



Comparison of Target Breast Volume Treated for Accelerated Partial Breast Irradiation (APBI) Devices

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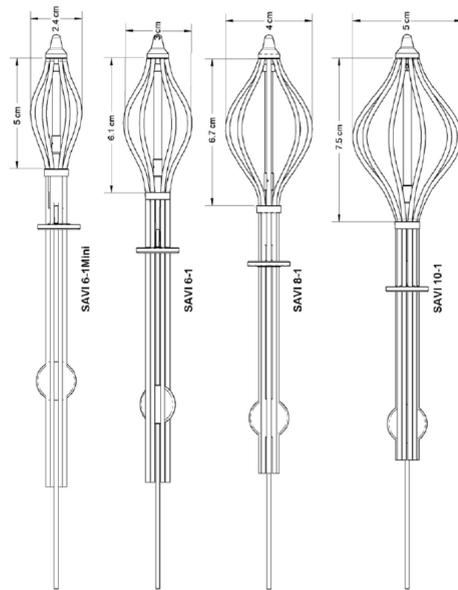


1. Introduction

The Strut Adjusted Volume Implant, SAVI, is a multi-catheter, single entry brachytherapy device for APBI designed for adaptability to anatomic constraints. There are four sizes with 6, 8, or 10 peripheral struts available for source dwell positions providing excellent dosing flexibility. Since the sizes were designed to fit multiple cavity sizes, a study was undertaken to evaluate the amount of target breast tissue treated with each device, and compare that to published data for other available devices.

2. Methods and Materials

A retrospective review of 67 patients treated at the University of California San Diego was undertaken to evaluate the size of the treated target breast tissue. Mean sizes and ranges of the PTV-eval (one centimeter expansion of the cavity excluding the cavity volume, 5mm below the skin, and chest wall) were evaluated for each SAVI size. The data was further subdivided into patients with no normal tissue restrictions on the PTV-eval, and those with chestwall and/or skin restrictions, limiting the size and shape of the PTV-eval in order to compare with other brachytherapy devices.

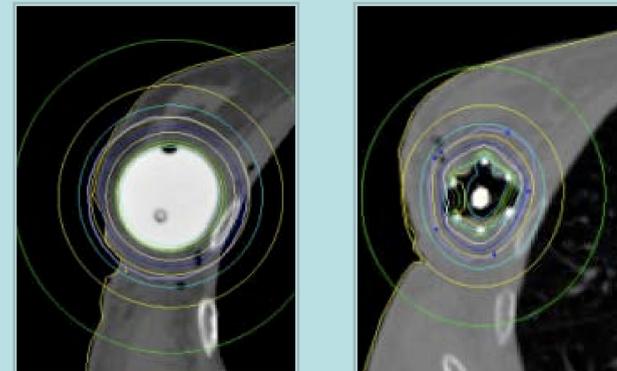


3. Results

A symmetrical expansion of 1 cm from the 6, 8 and 10 SAVI would give ideal PTV-eval volumes of approximately 59, 74, and 110 cc, respectively. In this patient population, the 6 mini, 6, 8, and 10 strut device treated a mean and standard deviation (with range in parentheses) of 45.2 ± 6 cc (37.9-53.9 cc), 47.6 ± 11 cc (23.2-65.9 cc), 71.9 ± 17 cc (40.5-105.1 cc), and 89.3 ± 22 cc (62-133.1 cc). Review of the data confirms that proximity to the skin, chestwall, or both reduced the PTV-eval. Published data on the Contura catheter demonstrates a mean PTV-eval of 89.7 cc (71.9-108.9 cc) and 94.9 ± 12 cc (74.4-119.8 cc) for the MammoSite.

SAVI Size	Ideal PTV Eval (calculated)	Actual PTV Eval (treated)	Range	Standard Deviation
6 mini		45.2 cc	37.9-53.9 cc	± 6 cc
6	59 cc	47.6 cc	23.2-65.9 cc	± 11 cc
8	74 cc	71.9 cc	40.5-105.1 cc	± 17 cc
10	110 cc	89.3 cc	62-133.1 cc	± 22 cc

Of the patients treated with the 6 mini or 6 SAVI, 86% had the PTV-eval reduced secondary to either proximity of skin or chestwall. Of all patients treated, 48% had skin bridges less than 7 mm, 30% less than 5 mm, and 15% less than 3 mm. Dosimetry for the entire cohort demonstrated a V90 (volume receiving 90% of the dose) of 96%, V150 and V200 (volume of tissue receiving 150 and 200% of the dose, respectively) of 27 and 13 cc.

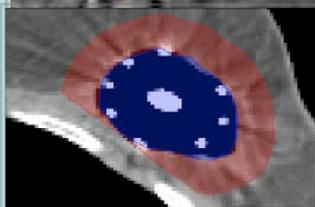
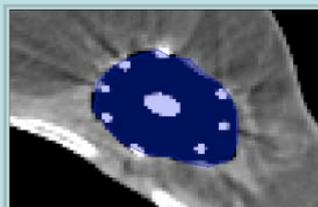
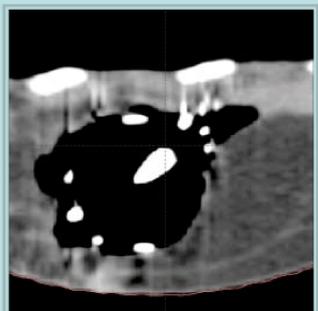


A side by side comparison of a MammoSite (left) and SAVI (right) in similar patients to demonstrate reduced PTV-eval in the case of close skin and chestwall spacing.

Skin Bridge size	Number of Patients
<7 mm	48%
<5 mm	30%
<3 mm	15%
Total (with chestwall spacing)	86%

4. Conclusion:

As expected, the size of the PTV-eval increases with size of SAVI catheter device. In this study, the 8 strut and especially the 10 strut device can treat an equivalent PTV-eval size well within the ranges published for MammoSite and Contura. The 6 mini device and 6 device, while treating less normal tissue, was usually chosen secondary to normal tissue proximity restrictions, limiting the amount of target tissue desirable to treat. In fact, many of these patients would not be eligible for balloon brachytherapy based on skin proximity of < 5 mm and < 3 mm, and disregarding chestwall proximity.



Top left: CT image of implanted SAVI device in a patient with close chestwall and skin spacing.

Top right: CT image with cavity contour of the same patient.

Bottom left: CT image of implanted SAVI device with cavity filled in of a patient with close chestwall spacing.

Bottom right: The red highlighted area represents the PTV-eval which is a one centimeter expansion around the cavity minus 5mm from the surface of the skin, the chest wall, and the cavity itself.