Issue 27, August 2014

AccuBoost® Booster Club

Notes from the Editor:

This issue covers some of the recent additions to the AccuBoost users group. It reports on new staff, plans for exhibiting at this year's ASTRO and the introduction of BioZorb, a 3-dimensional lumpectomy cavity marker for precise targeting of the dose.

The highlight of this issue is the announcement of the launch of the FAST NIBB, as the new hypofractionated AccuBoost study that delivers the accelerated partial breast dose in only 5 fractions.

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Inside this issue:

New AccuBoost Installations:

There have been a number of new installations since the last newsletter. Notable among the new additions are:

Steward Health Care System

St. Elizabeth's Medical Center in Boston, Massachusetts is part of Steward Health Care System. For a long time the radiation oncology facility at St. Elizabeth's had looked into adding brachytherapy to the services that they offered, but could not justify the cost. "With AccuBoost in the mix, introducing the brachytherapy modality became financially viable," states Ray Wilburn the Director of Imaging Services and Women's Health.

Other important additions to the AccuBoost users group are the **Cancer Treatment Centers of America** family of hospitals. The first of these CTCA installations was **Midwestern Regional Medical Center** in Zion, IL. The center is under the leadership of Bernard Eden, MD, the National Director of Radiation Oncology. The Zion facility started offering AccuBoost in June.

CTCA's Bernard V. Eden, MD, National Director of Radiation Oncology and Elizabeth Laspisa, Lead Radiation Therapist, pictured describing the AccuBoost procedure with a potential AccuBoost patient.

Cancer Treatment Centers of America
Winning the fight against cancer, every day.®

The Southeastern Regional Medical Center in Newnan, GA is another CTCA Hospital to offer the AccuBoost procedure. Sean Cavanaugh, MD, one of the radiation oncologists at the facility stated that "AccuBoost is all about accuracy of targeting the partial breast dose, and I am all for it." AccuBoost will soon be offered at other CTCA facilities.

ASTRO TARGETING CANCER CARE

Visit AccuBoost during ASTRO
Booth No. 218, Sept 14-16, San Francisco

New Addition to the Team

Gina Jones, Vice President of sales, is the latest addition to the AccuBoost team. Gina has a unique background as both a mammographer by training and a seasoned diagnostic equipment salesperson. Prior to joining the AccuBoost team she was the National Director of Sales at Aurora Medical Imaging and Senior Sales Executive at GE Medical Equipment.

Gina played an important role in the selection of mammography equipment for AccuBoost in the early days of development. She was impressed with the concept and kept an eye on the product for years until recently, when she decided to take the lead sales position. "When I first learned about AccuBoost, I was intrigued that the diagnostic platform that I had promoted all my active life had a role to play in the therapy business. I have tracked the status of AccuBoost in the market and finally came to the realization that the timing was right for me to get actively involved."

AccuBoost Celebrates 7th Anniversary

July is the 7th anniversary of the first patient treated with AccuBoost. Linda Schuk of San Antonio, TX was the first patient to receive her boost dose via AccuBoost. The then 61 year old Ms. Schuk received the treatment at the Texas Cancer Clinic under the supervision of Bradley Prestidge, MD. The treatment received extensive local and national coverage. During her interview with Channel 12 KSAT TV station she said "This procedure zeros in the radiation to where I had the cancer removed." Linda Schuk added that "Sometimes the treatment can be worse than the ailment. Any treatment that can improve the outcome and make it easier and more comfortable on the patient – I am all for it." The interview is recorded on AccuBoost's web site and can be accessed from the home page.

The interview is available on the AccuBoost website: ***www.accuboost.com***

AccuBoost at ASTRO

This year is the 8th year that AccuBoost is participating in the annual American Society for Therapeutic Radiology and Oncology conference. This year's ASTRO meeting will be held September 13-18 in San Francisco. In addition to exhibiting the latest developments and hardware, AccuBoost will have a series of "Meet the Expert" Q&A sessions at the booth. These sessions provide a unique opportunity for present and pending AccuBoost users to meet, exchange ideas and share experiences. The schedule for the in-booth presentations is shown below.

ASTRO
TARGETING CANCER CARE

AccuBoost "Meet the Expert" In-Booth Q&A Sessions			
Sun, Sept 14	11:20 – 12:20	Scot Ackerman, MD	*AccuBoost Workflow*
Sun, Sept 14	3:00 – 4:00	David Wazer, MD	*AccuBoost for APBI*
Mon, Sept 15	11:00 – 12:00	Anand Kuruvilla, MD	*What I like about AccuBoost*
Tue, Sep 16	11:00 – 12:00	Erich Randolph, MD	*AccuBoost in our Practice*

BioZorb the Missing Link for AccuBoost

BioZorb, as the name implies, is a 3-D bio-absorbable surgical site indicator that is inserted and sutured in the lumpectomy cavity at the time of surgery. The implantable device has 6 titanium radiopaque markers embedded in its structure to delineate the boundaries of the surgical cavity in all directions. The product was developed under the guidance of Gail Lebovic, MD, a prominent breast surgeon and the Chief Medical Officer of Focal Therapeutics, the West Coast company that manufactures the product.

BioZorb tissue markers are available in 6 convenient sizes to fit most lumpectomy cavities. The bio-absorbable structure of the device, when sutured in place, provides an open framework to prevent the lumpectomy cavity from collapsing and causing an unsightly deformity. The structure is expected to last more than one year before being absorbed – long enough for complete healing of the lumpectomy site. The semi-rigid design of the device allows for a 3-dimensional visualization of the excision site and is ideal for targeting - particularly for the partial breast dose.

"I'm a big fan of partial breast irradiation, and I know the BioZorb will help when Accuboost is used," states Gail Lebovic. She adds "this product is an ideal design for proper identification of the lumpectomy margins to target the radiation

dose. The device leaves behind a permanent fixed array of marker clips to trace the evolution of the excision site with clinical imaging. As a breast surgeon, I anticipate that the BioZorb will help improve the shape and contour of the breast after surgery, as the structural support will help to decrease tissue deficits at the surgical site as well. The results we have seen are very exciting."

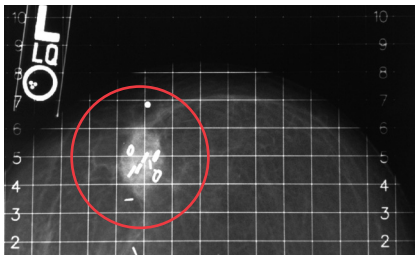

Image of a BioZorb marker in an AccuBoost patient.

Up to this point, the breast surgeons, who normally refer patients to radiation oncologists, had no significant involvement in the AccuBoost procedure. BioZorb is the innovation that establishes a role, and indeed an incentive, for the breast surgeons. By proper attachment of the 3-dimensional tissue marker, the breast surgeon actively participates and enables the most accurate targeting of the tumor bed dose. "We find BioZorb to be the missing link – as it defines an active role for the breast surgeons to participate in the delivery of the partial breast dose with ultimate accuracy" states Gina Jones, the VP of Sales for AccuBoost.

AccuBoost for FAST APBI Study

One of the conclusions of the breast brachytherapy panel during the recent ABS annual meeting was that the future trend for breast brachytherapy is toward non-invasive options and hypofractionation. To partially address this objective, Jaroslaw Hepel, MD and his colleagues at Rhode Island Hospital have embarked on a new investigation that delivers the accelerated partial breast (APBI) dose by AccuBoost in a more convenient 5 fraction schedule. This Phase I/II, study is the natural follow up to an earlier investigation, by the same group, that delivered the APBI dose in 10 fractions. One of the lessons learned in the earlier AccuBoost for APBI study was that, given a choice, patients and radiation oncology practitioners preferred a more convenient single daily fraction dosing schedule. It turns out that 10 fractions of radiation lasting up to

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AccuBoost for FAST APBI Study (Cont.)

two weeks was too long for the patient. Further, a twice daily regimen with at least 6 hours separation between treatments was time consuming and inconvenient for the patients and a daunting task for the facilities that offer brachytherapy services. Clearly, a once daily treatment is the preferred mode.

The objective of the FAST NIBB (Non-Invasive Breast Brachytherapy) study, as AccuBoost is referred to in the protocol, is to evaluate and report the rate of early and intermediate toxicity. The secondary objectives are to assess and report on the recurrence rate and cosmetic outcome. It is expected that the study will provide preliminary data to enable investigation of NIBB in a Phase III or IV follow-up trial.

The fractionation for the FAST NIBB study is 5 fractions of 5.7 Gy for a total of 28.5 Gy delivered over 5 to 10 days based on the preference of the patient and the schedule of the practice. The patient eligibility criteria is very similar to other APBI studies. The investigation is open to early stage cancer patients with histological diagnosis of invasive breast carcinoma or DCIS, life expectancy of more than six months who are treated with breast conservation. Lymph node positive patients, those with less than 2 mm margins are excluded, as are the patients with tumor sizes of more than 2 cm. Readers are encouraged to contact the principal investigator for a complete list of inclusion/exclusion criteria. In addition to Rhode Island Hospital, two other institutions will be treating patients under this protocol. The study is expected to treat 40 patients and last a little over a year.

The main goal of the study is to offer a convenient and comfortable treatment for breast cancer patients with early stage disease. There is no incentive to reduce the number of fractions at the present time under the current reimbursement conditions. However, if healthcare finance evolves from a “per fraction” to a “per patient” reimbursement model, the FAST NIBB approach, using AccuBoost, will offer a significantly lower cost option, as this approach saves the cost of both the invasive device and the associated surgeon’s fees.

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