The SAVI 6-1Mini APBI Applicator:
An Unique Solution For Small Lumpectomy Cavities And Skin Distances

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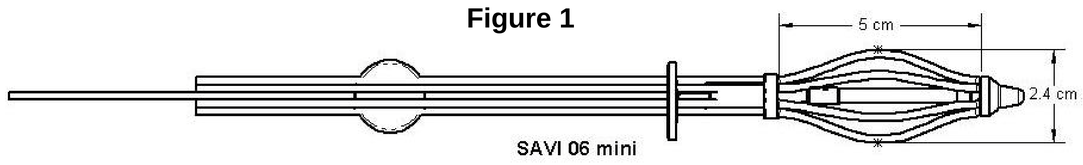
ASTRO Annual Meeting, Chicago 2009

Purpose:

The purpose of this study was to demonstrate that the SAVI 6-1Mini **(Cianna Medical**, **Aliso Viejo, CA)** multicatheter APBI applicator (***Figure 1***) was the applicator of choice, anatomically and dosimetrically, in patients in whom the breast size, the size of the lumpectomy cavity and its proximity to the skin precluded treatment and the use of other available APBI balloon–type applicators (MammoSite or Contura).

Figure 1



Method and Materials:

The study considered the first seven (7) patients who, because of the cavity size and/or inadequate skin distance, were not fit for an APBI treatment using other balloon-type devices. MammoSite-type and a Contura-type template plans were superimposed on the SAVI 6-1Mini CT original planning scan and pertinent dosimetric comparison were performed.

The SAVI 6-1Mini Planning Objectives: V95>95%, V150<50cc, V200<20cc and acceptable rib and skin maximum doses (< 34 Gy/100%RX).

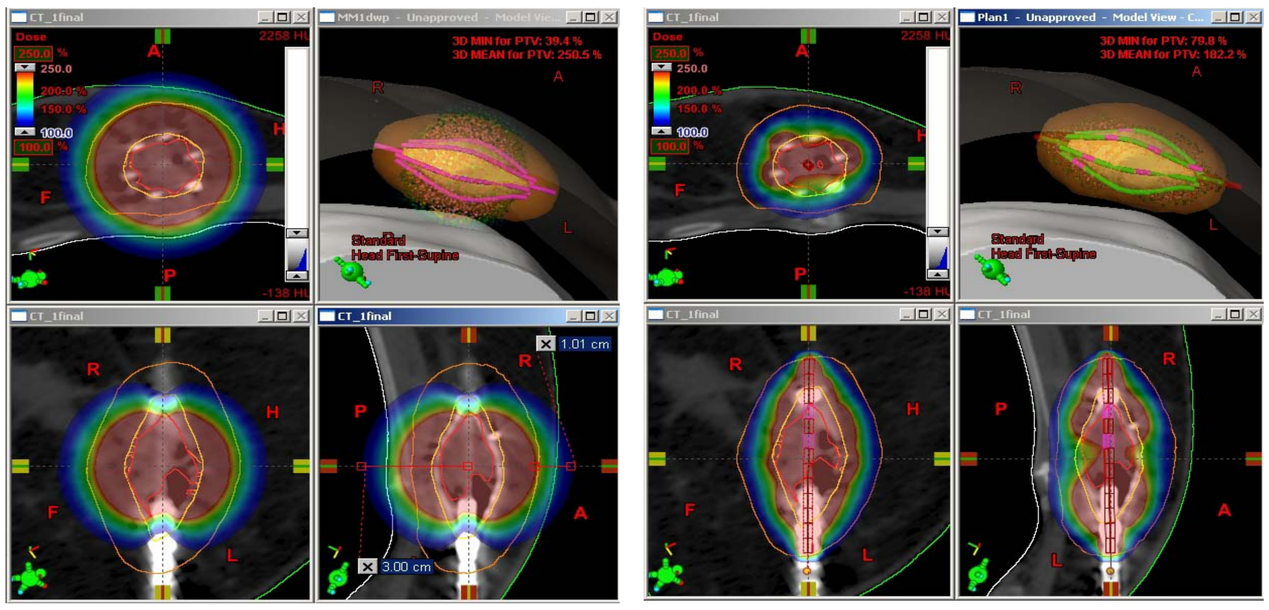


Figure 2

A single source dwell position was placed in the central lumen of the SAVI 6-1Mini device in order to create a virtual MM plan. 3.4 Gy were prescribed at 3 cm radial distance from this position (***Figure 2***) This is the equivalent radius of the PTV spherical volume created for a regularly filled 35.0 cc MM balloon.

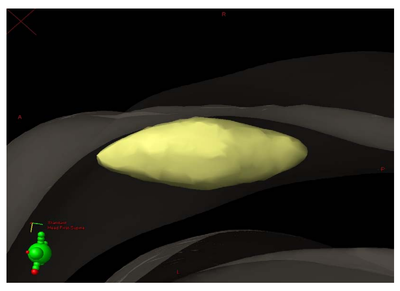
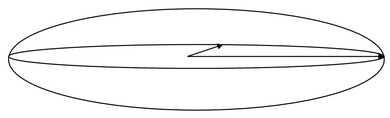


Figure 3: SAVI volume – CT based reconstruction

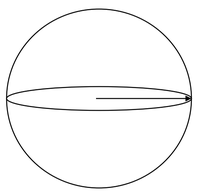
Ellipsoid Shape:

V = 4πabc/3



SAVI 6-1Mini

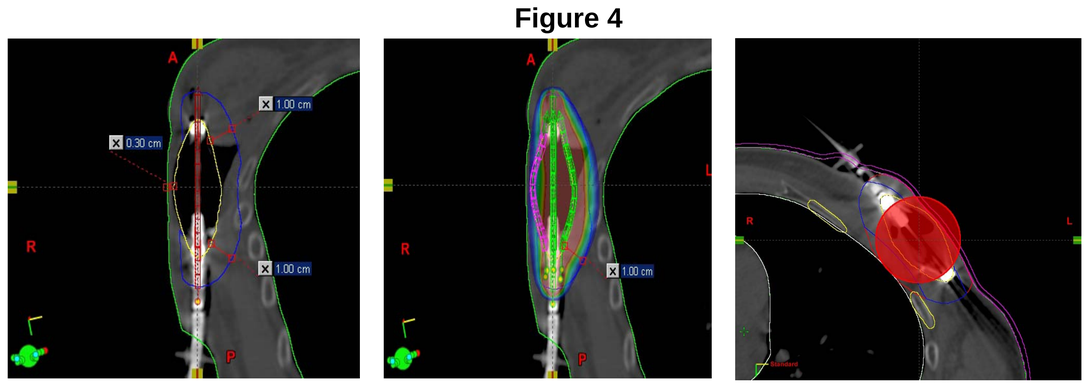
Sphere



MammoSite; Contura

Normal range for SAVI 6-1Mini CT-based reconstructed volume: **8.0 – 10.0 cc**, the equivalent of 1.2 – 1.3 cm radius balloon-type applicators. Properly inflated balloon-type applicators have a radius of at least 2.0 cm. Only under-inflated, distorted and highly asymmetrical balloons would have been a fit for lumpectomy cavity sizes in this range. Due to its rather **ellipsoidal shape** (***Figure 3***), the SAVI 6-1Mini device can accommodate anatomies unfit for a **spherical shape** applicator (MM or Contura). ***(Figure 4).***

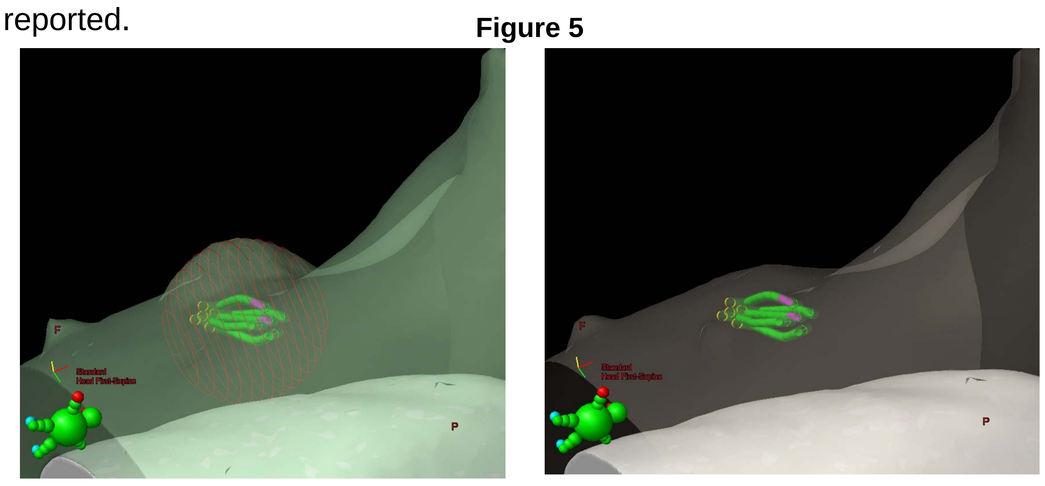
Figure 4



A Contura plan template was also superimposed on the CT image set and fit into the cavity volume. A plan was then created as to deliver the prescription dose to the same PTV surface as the one considered for the MM virtual plan.

A Body-Deformed Contour was created (***Figure 5***) in order to mimic the skin shape when a balloon-type device was virtually placed inside the cavity. More realistic maximum skin doses were than assessed and reported.

Figure 5



Results:

- **SAVI structure volume** range: 8.0 – 10.0 cc
- **V95** - % of PTV_EVAL covered by 95% PIL **range**: **96.3 - 98.3**; Avg = **97.3 %**
- **V90** - % of PTV_EVAL covered by 90% PIL **range**: **98.2 – 99.6**; Avg = **98.7 %**
- **Max Skin Dose Values** are, on average, **≤ 90% PIL** (30.6 Gy) (106% -max)
- **SAVI 6-1Mini –to-Skin Separation** ranged from **1.3 mm** to **7.4 mm**
- **V200** - cc of tissue getting at least 68 Gy (FTN factor) **≤ 14.1; Avg = 13.0 cc**
- **DHI** values range from **0.350** to **0.450** (for *SAVI 6-1Mini*)
- 5 cases of **IDC (T1N0M0)** and 2 of **DCIS (TisN0M0);** excellent cosmetic results at 6-month follow-up (5/7 cases), mild induration-residual seroma and minimal hyperpigmentation (2/7 cases – most recent) at 1-month follow-up.

Discussion:

Balloon-type applicators cannot accommodate volumes of less than 15cc without causing extreme patient discomfort, skin overstretching and prohibitive skin doses. Body contour modeling or editing should be employed in order to realistically account for skin stretching caused by the use of a balloon applicator when assessing the maximum dose to skin for comparative studies. An **Average Maximum Skin Dose** of 250%PIL (85 Gy) was estimated when the body surface was conformed to the shape of a MM or Contura applicator. This is still an unacceptable value, but a realistically lower value than the one obtained when contour modeling is not employed (~ 600%PIL or 204 Gy)

Due to variance in PTV_EVAL geometry and local breast morphology that comes with the use of balloon applicators, coverage indexes comparisons of **SAVI 6-1Mini vs MM or Contura** should be carefully considered. If considered, a clear assessment and specification of what is compared is mandatory.

Conclusions:

➢a reevaluation of DHI acceptance criteria for APBI for small cavity volumes is recommended. In our study, **DHI < 0.45 (SAVI 6-1Mini).** ABS BB TG recommends a **DHI ≥ 0.75**

➢APBI has become a very efficient and attractive method of treatment for women diagnosed with early stage breast cancers. Balloon-type applicators like MammoSite or Contura can accommodate a large range of clinical situations but fail to address the ones where the lumpectomy cavity volumes are below 15cc. The **SAVI 6-1Mini** applicator is the only implant solution for small lumpectomy volumes. Its design allows a proper dose optimization, excellent PTV coverage and acceptable skin sparing.

➢ the backscatter radiation component is almost nonexistent in SAVI 6-1Mini cases with minimal applicator-to-skin distances. Further evaluations of how that translates into skin surface dosimetry needs to be employed, via empirical research or the use of heterogeneity corrected computational algorithms.