

# Abstract Booklet

First U.S. INTRABEAM<sup>®</sup> User Meeting

Las Vegas, Nevada  
February 19–20, 2016

The statements of the healthcare professionals whose opinion is contained in this material reflect only their personal opinions and experiences and do not necessarily reflect the opinions of any institution with whom they are affiliated.

The healthcare professionals whose opinion is contained in this material may have a contractual relationship with Carl Zeiss Meditec and may have received financial compensation.

The following material may include discussion of device features and applications that are not FDA cleared in the United States.

# Table of contents

A Multi-Institutional Analysis of Intraoperative Radiotherapy for Early Breast Cancer: Does Age Matter?.....	4
Dosimetric Characterization and Calculation of the INTRABEAM System With a Needle Applicator in Heterogeneous Tissues.....	6
Factors Predictive of Aborted Intraoperative Breast Radiation Using the INTRABEAM System.....	8
In Vivo Dosimetry With Optically Stimulated Luminescent Dosimeters for Intraoperative Radiation Therapy.....	9
INTRABEAM Applicators: Spherical vs. Flat .....	11
INTRAOPERATIVE RADIATION THERAPY (INTRABEAM) Experience at the Leopoldo Aguerrevere Clinic Caracas, Venezuela .....	12
Intraoperative Radiotherapy for Early Breast Cancer and Age: Clinical Characteristics and Outcomes.....	13
Intraoperative Ultrasound for Targeted Intraoperative Radiotherapy Treatment Planning.....	14
IORT in the Pelvis: Implementation, Technical Challenges, and Questions.....	15
Mammographic Appearance of the Breast Following IORT (Intra-Operative Radiation Therapy).....	16
Novel Use of INTRABEAM System to Provide Intraoperative Radiation “Boost” to Surgical Resection Bed Following Pancreaticoduodenectomy for a Locally Advanced Pancreatic Carcinoma .....	17
Oncoplastic Procedure in Conjunction With IORT .....	18
Oncotype DX in Patients Treated with Targeted Intraoperative Radiotherapy .....	19
Optimized Monte-Carlo Based Dose Computation for Low Energy X-rays IORT Implemented in Radiance TPS.....	21
Radiographic Film Dosimetry as Predictor of Skin Toxicity from Intraoperative Radiotherapy .....	23
Short-Term Sequela of Intraoperative Radiation after Breast Conserving Surgery.....	26
An Oncology Nurse Navigator’s Unique Challenge: Survivorship Planning for Breast Cancer Patients Post Breast IORT .....	28
Targeted Intraoperative Radiotherapy for the Management of Infiltrating Lobular Carcinoma .....	30

# A Multi-Institutional Analysis of Intraoperative Radiotherapy for Early Breast Cancer: Does Age Matter?

Abbott AM, Largona C, Valente SA, Loftus L, Tendulkar RD, Greif J, Bethke K, Donnelly ED, Lottich C, Ross DL, Friedman NB, Bedi CG, Joh JE, Kelemen P, Hoefer R, Kang SK, Ruffer J, Police A, Fyles A, Graves GM, Wiley SC, Tousimis EA, Small W, Lyons J, Grobmeyer S

## Introduction:

Duration of whole breast radiation therapy (WBXRT) after breast conserving surgery (BCS) may lead to non-compliance, especially among the elderly. Accelerated partial breast irradiation, including single session intraoperative radiation therapy (IORT), may be an alternative that minimizes treatment demands while providing adequate local disease control and minimal morbidity. The purpose of this study was to evaluate the impact of age on outcomes after treatment with BCS and IORT.

## Methods:

A multi-institutional retrospective data collection registry was created to collect/combine patient and treatment characteristics from 19 centers utilizing IORT for early stage breast cancer from 2007-2013. Eligibility criteria were determined at each institution per consensus guidelines. The IORT system was designed to deliver 20 Gy of radiotherapy at the surface of the applicator. The primary endpoint was local recurrence rate and the secondary endpoint was complications. Outcomes were analyzed for ages  $< 70$  and  $\geq 70$  using mean and standard deviation or median and interquartile range. Comparisons between age categories were made using Welch two-sample t-test or Wilcoxon sign-rank test.

## Results:

The registry cohort included a total of 1086 patients. This study evaluated 686 patients (all were margin and lymph node negative, had no additional surgery, and  $\geq 6$  months of follow-up). 424 patients were  $< 70$  and 262 patients  $\geq 70$ . Mean age for patients  $< 70$  was 63 (range 78, 66) years and 75 (range 72, 80) years for the  $\geq 70$  cohort. Patients  $< 70$  were more likely to have longer operative times, higher rates of IORT used as planned boost, oncoplastic closure, receive chemotherapy, and post-operative external beam radiation. There were no significant differences between the groups in BMI, tumor histology, size, grade, receptor status, or IORT treatment times. The incidence of wound infection, hematoma, and seroma were not significantly different between the two age cohorts (Table 1). The median follow up was 1.06 (range 0.51, 1.9) years for  $< 70$  and 1.01 (range 0.5, 1.68) years for  $\geq 70$ . There were no axillary recurrences and only 5 (0.73%) breast recurrences (4 in  $< 70$  and 1  $\geq 70$ ,  $p = 0.65$ ) during follow-up.

## Conclusions:

On short-term follow-up, patients who received BCS and IORT experienced low local disease recurrence rates and the elderly were not at greater risk of wound complications compared to the younger cohort. IORT may be a reasonable alternative to WBXRT for patients with early stage breast cancer treated with BCS, regardless of advanced age.

**Table 1.** Cohort Demographics and Complications

	< 70 N = 424	≥ 70 N = 262	P-value
BMI (mean, SD)	29.08 ± 6.49	29.44 ± 7.28	0.54
<b>Tumor Type Invasive</b>			
Invasive Ductal	304 (73%)	192 (74%)	0.051
Invasive Lobular	13 (3%)	11 (4%)	
DCIS	18 (4%)	2 (0.8%)	
Mixed	79 (19%)	48 (19%)	
Other	5 (1%)	6 (2%)	
Tumor size (mean, SD)	1.14 ± 0.59	1.17 ± 0.58	0.50
ER positive	382 (90%)	242 (94%)	0.12
PR positive	343 (81%)	223 (86%)	0.078
HER2 amplified	28 (7%)	11 (4%)	0.42
<b>Tumor Grade</b>			0.92
1	173 (42%)	102 (40%)	
2	172 (42%)	125 (48%)	
3	67 (16%)	31 (12%)	
<b>IORT Type</b>			0.003*
Primary (at initial lumpectomy)	315 (75%)	215 (84%)	
Secondary (at second surgery)	32 (8%)	20 (8%)	
Boost (planned boost)	72 (17%)	20 (8%)	
Total OR time (median, range)	133 minutes [112, 169]	127 minutes [103, 152]	0.028*
IORT Time (mean, SD)	29.2 minutes ± 8.63	29.3 minutes ± 9.39	0.93
Oncoplastics closure	172 (47%)	80 (35%)	0.008*
Chemotherapy	33 (8%)	8 (3%)	0.018*
External beam radiation	119 (29%)	28 (11%)	< 0.001*
<b>Wound Infection None</b>			0.21
None	355 (84%)	210 (80%)	
Grade 0 (no signs of infection)	33 (8%)	21 (8%)	
Grade 1 (localized erythema)	16 (4%)	15 (6%)	
Grade 2 (early infection)	12 (3%)	9 (3%)	
Grade 3 (drainage required)	7 (2%)	7 (3%)	
Grade 4 (sepsis suspected)	1 (0.2%)	0 (0%)	
Hematoma	7 (2%)	1 (0.4%)	0.16
Seroma	35 (8%)	17 (6%)	0.48

\* Denotes statistical significance. Abbreviations: SD, standard deviation; DCIS, ductal carcinoma in situ; IORT, intraoperative radiation therapy; OR, operating room

# Dosimetric Characterization and Calculation of the INTRABEAM System With a Needle Applicator in Heterogeneous Tissues

Yu Chen, PhD, Salar Souiri, MS, Xin Qian, PhD, LinWang, MS, Maged Ghaly, MD, Yijian Cao, PhD, Abolghassem Jamshidi, PhD<sup>1</sup>

---

## Purpose:

The current practice in determination of dose at depths for intraoperative radiotherapy (IORT) using the INTRABEAM 50 kV x-rays is based on depth dose measurements in water for the x-ray source and associated applicators (so-called the source calibration and derived applicator transfer function). There is a necessity in more accurately determining depth dose when heterogeneous tissues need to be taken into account. For example, in a procedure to deliver IORT to vertebral metastases during kyphoplasty (Kypho-IORT), nearby spinal cord dose is desired besides prescribed dose to the metastases. We report the depth dose measurements in air, in solid water, and in bone materials for the INTRABEAM 50 kV x-rays with a needle applicator, and further develop a novel protocol to estimate doses in different combinations of heterogeneous tissues.

## Material/Methods:

The absolute dose was measured using a PTWTN34013W soft x-ray ion chamber. Gammex tissue equivalent materials of cortical bone slabs (minimum thickness of 2 mm) and solid water slabs (minimum thickness of 1 mm) were used. The INTRABEAM x-ray source together with a needle applicator was secured on the Intrabeam stand. The slabs lay on a 6 degrees of freedom treatment couch with a digitally controlled minimum step size of 0.1 mm. The depth of source to the ion chamber was accurately and reproducibly adjusted by moving the couch up and down.

## Results:

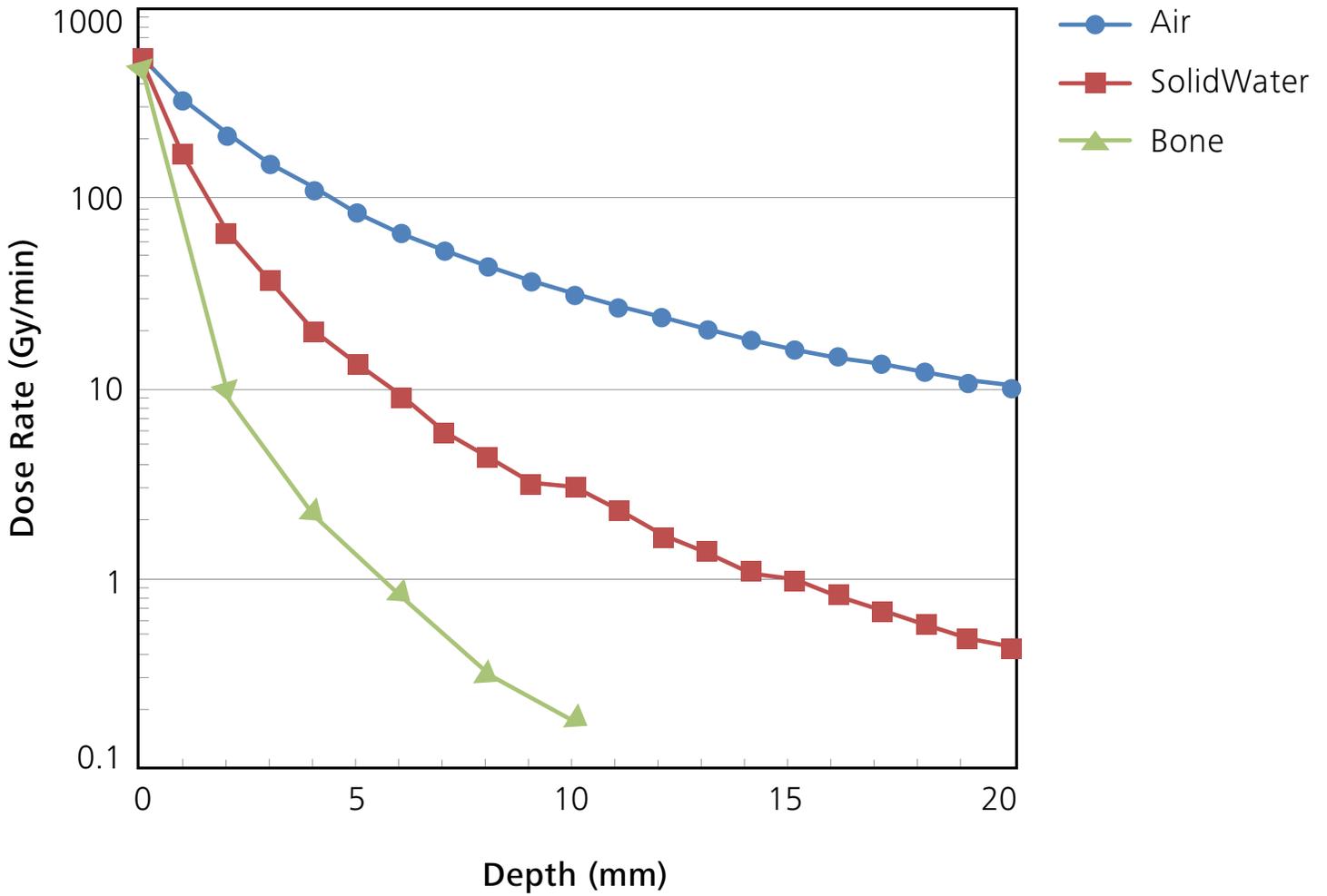
The preliminary results of depth dose measurements for INTRABEAM 50 kV x-rays with a needle applicator in air, in solid water, and in bone were shown in Figure 1. The measurements in bone would be extended to 20 mm. At a depth of 10 mm, the dose rates of the system are 31.5, 3.0, and 0.18 Gy/min in air, in solid water, and in bone, respectively, demonstrating more than an order of attenuation from air to water, and from water to bone. In a case of 20 mm lesion treated with an isodose of 10 Gy (at 10 mm depth of soft tissue and about 3.3 min of treatment time) during IORT, the dose from the attenuated x-rays that reach the spinal cord beyond 5 mm thick bone would be about 77 cGy (the dose rate is approximately 0.23 Gy/min at the depth of 8.5 mm in bone where the first 3.5 mm bone accounts for the equivalent 10 mm water depth).

## Conclusions:

The proposed method would be used to successfully estimate the dose to critical organs in IORT taking into account the heterogeneous effect. The further validation includes analytical calculation using known elemental composition and attenuation coefficient data of the phantom, and Monte Carlo simulation.

<sup>1</sup>Department of Radiation Medicine, Northwell Health, Lake Success, New York 11042

### INTRABEAM 50 kV Needle Applicator



**Figure 1.** Preliminary depth dose measurements for INTRABEAM 50 kV x-rays with a needle applicator in air, in solid water and in bone.

# Factors Predictive of Aborted Intraoperative Breast Radiation Using the INTRABEAM System

Lesly A Dossett MD MPH<sup>1</sup>, Andrea Abbott MD<sup>1</sup>, Weihong Sun<sup>1</sup>, Roberto Diaz MD<sup>2</sup>, Loretta Loftus MD<sup>1</sup>, M Catherine Lee MD<sup>1</sup>, Christine Laronga MD<sup>1</sup>

---

## Background:

Accelerated partial breast irradiation (APBI) is an option for adjuvant radiation therapy for select women with early stage breast cancer. Intraoperative radiation therapy (IORT) is a form of APBI that is delivered in a single session during surgery at the time of lumpectomy and sentinel lymph node biopsy (SLNB). In up to 20% of patients, planned IORT is not completed due to patient, equipment, or system factors; this leads to wasted resources and decreased patient satisfaction. Our objective was to evaluate factors predicting failure to complete planned IORT.

## Study Design:

IRB-approved, retrospective review of consecutive planned IORT cases from 2011 to 2015 at Moffitt Cancer Center. Eligibility criteria for IORT as definitive radiation therapy included: age  $\geq 60$  (age 50-59 cautionary), invasive ductal or mammary carcinoma, tumor  $< 3.1$  cm, ER positive, and clinically node negative. All patients underwent preoperative tumor localization and radiotracer injection. The decision to abort IORT was at the discretion of the attending breast surgical oncologist and radiation oncologist. Descriptive statistics were performed.

## Results:

21 of 145 planned IORT cases were not completed. Reasons for failure to complete IORT include inadequate applicators to skin distance [ $> 10$ mm superiorly, inferiorly, medially, and laterally] (n=17, 71%), altered wire localization findings (n=4, 19%), equipment failure (n=1, 5%) and hemodynamic instability (n=1, 5%). A need to take additional intraoperative margins was associated with failure to complete IORT due to loss of adequate skin-to-surface of applicator distance  $< 10$ mm. (p=0.005).

## Conclusion:

Careful preoperative planning and selection (uni-centric disease, well- defined margins on imaging, tumor location remote from skin) may reduce the need for additional margins intra-operatively and eliminate 90% of aborted cases. Awareness of these factors during one's IORT learning curve may lower the failure rate.

<sup>1</sup> Departments of Breast, <sup>2</sup> Radiation Oncology, H. Lee Moffitt Cancer Center, Tampa, FL

# In Vivo Dosimetry With Optically Stimulated Luminescent Dosimeters for Intraoperative Radiation Therapy

Yu Chen, PhD<sup>1</sup>, Anuj Goenka, MD<sup>1</sup>, Anurag Sharma, MS<sup>1</sup>, Lin Wang, MS<sup>1</sup>, Yijian Cao, PhD<sup>1</sup>, Abolghassem Jamshidi, PhD<sup>1</sup>

---

## Purpose:

The purpose of this study is twofold: 1) to investigate the feasibility of optically stimulated luminescent dosimeter (OSLD) as an in vivo dosimetry system for use in a Zeiss Intrabeam system; 2) to assess the in vivo dose for a patient with a pacemaker in left breast intraoperative radiation therapy (IORT) using the Intrabeam 50 kVp x-ray with a spherical applicator.

## Material/Methods:

The Landauer OSLD nanoDots were employed and calibrated under the conditions of 50 kVp Intrabeam x-ray with a 4 cm surface applicator. The energy dependent effect of the nanoDot response was examined by irradiating the nanoDots at different depths of water equivalent bolus. The nanoDots were then positioned in vivo at a patient's skin surface. The patient was under the breast IORT with a 4.5 cm spherical applicator. The nanoDots were located 5, 10, 15, and 20 cm away from the applicator and covered by a shielding sheet. There were two nanoDots at each location and each nanoDot was read three times to estimate the positioning and reading uncertainty to be  $\pm 5\%$ . A simple geometry model is utilized to estimate the radial distance of the nanoDots from the applicator surface, which assumed the applicator be normal to the flat patient skin surface. The nanoDots were put near a patient's pacemaker under and above the shielding sheet during the patient's left breast IORT.

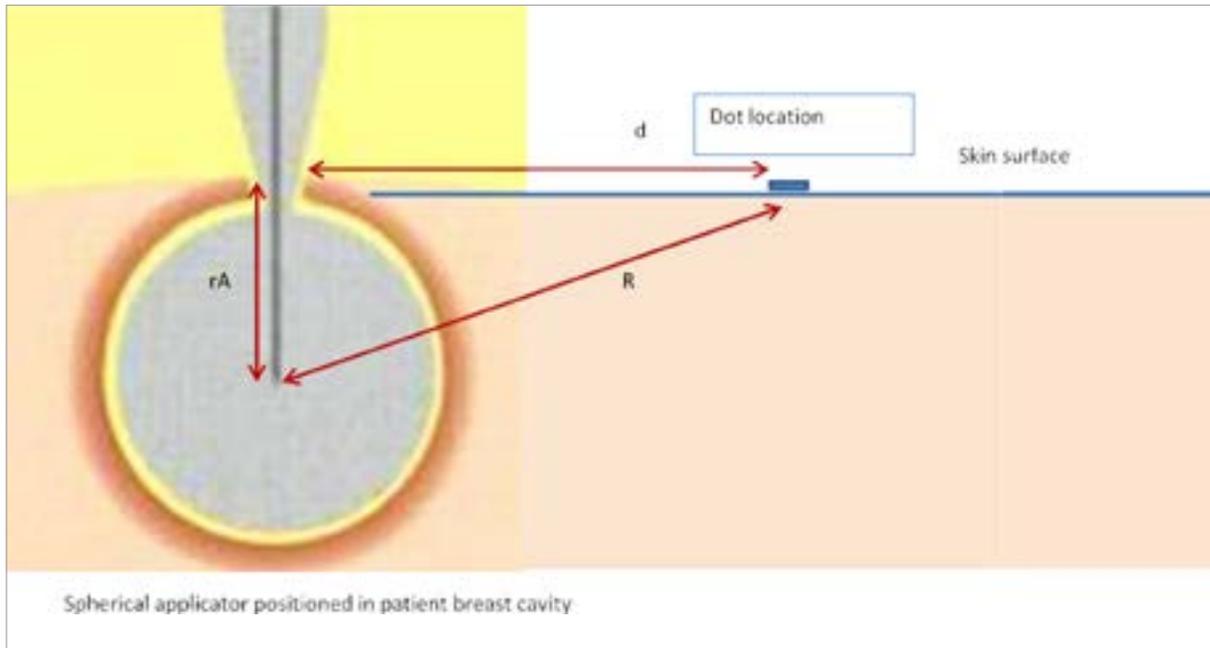
## Results:

The nanoDot demonstrated a relatively large response and negligible energy dependence beyond 1 cm depth in 50 kVp x-ray energy range, suggesting it be an appropriate dosimetry system with a great dynamic range of 1 – 2000 cGy. The in vivo skin surface doses during a typical breast IORT with a prescription of 20 Gy at a 4.5 cm spherical applicator surface were measured at 5, 10, 15, and 20 cm away to be  $159 \pm 11$  cGy,  $15 \pm 1$  cGy,  $6.6 \pm 0.5$  cGy, and  $1.8 \pm 0.1$  cGy, respectively. A power law fit to the dose versus the radius R from the source isocenter yields the dose fall off at the skin surface following  $R^{-2.5}$ , which may be due to an interplay effect between air (where the inverse square law holds) and tissue. The skin surface dose near the pacemaker was measured as  $4.0 \pm 0.8$  cGy. The larger uncertainty was due mainly to inexperienced positioning. The dose above the shielding sheet is negligible.

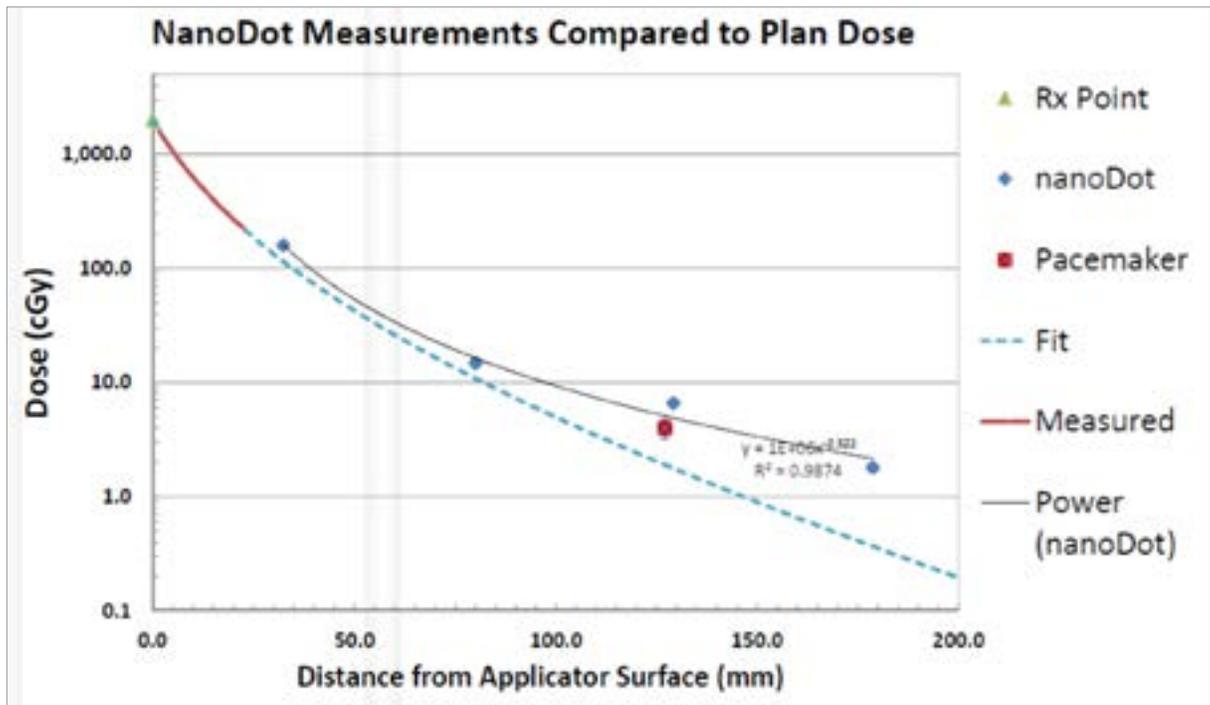
## Conclusion:

The calibration study suggests the appropriateness of the OSLD as the in vivo skin surface dosimeter in IORT using the Intrabeam system. The in vivo dose measurements revealed a possible phenomenon of air-tissue interplay in contribution to the observed skin surface dose, which is warranted a more detailed study such as using a phantom model.

<sup>1</sup>Department of Radiation Medicine, Northwell Health, Lake Success, New York 11042



**Figure 1.** A schematic description of radial distance R determination using the measured distance of d.



**Figure 2.** The depth dose measurements: Rx Point, Applicator Surface  $z = 0$ , Dose = 20 Gy; nanoDot at 4 locations of skin surface and converted to  $z = R - rA$ ; Pacemaker is roughly 15 cm away from a 5 cm spherical applicator; Measured are calibration data of the source and 4.5 cm spherical applicator, and Fit is an analytic function fit to the measured data which is extrapolated to  $z = 0$  (for Rx normalization) and  $z = 200$  mm to demonstrate an underestimate of far field dose; The Power law fit to the nanoDot points yields  $Dose \propto z^{-2.5}$ .

# INTRABEAM Applicators: Spherical vs. Flat

Anil Sethi PhD<sup>1</sup>, Bonnie Chinsky MS<sup>1</sup>, Bahman Emami MD<sup>1</sup>, William Small MD<sup>1</sup>

---

## Purpose:

INTRABEAM delivers high dose of radiation in an intra-operative setting (IORT) using a low energy X-ray source. Applicators of various size and shape are available to conform dose to the target volume: for example, spherical applicators are used for intra-cavitary breast applications; flat and surface applicators for superficial treatments. We compare dose characteristics of INTRABEAM applicators and suggest recommendations for clinical use.

## Material/Methods:

A 50-kV INTRABEAM X-ray device with 5 spherical (diameter: 3 – 5 cm), 6 flat (1 – 6 cm) and 4 surface (1 – 4 cm) applicators was commissioned at our institution. Dose parameters: output factors (OF), percent depth dose (PDD), surface dose (Ds), dose profiles (DP), and target dose homogeneity (DH) were measured using Gafchromic (EBT3) films. For a spherical applicator, dose is prescribed to the surface of the applicator. For flat or surface treatments, dose is delivered to an orthogonal plane 5mm or 0mm respectively from the end of the applicator. Film results were verified by repeat measurements with a thin-window parallel plate ion-chamber (PTW 34013A) in a water tank. Measurements were compared with the predictions of a Monte Carlo based treatment planning system (Radiance TPS).

## Results:

For spherical applicators, measured surface dose rate ranged between 1.1 Gy/min (3cm diameter) and 0.3 Gy/min (5 cm diameter). The corresponding dose homogeneity (max/min dose) over treatment volume (1cm thick spherical shell) was 3.5 and 2.9 respectively. For flat applicators, prescription dose rate at 5mm depth ranged from 1.8Gy/min (1cm diameter) to 0.2Gy/min (6cm diameter). In general, bigger applicators had lower dose rate, lower surface dose and greater dose homogeneity for a given treatment volume. For example, compared to 4cm flat applicator, 6cm applicator had a lower dose rate (x0.36), smaller surface dose (x0.46), and greater dose homogeneity (x2.2).

## Conclusion:

Accurate knowledge of dosimetric properties of INTRABEAM applicators is paramount for effective treatment planning. Results of dose measurements with various applicators and comparison with Monte Carlo based commercial treatment planning system will be discussed.

<sup>1</sup>Loyola University Medical Center, Maywood, IL 60153, USA

# **INTRAOPERATIVE RADIATION THERAPY (INTRABEAM)**

## **Experience at the Leopoldo Aguerrevere Clinic**

### **Caracas Venezuela**

---

Dr. Gerardo Hernández M., Dr. Ricardo Paredes H, Lic. Alecia Cosson, Dra. Claudia Gonzalez C., Dr. Juan Hernández R., Dr. Ivo Rodriguez, Lic. Jose Ghaleb, Dra. Elizabeth Gonzalez, Dra. Maria Mercedes Benitez, Dra. Wendy Hurtado, Dr. Nestor Sanchez, Dra. Consuelo Figuera

---

#### **Introduction:**

External radiation therapy has been the fundamental pillar when treating breast cancer. Partial radiation therapy (RT) and intraoperative radiation treatment (IORT) have created modifications that allow the irradiation of the breast to be performed at the surgical act delivering a single large fraction, or a "boost" dose directly at the tumor bed. In Venezuela breast cancer has become a public health issue, the incidence per year is of approximately 5000 new cases and a mortality of 2060, almost 90% of the patients need post-operative radiotherapy. At the present time 70% of the LINACS are non-operative due to lack of maintenance, in consequence the few working radiotherapy centres are overloaded with patients. They are located in few cities around the country, which implies traveling and sleeping expenses for the time of the treatment, and in some cases due to the forementioned reasons, the decision of a radical mastectomy is made. We will discuss patients treated with INTRABEAM (Carl Zeiss Surgical Oberkochen, Germany) at the Leopoldo Aguerrevere Clinic and the impact it has had in a country with this kind of medical problem.

#### **Material/Methods:**

Since September 2013 until December 2015 we have treated a total of 230 patients with the INTRABEAM unit. The selection of patients is crucial for the success of the IORT treatment, same protocol has been applied to every patient at the surgical act. Ages between 31 and 87 years in which 56% were single treatments and 44% were treated as a "boost" for external radiation therapy.

#### **Results:**

From the 230 patients 79% were infiltrating ductal carcinomas. An average tumor size of 1.5 cm for single dose and 2.1 cm for "boost", with approx. 25 minutes per IORT treatment. It has been well tolerated with only a 17% of transient fibrosis and a 12% of seromas. We have had no major complications like dehiscence of the wound or necrosis of the borders. No results for local recurrence due to short followup time.

#### **Conclusion:**

This preliminary presentation demonstrates that the technique and protocol used at our mastology unit with the intraoperative radiation treatment is safe and has many advantages including better comfort for the patient, cost-effective and with results comparable to external radiotherapy. Early diagnosis will make IORT the standard protocol for treatment. This type of treatment covers a significant part of the necessities, the procedure offers a viable solution for patients of breast cancer and can reduce the use of LINACS significantly. There is still much to be done to cover the needs of this medical health issue but if we extrapolate our experience to other centres it can make a significant contribution.

# Intraoperative Radiotherapy for Early Breast Cancer and Age: Clinical Characteristics and Outcomes

L. Loftus<sup>1</sup>, A. Abbott<sup>1</sup>, O. Rashid<sup>1</sup>, W. Sun<sup>1</sup>, W. Fulp<sup>1</sup>, G. Sokol<sup>2</sup>, C. Laronga<sup>1</sup>

## Introduction:

Breast conserving surgery followed by postoperative whole breast external beam radiotherapy has been the standard of care for patients with early stage breast cancer. However, the 3-7 weeks of therapy may be especially inconvenient for elderly patients. Accelerated partial breast irradiation (APBI), including targeted partial breast intraoperative radiation therapy (IORT) in a single session during surgery, is a newer technology that may be a reasonable alternative with adequate local disease control and minimal morbidity.

## Objective:

The purpose of this study was to evaluate age differences in outcomes of patients treated with breast conserving surgery and IORT utilizing the INTRABEAM radiotherapy applicator.

## Material/Methods:

After IRB approval, 100 female patients with early stage breast cancer who prospectively participated to receive treatment with lumpectomy and IORT from January 2011 to June 2013 were reviewed. Eligibility criteria included age > 59, invasive ductal carcinoma < 3.1 cm, clinically node negative, estrogen receptor positive, and technical feasibility to accommodate the radiation applicator with a skin to surface of applicator distance > 1 cm. The IORT system was designed to deliver 20 Gy of radiotherapy at the surface of the applicator. The primary endpoint was local recurrence rate. The secondary endpoints were complications of targeted radiotherapy and re-excision rates. The outcomes were analyzed for ages < 70 and ≥ 70.

## Results:

There were 43 patients < 70 and 57 patients ≥ 70. Patients < 70 had greater BMI mean 31.69 compared to ≥ 70 BMI mean of 28.01 ( $p = 0.0333$ ). There were no significant differences between the groups in tumor size, IORT time, operation length, hormone receptor status, sentinel node status, cancer grade or margin excision status. 35 (83.3%) of the < 70 and 47 (83.9%) of the ≥ 70 did not require additional surgery ( $p = 1.0000$ ). 8 (20%) of the < 70 and 8 (15.4%) of the ≥ 70 received external beam radiotherapy ( $p = 0.5860$ ). 38 (90.5%) of the < 70 and 51 (96.2%) of the ≥ 70 did not experience wound complications ( $p = 0.3967$ ). Wound infection rates were low for both groups, 4 (9.3%) < 70 and 1 (1.8%) ≥ 70 ( $p = 0.2096$ ). 42 (97.7%) of < 70 patients and 55 (98.2%) of ≥ 70 patients ( $p = 1.0000$ ) did not require additional biopsies on follow-up. The majority of the patients in both groups 27 (90%) < 70 and 37 (88.1%) ≥ 70, ( $p = 1.0000$ ) had BIRADS 2/3 rating on follow-up breast imaging. There were no differences between the groups for patients who received chemotherapy 5 (11.9%) < 70 and 4 (7.3%) ≥ 70, ( $p = 0.5007$ ). There were only 2 local recurrences in the entire cohort with a median follow up of 22 months (both patients ≥ 70).

## Conclusion:

On short-term follow-up, patients who received lumpectomy and IORT experienced low local disease recurrence rates and few wound complications. IORT may be a reasonable alternative to whole breast radiation therapy for patients with early stage breast cancer treated with breast conserving surgery, regardless of age.

# Intraoperative Ultrasound for Targeted Intraoperative Radiotherapy Treatment Planning

Dennis Holmes, MD

---

## Background:

A key criticism of targeted IORT is that it does not lend itself to CT-guided treatment planning as is now the standard with external beam radiotherapy. However, intraoperative ultrasound (IO) allows real-time image-guide treatment planning that enables accurate assessment of radiation applicator tissue conformity in addition to assessment of applicator surface-to-skin spacing to minimize skin toxicity.

## Methods:

Intraoperative ultrasound was typically used for TARGIT treatment planning in women undergoing IORT at the time of breast conserving surgery. Following placement of the Intrabeam applicator into the surgical bed, IO of the breast was performed by the surgeon to confirm conformity of the surgical margins to the applicator surface and to verify a minimum applicator surface-to-skin spacing distance of 5mm, the minimum distance considered safe. Ultrasound was performed using a portable unit equipped with a 5-10MHz transducer.

## Results:

Between May 2011 and November 2015, 103 patients underwent breast ultrasound for treatment planning at the time of BSC and IORT using the Intrabeam System. Average applicator size was 3.78 cm. Average applicator surface-to-skin distance was 10.4mm (Table 1). IO of the surgical bed following applicator placement enabled immediate evaluation of tissue conformity and application-to-skin spacing, which allowed immediate modification of the treatment set-up to improve conformity or skin spacing. No patients received IORT with less 5mm skin spacing, and no cases of skin necrosis or telangiectasias were observed among IORT recipients.

**Table 1**

Average Applicator Size	3.78 cm	
Average Applicator Surface-Skin Spacing	10.4 mm	
Applicator Surface-Skin Spacing		
Mm	N	%
5-7.0	20	19.4%
7.1-9.0	19	18.4%
9.1-11.0	28	27.2%
11.1-13.0	16	15.5%
>13.1	20	19.4%

## Conclusion:

IO ultrasound enables real-time TARGIT treatment planning to ensure optimal tissue conformity to the radiation applicator as well as assessment of the applicator surface to skin spacing to minimize skin toxicity.

# IORT in the Pelvis: Implementation, Technical Challenges, and Questions

JV Kuo<sup>1</sup>, M Al-Ghazi<sup>1</sup>, V Sehgal<sup>1</sup>, M Stamos<sup>2</sup>, J Carmichael<sup>2</sup>, A Pigazzi<sup>2</sup>

---

## **Introduction:**

Implementation of an IORT program for abdomino/pelvic tumors was undertaken at our institution. Though the faculty had experience with breast IORT and isotope-based brachytherapy, INTRABEAM system specific protocols for patient selection, patient counseling, scheduling, operative implementation, and follow up had to be developed.

## **Materials/Methods:**

5 patients (2 M, 3 F) with recurrent rectal cancer underwent exploratory laparotomy, R0 or R1 resections, and IORT. All pts had been discussed at multidisciplinary tumor board both before and after surgery/IORT. Mean age 58 yrs (46-70). Pts had prior radiation and chemotherapy in 4 of 5 cases with the IORT target area within/at the prior irradiation borders in all cases with prior irradiation. Treated areas were pelvic side wall (4) and common iliac area (1).

## **Results:**

Completeness of resection was R0 in 2 cases and R1 in 3 cases. Spherical applicators were selected for all cases. The flat applicator was also used in 1 case to extend the treatment area. Small lead shields were fashioned by cutting forms from lead drapes and wrapping them in sterile sheets (median 3 pieces per application). Median prescribed dose was 20 Gy @ surface (12.5 to 20 Gy). Beam time ranged from 15.8 – 26.5 minutes. All IORT applications were well tolerated. Only 1 application required temporary pause. Length of stay was 4 to 6 days. 1 pt required readmission for small bowel obstruction, which resolved.

## **Follow up results:**

Median follow up interval is 19.7 weeks (12 to 32). No recurrences have been documented so far. Complications reported in 2 of 5 cases (40%): 1 neuropathy and 1 ureteral stricture.

## **Conclusion:**

Implementation of IORT for abdominal and pelvic malignancies poses challenges for the colorectal program such as case selection and scheduling. Though the program is still under evolution, we will first discuss our solutions to such considerations as radiation safety monitoring, OR staff education, room set up and shielding, and documentation. Then, we will discuss challenges to using the INTRABEAM system in the pelvis, such as positioning, shielding, verification of conformance, applicator selection, dose selection, and post administration dismantling. We will invite discussion about collaborative program development between user sites.

<sup>1</sup> Department of Radiation Oncology, <sup>2</sup> Department of Surgery, University of California, Irvine

# Mammographic Appearance of the Breast Following IORT (Intra-Operative Radiation Therapy)

---

Dana Ataya MD<sup>1</sup>, Paulette Lebda MD<sup>1</sup>, Alice Rim MD<sup>1</sup>

---

## **Purpose:**

Intra-Operative Radiation Therapy (IORT) is a method employed for the treatment of breast cancer following lumpectomy where radiation is delivered intra-operatively within the lumpectomy bed. IORT has been found to be effective in preventing recurrent breast cancer, and is principally utilized in patients over the age of 50 with early stage breast cancer. As the utilization of IORT increases, recognizing the expected mammographic appearance of the breast following IORT becomes essential. The purpose of this presentation is to review the expected mammographic appearance of the breast following IORT.

## **Materials/Methods:**

Between October 2011 and October 2015, 65 patients underwent lumpectomy following IORT. Out of the 65 patients undergoing IORT, 49 patients had post-procedural annual mammograms available on our PACS, first obtained within 6-12 months following IORT. Available breast imaging of these 49 patients was reviewed and mammographic findings were documented.

## **Results:**

Approximately 88% of patients (43/49) presented with focal fat necrosis at the IORT/lumpectomy bed on post-procedural mammography. Approximately 8% of patients (4/49) presented with a scar and 8% of patients (4/49) presented with a seroma at the IORT/lumpectomy bed. Only one patient presented with skin and trabecular thickening post-IORT.

## **Conclusion:**

Focal fat necrosis without skin or trabecular thickening is the most common and expected mammographic appearance of the breast following IORT.

<sup>1</sup>Breast Imaging, Imaging Institute, Cleveland Clinic

# Novel Use of INTRABEAM System to Provide Intraoperative Radiation 'Boost' to Surgical Resection Bed Following Pancreaticoduodenectomy for a Locally Advanced Pancreatic Carcinoma

Song Kang MD, Mark Fleming MD, Richard Hoefler DO FACS<sup>1</sup>

---

## Background:

This 50 yr. old African American male presents with a 14-day history of abdominal pain and anorexia. CT Scan revealed a 3.4 x 3.7x 4.7 hypo-attenuated mass in the region of the uncinata process, contacting directly 50% of the superior mesenteric vein and approximately 25% of the superior mesenteric artery as well as contacting the left renal vein. The pancreatic duct was dilated measuring 0.7 cm. An endoscopic ultrasound guided FNA biopsy was non-diagnostic, and percutaneous CT guided biopsy confirmed a Pancreatic Carcinoma.

## Methods:

CEA was 14.5 and Ca19-9 was 76. The patient underwent Neoadjuvant chemo-radiation with protracted infusion 5FU and 4500 cGy to the pancreas and regional nodes, followed by a boost to the pancreas to a total dose of 5040 cGy. Repeat staging showed a good response with the tumor measuring 3.3 x 3.1 cm, and the association of the tumor to the SMV and SMA being improved. Repeat Ca19-9 was 3. The patient was taken to surgery and underwent an exploratory laparotomy with pylorus-preserving pancreaticoduodenectomy. A boost of intraoperative radiation to the uncinata margin at the superior mesenteric vein, superior mesenteric artery and inferior vena cava was given using the INTRABEAM device.

## Results:

The patient had a satisfactory postoperative course and was discharged on the 11th postoperative day. At discharge, the patient had evidence of delayed gastric emptying requiring home TPN. Additionally, the patient has some symptoms of radiation colitis managed medically. The patient was able to return to a regular diet, and the TPN was discontinued. The patient then received six months of adjuvant chemotherapy with Gemcitabine.

## Conclusion:

Surveillance follow-up for over 87 months, finds the patient free of disease. The radiographic features of this distinctive case are reviewed, and technical aspects of the procedure discussed. This is the first reported successful use of intraoperative radiation using the INTRABEAM device for a boost of radiation to the pancreatic resection

<sup>1</sup> Pancreatic Consortium, Sentara Cancer Network

# Oncoplastic Procedures in Conjunction with IORT

S. Chace Lottich MD, Darrel Ross MD, Thomas Jackson MD, Erin A. Zusan MD, Chandrika Patel MD, Eugene Hsiao MD<sup>1</sup>

---

## **Background:**

In the past decade, breast cancer patients have benefited from the addition of oncoplastic procedures at the time of lumpectomy with improved cosmesis and symmetry. With the publication of the results of the international TARGIT A trial in June 2010, IORT has become an increasingly important element of local therapy. Our objective was to evaluate the results for patients undergoing combined IORT and oncoplastic procedures.

## **Methods:**

For the past three years, we have offered IORT to our breast cancer patients with favorable tumors. Our selection criteria includes patients > 45 years of age, tumors < or = 3.5 cm in size, LN negative, Grade 1-3, DCIS < 20%, and ER+. In patients whose final pathology demonstrated adverse factors, IORT was utilized as a boost. We established an IRB approved data base and performed a retrospective review of our patients who met the above criteria between 2012 and 2015. A cosmesis score was based on a 1-4 point scale. Patients' cosmesis was assessed both by the radiation oncologist and breast surgeon at follow up visits alternating on an every six month basis.

## **Results:**

Of our 197 patients treated during this time frame, 118 patients also had oncoplastic procedures (60%) at the time of lumpectomy. Complications for the entire group were low with an overall seroma rate of 11% and recurrence to date in only two patients (1%). The cosmesis score was 1 (excellent) in 76% of the patients and 2 (good) in 21% of patients for a 97% overall good to excellent score in the first three years of follow up.

## **Conclusion:**

The addition of IORT to oncoplastic procedures allows patients the benefit of both improved cosmesis and shortened treatment times. Recurrence rates are low and complications minimal.

<sup>1</sup>Community Health Network, Indianapolis, Indiana

# Oncotype DX in Patients Treated with Targeted Intraoperative Radiotherapy

Deneve JL, Lee MC, Khakpour N, Kiluk JV, Acs G, Laronga C

---

## Background:

Targeted intraoperative radiotherapy (IORT) as an alternative to whole breast irradiation (WBI) is being offered to patients (pts) with clinically low-risk breast cancer. Oncotype DX (ODX) testing is used in early stage breast cancer to guide adjuvant treatment and has been used to predict risk of locoregional and distant recurrence. We compare our clinical selection criteria for pts treated with IORT with prediction of risk on post-operative ODX analysis.

## Methods:

After IRB approval, a prospective series of pts having IORT were reviewed. Eligibility for IORT [low risk breast cancer] included women over 60 with estrogen receptor-positive, her2 negative, and clinically node-negative invasive ductal cancer < 3 cm in size. Subsequent ODX analysis was obtained based on institutional guidelines. Clinicopathologic variables and adjuvant systemic therapy use for pts treated with IORT was compared between those with and without ODX testing.

## Results:

Twenty-eight pts underwent lumpectomy, sentinel lymph node biopsy (SLN) and concurrent IORT over a 6 month period. Seven pts (25%) (median age 77 years) underwent ODX testing. In the ODX cohort, when compared to those without ODX analysis (Control), all pts had invasive ductal histology (100% vs 90%,  $p=0.70$ ), had slightly larger tumors (1.29 cm vs 1.18 cm,  $p=0.71$ ) and were more frequently intermediate grade or higher (86% vs 43%,  $p=0.012$ ). Three pts (11%) were sentinel lymph node (SLN) positive on final pathology (2 in the ODX group,  $p=0.08$ ).

No pt underwent axillary node dissection. All pts received 20 Gy of IORT, delivered via a 3 cm applicator in 71% or a 3.5 cm applicator in 29%. Seven patients (2 in ODX, 5 in Control,  $p=0.31$ ) had positive microscopic margins after treatment and 6/7 underwent re-excision to negative final margins. Median ODX recurrence score (RS) was 23 (range, 4-30), 71% were intermediate risk for recurrence. Two patients, both in the ODX group, received additional WBI for positive SLN ( $p=0.013$ ). Adjuvant chemotherapy was administered in one patient (14%) with a node positive, T1c tumor and ODX RS of 30 (Table 1). Except for higher grade, no statistically significant differences were identified between cohorts prompting ODX ordering.

## Conclusion:

ODX analysis in pts treated with IORT revealed a higher risk for recurrence than predicted on our clinical selection criteria for low risk breast cancers. The utility of ODX on improving risk assessment and selection of candidates for IORT is provocative but requires further testing.

**Table 1.** Comparison of IORT patients who underwent ODX analysis

VARIABLE	ALL N = 28	ODX N = 7	CONTROL N = 21	P-value
Age	72.5 (57-88)	76 ± 5	72 ± 9	0.13
Post-menopause	28 (100)	7 (100)	21 (100)	NS
ER Positive	28 (100)	7 (100)	21 (100)	0.70
ER%	97 ± 5	97 ± 3	97 ± 5	0.74
<b>Histology</b>				
DCIS	1 (3.5)	0	1 (5)	
IDC	26 (93)	7 (100)	19 (90)	
ILC	1 (3.5)	0	1 (5)	
Tumor Size (Mean in cm, Std Dev)	1.21 ± 0.97	1.29 ± 0.4	1.18 ± 1.1	0.71
<b>Tumor Classification</b>				
Tis	1 (3.5)	0	1 (5)	
T1a	3 (11)	0	3 (14)	
T1b	16 (57)	3 (43)	13 (62)	
T1c	7 (25)	4 (57)	3 (14)	
T2	1 (3.5)	0	1 (5)	
<b>Tumor Grade</b>				
Low	12 (43)	0	12 (57)	
Intermediate	15 (54)	6 (86)	9 (43)	
High	1 (3.5)	1 (14)	0	
<b>Nodal Status</b>				
NO (i-)	25 (89)	5 (71)	20 (95)	
NI	3 (11)	2 (29)	1 (5)	
Oncotype Testing	7 (25)	7 (100)	0	NS
RS	23 (4-30)	23 (4-30)	0	
10 Yr % Recur	15 (4-20)	15 (4-20)	0	
<b>ODX Classification</b>				
Low	2 (7)	2 (29)	0	
Intermediate	5 (18)	5 (71)	0	
Whole Breast	2 (7)	2 (29)	0	0.013
<b>Irradiation</b>				
Chemotherapy	3 (11)	1 (14)	2 (10)	0.76
Follow Up (Mean in months, Std. Dev)	1.9 ± 2	2.7 ± 2	1.6 ± 2	0.13

# Optimized Monte-Carlo Based Dose Computation for Low Energy X-rays IORT Implemented in Radiance TPS

M. Vidal<sup>1</sup>, P. Ibáñez<sup>1</sup>, P. Guerra<sup>2</sup> and J.M. Udías<sup>1</sup>

---

## Introduction:

Intra-Operative Radiation Therapy with low energy X-rays (XIORT) is largely used for breast cancer treatment<sup>[1]</sup> and more and more centers are now involved in other clinical applications such as kyphoplasty<sup>[2]</sup> and superficial intraoperative radiotherapy<sup>[3]</sup>. These treatment areas are heterogeneous and dose gradients are very high. Users need a precise and fast method to compute dose distributions in patient data. This work proposes a fast and precise method to calculate dose distributions delivered by INTRABEAM (Carl Zeiss Meditec) from pre-processed Monte-Carlo phase space data, optimized to user-provided simple experimental data.

## Methods:

We developed a strategy to determine realistic Phase Space (PHSP) files. On one hand, monoenergetic PHSP files were generated with a full Monte-Carlo simulation using the penEasy<sup>[4]</sup> code, a simulation for each energy up to 50 keV, in 1 keV bins. It takes several hours of CPU time to build up a database, but this only needs to be done once. These monochromatic PHSP files were binned and parameterized in terms of the relevant variables to make them easy to manipulate. On the other hand, percentage depth dose (PDD) curves were computed from each of the monoenergetic PHSP.

A combination of those PDD is fitted to the experimental PDD of each applicator by means of a genetic algorithm<sup>[5]</sup> which optimized the energy spectrum. Finally, the binned precomputed monoenergetic PHSP files and the energy spectrum obtained by the genetic algorithm were combined to build the PHSP file optimized to describe the dose distribution of the considered applicator. From the final optimized PHSP file, the dose is computed by an in-house hybrid Monte Carlo algorithm<sup>[6]</sup> which takes into account condensed history simulations of both photoelectric and Compton interactions for X-rays up to 50 keV. The whole dose optimization and computation process was validated against Monte-Carlo simulations performed with penEasy as well as with gafchromic films dose measurements both in water and heterogeneous phantoms (bone, lung, air) for the spherical, needle, surface and flat applicators.

## Results:

Once the monoenergetic PHSP files and PDD database has been computed and stored, building the PHSP file optimized to a particular depth-dose curve in water only takes a few minutes in a single core (i7@2.5 GHz), for all the applicators considered in this work. From that PHSP file, the hybrid Monte-Carlo code is able to compute dose distributions within 5 minutes. For all the applicators, dose distributions computed with the proposed strategy are

<sup>1</sup> Grupo de Física Nuclear, Dpto. Física Atómica, Molecular Nuclear, Moncloa Campus of International Excellence, Universidad Complutense de Madrid, Madrid, Spain

<sup>2</sup> Department of Electronic Engineering, ETS de Ingenieros de Telecomunicación, Moncloa Campus of International Excellence, Universidad Politécnica de Madrid, Madrid, Spain

in good agreement with the Monte-Carlo simulations performed with penEasy. Gamma index calculation shows that more than 95% and 90% of the voxels fulfill the dose distance criteria of 2%/1mm in water and in the heterogeneous phantoms respectively.

**Conclusion:**

The Monte-Carlo PHSP files fitted to the experimental PDD for each applicator as described here, combined with the hybrid MC dose calculation tool compute fast and precise dose. This method is implemented into Radiance® (GMV SA, Spain), an IORT Treatment Planning System, for spherical, needle, surface and flat INTRABEAM® applicators.

**References:**

- <sup>[1]</sup> Vaidya, J. S. et al. 2010. TARGIT-A trial. *Lancet*, 376, 91-102.
- <sup>[2]</sup> Schneider, F et al. 2011. *Int J Radiat Oncol Biol Phys*. 81(4):1114-9.
- <sup>[3]</sup> Schneider, F. et al. 2014. *J Appl Clin Med Phys*, 15, 4502.
- <sup>[4]</sup> J. Sempau et al. 2011. *Med. Phys*. 38(11), 5887.
- <sup>[5]</sup> C. Fernández-Ramírez et al. 2008. *Phys. Rev. C* 77(6), p. 065212.
- <sup>[6]</sup> M. Vidal et al. 2014. *Radiother. & Oncol*. 111(S1).

# Radiographic Film Dosimetry as Predictor of Skin Toxicity from Intraoperative Radiotherapy

Aaron Pederson, MD, Caleb Price, PhD, Michael Hasselle, MD, Chante Frazier, MS, Elena Rehl, MD, William Burak, MD

---

## Purpose:

Measurements of lumpectomy cavity and skin dose with RTQA2 radiochromic film is used to verify accurate delivery of Intraoperative Radiotherapy (IORT) and predict which patients may be at risk of skin toxicity. This study is a retrospective review of breast cancer patients treated at a single institution to describe the relationship between measured skin dose and early toxicity.

## Material/Methods:

Prospective dose measurement using in vivo dosimeters has been performed on all patients undergoing INTRABEAM IORT at Memorial University Medical Center (Savannah, GA) since the inception of the IORT program. All breast cancer patients were prescribed 20 Gy to the lumpectomy cavity surface using standard 3, 3.5, 4, 4.5, and 5 cm spherical applicators with a 50 kV, 40 mA x-ray beam. Film dosimeters were placed within the lumpectomy cavity and anterior to the superior and inferior skin surfaces (Figure 1). Protective 2 mm lead equivalent shielding was placed to reduce in-room exposure.

## Results:

Between 11/2012 and 10/2015, 262 consecutive patients received IORT with in vivo film dosimetry. Average lumpectomy cavity dose was  $19.1 \pm 2.8$  Gy. Measured skin dose was  $3.1 \pm 1.7$  Gy (superior) and  $2.8 \pm 1.6$  Gy (inferior). There were two skin dose measurements  $> 10$  Gy. A patient received 14.8Gy skin dose causing moist desquamation (Grade 3) that healed by 3 months and later developed moderate fibrosis with telangiectasia (Figure 2-4). Another patient received 10.5 Gy skin dose causing dry desquamation (Grade 2) and underwent three seroma aspirations (Figure 5, 6). The remaining 260 patients had minimal skin effects, none above Grade 1.

## Conclusion:

Film dosimetry is useful to verify accurate lumpectomy cavity dose during IORT and skin dose measurements can predict early toxicity. No Grade 2/3 acute skin toxicity developed when skin dose measured  $< 10$  Gy. These results confirm the low rate of skin toxicity using INTRABEAM IORT for breast cancer and suggest that skin dose  $> 10$  Gy be used as a guide to offer earlier use of topical skin care for these patients. Use of Aquaphor™, Silvion™, and topical Vitamin E have proven useful in this institutional experience.



**Figure 1:** Typical arrangement of film dosimeters placed prior to initiation of IORT showing superior (blue arrow) and inferior (yellow arrow) skin placement.



**Figure 2:** Preoperative photograph of patient.



**Figure 3:** Photograph at 1 month postoperatively showing healing moist desquamation after high skin dose measurements (Superior 6.9 Gy, Inferior 14.8 Gy) were recorded.



**Figure 4:** Photograph showing resolution of acute skin effects by 3 months with mild induration and telangiectasia.



**Figure 5:** Preoperative photograph of patient.



**Figure 6:** Photograph at 1 month postoperatively showing erythema with healing dry desquamation after high skin dose measurements (Superior 10.5 Gy, Inferior 3.0 Gy) were recorded.

# Short-Term Sequela of Intraoperative Radiation After Breast Conserving Surgery

Goble, Rachel N.<sup>1</sup>; Drukteinis, Jennifer<sup>1</sup>; Lee, M Catherine<sup>1</sup>; Khakpour, Nazanin<sup>1</sup>; Kiluk, John V.<sup>1</sup>; Laronga, Christine<sup>1</sup>

---

## Background:

Intraoperative radiation therapy (IORT) is an emerging option for partial breast radiotherapy in select women with early breast cancer. Our objective was to assess short-term clinical and sonographic findings after breast conservation (BCT) and IORT.

## Methods:

An IRB-approved, single institution retrospective chart review was conducted of patients (pts) treated with BCT/IORT from 1/2011- 6/2012. Follow-up clinical breast exams and ultrasounds (US) obtained 6 and 12months after BCT/IORT were retrospectively reviewed by a breast radiologist (JD) for sonographic findings (Table 1). P-values were calculated using McNemar's test, Wilcoxon Rank Sum Test, and Chi-square.

## Results:

71pts underwent BCT/IORT. Mean age was 71.6 yrs (range 54-88). Of 71pts, 10 (14%) / 5 (7%) pts were symptomatic at 6/12month follow-up respectively. Eleven pts had deep tissue closure (DTC) of the lumpectomy cavity with 5/11 (45%) DTC pts being symptomatic at follow-up vs. 5/60 (8%) without DTC. 38/71 (54%) pts had at least one US; 35pts had 6month US (22 without a 12month US) and 16pts had a 12month US (3 without a 6month US). All 38pts had a seroma but, 10/38 (26%) pts were symptomatic.

At 6months, 9/35 (26%) pts had a symptomatic seroma [7 (78%) with pain and 2 (22%) with overlying skin hyperemia]. Two pts required seroma aspirations at 6months; 1 had repeat aspiration at 12months. At 1- year follow-up, 4/9 (44%) pts had persistent symptoms. One asymptomatic pt at 6months reported pain at 1 year despite no change in seroma appearance [total 5/16 (31%)]. At 6 months, DTC resulted in smaller seroma cavity volumes compared to those without closure ( $p = 0.03$ ). However there was no difference in cavity resorption between the two groups over time ( $p = 0.67$ ) and no significant change in seroma volume or wall thickness for either group. There was no difference in sonographic findings between the two groups at 6/12months.

## Conclusion:

Presence of a seroma is commonplace post BCT/IORT; symptomatic seromas are uncommon. DTC generated smaller but more symptomatic seromas. Longer follow-up with serial US performed in all BCT/IORT pts is advisable to document natural progression of symptoms and seromas.

<sup>1</sup> Moffitt Cancer Center, Tampa, FL, United States.

**Table 1.** Sonographic Findings after Breast Conserving Surgery and Intraoperative Radiation

	6mo US N = 35	12mo US N = 16
Seroma size (mean)	24.1x15.6x18.8mm	20.6x11.3x18.8mm
Seroma wall thickness (mean)	3.02mm	2.16mm
Seroma volume (mean)	8.27cc	9.21cc
Symptomatic	9 (26%)	5 (31%)
Complex seroma with adherent hyperechoic debris	12 (34%)	5 (31%)
Hematoma	4 (11%)	0 (0%)
Thin septations	14 (40%)	8 (50%)
Thick septations	8 (23%)	2 (13%)
Simple seroma	9 (26%)	4 (25%)
Low level internal echoes	9 (26%)	3 (19%)
Deep tissue closure (DTC)	10	6
DTC seroma size (mean)	19.9x10.6x15.0mm	17.8x8.5x16.3mm
DTC seroma wall thickness (mean)	4.8mm	2.3mm
DTC seroma volume (mean)	5.74cc	6.86cc

# An Oncology Nurse Navigator's Unique Challenge: Survivorship Planning for Breast Cancer Patients Post Breast IORT

Jeannine Graves, RN, BSN, CNOR, OCN, MPA<sup>1</sup>

---

## Background:

Despite the vast array of clinical information available for breast cancer survivors, there is surprisingly little known or written about the unique needs of patients who are status post breast IORT. For several years, Oncology Nurse Navigators provided patients with standard pre- and post-op information and support regarding surgery and radiation. They also provided information designed to help these patients navigate through the early post-radiation therapy side effect management, including long-term management of post-radiation conditions.

Using the framework provided by our national Oncology leadership for Nurses, I formulated a navigation pathway which focuses on the expedited treatment journey (from surgery to hormonal therapy) and how to incorporate this new technology into their understanding of their physician's approach for their care.<sup>[1,2]</sup> As rewarding as this treatment is for patients who are fortunate to be within selection criteria, these patients require a structured needs assessment and individualized education in order to provide the best outcome.<sup>[3]</sup>

## Methods:

The items listed below constitute the framework of the patient assessment performed by the Nurse Navigator in order to ensure a comprehensive patient teaching experience:

1. Educational level
2. Understanding of the differences between "traditional" treatment and the use of Breast IORT
3. Willingness to adhere to the surgeon's instructions for post-op activities to improve outcomes
4. Ability to manage potential post-op complications, should they arise

From this assessment, the Nurse is able to develop a patient-specific plan of care to enhance the immediate post-operative recovery and minimize the occurrence of post-op infection and/or wound complications. In our community hospital, we have the ability to navigate all breast cancer patients and have noticed the tendency for Breast IORT patients to overestimate their physical readiness to return to activities of daily living soon after their procedure. To counteract this tendency, a careful patient assessment is performed to assist the navigator to determine the key points of instruction necessary to promote wound healing and prevent unnecessary post-op complications.

<sup>1</sup> Clinical Coordinator, Oncology Programs Sutter Cancer Center, Sacramento, Sutter Health

Following the patient assessment parameters mentioned above, the nurse will plan a pre-operative educational session, including elements of adult learning theory, to enhance the patient's understanding of the information presented. A key family member is asked to attend this educational session in order to ensure more information is retained for later review. Next, the rationale for clinical selection by the surgeon is reviewed. Many misunderstandings are clarified with this topic alone, which enhances the patient's understanding of her role in her recovery and surveillance in survivorship.<sup>[4]</sup> The next topic covered includes the intraoperative phase and the body's response to the kv dose provided to the tumor bed.

Additional time is devoted to pictorial aides to help visual learners understand the delivery system and its purpose. The last part of the discussion covers the importance of slowly advancing upper body range of motion activities and a gradual return to full activities of daily living when cleared by the surgeon. An initial survivorship discussion is included to enhance the patient's participation in her care which enhances outcomes and increases adherence to self care and surveillance which contributes to long-term survival.<sup>[5]</sup>

## References:

- <sup>[1]</sup> Verma S et al. *Curr Oncol*. 2011;18 (suppl 1):S3-9.
- <sup>[2]</sup> Gold DT, McClung B. *Am J Med.*, 2006; 119 (4 suppl 1): S32-37
- <sup>[3]</sup> Davidson B et al. *J Support Oncol*. 2007;5(3):139-143
- <sup>[4]</sup> Institute of Medicine of the National Academies. *Cancer Survivorship Care Planning Fact Sheet*. November 2005
- <sup>[5]</sup> Jones R, Regan M, Ristevski E, Breen S. Patient's perception of communication with clinicians during screening and discussion of cancer supportive care needs. *Patient Educ Coun*. 2011 Jan 18

# Targeted Intraoperative Radiotherapy for the Management of Infiltrating Lobular Carcinoma

Dennis Holmes, MD

---

## Background:

IORT and other forms of PBI have been widely adopted as alternatives to whole breast radiotherapy following breast conserving surgery (BCS) in the management of early stage invasive breast cancer. However, the use of IORT in the management of the invasive lobular carcinoma (ILC) subtype has traditionally been discouraged due to the paucity of prospective efficacy data supporting its use in the management of ILC. Further limiting the use of IORT in the management of ILC are the challenges related to evaluating the extent of disease in this histological subtype.

## Methods:

Women with biopsy proven clinical stage I/II, node negative, ILC underwent bilateral digital mammography, ipsilateral breast ultrasound, and bilateral breast CE-MRI prior to being selected for BCS, IORT, and sentinel node biopsy. Utilizing an interdepartmental treatment policy, women were considered eligible for IORT if their lesion measured  $\leq 3$ cm in maximal diameter on all preoperative imaging studies.

## Results:

Between July 2012 and June 2015, ten (10) women completed both BCS and IORT. Median patient age was 62 years (54-79). Two (2) patients required subsequent mastectomy for extensive multifocal disease and a third patient required whole breast radiotherapy due to a positive sentinel node. Median applicator size was 4cm (3-5cm). Median maximal lesion size, combining all imaging studies for each patient, was 16.5mm (0-23). Median lesion size in the surgical pathology specimens was 12.5mm (1.4-24). One tumor had mixed ductal and lobular features. Eight patients received concurrent IORT, while two others received IORT at the time of margin re-excision. Median follow-up was 24.5 months (6-42) for the entire cohort and 20 months (6-42) excluding the two patients requiring mastectomy. To date, no patient has experienced a loco-regional or systemic recurrence.

<b>ILC size on final pathology</b>	Median: 12.5mm (14-24)	
<b>ILC maximal size on imaging</b>	Median: 16.5mm (0-23)	
<b>Follow-up (entire Cohort)</b>	24.5 months (6-42)	
<b>Follow-up (BCS cohort)</b>	20 months (6-42)	
<b>Final BCS margin status</b>		
<b>Negative</b>	8	80%
<b>Positive</b>	2X	20%
<b>Local Recurrence</b>		
<b>No</b>	10	100%
<b>Yes</b>	0	0%
<b>Additional therapy</b>		
<b>No</b>	7	70%
<b>Yes</b>	3X,Y	30%
<b>Successful BCT</b>		
<b>Yes</b>	8	80%
<b>No</b>	2X	20%

<sup>x</sup>required mastectomy

<sup>y</sup>required whole breast radiotherapy

### Conclusions:

Assessing the extent of disease of ILC remains a challenge for all imaging studies. Nonetheless, early evidence suggests that selected patients with ILC may be successfully managed with IORT with low risks of surgical morbidity or local recurrence.

The 2016 U.S. INTRABEAM® User Meeting has been sponsored by ZEISS.

Not all products, services or offers referenced in this presentation are approved or offered in every market and approved labeling and instructions may vary from one country to another.

SUR.8403