



Published in final edited form as:

*J Med Imaging Radiat Oncol.* 2018 December ; 62(6): 835–840. doi:10.1111/1754-9485.12790.

## Utility of CT Imaging in a Novel Form of High-Dose-Rate Intraoperative Breast Radiation Therapy

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### Abstract

**Introduction**—Intraoperative radiation therapy (IORT) is an alternative to whole breast radiation following breast conserving surgery. Conventional breast IORT is limited by lack of cross-sectional imaging. In response, our institution developed *Precision* Breast IORT (PB-IORT) which utilizes intraoperative computed tomography (CT) images for confirmation of brachytherapy applicator placement and for treatment planning. The purpose of this study is to determine the utility of CT imaging in PB-IORT in the first 103 patients treated in two prospective clinical trials.

**Methods**—We retrospectively reviewed the first 103 patients treated with PB-IORT. All patients underwent breast surgery and placement of a multi-lumen brachytherapy applicator. Patients had a CT scan followed by high-dose-rate (HDR) brachytherapy. Endpoints were the number of patients having more than 1 CT during PB-IORT and the number of treatment plans having image-based modifications.

**Results**—After initial CT scan, 27 patients (26.2%) had findings prompting surgical applicator adjustment. One patient underwent an additional scan to localize a biopsy clip and aid in excision to negative margin. 81 patients (78.6%) had dosimetry modifications based on CT findings with 36 plans (35.0%) adjusted to protect the skin or chest wall and 45 plans (43.7%) to protect both the skin and chest wall.

**Conclusions**—CT findings prompted treatment alterations in the majority of patients treated with PB-IORT to enhance tissue conformity and to sculpt the radiation dose away from normal tissues. CT imaging is unique to PB-IORT. These findings suggest the potential clinical superiority of PB-IORT given its allowance for patient-specific alterations.

## Keywords

Breast conservation therapy; Breast neoplasms; Intraoperative care; Radiotherapy; Radiotherapy; image guided

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## Introduction

Over the past several years, intraoperative radiation therapy (IORT) has gained favor as part of the treatment paradigm for breast conserving therapy (BCT; lumpectomy plus adjuvant radiation therapy) in the treatment of early stage breast cancer. The replacement of postoperative whole breast irradiation and other forms of partial breast irradiation with IORT is appealing to both patients and health care providers alike, given the reduction in total treatment time and cost (1–3). Two large randomized trials have demonstrated acceptable efficacy of IORT in appropriately selected patients (4, 5).

The targeted intraoperative radiation therapy (TARGIT) trial compared targeted single-dose IORT versus fractionated external beam radiotherapy for the treatment of breast cancer. This technique delivered 20 gray (Gy) to the surface of the lumpectomy bed, resulting in a low dose (5–7 Gy) received at a depth of 1 centimeter (cm) from the surface of the applicator (4). The intraoperative radiotherapy versus external radiotherapy for early breast cancer (ELIOT) trial utilized electrons to deliver a higher dose (21 Gy) to the lumpectomy bed, including tissues up to 1 cm in depth. While this protocol gave a higher dose to the tumor bed than delivered in the TARGIT trial, it was also associated with an increased rate of late toxicity (5). Importantly, while some centers currently practicing IORT utilize ultrasound to assist with appropriate placement of the applicator, this was not described in either of the aforementioned studies (6). Both trials lacked usage of intraoperative cross-sectional imaging to ensure appropriate placement of the brachytherapy applicator and to ensure calculation of customized dosimetry.

In order to address technical limitations of conventional breast IORT (CB-IORT), such as the treatment delivered in the TARGIT trial, investigators at the University of Virginia developed *Precision* Breast IORT (PB-IORT). This novel breast IORT technique delivers high-dose-rate (HDR) brachytherapy through a multi-lumen applicator placed into the lumpectomy bed at time of breast conserving surgery. Computed tomography (CT) is obtained, allowing the surgeon to alter placement of the applicator within the cavity while also facilitating treatment planning by the radiation oncologist (7). The use of HDR brachytherapy allows for the delivery of 12.5 Gy to tissue 1 centimeter (cm) from the applicator's surface, which is significantly higher than the 5–7 Gy delivered during CB-IORT (8). A 28 patient phase I safety and feasibility trial was completed, and 75 patients have been accrued into the ongoing phase II trial which was designed to evaluate the long-term efficacy of PB-IORT (7). The purpose of the current study is to report on the utility of CT imaging in PB-IORT, both in regard to surgical applicator placement and in adjustments to dosimetry planning, for the first 103 patients treated in these prospective trials. This analysis has potential implications for the evaluation of CB-IORT, as CT imaging is unique to PB-IORT.

## Materials and Methods

Both the phase I and phase II PB-IORT trials were approved by the institutional review board prior to study initiation, and all patients signed informed consent for study participation. Eligibility criteria include women aged 45 and older with newly diagnosed ductal carcinoma in situ or invasive breast carcinoma who opted to be treated with BCT. Patients with invasive breast cancer had pathologically proven negative axillary nodes. PB-IORT was performed at the time of breast conserving surgery or as a separate procedure within 30 days of the initial operation. For patients undergoing PB-IORT at a time separate from breast conserving surgery, no oncoplastic procedures were performed during the lumpectomy; if necessary, these were performed following PB-IORT. Exclusion criteria included patients with tumors greater than 3 cm in size, nodal disease, treatment with neoadjuvant therapy, known BRCA mutation, and breast implants.

At the primary treatment site (University of Virginia), PB-IORT took place within an integrated brachytherapy suite. The breast surgeon performed the lumpectomy or reopened the previous lumpectomy site, the multi-lumen brachytherapy applicator (Contura multilumen balloon, Hologic, Inc., Bedford, MA) was then placed into the surgical bed, and the skin was closed over the applicator (8). A CT scan was then obtained via an integrated CT-on-rails system (9). The CT-on-rails allowed CT scans to be obtained without moving the patient. The CT images were first reviewed by the surgeon to verify appropriate applicator placement. If deemed inappropriate, the surgeon could then reopen the surgical bed to adjust placement of the applicator. Additional CT images would then be obtained to verify improved positioning.

In order to make PB-IORT more generalizable to institutions that do not have an integrated brachytherapy suite, the phase II trial was opened at a secondary treatment site (Thomas Jefferson University; TJU). At TJU patients underwent BCS and applicator placement in the outpatient operating room. Surgeons used ultrasound to assist in confirmation of catheter placement. The patients were then recovered and taken to the brachytherapy suite where a CT was obtained. While surgical adjustments could be made in the operating room at the primary treatment site, the lack of intraoperative CT imaging at the secondary treatment site resulted in a narrower scope of possible surgical adjustments including evacuation of air from the balloon or slight catheter repositioning—all of which were performed prior to acquisition of the CT and thus not recorded as image-guided surgical adjustments.

Importantly, at both locations, the CT images were used by the radiation oncology teams to calculate the dose and optimize customized delivery of 12.5 Gy in a single fraction to the planning target volume (distance of 1 cm around the balloon surface) with an iridium 192 HDR brachytherapy source. This dose was selected to increase the dose at a depth of 1 cm as compared to alternative low-energy kV IORT techniques while maintaining an acceptable dose at the surface of the applicator (7, 8, 10). This dose was tumoricidal to a depth of 1 cm from the applicator surface. The HDR brachytherapy was then administered without altering the position of the patient to ensure stable positioning and accurate dose delivery. Once treatment was completed, the applicator was removed, and the skin incision was closed. According to the protocol of the ongoing phase 2 clinical trial—as well as for the previously

published phase 1 trial results—whole breast irradiation (WBI) to a dose of 45 Gy in 25 daily fractions was recommended for patients found to have a positive surgical margin following delivery of PB-IORT.

The CT scans of the first 103 patients who participated in prospective clinical trials of PB-IORT were retrospectively reviewed. The first 28 patients were enrolled in the phase I trial, and the subsequent 75 are enrolled in the ongoing phase II trial. Both the number of total CT scans performed and the reasoning for additional scans was recorded. Treatment plans were reviewed to assess if the radiation treatment plans were adjusted from the regular spheroid shape after imaging revealed the applicator was close to the skin or the chest wall. This study focuses on the intraoperative CT findings that led to surgical changes and the use of the CT images to make adjustments to the dosimetry.

## Results

### Applicator Positioning

CT images prompted surgical adjustment of the applicator in 27 (26.2%) patients in this cohort. After initial review of the intraoperative CT images, surgical manipulations were performed to eradicate large air cavities visualized on imaging and/or to improve the tissue conformity between the balloon and the breast tissue. After the identification of an air cavity between the applicator and breast tissue, the air was suctioned through the applicator's vacuum port to allow for apposition between the balloon and breast tissue. In the case of tissue conformity—defined as the position of the brachytherapy applicator in relation to the adjacent breast tissue to receive treatment—several surgeon-directed mechanisms were used to improve imperfections seen on intraoperative imaging. These included surgical adjacent tissue transfers to obliterate gaps between the balloon and breast tissue and methods of external compression to improve apposition of tissue (Fig. 1A). In cases of air cavities and tissue conformity issues seen on initial imaging, all patients received an additional intraoperative CT scan to verify successful adjustments. The post-adjustment CT scan was then used for radiation treatment planning (Fig. 1B).

In one patient, the initial CT scan was used to identify a previously placed biopsy clip that was not excised during initial lumpectomy. A second intraoperative CT was obtained to identify the biopsy clip and associated tumor after displacement of the localization wire led to absence of the clip in the removed lumpectomy specimen. Using intraoperative image guidance, the clip was located, and the tumor was successfully excised to negative margins.

### Treatment Planning

Eighty-one (78.6%) patients had changes made to the initial dosimetry plan based on intraoperative CT findings. These dosimetric changes represented customization of the treatment plan in order to optimize radiation dosimetry, and the modifications enabled protective sculpting of the radiation dose off of the chest wall or skin (Fig. 2). Thirty-six (35.0%) of these patients had dose adjustments to protect the skin or chest wall, and 45 patients (43.7%) had adjustments to protect the skin and chest wall.

## Treatment Details

The median planning time was 47.8 minutes, the median total radiation delivery time was 25.6 minutes, and the median IORT treatment time (planning plus radiation) was 75.1 minutes. The median total procedure time was 146.8 minutes. Three patients were found to have positive margins on final pathology, and 2 of these patients proceeded with a re-excision. All 3 patients received WBI. In addition, 2 patients were found to have negative, but close margins. One of these patients underwent re-excision, and both patients received WBI.

## Discussion

We evaluated the utility of CT imaging use during PB-IORT for the treatment of breast cancer and found that the use of cross-sectional imaging resulted in applicator repositioning and/or dose modifications in the majority of patients. The incorporation of intraoperative CT in PB-IORT allows for surgical adjustment and subsequent confirmation of appropriate applicator placement as well as 3-dimensional treatment planning (7). This is in contrast to the methods of CB-IORT utilized in the TARGIT and ELIOT trials, which did not employ routine intraoperative imaging. Rather, both techniques relied solely on visual placement of the applicator into the lumpectomy bed (4, 5).

Two subsequent CB-IORT trials did utilize intraoperative imaging with either ultrasound or megavoltage portal imaging (6, 11). While these techniques may be superior to the complete absence of image-guidance, there are several important limitations. Ultrasound permits the visualization of soft tissues, but it can be challenging to interpret exact depth and size measurements as images can be prone to tissue distortion based on variance in probe pressure (12). Additionally, detection of air cavities or poor tissue conformation is impacted by posterior acoustic shadowing. Posterior acoustic shadowing occurs when the evaluated tissues are of different densities, resulting in the reflection of the ultrasound waves with subsequent obscuration of the images. Because of the obligate presence of air in both the lumpectomy bed and the balloon of the multi-lumen brachytherapy applicator, acoustic shadowing poses a ubiquitous problem. The utility of intraoperative ultrasound in this setting is therefore limited to the evaluation of the anterior surface of the breast-applicator interface (13).

Localization portal imaging utilizes a small amount of radiation to obtain still images of the treatment area to ensure alignment between the collimator and shield to maintain appropriate positioning of the target breast parenchyma. Adjustments can then be made with repeat portal images taken until appropriate alignment is achieved (11, 14). While this technique is useful to assure the alignment of the external radiation field and lumpectomy cavity, it is ineffective in detecting poor tissue conformity or air cavities (14). Many of the clinically actionable findings identified in the current study would not have been recognized on localization portal imaging or ultrasound alone, resulting in treatment planning via inadequate catheter placement. Most importantly, these two imaging techniques do not allow for image-directed treatment planning.

The use of CT imaging provides 3-dimensional visualization of the lumpectomy cavity and the multi-lumen brachytherapy applicator. This allows for adjustments in applicator placement as well as the collection of information regarding projected dose to adjacent organs and structures, including the skin, chest wall, and heart (7). HDR is known to increase the risk of secondary malignancies following breast irradiation, including lung, bone, and soft tissue tumors (15, 16). In addition, radiation exposure has been shown to cause myocardial fibrosis and the potentiation of coronary artery disease (17). The maximum radiation doses received by the heart, lungs, and skin are consistently lower for IORT than for external beam whole breast radiation, and thus associated with a lower estimated risk for radiation-associated damage or oncogenesis (16, 18, 19). The additional ability for PB-IORT to allow for alteration of the regular spheroid dose shape to adjust away from the skin and chest wall suggests its capacity to further decrease the radiation dose—and potential deleterious effects—delivered to these structures.

While new to breast surgical oncology and IORT, many other surgical specialties have utilized intraoperative imaging for some time. Intraoperative hepatic ultrasound is now common practice during segmental liver resection, allowing for identification of small metastases with greater sensitivity than CT or magnetic resonance imaging. Similar to image-guidance in IORT, use of this intraoperative imaging modality results in modification of the surgical procedure in approximately 50% of patients (20). Intraoperative CT is also being incorporated into spine surgery to improve the accuracy of instrumentation, among other benefits (21).

Though the addition of intraoperative CT had clinical implications in the majority of patients treated with PB-IORT in this study, there are drawbacks to this approach. The addition of the scan exposes the patient to ionizing radiation, with more than one CT scanned performed in 27 of the 103 included patients. However, patients receiving external beam whole breast radiation also undergo at least one CT for treatment planning as well as another CT or x-ray images at some point during the radiation treatment course. Additionally, it is possible that the scan's allowance for dose adjustments to sculpt the radiation dose away from the skin, chest wall, and deeper structures including the heart balances out the overall increase in radiation secondary to the repeat CT in these patients (7).

Patients undergoing PB-IORT are also exposed to increased anesthesia time compared to CB-IORT and standard lumpectomy without IORT. The utilization of intraoperative CT imaging at the primary center, as well as delivery of IORT, certainly does add time to the procedure. However, any time added to the procedure as a result of the CT scan is predominantly due to the need for surgical adjustments to the catheter—which potentially makes PB-IORT more effective—as well as the treatment planning. While increased anesthesia exposure is never ideal, we believe that for otherwise healthy patients, the benefits to the patient-specific intraoperative delivery of radiotherapy outweigh the risks associated with the increased operative time. In addition, many facilities currently performing IORT will be unable to immediately incorporate intraoperative CT imaging based on lack of facility capabilities. In order to assess this real issue in resources, the phase II PB-IORT trial was opened at a second site that does not have an integrated brachytherapy

suite. Patients treated at this second site still benefit from image-based radiation treatment planning.

## Conclusion

The use of intraoperative CT in the novel PB-IORT technique allowed for patient-specific changes to dosimetry planning in the majority of patients as well as the surgical adjustment of the applicator to eradicate air cavities and to improve tissue conformity in nearly one-third of patients. Furthermore, the need for surgical adjustments in over one-fourth of patients in response to inadequate placement visualized on the initial CT suggests that without image confirmation in CB-IORT, many patients may be treated with imperfect catheter placement.

While the long-term efficacy of PB-IORT continues to be evaluated in an ongoing phase II trial, these findings suggest the potential for this novel technique's clinical superiority through avoidance of applicator placement errors and the ability to customize radiation dosimetry to minimize dose to adjacent normal structures.

## Acknowledgments

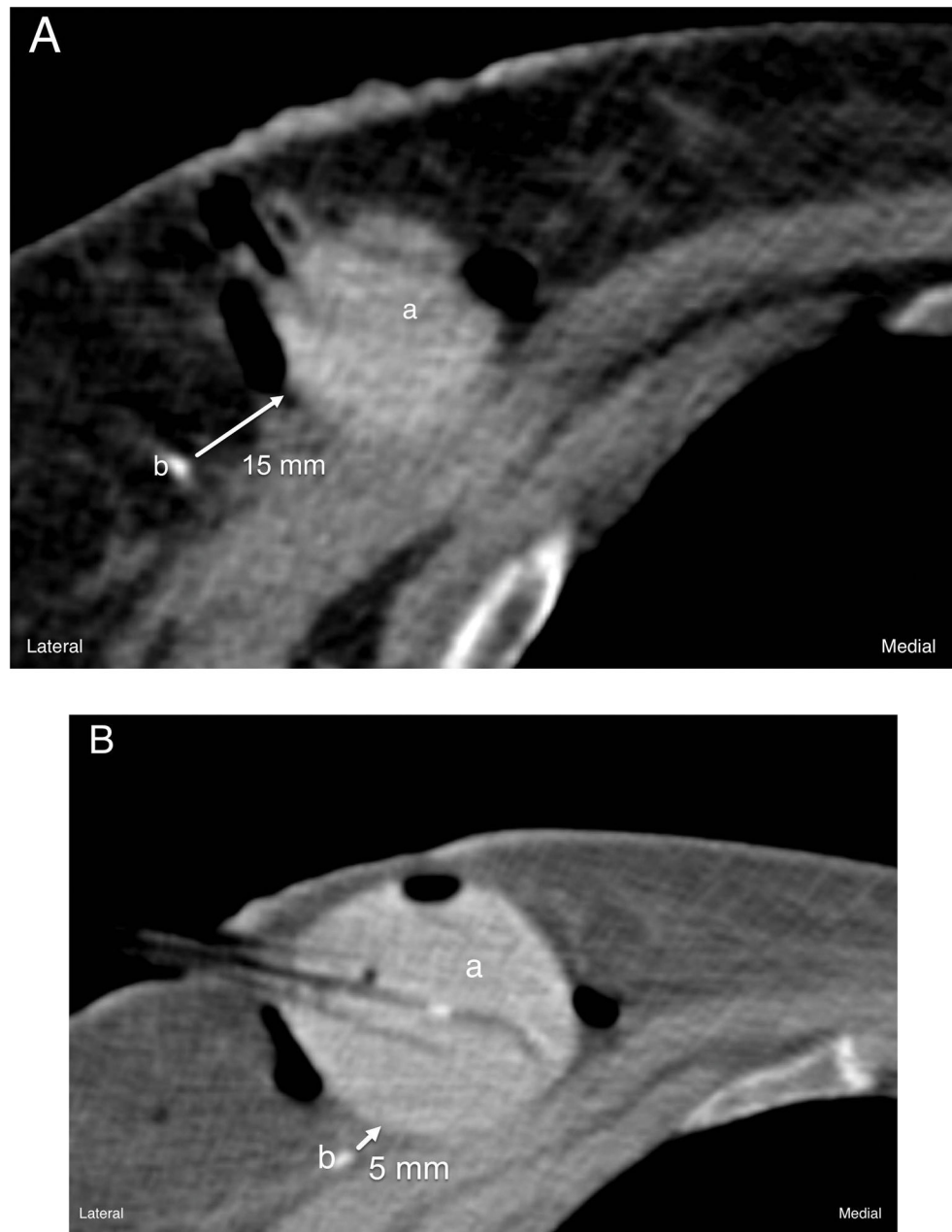
Funding for this study was provided by an American Cancer Society Institutional Research Grant (144372) and National Institutes of Health surgical oncology grant T32CA163177. The authors declare no conflicts of interest.

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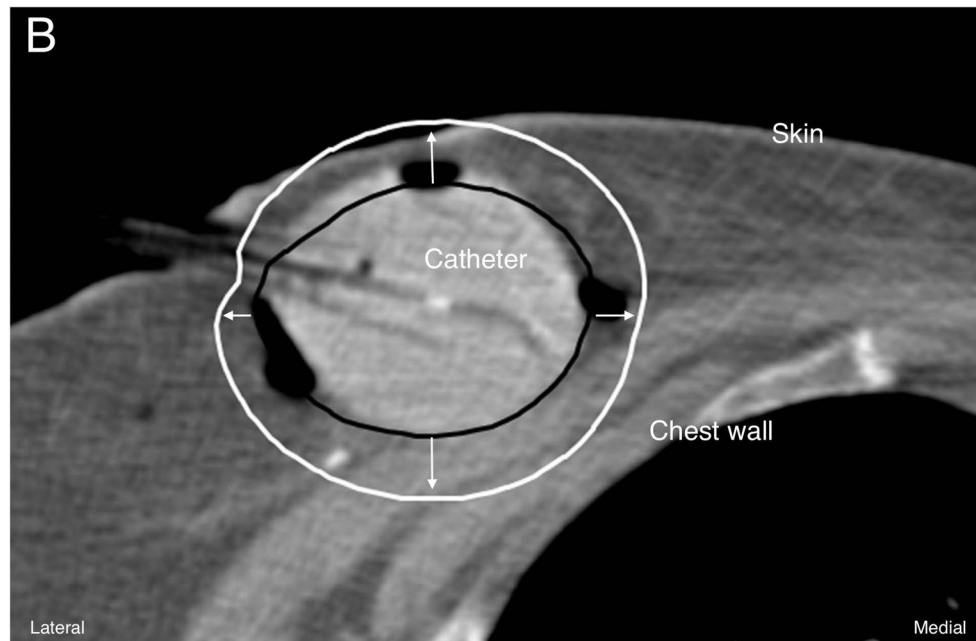
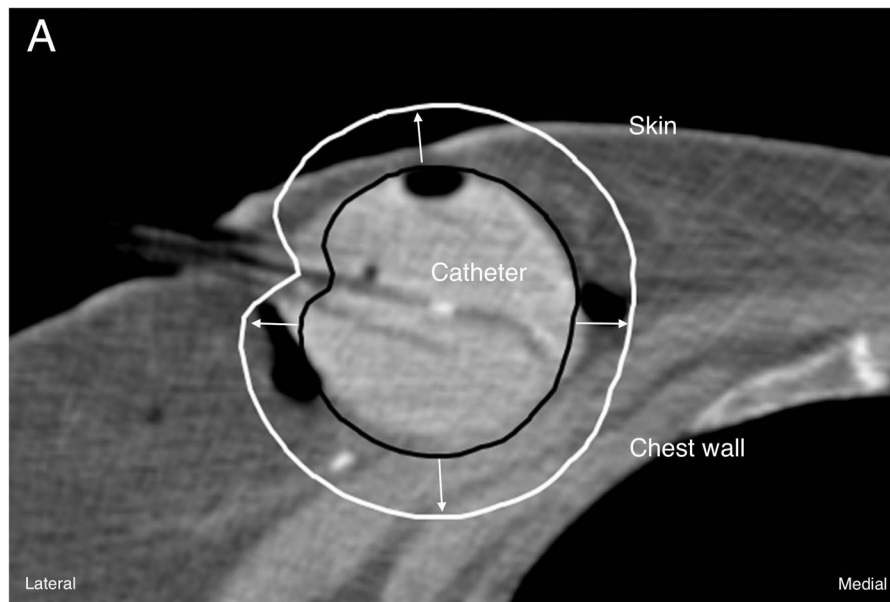
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**Fig. 1.** These figures represent an example of a surgeon manipulating catheter placement in order to improve tissue conformance between the balloon and breast tissue. **A** Initial CT image. After lumpectomy, brachytherapy catheter (a) was placed in the lumpectomy bed. Initial intraoperative CT revealed the balloon was 15 mm from the surgical clip (b) placed in the lateral margin. **B** Repeat CT image. Surgeon performed an adjacent tissue transfer and repositioned catheter. Second intraoperative CT shows the balloon (a) to be 5 mm from the lateral surgical clip (b) which was then encompassed in the treatment plan (up to 10 mm from balloon surface).



**Fig. 2.** Benefit of customized treatment planning with multi-lumen catheter. **A** Uniform spherical dose distribution (treatment area denoted by arrows) prior to customized optimization. Unacceptable dose distribution due to maximum skin dose of 154% and maximum chest wall dose of 113%. **B** Customized dose distribution (treatment area denoted by arrows) in same patient using optimization from multi-lumen, multi-channel catheter achieved lower skin (118%) and chest wall (96%) dosing with acceptable target volume coverage to within 10 mm from the surface of the balloon.

**Table 1**Treatment Details for Patients Undergoing *Precision* Breast Intraoperative Radiation Therapy.

	<b>n = 103</b>
<i>Tumor characteristics</i>	
Histology	
DCIS	32 (31.1%)
IDC	61 (59.2%)
ILC	9 (8.7%)
Tubular carcinoma	1 (1.0%)
Laterality	
Right	51 (49.5%)
Left	52 (50.5%)
Receptor status	
ER+	97 (94.2%)
PR+	68 (66.0%)
HER2+	10 (9.7%)
<i>Treatment characteristics</i>	
IORT planning time (min)	47.8
IORT radiation time (min)	25.6
IORT treatment time* (min)	75.1
Total procedure time (min)	146.8
<i>Post-procedure details</i>	
Close or positive margins	5 (4.8%)
Surgical re-excision	3 (2.9%)
Whole breast irradiation	5 (4.8%)

Categorical variables listed as N (%) and continuous variables listed as median.

DCIS = Ductal carcinoma in situ; IDC = Infiltrating ductal carcinoma; ILC = Infiltrating lobular carcinoma; ER+ = Estrogen receptor positive; PR+ = Progesterone receptor positive; HER2+ = Human epidermal growth factor receptor 2; IORT = Intraoperative radiation therapy

\* IORT treatment time is the total of IORT planning and radiation times