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The role of contouring guidelines in post mastectomy radiation therapy effectiveness: A case study of silicone implants and literature review of existing evidence

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Abstract

Post-Mastectomy Radiation Therapy (PMRT) in patients with silicone breast implants presents challenges regarding implant integrity. Hence, it is important to examine the implications of treating implants as organs at risk (OARs). A patient with bilateral breast cancer underwent mastectomies with LD flap and silicone implant reconstruction, followed by PMRT. ESTRO-ACROP guidelines were used for contouring, excluding the implant from the target volume. Despite receiving radiation, the implant remained intact during follow-up. The literature shows PMRT increases implant complication risks, but current guidelines lack specific implant dose constraints. Surgical techniques and radiation effects on silicone influence outcomes. This case highlights the potential for implant preservation with LD flap support, a scenario not fully addressed by existing guidelines. There's a need for refined guidelines considering implants as OARs with specific dose limits to improve outcomes in implant-based PMRT.

Introduction

Breast cancer management strategies have significantly evolved, yet the challenge of optimizing post-mastectomy radiation therapy (PMRT) persists. PMRT is a cornerstone of treatment for high- risk breast cancer patients. While PMRT plays a significant role in reducing the risk of local recurrence and improving overall survival [1], it also carries potential consequences for breast reconstruction outcomes [2]. Traditionally, radiation therapy planning focuses on sparing critical organs such as the heart, lungs, and contralateral breast, known as organs at risk (OARs), necessitating a strategic approach of irradiation to maximize therapeutic gain while minimizing adverse effects. For many women undergoing mastectomy, the placement of a silicon breast implant as part of reconstructive surgery has become a common practice. It has been noted that the breast reconstruction can improve the cosmetic effect and quality of life of patients after mastectomy, and more than 50% of breast cancer patients receive breast reconstruction after mastectomy [3,4]. However, the integration of post-mastectomy radiation therapy (PMRT) in patients with silicone implants presents unique challenges, particularly regarding the preservation of implant integrity and minimizing radiation-induced complications. One of the notable complications associated with PMRT is the increased likelihood of implant removal. Radiation can cause changes in the skin and underlying tissues, leading to complications such as capsular contracture, implant malposition, and chronic pain. Studies have shown that nearly 44% of women with locally advanced breast cancer who underwent mastectomy, reconstruction, and PMRT experienced unplanned implant removal [5,6]. A previous study has been reported that the exposure dose to breast implant is one important factor for capsular contracture [7]. A study revealed that the incidence of clinically relevant capsular contracture (Baker III–IV) was 22.9%, with a total occurrence of capsular contracture (Baker I–IV) in 47.5% of patients after a median follow-up of 22 months, high-

lighting the significant risk of this complication following post-mastectomy immediate breast reconstruction and radiotherapy (PMRT) (IBR) [8]. The reasons for implant removal vary, with infection, wound breakdown, and breast asymmetry being some of the most common causes [9]. This high incidence of implant removal post- PMRT underscores the importance of informed decision-making and setting realistic expectations for patients considering implant-based breast reconstruction. Recent research and development suggest that silicone breast implants should also be considered as an OAR, given the potential for radiation-induced complications, including capsular contracture, fibrosis, and implant deformation [7,10]. Another study highlighted that radiation therapy (RT) significantly increases the risk of permanent breast implant (PI) removal, with 22% of RT patients requiring PI removal compared to only 4% in non-RT patients, emphasizing the impact of RT on implant-based breast reconstruction outcomes [11]. Another study also corroborated the inclusion of implant during OAR delineation with a comparison of doses to the implant with V40, V50, Dmax, and Dmean as the exposure dose and volume to implant parameters. An implant-sparing approach called Helical-altered fractionation for implant partial omission (HALFMOON) reduced the radiation dose to the implant and OAR and optimized target coverage in patients with a sub-pectoral or pre-pectoral implant placement, resulting in a high-dose conformity of the target with a significant reduction of radiation dose delivered to implant [12]. Although the benefits of reducing exposure dose to breast implant are evident with a promising potential to reduce the risk of capsular contracture and IMRT's known suitability for its use in breast cancer after mastectomy and iBRT, there is a lack of proper guidance to identify the optimal irradiation technique to reduce the exposure dose to breast implant. This case report and accompanying literature review explore the implications of considering silicone implants as an OAR in the context of PMRT. European Society for Radiotherapy and Oncology and the Association of Clinical Oncologists of Radiation Oncology Physics (ESTRO-ARCOP) has developed several contouring guidelines. According to them, the target volumes for implant-based radiation the implant is not part of the clinical target volume (CTVp_chestwall), but it is also not considered an OAR (Organ at risk-- normal organs that need to be protected from radiation), implying that reducing dose to the implant is not considered a goal in itself and may be the cause of the implant toxicities. The guidelines did not indicate specific dose constraints for the implant [12]. This case report and literature review endeavour to synthesize the current knowledge and identify the optimal approach to PMRT that maximizes therapeutic benefits while safeguarding the integrity of OARs. By establishing a clear rationale for this review, we seek to contribute to the ongoing discourse and support evidence-based clinical decision-making in the management of breast cancer post-mastectomy.

Patient information: A premenopausal female presented at a hospital with complaints of bilateral breast lumps. She had no other symptoms.

Diagnostic assessment

Core biopsy from both breast lesions indicated invasive ductal carcinoma grade 2. The estrogenic receptors (ER) and Progesterone Receptors (PR) status were positive for bilateral lumps, and Human Epidermal Growth Factor Receptor 2 (HER2/neu) was 1+ score for the left lump and 3+ score for the right lump. Fine needle aspiration cytology (FNAC) from the left axillary lymph node was positive for malignancy.

Radiological Examination Mammogram revealed a spiculated lesion measuring 5 x 4.1 cm with micro-calcifications in the upper outer quadrant (UOQ) of the left breast. Another lesion measuring 3.4 x 3.6 cm was noted in the UOQ of the right breast, also with micro-calcifications. MRI of bilateral breasts showed a lesion measuring 3.0 x 2.4 x 2.5 cm in the UOQ of the right breast at the 9-11 o'clock position, BIRAD IVC, and another lesion measuring 5.0 x 3.7 x 6.9 cm in the central quadrant of the left breast at the 2-5 o'clock position, 8 cm from the nipple, BIRAD V. Both lesions demonstrated restricted diffusion on DWI images. PET CECT demonstrated FDG-avid enhancing lesions in the UOQ of both breasts, with associated skin thickening over the left breast. A few small FDG-avid lymph nodes were observed in left axillary levels I and II. No enlarged internal mammary or supraclavicular lymph nodes were noted. She was staged as cT4bN1M0 for the left breast and cT2N0M0 for the right breast.

Therapeutic intervention: She completed six cycles of neo-adjuvant chemotherapy and trastuzumab. Post-chemotherapy PET CT scan showed a complete response to treatment. She underwent a skin-sparing right modified radical mastectomy (MRM) with right axillary lymph node dissection (ALND) and a skin-sparing left MRM with left ALND, with bilateral latissimus dorsi (LD) flap reconstruction with silicone implants. An incision was made along the back of the bra line, and the LD muscle was harvested along with a skin paddle. This harvested muscle was then shifted to the breast defect site. The LD muscle was securely stitched to the chest wall, and a pocket was created for the implant between the LD muscle and pectoralis major muscle. A 305 silicone implant was placed into the pocket to address the skin defect. The remaining skin was carefully sutured to complete the reconstruction.

Histopathological examination post-surgery: Histopathological examination post-surgery showed two foci of invasive duct carcinoma of no specific type in the right breast. Ductal carcinoma in situ (DCIS) was seen, with lymph vascular space invasion (LVSI) and without skin or nipple-areolar complex involvement. The right breast was staged as ypT1bN0, ER/PR, and HER2 Positive. The left breast exhibited invasive carcinoma with high-grade DCIS and LVSI. One out of 14 lymph nodes showed micro metastasis, with no dermal or vascular invasion. The left breast was staged as ypT1cN1mi, ER/PR positive, and HER2 Negative. She continued with trastuzumab every three weeks with adjuvant hormonal therapy of tamoxifen. Her case was discussed at the Multi-Specialty Clinic and was planned for post-mastectomy radiation therapy (PMRT) to the left side chest wall and non-dissected axilla with the deep inspiratory breath-hold (DIBH) technique.

Post-mastectomy radiation planning: She underwent a computed tomography (CT) scan for radiation planning using a Siemens Som atom CT scanner. The scan was performed with the DIBH technique, with hands above her head, and intravenous contrast administered. A thermoplastic cast was used for immobilization, and the scan was acquired with a 3 mm slice

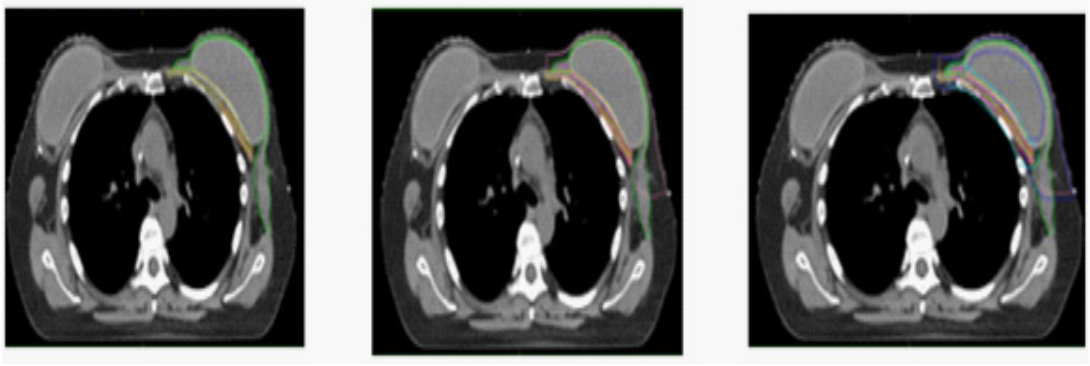

Figure 1: Contouring of the left chest wall and nodal areas and the implant.

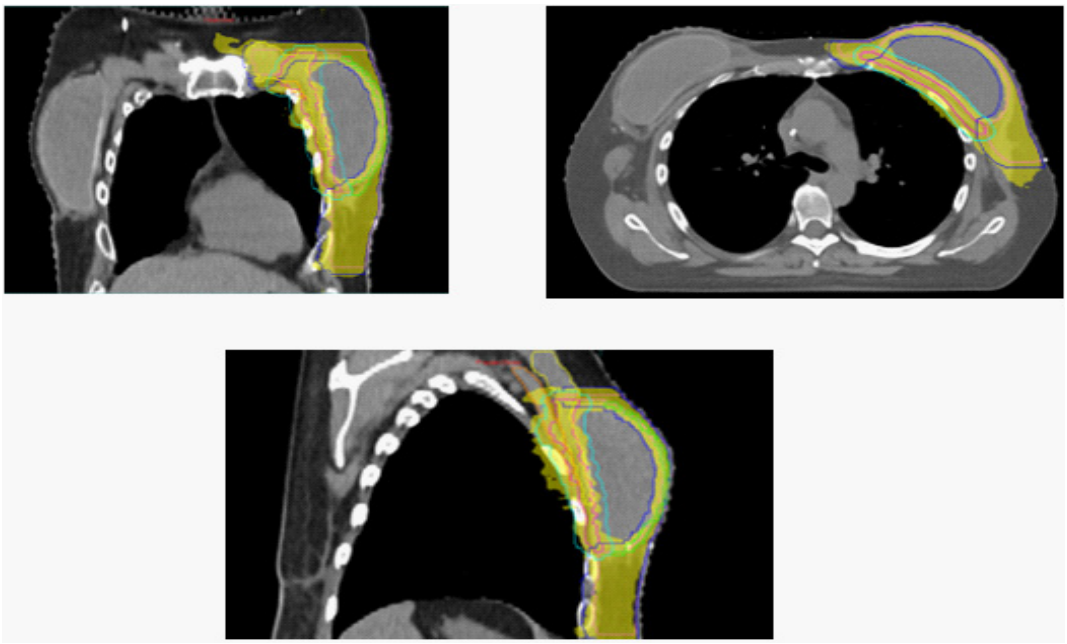

Figure 2: Dosimetry and colour wash of the left chest wall and nodal areas and the implant.

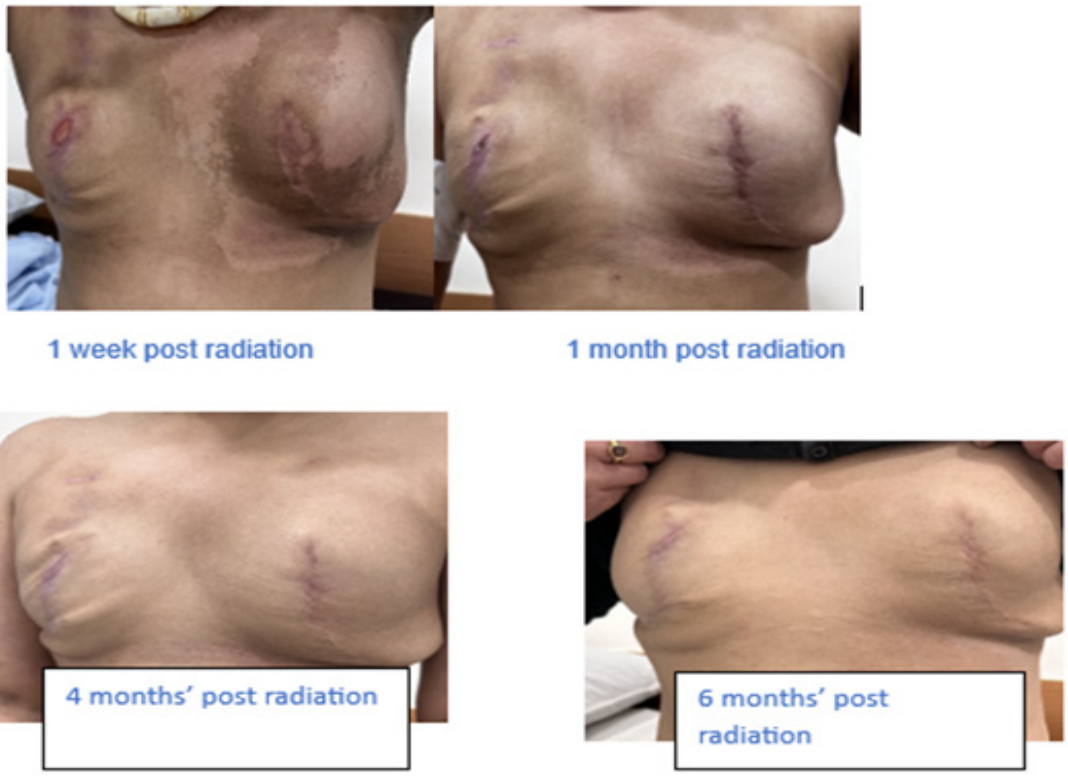

Figure 3: Follow-up at 1 week, 1 month, 4 months, and 6 months after post-radiation.

thickness. Target contouring was carried out following the European Society for Radiotherapy and Oncology (ESTRO) Advisory Committee for Radiation Oncology Practice (ACROP) consensus guidelines for post-mastectomy radiation therapy after implant-based immediate reconstruction for early breast cancer for pre-pectoral implant position. However, her reconstructive procedure differed from the scenarios described in the ESTRO ACROP guidelines, as LD muscle was used as a supportive material instead of synthetic mesh or bio-mesh as is usually used. The clinical target volume for the left chest wall (CTV-LCW) was defined to include both the ventral (CTV-LCW ventral) and dorsal (CTV-LCW dorsal) regions, encompassing the implant. The CTV-LCW dorsal included the pectoral muscles beneath the implant, covering residual glandular tissue, while excluding the ribs. The CTV-LCW ventral encompassed the tissue between the implant and skin, cropped 3 mm from the skin surface, covering subcutaneous lymphatics, residual glandular tissue, and the part of the LD muscle used to create the pocket for the implant.

Yellow colour wash is indicative of 95% of the prescribed dose. The medial-lateral extent of CTV-LCW ventral reached the dorsal contour (as shown in the figure) and extended 2 cm below the mammary fold. The medial extent of the CTV-LCW ventral was till the lateral perforating mammary vessel. The lateral extent was marked with the help of wires put clinically on the mid-axillary line and also where the LD muscle took a curve as seen on the planning CT scan. Cranial extent of CTV-LCW was the infraclavicular area and caudal extent was till 2 cm below the inframammary fold. The CTV-LCW ventral and dorsal excluded the silicone implant. The left supraclavicular fossa (SCF) was included in the treatment volume due to clinically node-positive disease. The CTV for the left SCF was delineated following Radiation Therapy Oncology Group (RTOG) guidelines. A planning target volume (PTV) margin of 5 mm was added to both CTV-LCW and CTV-SCF as per institutional protocol. She was planned to receive 50 Gy in 25 fractions to both the PTV and CTV (Lowenthal and Lawders) and the SCF, using Volumetric Arc Therapy (VMAT) with 3 partial arcs of 210 degrees, 30 degrees, and 30 degrees with 2 rotations with 6 MV photons on the Monaco Planning System (v6.1.2.0) with Monte Carlo algorithm with a grid size of 3 mm. Treatment was delivered on Elekta Accesses.

Dosimetry: The V95 coverage for CTV-LCW dorsal and CTV-LCW ventral was 98.6% and 93%, respectively, while the corresponding PTV V95 values were 86.4% and 86.9%. For the SCF, the V95 for CTV and PTV was 98.6% and 86.4%, respectively. Efforts were made to minimize the dose to the silicone implant, with a mean dose of 41.8 Gy and a maximum point dose (0.035 cc) of 54.3 Gy (108.6%). Volume receiving 20 Gy (V20) for the implant was 99.9%, V30 was 86.9%, V40 was 63%, V50 was 17.6%, and V55 was 0%. Doses to other organs at risk were within tolerance limits.

Adverse and unanticipated events: At the start of the treatment, she exhibited fair cosmesis due to suboptimal implant geometry and the absence of the nipple-areola complex. During the course of radiation therapy she was reviewed weekly in the OPD with hemograms and local examination of the treated skin and breasts. A grade 1 skin reaction as per CTCAE criteria was noted during the 2nd week of the treatment. By the third week, mild skin reactions Grade 2, were observed. She did not show any signs of acute radiation dermatitis or haematological toxicities. Importantly, there were no observed changes in the shape of the implant, no contracture, rupture, or removal of the implant, indicating that the implant remained unaffected by the radiation therapy. Intervention adherence and tolerability. It is to be noted that the intervention adherence at baseline was high, but by week 3, the patient missed one session, indicating a slight drop in adherence.

Follow-up: She was initially kept on 3-week follow-up with physical visits or Photographic reviews. At three-months and six months and eleven months follow-up post-radiation, she had no complaints. The radiation reactions had subsided. The integrity and cosmesis of the breast implants were preserved, highlighting the therapy's safety concerning both acute side effects and implant-related complications.

Discussion

Breast reconstruction following mastectomy is a critical component of breast cancer treatment, offering significant psychological and aesthetic benefits to patients. However, the integration of post-mastectomy radiotherapy (PMRT) presents unique challenges and considerations, particularly regarding the choice of reconstruction technique and the approach to the irradiation including the selection of the area of irradiation interest, timing, contouring pattern, and the dose limit. One of the key factors driving the clinical adoption of PMRT in real-world settings includes the recent status of PMRT related knowledge base. A Surveillance, Epidemiology, and End Results (SEER) data-based population-cohort study on women with stage I to III breast cancer undergoing mastectomy from 2000 through 2011 revealed that the change in the NCCN guidelines have gained clinical traction in PMRT recommendations among patients with tumors 5 cm or smaller and 1 to 3 positive nodes without an associated decrease in receipt of reconstruction [13]. The reconstructions of post mastectomy breast can be Implant-based or autologous based. Autologous implants use tissue from abdomen or back, while non autologous implants may be saline, silicone, gummy bear, round, smooth and textured implants, most popular of which are saline and silicone implants. Implant placement post MRM most commonly uses techniques such as pre-pectoral and sub-pectoral implant placements. Pre-pectoral placement of implant, gives advantage of preventing breast implant animation defect and less pain during recovery. As this implant is located above the pectoralis major muscle, any movement of breast as a result of arm movement doesn't impact appearance of implant. However, it is seen to have high risk of implant loss and skin rippling in thin skinned individual. Sub pectoral implant has less chances of implant loss as it is lies beneath the pectorals major and serratus anterior muscle providing an additional layer of vascularised tissue over implant and aesthetically it is superior to pre-pectoral but has more pain during recovery and more animation deformity [14]. The choice of surgical approach for implant placement significantly impacts the outcomes and complications associated with PMRT, including the choice of biomaterials, the positioning of a breast implant during immediate breast reconstruction, or the timing of reconstruction. For example, a retrospective study in 2019 reported that the use of acellular dermal matrix (ADM) was associated with an increased incidence of infections and seromas in both radiated and non- radiated cohorts due to increased inflammatory response and the need for larger surgical pockets which promotes bacterial colonisation [15]. Interestingly, within the radiated subgroup, the incidence of expulsion was significantly lower with ADM use, due to reinforcing the tissue coverage and reducing mechanical stress and fibrosis related implant expulsion indicating a potential benefit in reducing implant loss

despite higher complication rates. Another prospective observational study assessed bovine derived ADM and revealed minimal incidents of implant loss and a safe option with respect to PMRT [16]. Moreover, a largest prospective multi-center study on breast reconstruction outcomes demonstrated that autologous reconstruction provides better patient-reported outcomes and a lower risk of complications compared to implant-based approaches in patients undergoing postmastectomy radiation therapy (PMRT) mainly because autologous tissue are more resistant to the effect of radiation, and capsular contracture have been found to be less in these cases [5]. Although both pre-pectoral and retro-pectoral implant placement techniques facilitate optimal coverage of the chest wall with acceptable doses to the heart and lung from the PMRT perspective, many researchers have reported suboptimal implant outcomes associated with pre-pectoral and sub-pectoral placement approaches [17]. Another study assessing the surgical effectiveness of skin- preserving, staged, microvascular, breast reconstruction found it safe when considered with PMRT with an acceptable tissue expander loss [18]. A retrospective study in 2021 found a safe and effective alternative to conventional surgical approaches using lattisimus dorsi muscle flap (LDMF) as it provides vascularized tissue support [19]. Our case findings were found consistent with the same despite the use of both LD flap and the implant. This approach leverages benefits of autologous tissue coverage while maintaining volume and shape provided by an implant. LD flap acts like a protective soft tissue envelope that may improve the outcome. Besides surgical options influencing the implant outcomes associated with PMRT, the nuances of irradiation techniques also determine the fate of a breast implant through mechanical and biological effects. Mechanically, radiation exposure can degrade the polymeric structure of silicone. High-energy radiation, such as gamma rays or electron beams, induces chain scission or cross- linking in silicone polymers, leading to changes in elasticity, brittleness, or surface integrity. Prolonged exposure may cause cracks, discoloration, or loss of structural stability, impacting the implant's durability. Biologically, irradiation can alter the implant's interaction with surrounding tissues. Radiation may enhance oxidative stress, creating reactive oxygen species (ROS) that affect the biocompatibility of silicone. These biomaterial alterations have potential implications on capsular contracture, as changes in surface properties and tissue interactions may exacerbate fibrous capsule formation and contracture severity. Also, it is to be noted that the size of the PTV is mostly defined by the implant size and the respective anatomy of the patients. A larger implant implies a larger surface area, which may also increase the risk of capsular contracture [8]. Moreover, a prospective multicentre cohort study reported the worsening of Patient reported Outcomes (PROs) following PMRT, highlighting the need for a guideline for dose constraint to the silicone and thereby improving the cosmetic outcomes [20]. We tried to adhere to the ESTRO-ACROP guidelines. Although they do advocate a full understanding of the surgical procedure, to predict disease spread in each individual case to decide on contouring the CTVp_chestwall, the procedure of the implant done in our case (creating a pocket for the implant) has not been discussed in any of the guidelines, indicating the key strength of our case. The dose constraints applied to the implant in our case, seems to have been well tolerated, but need validation through more studies. Moreover, our case explores a robust framework for defining the target volumes for implant-based radiation therapy. The guidelines specify that the implant is neither a part of the CTVp_chestwall nor considered as an organ at risk (OAR) [21]. Minimizing radiation exposure to breast implants during radiotherapy may reduce complications. While newer techniques protect the heart and lungs, their impact on breast complications after reconstruction remains unclear, implying there remains limited clinical attention to the reducing the dose to the implant. A notable limitation is that the ESTRO-ACROP guidelines do not address specific dose constraints for the implant. The guidelines also advocate for a comprehensive understanding of the surgical procedure to predict disease spread and accurately contour the CTVp_chestwall. This case study demonstrated an effective technique for the breast reconstruction followed by PMRT with minimal adverse events, the surgical procedure involved creating a pocket for the implant, a technique not explicitly covered by the guidelines. This potentially contributed to the lack of implant-specific dose constraints, which could be a factor in implant toxicities. This gap highlights the need for more detailed guidelines that consider the nuances of various surgical procedures and their implications for radiation therapy.

Conclusion

In summary, this review and case study highlight the critical factors influencing implant-based breast reconstruction in patients undergoing Post-Mastectomy Radiotherapy (PMRT). Key findings include the significant role of surgical techniques, such as implant placement and the use of Acellular Dermal Matrix (ADM), in influencing post-PMRT outcomes, including complications and implant loss. Radiation-induced mechanical and biological effects, including degradation of silicone and exacerbation of capsular contracture, also play a vital role in implant failure. Importantly, while current guidelines such as the ESTRO-ACROP provide general recommendations, they lack specific dose constraints for implants, which may contribute to toxicities and complications. These findings underline the need for further research to address the gap in the guidelines regarding implant-specific dose constraints and to refine radiation planning techniques, especially for patients with complex surgical reconstructions. Clinically, a call to action is essential for the development of more comprehensive guidelines that consider the impact of surgical procedures on radiation therapy, ensuring improved implant outcomes and patient quality of life in the context of PMRT.

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