The impact of radiotherapy in pre-pectoral implant-based breast reconstruction: a narrative review

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Background and Objective: Pre-pectoral implant-based reconstruction (PIBR) is becoming increasingly popular. It is known that the data available so far are limited regarding the effect of post-mastectomy radiotherapy (PMRT) in PIBR. This as well true with data about effect of previous breast radiotherapy (RT). Relatively few studies were undertaken and their outcomes were released in the last few years. Some of them were designed to address impact of RT. Others just mentioned its effect on their cohort. Hence this review was undertaken to study the effect of RT (both pre- and post-mastectomy) on PIBR.

Methods: A narrative review of literature was undertaken. The search strategy was limited to articles written in English language. A systematic search was performed in all electronic databases (PubMed, Web of Science, Scopus, EMBASE). All studies, over the last 10 years were included, that reported or mentioned effect of RT on patients who had PIBR. The quality of each included study was assessed with the Newcastle-Ottawa Scale (NOS).

Key Content and Findings: Nineteen studies reporting on impact of RT in PIBR or mentioned its effect have met the inclusion criteria.

Conclusions: PMRT appears to be well tolerated in immediate PIBR with no excess adverse effects when used with acellular dermal matrix (ADM)/mesh at least in short term. Previous RT per se is not an absolute contraindication to the procedure. More studies are needed.

Keywords: Pre-pectoral implant-based reconstruction (PIBR); breast reconstruction; breast radiotherapy

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Introduction

Background

Pre-pectoral implant-based reconstruction (PIBR) is becoming increasingly popular due to the preservation of normal chest wall anatomy. It avoids the surgical morbidity associated with chest wall muscle dissection; eliminating animation deformity and replacing the new breast implant in its normal anatomical plane where the breast tissue was removed (1).

The main indication for this technique is immediate breast reconstruction following mastectomy for cancer or for risk-reducing surgery. PIBR can potentially be very useful in breast revision surgery, particularly to correct animation deformity and capsular contracture.

This procedure can be considered in any patient

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who would normally be suitable for an implant breast reconstruction. It may be preferable in athletes, may be more suitable for non-smokers, those with no history of previous radiotherapy (RT) and patients with grade 1 or 2 ptosis. Breasts with grade 3 ptosis and anticipated breast weight more than 500 g can potentially be offered this technique with a dermal sling.

The procedure is generally offered to patients who are fit and well, with no major comorbidities or well-controlled minor comorbidities, body mass index (BMI) <35 kg/m^2, no previous RT damage to the chest wall and with a resectable tumour. Patients with a type 3 breast according to the Breast Tissue Coverage Classification developed by Rancati *et al.* (that is a thickness of the sub-cutaneous layers at pre-operative digital mammogram more than 2 cm) are particularly suited to PIBR (2).

The technique is generally avoided in tumours involving the skin, chest wall muscle, locally advanced ones, inflammatory breast cancers and in those with an increased chance of chest wall recurrence (3).

It is usually used with acellular dermal matrix (ADM) to cover it under well vascularised skin flaps. Complete or partial coverage ensures that the ADM/mesh is placed exactly in the required position with minimal fixation. A few studies have suggested a decreased incidence of capsular contracture following complete coverage though randomized controlled studies are lacking (4-7).

Anterior coverage with ADM results solely in coverage of implant anteriorly, so the posterior aspect of the prosthesis is formed by the underlying pectoralis major muscle. The anterior coverage requires greater attention to technique in positioning the implant and ADM compared to complete coverage with ADM. However, it may more closely mimic the function of the pectoral muscle in implant reconstruction in reducing implant visibility along the upper pole. Many surgeons believe there may be an increased risk of implant rotation and herniation though specific published evidence is not available (3).

In large ptotic breasts where a skin reduction pattern is employed, a dermal flap along with the ADM/mesh can constitute a complete pre-pectoral pocket. The presence of a dermal flap contributes to lower pole soft tissue coverage while the ADM/mesh completes the coverage superiorly if required (8). This may be a suitable option in ptotic breasts in patients who have a high BMI, though with an increased risk of perioperative complications (9).

Different biological and synthetic meshes are available in the market and their use may be based on local availability, patient and surgeon preference and the cost-effectiveness. It is well known that biological meshes undergo collagen remodelling and re-vascularisation, while synthetic meshes integrate through fibrosis (3). Good quality long-term comparative studies of different meshes and ADMs remain to be published. Nevertheless, a wide variety of meshes and ADMs are in common usage globally.

Furthermore, the data available so far are limited regarding the effect of post-mastectomy radiotherapy (PMRT) including capsular contracture, implant loss and cosmesis. Similarly, comparative data concerning the effect of previous RT are scarce in the literature. This review looks to collate the information we have regarding RT in PIBR thus far. We present the following article in accordance with the Narrative Review reporting checklist (available at https://abs.amegroups.com/article/view/10.21037/abs-21-132/rc).

Objective

This review aimed to assess the effect of RT on the outcome of PIBR.

Materials, methods and results

The main outcome of this narrative review included both major and minor complications of PIBR in patients who received RT either pre- or post- mastectomy.

To identify all available studies, a systematic search was performed in all electronic databases (PubMed, Web of Science, Scopus, EMBASE). We used medical subject headings (MeSH) and free-text words using the following search terms in all possible combinations: “prepectoral implant reconstruction”, “prepectoral breast reconstruction”, “breast implant reconstruction”, and “radiotherapy”. The last search was performed in October 2021 (*Table 1*).

Study selection

Two investigators independently reviewed articles for eligibility based on the study titles and abstracts, and studies that met the inclusion criteria were retrieved for full-text assessment, data extraction, and inclusion in the review. All disagreements were resolved by consensus.

Data collection process

Two independent authors analyzed each article and

Table 1 The search strategy summary

Items	Specification
Date of search	15 October 2021
Databases and other sources searched	PubMed, Web of Science, Scopus, EMBASE
Search terms used	"Prepectoral implant reconstruction", "prepectoral breast reconstruction", "breast implant reconstruction", and "radiotherapy"
Timeframe	Studies published between 2011 and October 2021
Inclusion and exclusion criteria	Inclusion criteria: all studies, over the last 10 years, that reported or mentioned effect of radiotherapy on patients who had PIBR were included. The search strategy was limited to articles written in English language
	Exclusion criteria: papers regarding animal studies, editorials and case series with less than 10 patients were excluded
Selection process	Two independent authors analyzed each article and performed the data extraction independently. Duplicate studies were removed. Further they reviewed independently the eligibility of studies in abstract form and in full text by assessing if the inclusion criteria and outcome measures were met. Discrepancies were resolved by consensus

performed the data extraction independently. Duplicate studies were removed. Further they reviewed independently the eligibility of studies in abstract form and in full text by assessing if the inclusion criteria and outcome measures were met. Discrepancies were resolved by consensus.

Eligibility criteria

We included all studies, over the last 10 years, that reported or mentioned effect of RT on patients who had PIBR.

The search strategy was limited to articles written in English language; moreover, papers regarding animal studies, review articles, editorials, and case series with less than 10 cases were excluded (*Figure 1*).

The quality of each included study was assessed with the Newcastle-Ottawa Scale (NOS): it contains eight items, categorized into three domains: (I) selection of study (four points); (II) comparability of groups (two points); (III) ascertainment of exposure and outcomes (three points) for case-control and cohort studies, respectively. A star system is used to allow a semi-quantitative assessment and researchers assign up to a maximum of nine points (*Table 2*). Nineteen studies met inclusion criteria and their related results to our review were summarised in *Table 3*.

Discussion and summary

Relatively few studies were undertaken and their outcomes were released in the last few years. Some of them were designed to address impact of RT. Others just mentioned its effect on their cohort.

Overall, early experiences revealed that adjuvant RT is well tolerated with PIBR (10). However, patients may need further interventions, including lipomodelling following PMRT. Sbitany *et al.* observed that PIBR had similar outcomes in the setting of PMRT to that of sub-muscular ones (11). Furthermore, the authors found no difference in complication rates between pre-pectoral and sub-pectoral implant-based breast reconstruction. Despite the results being based on single surgeon experience; their outcome was taken significantly in writing of the joint consensus guideline from European and USA breast and plastic and reconstructive surgeons which was published in May 2019 (3) when authors agreed that PMRT appears to be well tolerated in immediate PIBR with no excess adverse effects. Hence, they recommended that PIBR could be offered to patients who need planned PMRT. Especially that this procedure is used with ADM that can lead to decrease rate of capsular contracture. Furthermore, ADM provides protective effect. Two studies were referred to in regards ADM role by authors to reach such consensus (6,12).

Furthermore, the consensus that was reached revealed that the experience with previous RT is limited and influenced mainly by the degree of damage caused by RT and patient preference (3). Hence, it is recommended that each patient should be individually assessed.

Since the time of editing the consensus, a few publications were released concerning PIBR and previous

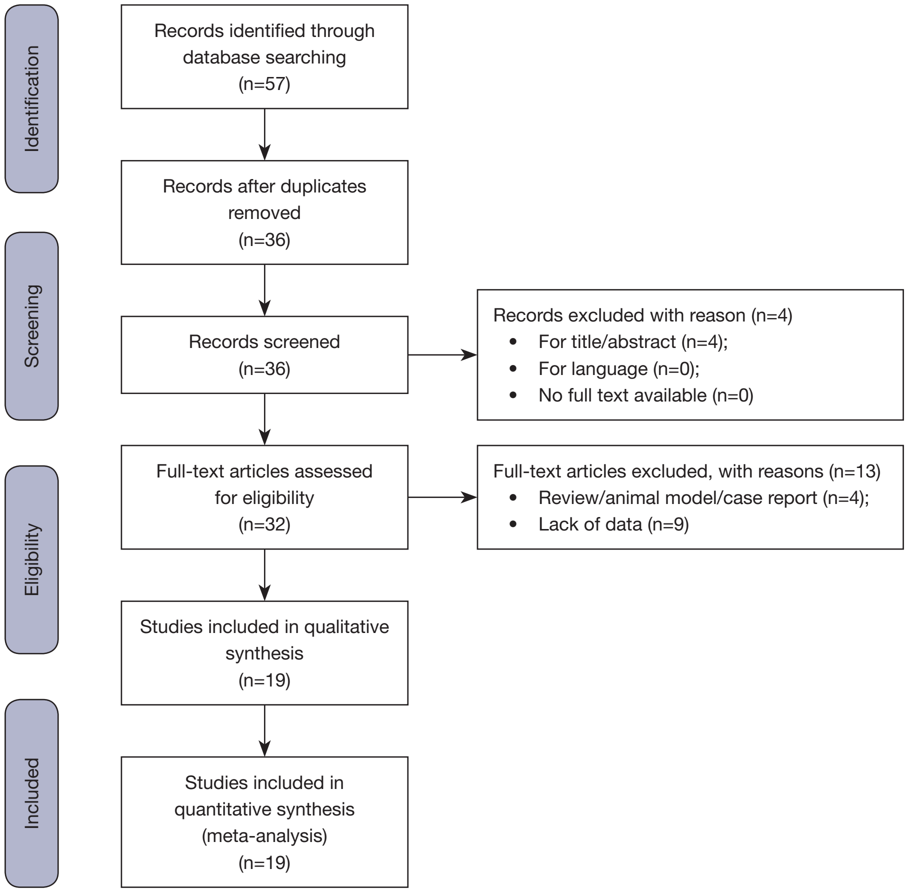

Figure 1 Summary of database search process (identification, screening, eligibility and inclusion).

RT. In 2020, Razzouk *et al.* found that lipofilling combined with PIBR after RT is a method that yields a satisfactory cosmetic outcome with a low complication rate and which can be an attractive alternative to flap-based reconstruction in some irradiated patients. The study was multicentric but retrospective (13).

Recently, Sinnott *et al.* published results of their study. It was a retrospective one (14). They aimed to compare the impact of pre-mastectomy *vs.* post-mastectomy RT on outcomes after pre-pectoral breast reconstruction. Patients were recruited over a 9-year period. They found that in pre-pectoral implant breast reconstruction, pre- and post-mastectomy RT were associated with higher rates of infection and implant loss compared with non-radiated patients. PMRT was associated with a higher rate of capsular contracture compared with non-radiated patients, and a comparable rate of capsular contracture compared with pre-mastectomy radiation therapy patients. Pre-mastectomy RT was associated with a higher rate of seroma compared with post-mastectomy RT and non-radiated patients.

Coyette *et al.* similarly concluded that prior breast irradiation does not increase postoperative complication rates. However, they had small cohort; 64 mastectomies and only 3 of them had pre-mastectomy RT (15).

In early 2020, Chandarana *et al.* published the results of National Braxon Audit Study Group (BAG) from UK. They found no relation between irradiation and rate of complications. However, they recommended longer follow-up duration to study the impact of RT (16). Their results were based on 406 mastectomies. Sixty-two of them had post-mastectomy RT. Moreover, only 15 had pre-mastectomy RT. It is worth to be mentioned in such a non-randomised study there may be significant selection bias in choice of operative technique.

These results were included in the international Braxon Audit Group (iBAG) study which represents the largest evidence on PIBR with mesh up to now according to our

Table 2 Studies assessment according to NOS star system

References	Selection				Comparability	Outcome assessment		
	1	2	3	4	1	1	2	3
Mathew J *et al.*, 2021	*	*	*	*	**	*	*	
Thuman JM *et al.*, 2021	*		*	*	*	*	*	
Coyette M *et al.*, 2021	*	*	*	*	**	*	*	*
Sinnott CJ *et al.*, 2021	*	*	*	*	**	*	*	
Razzouk K *et al.*, 2020	*		*	*	*	*	*	*
Masià J *et al.*, 2020	*	*	*	*	*	*		
Safran T *et al.*, 2020	*	*	*	*	**	*	*	*
Polotto S, 2020	*	*	*	*	**	*		
Chandarana M *et al.*, 2020	*	*	*	*	**	*	*	*
Bilezikian JA *et al.*, 2020	*	*	*	*	**	*	*	*
Sobti N *et al.*, 2020	*	*	*	*	**	*	*	*
Momeni A *et al.*, 2019	*	*	*	*	**	*	*	*
Reitsamer R *et al.*, 2019	*	*	*	*	**	*	*	*
Viezel-Mathieu A *et al.*, 2020	*	*	*	*	**	*	*	*
Sigalove S, 2019	*	*	*	*	**	*	*	*
Casella D *et al.*, 2019	*	*	*	*	**	*	*	*
Sbitany H *et al.*, 2019	*	*	*	*	**	*	*	*
Sinnott CJ *et al.*, 2018	*		*	*	**	*	*	
Elswick SM *et al.*, 2018	*	*	*	*	*	*	*	

*, 1 star point; **, 2 stars points. NOS, Newcastle-Ottawa Scale.

review. It was published in August 2020 (17). Their results did not reveal statistically significant correlation between RT and postoperative complications, except for capsular contracture, that even so did not reach a high percentage (about 5%). This result was based on studying in details the effect of irradiation on 198 reconstructed breasts (45 received pre-mastectomy irradiation and 159 had PMRT). Despite that it is a retrospective study. This audit is valuable as it was international and multicentric. They collected data of experience on PIBR with Braxon ADM from 30 centres across Spain, UK, and Italy.

iBAG results agreed with Elswick *et al.* results (18) that was published in 2018 regarding impact of PMRT on PIBR and that capsular contracture is higher in irradiated group. However, this study was limited by a short follow-up after definitive implant placement (9 months).

In the same year 2018, Sinnott *et al.* compared the impact of PMRT in pre-pectoral *vs.* sub-pectoral procedures (19). They found that sub-pectoral reconstruction showed higher capsular contracture rate than PIBR especially in irradiated breasts. Worth to be mentioned that the two groups were not matched. PIBR procedures number outweighed that of sub-pectoral ones (426 *vs.* 163). Also, the number of irradiated reconstructed breast in PIBR was 56 when it was on 23 in the sub-pectoral group. Yet PIBR outcome was more favourable regarding effect of PMRT. Again, this is a non-randomized retrospective study.

Furthermore, Sobti *et al.* studied capsular contracture rate in direct to implant sub-pectoral *vs.* pre-pectoral reconstruction (20). They found capsular contracture rate greater in the first group. In fact, they reported that sub-pectoral implant placement was nearly 4 times as likely to result in capsular contracture (P<0.01). They had small cohort of 47 patients (81 breasts). Thirty-two of them

Table 3 Results of included studies

First author, year	Patients/breasts, n	Radiation, n	Hematoma, n	Seroma, n	Infection, n	Capsular contractures, n	Wound dehiscence, n	Implant loss, n
Mathew J *et al.*, 2021	85 breasts	21	1	1	1	–	8	2
Thuman JM *et al.*, 2021	109 breasts	44	0	20 (12*)	15 (10*)	12 (7*)	2 (1*)	5 (2*)
Coyette M *et al.*, 2021	50	12 (3 pre-Mx)	2	1	1	–	2	2
Sinnott CJ *et al.*, 2021	369/592	71 (26 pre-Mx)	1	5 (4*)	30 (12*)	33 (17*)	5 (2*)	30 (13*)
Razzouk K *et al.*, 2020	136	136	–	7	1	–	–	3
Masià J *et al.*, 2020	1,186/1,450	198 (45 pre-Mx)	31 (4*)	111 (22*)	70 (10*)	31 (10*)	67 (8*)	94 (22*)
Safran T *et al.*, 2020	201/313	96 (38 pre-Mx)	9	7	7	–	2	8
Polotto S, 2020	186	28	1	16 (2*)	9	4 (3*)	5	3 (1*)
Chandarana M *et al.*, 2020	324/406	77 (15 pre-Mx)	10	29	13	1	8	26
Bilezikian JA *et al.*, 2020	131	22 (10 pre-Mx)	–	–	10 (1*)	131	–	10 (1*)
Sobti N *et al.*, 2020	20	20	0	0	0	12	–	0
Momeni A *et al.*, 2019	40/69	12 (4 pre-Mx)	–	4	3	–	–	1
Reitsamer R *et al.*, 2019	134/200	58 (26 pre-Mx)	8 (3*)	29	1*	–	–	7 (2*)
Viezel-Mathieu A *et al.*, 2020	39/60	12	2	0	2 (1*)	–	–	0
Sigalove S, 2019	33/52	34	–	1*	–	0	1*	1*
Casella D *et al.*, 2019	397/521	131 (71 pre-Mx)	1	5	12	19	7	16
Sbitany H *et al.*, 2019	175 breasts	40 (14 pre-Mx)	2	2	11	–	4	4
Sinnott CJ *et al.*, 2018	274/426	45	0*	1	12 (3)*	22 (9*)	4 (1*)	17 (3*)
Elswick SM *et al.*, 2018	54/93	54	2 (1*)	5 (3*)	13 (10*)	1*	4 (1*)	1*

Complications are referred to all patients enrolled; number of complications referred to irradiated patients out of total number of complications are reported in parentheses with *; complications referred to irradiated patients are reported with *. Mx, mastectomy.

had PIBR. Of which 20 were irradiated. The remaining 49 breasts that had sub- pectoral reconstruction, 27 of them were irradiated.

On the other hand, Momeni *et al.* (21), who published their results just 1 year earlier than Sobti *et al.*, had a slightly larger cohort of 80 patients. Forty of them had PIBR. Most of them had an expander to implant procedure (two-stage procedure). In both sub- and pre-pectoral group, a small number had RT; 12 in pre-pectoral group and 14 in the sub-pectoral one. Their results revealed a favourable outcome in a well-matched patient population in immediate pre-pectoral tissue expander insertion with anterior ADM coverage compares to sub-pectoral tissue expander placement. The matched-pair analysis made their results somewhat more valuable though still falls short of a well powered randomised trial.

Casella *et al.* compared two-stage reconstruction with direct to implant (DTI) PIBR (22). They found that PMRT is significantly associated to a higher risk of developing surgical complications in DTI PIBR. That was contradicted by Reitsamer *et al.*, who reported no significant complications in irradiated group that were reconstructed with PIBR using one-stage direct to implant with ADM/mesh (23). They commented that capsular contractures grade III or IV could not be observed in patients with previous RT or in patients with RT to the reconstructed breast.

Viezel-Mathieu *et al.* also compared pre-pectoral approach with a sub-pectoral one (24). However, they used direct to implant procedure (one-stage) in the pre-pectoral group (39 patients) *vs.* two-stage implant reconstruction in the sub-pectoral group (38 patients) making comparisons more difficult. Again, this study detailed the PMRT in each group and reported no poor outcomes in those who had PIBR, i.e., 12 patients out of 39. In favour of this study that both groups were comparable in size and demographics including age, diabetic and smoking status, and receiving neoadjuvant/adjuvant therapy. However, only 12 patients in PIBR received PMRT when 20 where irradiated in the sub-pectoral group. However, as it is not our aim to compare sub- with pre-pectoral procedure. This unlikely will affect our outcome.

Sigalove's study warned against PIBR in previously irradiated breasts (25). The author concluded that for patients who have been radiated in the past, care should be exercised when considering PIBR without a concurrent vascularized muscle flap. However, immediate PIBR followed by RT appears to be well tolerated, with no excess risk of adverse outcomes, at least in the shorter-term follow-up reported. The study had 52 PIBR procedures. Thirty-four of these reconstructed breasts had PMRT. They had only one reconstruction loss and another one had seroma. Their average follow-up was 25 months. The author acknowledged that longer follow-up is required. Furthermore, that their outcome is preliminary.

Thuman *et al.* published their outcomes in June 2021 (26). They compared impact of RT on pre-pectoral *vs.* sub-muscular implant-based reconstruction. The retrospective study was run over 7 years and included 387 breasts. Almost two third of them had a sub-muscular approach (287 breasts). They found that the pre-pectoral group (109 breasts) had a significantly lower incidence of reconstructive failure than sub-muscular placement regardless of RT status. They concluded that PIBR performs clinically better than sub-muscular in non-radiated patients compared with radiated ones; however, no statistical significance was identified. The authors recommended a larger study to get more statistically significant difference if any, which seems appropriate. The two groups were not matched. Only 44 reconstructions were irradiated in pre-pectoral group compared to 141 ones in the sub-muscular group. This mismatch weakens this comparison. However, if PIBR group to be considered solely in our review. It shows that this procedure has tolerance for PMRT.

Mathew published a retrospective study designed to compare short to medium term outcome of pre-pectoral *vs.* sub-pectoral implant-based reconstruction with ADM (27). He included 109 breasts reconstruction, 85 PIBR and 24 sub-pectoral. Whilst the effect of RT was not a primary end point of the study, yet the cohort is included in our review. Thirty-six patients had RT. Twenty-one of them belonged to pre-pectoral group. Two of 36 patients who received RT lost their implants compared with one in 73 who did not receive RT. Furthermore, eight patients in RT group had fat grafting compared with 17 in those who did not receive RT, though these events did not achieve statistical significance. Hence, he commented that RT did not have a significant adverse outcome in the short to medium follow-up in both groups, but its long-term impact has not been addressed. Mismatched two groups and relatively short follow-up period for average 2 years make it difficult to draw firm conclusions from the study.

Safran *et al.* experience showed no significant differences in complication rates for patients who had PIBR and PMRT (28). Their cohort was of 201 patients and 313 breasts. Only 58 of them received PMRT. This result agreed with Polotto *et al.* outcome that had even a smaller cohort of irradiated patients, i.e., 28 out of 186. But they reported slightly higher rate of capsular contracture in irradiated group compared to non-irradiated ones (29).

Last but not least, Bilezikian *et al.* reported that PIBR represents a beneficial shift in breast reconstruction regardless of irradiation and other risk factors. They linked their conclusion to intraoperative evaluation of the vascular integrity of mastectomy skin flaps with fluorescent imaging. They used tissue expanders whenever skin flaps had poor vascularity.

A cohort of 131 patients whom they followed only for 21 months were included. Eight of them had tissue expanders. Twelve had PMRT and ten had pre-mastectomy RT. Only one of the irradiated group had implant loss. When non-irradiated group had nine. Furthermore, all the patients regardless of radiotherapy had capsular contracture grade one or two (30).

Our review is limited being a narrative one. There is a paucity of studies about PIBR in general. We found only 7 studies which, met criteria that were designed to study impact of RT in PIBR (11,13,14,18,19,26,29).

Furthermore, less is available about impact of RT on PIBR with stratification one-stage *vs.* two-stage and use of ADM or not. Only one study did not use ADM (15) and a direct comparison of reconstruction with and without ADM in the same reconstructive plane, whilst perhaps difficult to design and recruit to, would give enormously valuable information. Moreover, most of studies were retrospective, single-centre and had short-term follow-up durations. Hence, longer follow-up is needed to better understand the impact of RT in PIBR.

In summary, previous RT is not a contraindication to the procedure though evidence on the relative complication risk for these patients is contradictory. Furthermore, PMRT appears to be well tolerated in immediate PIBR with no excess adverse effects especially when used with ADM/mesh at least in the short-term. More studies are needed to examine the long-term impact of RT with this technique and indeed the long-term outcomes for pre-pectoral implants in terms of cosmesis, practicalities of revision over time and the need for salvage autologous reconstruction at a later stage.

There is a clear paucity of suitably powered randomized studies in these patients. The large number of meshes/ADMs available and lack of standardised surgical techniques make comparisons difficult and conclusions must be drawn on low level evidence. Randomised trials are badly needed.

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