast cancer occupies the first place in female cancers in Arab population, with Bahrain having the highest incidence [15]. Although breast cancer awareness campaigns are common, the percentage of cases diagnosed by screening is low. The patients tend to present with locally advanced tumors more often compared to Western countries. One of the key factors could be the cultural inhibition of Arab women to seek attention for breast disease. However, the mean age of patients with breast cancer is less compared to Western statistics. This could be the reason why the rate of breast conservation and the rate of utilization of breast reconstruction post mastectomy are comparable to the West [16].

Adjuvant post-mastectomy radiation therapy (PMRT) is considered the standard of care for all patients with intermediate or high-risk disease characteristics [17]. In our study, we observed that 70.49% of post mastectomy patients with IBR (Implant Based Reconstruction) received adjuvant radiation as part of their oncological treatment. There have been several studies analyzing the importance of adjuvant radiation in preventing local recurrence in post mastectomy setting [18]. However, it is also established in literature that radiotherapy following breast reconstruction with prosthesis is associated with a higher rate of reconstruction failure and increased rate of complications [19-21]. In radiotherapy,

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the high energy ionizing radiation acts by causing direct damage to DNA and the free radicals generated in the course, cause damage to protein and cell membranes. Although this phenomenon is beneficial in limiting cancer cells proliferation, the same effect on other rapidly proliferating cells like mucosa, skin and bone marrow can cause deleterious side effects. The acute adverse events may be as simple as erythema, desquamation or dryness to severe effects like bullae formation, skin necrosis and ulceration. The long-term effects include fibrosis, impediment to wound healing by inhibition of angiogenesis, telangiectasia formation and increased potential for carcinogenesis [22]. Some of these effects may last from 6 months to several years post radiation [21,22]. These effects pose significant challenges in breast reconstruction to the surgeons.

Our study features the subset of breast cancer patients who opted for immediate DTI (Direct-To-Implant) reconstruction following mastectomy. There are studies in literature to support that autologous breast reconstruction does better than implant based reconstruction (IBR) when subjected to PMRT [23]. It is hypothesized that immediate implant reconstruction can increase the flap tension, which in turn leads to more chances of flap necrosis, wound dehiscence and implant failure [6]. On the other hand, some studies have reported an increased risk of reconstructive failure in patients with tissue expander radiation compared to those with radiation to permanent implants. The aesthetic results with two-stage reconstruction were recorded to be slightly better with no difference in patient reported outcomes [24]. This being said, from the patient's perspective, the advantage of having a single procedure for implant reconstruction rather than a two-stage delayed reconstruction, cannot be overlooked. In our study, patients who had autologous breast reconstruction or initial reconstruction with tissue expander were excluded to maintain uniformity in the study population.

Age group, as a single factor, showed no apparent bearing on the final cosmetic outcome in our study. Cordoba et al showed a significant increase in the acute and late skin toxicity for radiation in older patients [25]. This was reflected to a certain extent in our study. However, when it comes to final cosmetic outcomes, we found that the older patients tend to be more satisfied compared to their younger counterparts with the same complications profile. This was corroborated by the significantly higher Breast-Q scores of the patients from 50-70 years age groups just prior to adjuvant radiation and at multiple points following radiation therapy.

With regard to patient factors like obesity (BMI>50), hypertension and diabetes mellitus, some scholars have documented an increased risk of implant complications [26,27] , but our study did not reveal any significant correlation between them and final outcome. Of all the patients who developed infection, 72% had diabetes mellitus and this could be seen as a potential risk. But overall, the number of diabetic patients in the group who developed infection is not significant (28%). Some correlation (33%) was noticed with obesity causing increased complications, but the number was too small to ascertain the association (2 out of 6 patients). Nevertheless, the observation that radiation induced skin toxicity increases with higher breast volume is well documented in literature [26]. Some studies have also recorded higher rates of reconstruction failure in hypertensive patients due to defective microcirculation [28].

With regard to breast implant type, although there is literature to show higher cosmetic satisfaction rates with silicone implants, there is no significant difference documented in complication rates between saline and silicone breast implants or between smooth and textured implants [29,30]. Our study features 14% of patients with radiation to textured implants and no statistical correlation was appreciated in end cosmetic results. The placement of implants, however, has a greater impact on PMRT induced side effects. Subpectoral placement is associated with higher likelihood of capsulorrhaphy and animation deformity. Prepectoral implants were noted to have more seromas and infections [30]. This comparison could not be made in our research as all patients in our study group underwent prepectoral implant reconstruction.

Another factor we studied with regard to PMRT related implant complications was the type and stage of the tumor. Although molecular markers of the cancer did not play a direct role in the development of complications, they still exerted an impact over the final cosmetic outcome by influencing the radiation dynamics. Triple-negative or poorly differentiated breast cancers and node positivity warrant adjuvant radiation [31]. The initial stage of the tumor has a bearing on determining the need for radiation, T3/T4 tumors due to possible close margins and extensive lymphovascular invasion being the usual indications for an additional scar boost [32]. In our study, 24.4% of the patients had triple negative cancers and 41% T3/T4 tumors. Most of the patients who developed seroma and implant loss had received chest wall irradiation and boost dose, making the higher T stage a likely contributing factor for this complication. The other important factor that led to unfavorable cosmesis was complete axillary dissection during surgery. Lin et al in their study demonstrated an increased skin thickness ratio (STRA) before, during and 1 year post radiation, in patients who received full axillary dissection [33]. This could be due to the lymphatic congestion that occurs in the breast after extensive axillary manipulation compounded by RT induced fibrosis. This in turn results in an adverse cosmetic effect in reconstructed breasts. Our study group consisted of 44 patients who had undergone axillary clearance, 41% of whom had at least one form of complication resulting in cosmetic dissatisfaction. Another less explored factor is the association between the type of incision and PMRT related implant complications. We used

inframammary or peri areolar reduction pattern incisions depending on the breast volume of our patients. It has been documented in literature that peri areolar incisions are more related to necrotic complications compared to inframammary or radial incisions [34,35]. We noticed that seromas were difficult and more chronic and late wound dehiscence post radiation were common in reduction pattern incisions where the same incision was used for axillary management. More studies are needed to reiterate this finding.

The idea of adjuvant chemotherapy influencing radiation effects on reconstructed breasts is debatable. It is accepted that chemotherapy causes immunosuppression and fat necrosis, which when combined with the flap ischemia and fibrosis caused by PMRT are risk factors for implant related complications [36]. Lam et al. showed in their study that prosthetic complications increased from 5.3% to 11.3% respectively, when adjuvant chemotherapy was given alone or when it was followed with radiation [19]. Yet, some studies have shown no definite correlation between the PMRT only or PMRT with adjuvant chemotherapy groups [37]. These analyses have led to the comprehension that PMRT and adjuvant chemotherapy could be independent risk factors for implant associated complications and therefore, poor cosmesis. In this study, 11 patients out of 36 who took chemotherapy along with adjuvant radiation developed at least one complication influencing the final cosmetic outcome.

Generally, as per the current standards of practice recommendations, patients undergo moderately hypo-fractionated regimens in adjuvant settings, with data showing equivalent late toxicity as compared to conventionally fractionated regimens. However, there is still a paucity of data when it comes to the use of moderate hypo-fractionation with respect to immediate reconstruction [31]. Conflicting reports of acute and late complications with moderate hypo-fractionation have been published [38,39]. Results from long term studies similar to the FAST-Forward trial are needed to establish the benefit of hypo-fractionation in PMRT setting. As far as scar boost is concerned, there is no consensus at present on how to handle positive superficial margins [31]. It was recently reported that 80% of local recurrences in NSM/SSM occur near the tumor bed, primarily on the skin or subcutis due to possible harboring of residual tumor cells in tissue left in NSM, while trying to preserve dermal lymphatics [40]. This was probably why scar boost was recommended as a standard to be combined with chest wall radiation to prevent local recurrence. But there are studies that demonstrated increased rates of infection, skin necrosis and implant failure, when boost was used in reconstructed breasts. Naoum et al also made the interesting observation that it did not improve overall local recurrence in high-risk groups [41]. In our study, we noticed higher odds of patients developing nipple necrosis and implant loss, when given scar boost, resonating with the idea of reserving boost only for inflammatory breast cancer and high-risk patients who did not opt for any reconstruction.

We acknowledge the limitations in our study. Firstly, some of the patients in the beginning of the study period received the regime of 45 Gy in 20-25 fractions with boost planned for close margins. As the study evolved, the regime was standardized to 50 Gy in 25 fractions and boost reserved only if margins were positive or significant skin involvement was present. Secondly, some patients towards the end of the study period were followed up only to the point of 6 months post radiation and this could have influenced the mean BREAST- Q scores. Literature review showed longer follow up period can better the cosmetic scores, as radiation induced fibrosis and chronic seromas would take longer to subdue [42]. Finally, the study was conducted and discussed in a surgeon's perspective, the focus being on cosmetic satisfaction as perceived by the patient. Hence, radiation parameters like determining Clinical target Volume (CTV), Planning Target Volume (PTV), distribution of radiation dose, possible hot spots were not analyzed and discussed in our study.

Conclusion

Several factors including the stage of the disease, type of implant reconstruction, axillary management, adjuvant therapy, radiation planning technique, post reconstruction implant shifts, and the wound healing process have an impact on the overall cosmetic outcome after immediate breast reconstruction. These factors, either independently or along with radiation therapy parameters, can contribute to implant failures in the long term and short term. So, good communication among the treating teams in selection of patients, patient counselling on anticipated complications, identifying comorbidities leading to poor wound healing and proper PMRT planning can benefit patients opting immediate implant-based reconstruction after mastectomy and lead to highly desirable cosmetic results, as outlined in our study.

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Conflicts of interest

The author(s) declare(s) that there is no conflict of interest regarding the publication of this article.

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