On the need of in vivo verifications as quality control for intraoperative electron radiotherapy in breast cancer

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ABSTRACT

Intro

Intraoperative electron radiotherapy (IOERT) is a technique which aims to deliver radiotherapy during oncological surgery. Although tTe applicator and shielding disc placement are correlated with PTV underdosage and Organs at risk (OAR) irradiation, in-vivo verification of these parameters is scarcely reported. The aim of our study is to report and analyze possible causes of the misalignment using radiochromic films and compare our results to others reported in the bibliography.

Materials and Methods

From November 2019 to April 2023 in vivo dosimetry was performed for 33 patients. IOERT was performed using a LIAC (Sordina) electron accelerator. We attached a radiochromic film to the upper side of the shielding disc. The percentage of the irradiation circle outside the disc was recorded and various parameters (applicator angulations, prescription depth, tumor location and breast size) were analyzed to find possible correlations.

Results

For 29 patients 20 Gy were prescribed while 10 Gy were prescribed to four patients. The average irradiated area outside the disc was 19% (0%-56%) corresponding to a surface of 4,5 cm^2 (0-17.4 cm^2). The applicator of 5 cm was used for most of the patients. The mean prescription depth was 1.4 cm (0.5-2.5 cm). We found no correlation between the analyzed parameters and misalignment.

Conclusion

This study confirms the presence and magnitude of the misalignments. We strongly recommend in-vivo dosimetry as a quality check during IOERT procedures. The misalignment has no correlation with tumor localization parameters, so the solution could be based on technical improvements of the applicator

INTRODUCTION

Adjuvant radiotherapy (RT) after breast conservative surgery is considered the standard treatment for early breast cancer as it reduces local recurrences [1]. Intraoperative electron beam radiotherapy (IOERT) can be used both as partial breast irradiation [2,3] or as an anticipated boost. In both cases the main benefit for the patients is a shortening of the total radiotherapy treatment time [4,5].

During the delivery of IOERT a shielding disc is placed between the tumor bed and the pectoralis fascia to avoid unnecessary irradiation of the nearby organs at risk (OAR). The alignment (centering and perpendicularity) of the applicator axis and the shielding disc is challenging due to tissue irregularities, the disc not being visible and inclinations of the applicator. It has been described [6] how possible misalignments affect dose distribution. Translations and rotations between the applicator and the disc axis can imply a slight underdosage of the CTV and OAR irradiation.

In vivo dosimetry is common in external radiotherapy, and it is used to verify correct dose delivery, especially in complex techniques [7,8]. Despite this fact, in the case of IOERT, only a few in vivo dosimetry experiences have been reported [9-11]. The main reasons against in vivo IOERT dosimetry are often related to the choice of detectors, particularly in terms of accuracy, radiation field perturbation, workflow alteration and the need to preserve sterility around the surgical area. Although film dosimetry does not provide real time information, it has proven to be a reliable tool to assess the correct alignment of the applicator and the shielding disc [9,12], moreover the visual analysis of the image can provide the surgeon effective feedback about the actual accuracy of the procedure.

Some groups have reported results of in-vivo dosimetry [11] and treatment verification [9] when performing IOERT and assessed the risk of relative movement between the disc and the applicator [12]. Other groups have proposed the use of imaging devices such as ultrasound [12] or a C-arm [13] prior to irradiation. None of these groups have investigated the possible movements during irradiation nor analyzed the possible causes of the misalignment.

In the present work we analyzed the misalignment present in a series of 33 patients treated with our current standard clinical practice. We compared our results with previously reported results that used a different model of shielding disc and accelerator. Furthermore, we analyzed other variables which might affect the correct positioning of the disc such as breast size before surgery, inclination of the applicator, energy used or misalignment direction in relation to gravity. Additionally, we analyzed the impact of strategies such as checking the disc position with intramuscular needles after the setup and before and after irradiation.

MATERIALS AND METHODS

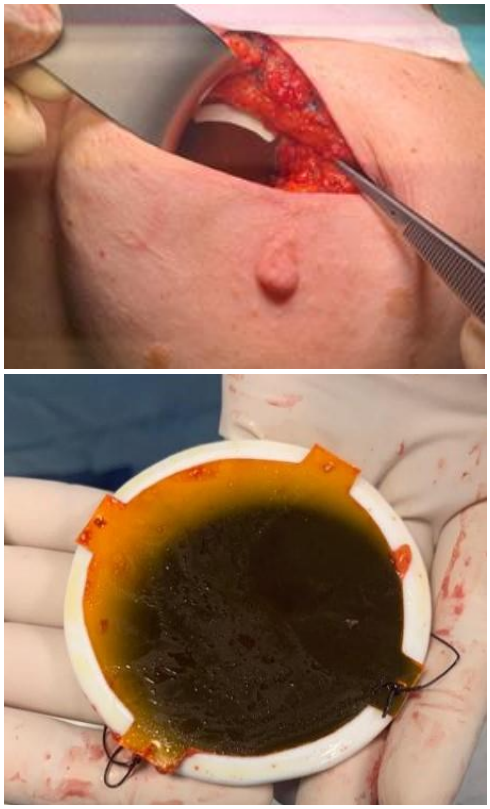
1. Data acquisition

From November 2019 to April 2023 in vivo verifications were performed for 33 patients affected by early-stage breast cancer who underwent IOERT. The Inclusion criteria for boost treatment were: patients over 18 years; any tumor size allowing for a conservative surgical approach; free surgical margins; positive or negative sentinel nodes and any immunohistochemistry and histological grade. Inclusion criteria for exclusive radiotherapy were: patients over 60 years of age; histological diagnosis of invasive ductal carcinoma grade 1 or 2; no positive sentinel nodes; tumor size under 2 cm; free surgical margins and luminal A like. Previous irradiation of the affected breast was considered as an exclusion criteria.

Lumpectomy was performed with an incision centered over the tumor. Sentinel node or axillary lymph node dissection was performed according to the current guidelines [14]. A mammogram of the tumor was performed, and the radiologist macroscopically reported the tumor margins. Intraoperative assessment of histology margins was performed by the pathologist, reporting the nearest margin distance to the tumor. After the excision of the tumor, the surgeon mobilized the part of the remaining breast around the tumor bed by separating the deep side from the fascia of the major pectoral muscle and the superficial side from the subcutaneous tissue to insert the shielding disc. The surgical margins were then sutured together to irradiate the tissue.

A 10 MeV mobile electron linear accelerator LIAC (S.I.T. Sordina IORT Technologies S.p.A, Italy) was used. The electron beam was delivered through applicators with different diameters, ranging from 3 to 10 cm, always with a flat end. To spare underlying tissues from radiation, a shielding disc was used. The protective disc consists of a steel disc that is inserted in a PTFE (Polytetrafluoroethylene) sleeve. The orientation of the disc is such that the sleeve is facing upwards (towards the tumor bed) to efficiently shield backscattered electrons and avoid undesired overdosage of the surrounding tissue (Fig.1).

Fig.1 Surgical setup of the in-vivo verification procedure. Up: Positioning of the disc and film prior to irradiation. Down: in-vivo verification after irradiation.



To perform the in vivo film verification several radiochromic film (RTQA-2, GAFChromic™ Ashland) templates were created and sterilized by hydrogen peroxide plasma, following the manufacturer recommendations, and then sutured on the outer face of the protective disc (Fig.1).

After removal of the tumour, a shielding disc was sutured to the pectorialis fascia. The diameter of the disc was, for most of the cases, 1 cm larger than the applicator. The sterile applicator was placed directly in contact with the target volume with a plastic film to

ensure the tissue laid flat at the applicator end. The applicator size was chosen to ensure the proper coverage of the clinical target volume (CTV), defined as a volume of 2 cm beyond the former macroscopic tumor edge. The energy of electron beams was chosen according to the depth of the tumor bed which was measured in several points within the CTV with a needle, before IOERT. The docking was first performed by rigid tube attachment to the linear accelerator and later by moving the gantry until it reached the proper position through manual alignments. The dose was prescribed at the 90% isodose [15] either prescribing a dose of 20 Gy, for exclusive treatment, or of 10 Gy, as a boost.[16-18] After IOERT, the sutures and disc were removed, and the direction of the gravity was drawn on the surface of the film. Finally, the surgeon then completed the remaining surgical procedure.

The study was conducted in three stages. First, the disk positioning for the first 10 patients was evaluated without performing any positioning checks. In the next patients, the disc positioning was verified right before the docking procedure, to analyze if better alignment was observed. This was done by checking the presence of the disc in the area surrounding the applicator with an intramuscular needle. For a subgroup of six of these patients the same verification was performed after irradiation to check if any movements had occurred during the time where the irradiation was taking place.

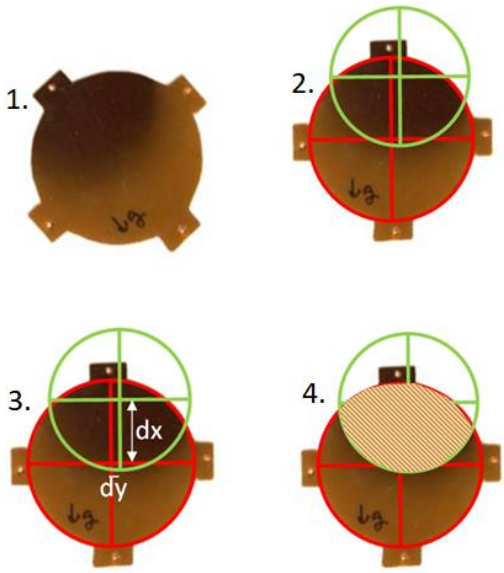
2. **Data analysis**

After the irradiation, the radiochromic film was removed, cleaned and scanned (Fig.2) using a flatbed scanner (EPSON 10000XL). The percentage of the irradiation circle outside the disk was determined. We followed these main steps (Fig.3):

1. Graphically overlapping the shielding disc circumference and the circle corresponding to the beam size (dependent on the applicator diameter).
2. Calculating the percentage and total expected area of the beam outside the shielding disc.
3. Determining the disc size that would have prevented any irradiation from escaping if the center of the disc was maintained.

Fig.2 Scanned radichromic film after in-vivo verification. Left: Radiochromic film corresponding to patient 5 (with a 34% of the irradiated area falling outside the disc. Right: Radiochromic film corresponding to patient 10 (with only a 3% of the irradiated area falling outside the disc.

Fig.3 Misalignment analysis procedure. 1: Film is scanned 2: Two circles of the size of the collimator and disc are superimposed to the image. 3: distance between the circles is determined. In the cases where gravity direction is registered, the parallel and perpendicular components are also registered. 4: From the two circumferences radius and the distance between the centers, the superposing area can be derived.



The percentage of the irradiated area outside the disc was compared with various parameters such as applicator angulations, prescription depth, tumor location and breast size to find possible correlations between them and the amount of misalignment. Breast size was determined by using diagnostic mammography and measuring its base in the widest region as well as the total height of the exploration. We also registered the location of the tumor regarding the quadrant of the breast.

The correlation between the variables and the amount of misalignment was analyzed using a Spearman correlation coefficient using R Studio (2023.03.0 version).

RESULTS

Most of the patients were treated using a 5 cm diameter applicator (range 4 cm to 6 cm) and a 6 cm diameter disc (5 to 8 cm) (Table 1). The mean prescription depth was 1.4 cm (range 0.5 cm to 2.5 cm). The energy used to treat the CTV ranged from 4 MeV to 8 MeV, 6 MeV being the most frequent (used for 14 (42%) patients). Lesions were treated in all quadrants of the breast.

As can be seen in Table 1 the postprocessing analysis of the dose distribution measured on the films provides a quantitative estimate of the misalignment between the applicator and the disk. For the 33 analyzed patients, the average surface outside the protective disc was 19% of the irradiated area (range 0% to 56%) corresponding to an average surface of 4.5 cm^2 (range 0 to 17.4 cm^2). The inspection of the disc positioning during surgery for the last

23 patients was not enough to limit the amount of misalignment, in fact we observed misalignments leading to 56% of irradiated area outside the disc for cases where the disc positioning was checked before irradiation. Nevertheless, the disc was repositioned for 3 patients after checking with the needle that the alienation was not correct, although for these some misalignment was still present, it was below the average of 20%. Furthermore, it evidenced that either rotations between the applicator and the disc were present and/or there was displacement during the irradiation due to patient breathing or disc slipping due to gravity. For 5 out of 6 patients a movement of the disc in the direction of gravity was detected with the intramuscular needle check after irradiation. The direction of these movements always followed the direction of gravity.

We analyzed the correlation between pitch, roll, maximum rotation, prescription depth, energy used, breast size and breast quadrant against percentage of misalignment and found no strong correlation. Only a weak correlation was found for the pitch (r = 0,25) and depth (r = 0,23) variables. A qualitative analysis of the effect of gravity was performed on 23 patients (Figure 4) showed a tendency of the disc to "slip" towards the gravity direction. As it can be seen in Figure 4, using a 2 cm bigger disc in relation to the applicator would only have avoided irradiation outside the shielding disc for 5 extra patients. If the systematic shift could be corrected, we would expect at least 14 patients to have no irradiation beneath the disc.

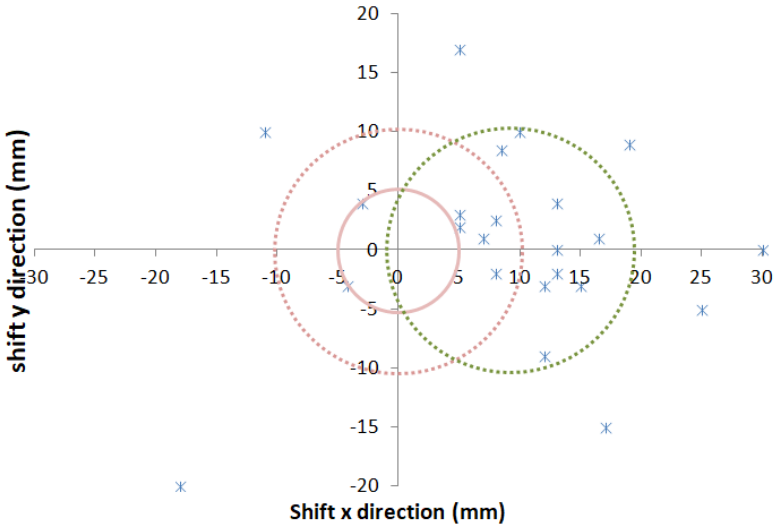


Figure 4. Analysis of shift direction relative to gravity. Shifts in y direction are positive in the direction of gravity. Shifts in x direction are shifts orthogonal to gravity. Red solid circle corresponds to the disc to collimator margin used for clinical practice (1 cm larger than the collimator). Red dashed circle corresponds to the hypothetical case of using a 2 cm larger disc than the collimator size. The green dashed circle corresponds to a disc 2 cm larger centered at the average gravity-related observed shift.

Most of the patients needed a disc at least 2 cm bigger than the applicator used. Seventeen of the 33 patients would have received no irradiation outside the disc if that approach was used. For 9 patients a disc 3 cm larger than the applicator was needed and for 5 cases we needed at least 4 cm larger. For only two cases the irradiated area fell completely within the disc area, meaning that we observed some amount of misalignment for 94% of our patients.

DISCUSSION

It is a well described fact that the correct alignment between the applicator and the shielding disc is a critical step in the delivery process for IOERT [9-13]. Nevertheless, in vivo dosimetry is not regularly performed for these treatments. There have been some groups [9-12] that reported the results obtained in their practice, and that have described their procedure to improve the results. However, the use of accelerators, material and surgical procedure could have an impact in achieving a successful alignment of the electron applicator with the shielding disc. From our experience the procedure to perform in-vivo verification was feasible and did not increase the surgery time significantly.

Ciocca et al [11] used radiochromic films to verify the correct delivery of the prescribed dose to the tumor bed surface. Although differences up to 7% were observed and QA thresholds were set from the experience, no information was derived as for the origin of the discrepancies. Furthermore, as dose measurements were performed in the central area of the applicator, no information was obtained regarding any geometrical miss.

Severgnini et al [9] performed in vivo dosimetry using radiochromic films on both surfaces of the shielding disc and reported misalignments for a series of 31 patients. The model of the disc used in this study is not designed to be sutured, so the first 16 patients of the study were treated without suturing the disc. In the results this group reported that the 21 following patients, for which an in-house suturing method was developed, presented

better results regarding disc alignment, but nevertheless irradiated areas outside the disc up to 60% were found. The same group later reported [12] the risk analysis for the patients treated with IOERT and pointed out that disc misalignment was the most important risk factor during the process. They reported a reduction of this risk by systematically using the biggest available shielding disc, even if this solution comes at the expense of a larger surgical incision and cosmetic outcomes. Furthermore, they performed ultrasound imaging before irradiation to ensure correct alienation. Unfortunately, in this report the reduction of the misalignment is not quantified and compared to the previous publication.

Other groups [13,19] have also reported on their strategies to mitigate the amount of misalignment using imaging with a C-arm or using rods to rigidly attach the disc to the applicator. The use of a C-arm imaging prior to irradiation could be a solution, but it increases the intervention time substantially [13], and would not prevent any movement produced between the docking and the end of the irradiation. Although the use of an in-house fixation system looks promising [19] it has only been tested in one model of accelerator, one energy of the beam and one size of applicator, and it should be further validated before implementing it to other scenarios.

Our results confirmed a systematic misalignment between the applicator and the shielding disc, comparable to other literature reports [9-12]. To the authors' point of view, the fact that similar uncertainties are obtained in the same procedure in a different cohort of patients, using a different accelerator and shielding disc, and with a completely independent team of specialists, is worth noticing. This fact suggests that applicator to disc shifts are expected to be present during the procedure and that the magnitude of the shifts is such that around 20% of the irradiation field falls outside the shielding disc even when it is sutured to the pectoralis fascia.

As none of the analyzed parameters correlate well with the amount of misalignment, in-vivo verifications should be used as a quality check during IOERT process for all patients and methods should be developed to improve the procedure [12]. It has been proven that radiochromic checks are feasible and it does not increment the procedure time nor implies any risk for the patient. We believe that, as stated by other groups [9,12], in-vivo IOERT verification should be performed systematically.

There are some limitations, however, in our study. The first one is that the reduced number of patients could impair the possibility to draw any sound statistical conclusions. Although more patients could be added to the study, to the author's point of view, the fact that there is a systematic misalignment between the disc and the applicator is sound. Any possible correlations with other parameters could emerge, but we observed no tendencies indicating such possibilities. Another limitation is the use of flat applicators only. The manufacturer provides a set of oblique applicators, but it is the clinical practice in our institution to use flat shapes only as our experience is obtained using this procedure.

The use of in-vivo verification did not only provide us with valuable information about the quality of our treatments but also served as visual feedback for the surgeons. Some movement of the disc was detected in the lapse of time between the end of the positioning and the end of irradiation suggesting that suturing the disc sutures does not properly hold the disc in place for some cases. Although we were not able to eliminate the misalignment, the extra care to double-check the positioning of the disc reduced the misalignment below 20%, except for the cases where the disc slipped during irradiation. To our knowledge, there is no solution for this problem provided by the manufacturers of the accelerator.

More work is currently being done to further reduce the misalignment between the applicator and the disc, including the development of tools to avoid any possible movement between applicator and disc.

CONCLUSIONS

The in vivo verifications confirm how, in general, misalignment of the shielding disc is present to different degrees for all our treated patients similarly to literature reports. Information obtained by checking the disc position makes it possible to estimate, though only at the end of the treatment, the dose distribution in the target and normal tissue. A preliminary set of parameters that might affect the amount of misalignment has been analyzed. From our analysis we can derive that the amount of misalignment is not clearly correlated with a single parameter, thus a hardware improvement of the procedure should be developed. Although no clear solution is not yet available, the information obtained by the in vivo verification could help to allow for a quantification, *a posteriori*, of the degree of success or failure of an IOERT breast treatment.

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Table 1. Treatment characteristics (energy, collimator and disc size, prescribed dose and collimator angulations) and misalignment results (area outside the shielding disc and percentage with respect the irradiated area)

Patient number	Energy (MeV)	Collimator diametre (cm)	Disc diametre (cm)	Prescribed dose (Gy)	Pitch (º)	Roll(º)	Area ouside disc (cm2)	Percentage ouside disc
1	4	5	6	20	7	17	1,00	5%
2	6	6	7	20	25	17	6,37	23%
3	8	5	6	20	7	14	1,52	8%
4	8	5	6	20	25	18	3,00	15%
5	8	4	5	20	10	41	4,73	38%
6	8	6	8	10	10	24	3,34	12%
7	4	5	6	20	7	32	2,94	15%
8	6	5	6	20	5	15	3,54	18%
9	6	5	6	10	-2	0	4,65	24%
10	8	5	6	20	0	0	0,73	4%
11	6	5	6	10	-1	6	1,33	7%
12	8	5	6	20	17	17	9,80	50%
13	6	5	6	20	7	5	1,49	8%
14	4	6	7	20	9	2	0,00	0%
15	8	6	7	20	3	0	7,94	28%
16	6	5	6	20	25	9	5,20	26%
17	6	5	6	20	14	5	3,90	20%
18	6	5	6	20	6	10	0,00	0%
19	8	5	6	20	7	25	2,93	15%
20	6	5	6	20	0	50	4,38	22%
21	8	5	6	20	14	6	7,70	39%
22	10	6	7	20	15	41	3,86	14%
23	6	6	7	20	0	13	17,35	61%
24	6	5	6	10	-13	20	2,80	14%
25	8	5	6	20	10	29	4,90	25%
26	10	4	5	20	-13	19	3,30	26%
27	8	6	7	20	0	0	12,45	44%
28	8	5	6	10	10	29	5,77	29%
29	4	6	7	20	0	0	4,10	15%
30	6	7	8	20	8	31	4,47	12%
31	4	5	6	20	8	5	7,33	37%
32	6	5	4	20	30	10	1,65	8%
33	4	5	6	20	28	5	3,63	18%