

precision

a newsletter by Advanced Radiation Therapy

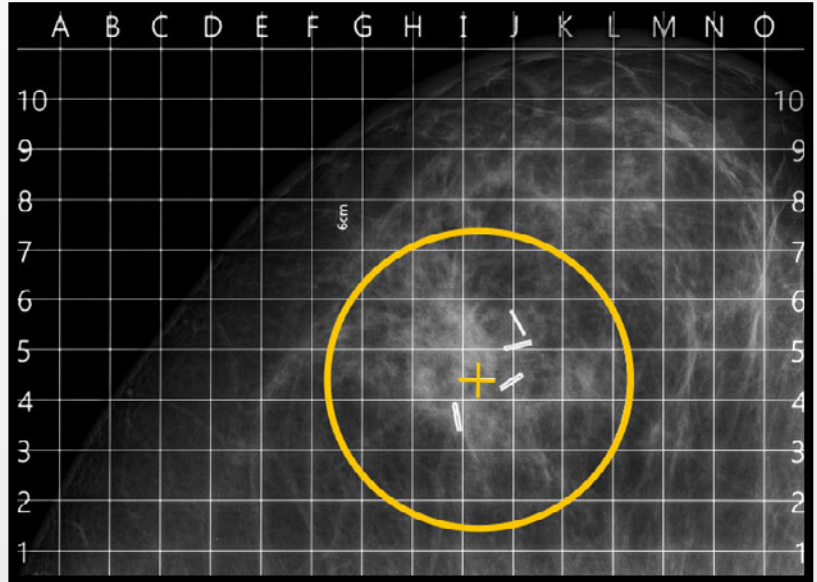
P. 02

**Advanced Radiation Therapy
Launches *PreciseRT™***



ART is announcing
that based on

over a decade of excellent clinical results with its flagship product, it is launching its most advanced technology package, *PreciseRT™*. This new portfolio product introduces a digital mammography based, platform, significantly reducing the overall time for patient setup, improving image quality and simplifying patient flow. “We have been developing this technology for some



Where Precision Meets Accuracy

time now and have designed it to meet the clinical challenges of treating breast cancer with radiation

Continued on page 2.

P. 02

**Responding To Changing
Times –**

Observations of The Editor

P. 03

**Florida Cancer Center
Upgrades to *PreciseRT***

P. 04

**5-Year Multicenter APBI
Clinical Data Shows
Excellent Results**

P. 06

**Webinar: “Maximizing
Accuracy and Precision....”**

P. 07

**Bill Dowd Joins The Advanced
Radiation Therapy Team**

Responding To Changing Times – Observations of the editor

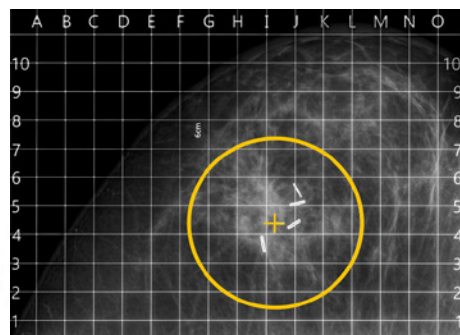
Ray Bricault, COO

As the world around us is changing in response to technological developments, pandemic induced social and business limitations, modified clinical priorities as well as the general needs of our customers, we are adapting as well. With this, our first electronic newsletter, we review our key responses to these changing times with the launch of the PreciseRT product, investing in our customer outreach capabilities and review the most recent clinical publications with our non-invasive breast brachytherapy technologies, AccuBoost and PreciseRT.

ART Launches *PreciseRT™* (cont. from p. 1)

in ways which optimize the cosmetic and clinical outcomes in consideration of the adjuvant surgical techniques commonly employed today” says Piran Sioshansi, President and CEO of Advanced Radiation Therapy (ART).

Included in the PreciseRT package, is a completely reimagined imaging platform that incorporates enhancements based on requests from the current user base. The new platform, with integrated motion management allows for immobilization of the breast with real-time imaging and treatment, which drives



Digital Mammography Image + Overlay

many of the benefits of the NIBB technique. The ability to identify the immobilized target, within the breast, using a high contrast imaging technology provides clinicians with the utmost precision and accuracy



PreciseRT™
immobilize. image. irradiate.

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ART Launches *PreciseRT™* (cont.)

in targeting. This targeting confidence can be leveraged toward the use of close margins and the many clinical benefits that potentially stem from a smaller treatment volume.

Learn more at www.PreciseRT.com

Florida Cancer Center Upgrades to *PreciseRT™*



Sandra Sha, MD

In August, Central Florida Cancer Institute (CFCI), one of the longest term providers of AccuBoost therapy, updated their equipment to the new PreciseRT digital platform. The clinical team at CFCI has over a decade of experience in offering the AccuBoost treatment on the first-generation platform and has seen excellent clinical results. CFCI has acquired the new platform with the goal of improving the treatment workflow, reducing treatment time, improving the patient experience, and to benefit from the updated user interface.

Dr. Sandra Sha (pictured), a distinguished physician as recognized by the Florida Medical Association specializing in breast cancer treatment, commented, “Our purchase of the PreciseRT solution is the latest technology update we have added to bring the most advanced breast cancer treatment technologies to the women of Central Florida. Having seen excellent clinical results in our use of the AccuBoost technique for over a decade, we wanted to add the capabilities and benefits this new release offers to our patients.”

Lead therapist and long time user, Michele Jolly, added, “After only a couple days of use, the advantages of the new low profile design have already been realized. Patient setup, particularly for heavier patients, is much easier, and the revised patient flow is very efficient.”

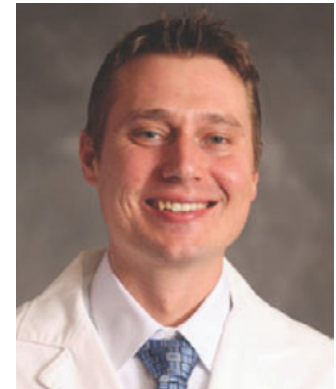
5-Year Multicenter APBI Clinical Data Shows Excellent Results

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Clinical Investigation

Phase 2 Trial of Accelerated Partial Breast Irradiation (APBI) Using Noninvasive Image Guided Breast Brachytherapy (NIBB)

Jaroslaw T. Hepel, MD,^{*,†} Kara L. Leonard, MD,^{*,†} Sandra Sha, MD,[‡] Theresa A. Graves, MD,[§] Doreen L. Wiggins, MD,^{||} Dean Mastras, MD,^{||} Ann Pittier, MD,^{||} Brown University Oncology Research Group,[¶] and David E. Wazer, MD^{*,†}



Jaroslaw Hepel, MD

In July 2020, the Red Journal published a clinical update for an FDA registered multicenter clinical study of Non-Invasive Breast Brachytherapy APBI trial with excellent results (ref NCT1463007)¹.

This publication presented the 5-year follow-up data for a cohort of 40 patients treated with a dose of 34 Gy in 10 fractions with patient, tumor and treatment characteristics as show in Table 1. The reported rates of good/excellent cosmesis were 95% at 2 years and 100% at 5 years. The study reports well managed toxicities, with no late Grade 3 or higher late toxicities seen at any point. Grade 2 toxicity was 5% and 10% at 2 and 5 years, respectively. As can be seen in Table 2 from the report, late toxicity was very well controlled and the only grade 2 toxicity seen was from telangiectasias.

Table 1 Patient, tumor, and treatment characteristics

Characteristics	Values
Age, y	
Mean	68
Range	50-92
Histology, n (%)	
IDC	22 (55%)
Inv. mucinous	2 (5%)
Inv. tubular	1 (2.5%)
DCIS	15 (37.5%)
Tumor size, cm	
Mean	1.1
Range	0.3-3.0
Lymph node status, n (%)	
Positive	0 (0%)
Receptor status, n (%)	
ER positive	39 (97.5%)
Her-2-Neu positive	0 (0%)
Volume, mean (range), cm ³	
Whole breast	1591 (365-3569)
Tumor bed	22.4 (1.1-69.6)
Breast compression, cm	
Mean	6.5
Range	3.4-9.4
Applicator type, n (%)	
First generation	8 (20%)
Mixed	18 (45%)
Second/third generation	14 (35%)
Treatment schedule	
Daily	29 (72.5%)
BID	11 (27.5%)

Abbreviations: BID = twice daily; DCIS = ductal carcinoma in situ; ER = estrogen receptor; IDC = invasive ductal carcinoma; Inv = invasive.

As related in the initial study publication(Hepel, 2014)², this study allowed patients to self-select to either a once or twice per day treatment schedule. Analysis of 5 year data shows no statistical correlation to treatment schedule for either cosmesis or toxicity. As 73% of patients self-selected to the once-per-day

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5-Year Multicenter APBI (cont.)

option arm of the study, it inspired the authors to investigate, in an FDA registered multicenter clinical trial (ref NCT01961531), a hypofractionated APBI regimen of 28.5Gy if 5 daily fractions. The published report from this trial has shown excellent cosmesis and toxicity(Hepel, 2018)³. This study takes on particular clinical relevance in light of the current NIH and industry guidance toward hypofractionation where clinically appropriate in response to COVID-19 industry guidance.

An interesting observation was made by Dr. Hepel, author of the study, and his colleagues, “ Importantly, the rate of grade 2 to 4 subcutaneous fibrosis was 0% compared with 31 % in our experience with 3D-CRT APBI”. ART has received numerous field observations of minimal subcutaneous fibrosis, but this was the first peer reviewed published result corresponding to those observations.

Toxicity	Grade 1 n (%)	Grade 2 n (%)	Grade 3-5 n (%)
Hyperpigmentation	23 (58%)	0	0
Telangiectasia	11 (28%)	2 (5%)	0
Skin atrophy	0	0	0
Subcutaneous induration/fibrosis	12 (30%)	0	0
Seroma	2 (5%)	0	0
Fat necrosis	3 (8%)	0	0
Deformity nipple/areolar	0	0	0
Breast volume loss/ hypoplasia	14 (35%)	0	0

1 Hepel JT, Leonard, KL, Sha S, Graves TA, Wiggins DL, Mastras D, Pittier A, Wazer, DE, Phase 2 Trial of Accelerated Partial Breast Irradiation (APBI) Using Noninvasive Image Guided Breast Brachytherapy (NIBB), 2020, PMID 32721422

2 Hepel JT, Hiatt JR, Sha S, Leonard KL, Graves TA, Wiggins DL, Mastras D, Pittier A, Wazer DE, The Rationale, technique, and feasibility of partial breast irradiation using noninvasive image-guided breast brachytherapy, Brachytherapy 13(2014), pp 493-501. PMID:24997723.

3 Hepel JT, Yashar C, Leonard KL, Einck JP, Sha S, DiPetrillo T, Wiggins D, Graves TA, Edmonson D, Wazer DE, Five fraction accelerated partial breast irradiation using noninvasive image-guided breast brachytherapy: Feasibility and acute toxicity, Brachytherapy, 2018, 17(5): P 825-830.PMID 29936130.

Click to download the [complete publication here.](#)

An Educational Webinar with David Wazer, MD



David Wazer, MD

On October 29, 2020, Advanced Radiation Therapy was joined by David Wazer, MD, Professor & Chairman of the Department of Radiation Oncology at Rhode Island Hospital & Brown University School of Medicine for an educational webinar about “Maximizing Accuracy and Precision in Partial Breast Irradiation”.

“High Accuracy and High Precision is most optimal for partial breast irradiation”

- David Wazer, MD

In view of the changing landscape within radiation therapy and the drive toward hypofractionated treatments, optimizing Accuracy and Precision are absolutely essential for good outcomes. This presentation revisited the basic principals of accuracy and precision on the targeting and delivery of partial breast radiotherapy. Unique to this lecture were details on how Non-Invasive Breast Brachytherapy (NIBB) can ford the gap between the best surgical practices for surgery (Oncoplasty) and targeting of the appropriate tissues within the breast after surgical rearrangment. The presentation was focused, intriguing, and accompanied by an engaging Q&A session by attendees.

Watch the recording from the webinar with Dr. Wazer at: www.PreciseRT.com

Bill Dowd Joins ART as Chief Commercialization Officer



Bill Dowd, CCO

In September 2020, Bill Dowd (pictured), a highly accomplished and trusted executive in the field of radiation therapy has joined ART as it releases its PreciseRT product. His business background has long focused on launching and promoting of the state-of-the-art technologies and sales of high-end medical equipment in the radiation oncology market. For the last ten years he has taken increasingly more important executive positions at cornerstone companies in the industry, including Nucletron(Elekta), Mick Radionuclear(Bebig) and C-Rad.

“I am very excited to join Advanced Radiation Therapy and lead them through the launch of their new breast radiotherapy product which provides exceptional clinical benefits to women diagnosed with breast cancer,” commented Bill.