

The SAVI™ 6-1Mini Multicatheter APBI Applicator and Its Use in Patients with Small Lumpectomy Cavities or Inadequate Skin Distance: Early Clinical Experience

S. Morcovescu¹, J. D. Morton², K. Perry³

¹AROS LLC, Colleyville, TX,

²Texas Oncology Denton, Denton, TX,

³North Texas Hospital, Denton, TX

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Abstract

Purpose:

The SAVI 6-1Mini multicatheter APBI applicator and its use in patients with small lumpectomy cavities or inadequate skin distance: early clinical experience

Method and Materials:

The purpose of this study was to determine whether the use of the SAVI 6-1Mini multicatheter allowed acceptable dosimetrical results in patients in whom the size of the lumpectomy cavity and its proximity to the skin precluded treatment and the use of other available APBI applicators (MammoSite or Contura).

Results:

The study considered the first two (2) patients who, because of the cavity size and/or inadequate skin distance, were not fit for treatment using other balloon-type devices. A MammoSite and a Contura template plan was superimposed on the SAVI 6-1Mini CT scan and pertinent dosimetric comparison was performed.

The size of the lumpectomy cavities, 9.6cc and 8.5cc respectively, demanded the use of a treatment device of dimensions not accommodated by APBI balloon-type devices, normally inflated above the 35cc volume range. The use of any of these balloon-type devices would have been prone to cause extreme patient discomfort, skin overstretching and very high skin doses, consequently. The minimum skin distance was 1.3 mm and 13.9 mm respectively. With the use of the SAVI 6-1Mini device we were able to accomplish an excellent coverage D95 of 97% and 98.6%, D90 of 98.7% and 99.6%, V200 of 10.2cc and 17.1cc, Max Skin Doses of 105.7% and 72.5% respectively.

Conclusions:

The SAVI 6-1Mini proved to be a unique solution for the cases considered for this study. Differential loading of the device catheters allowed reduced skin dose without compromising the planning target coverage or critical organs (rib, lung). The use of this device has the potential to increase the use of APBI in patients where the cavity size and/or skin distance would not allow the use of balloon-type devices.

Method and Materials

Because of the small lumpectomy cavity sizes, 9.6cc and 8.5cc respectively, the SAVI 6-1Mini device (Figure 1) was the applicator of choice in our first two cases presented in this study. The SAVI 6-1Mini catheters were differentially loaded following a PTV optimization process, in order to allow V95>95%, V150<50cc, V200<20cc and acceptable rib and skin maximum doses.

These two cases were further evaluated in a comparison study with two other commonly used APBI treatment balloon-type devices, MammoSite and Contura.

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

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 MammoSite virtual plan (Figure 3).

A Body-Deformed Contour was created (Figure 4) in order to mimic the shape of the skin when a balloon-type applicator was virtually placed inside the cavity. More realistic maximum skin doses were than assessed and reported.

Results

#	Applicator type	V100 (cc)	V95 (%)	V90 (%)	V150 (cc)	V200 (cc)	DHI	Max skin dose (%)	Max CW dose (%)	PTV volume (cc)	Min Skin Distance (mm)
1	SAVI 6-1Mini	47.2	98.6	99.6	27.4	17.1	0.419	72.5	170.3	48.92	13.9
	MM1dw	73.3	96.5	98.3	25.1	5.1	0.658	147.2	355.7	82.0	
	Contura	77.0	99.1	99.8	28.7	7.8	0.627	143.0	325.3		
2	SAVI 6-1Mini	24.8	97.0	98.7	16.0	10.2	0.355	105.7	163.9	26.3	1.3
	MM1dw	78.4	98.4	99.0	30.0	8.2	0.617	582.7	323.1	82.0	
	Contura	79.4	99.3	99.6	31.6	9.5	0.602	592.8	280.1		

Discussion

Because of the size of the cavity in the case of SAVI 6-1Mini, V150/V100 volume ratios tend to exceed the 0.5 value, therefore a reevaluation of DHI acceptance criteria for APBI for small cavity volumes is recommended. 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. Properly inflated balloons can fill up cavities of at least 30cc, normally larger than 35cc. The SAVI 6-1Mini applicator proves to be the only implant solution for small lumpectomy volumes, below 15cc. Its design allows a proper dose optimization, with excellent PTV coverage and acceptable skin sparing.



Figure 2

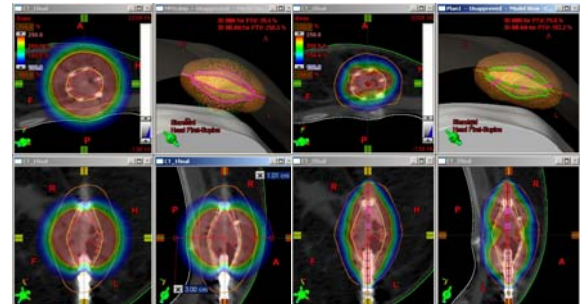


Figure 3

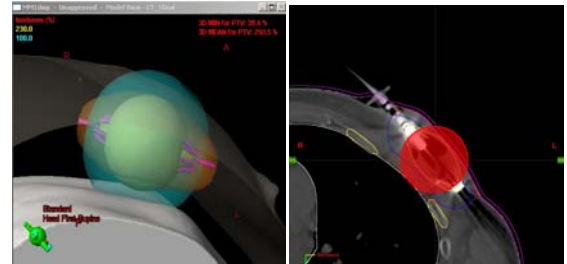
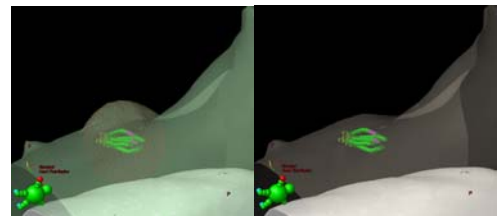


Figure 4



Conclusions

Lumpectomy cavity volumes of less than 10 cc can now be accommodated by SAVI 6-1Mini, a special APBI device designed by Cianna Medical (Aliso Viejo, CA). Because of possible differential loading of up to 7 catheters, even cases that would normally not meet the criteria outlined in NSABP B-39 can now be successfully treated without any clinical or dosimetric compromises.

The 95% isodose line coverage in all three situations is very similar, in the 96.5% – 99.8% range. Though, the maximum skin dose and the maximum rib dose vary greatly, especially for the case where the recorded SAVI 6-1Mini-to-skin distance was 1.3 mm.

Balloon-type applicators cannot accommodate volumes of less than 15cc without causing extreme patient discomfort, skin overstretching and prohibitive skin doses, up to almost 600% of the prescription dose, as the study shows. Body contour modeling or editing should be employed in order to realistically account for skin stretching and shaping caused by the use of a balloon applicator in a lumpectomy volume less than 15cc, when assessing the maximum dose to skin for comparative studies. Maximum skin doses of 244.3% (MM) and 249.4 % (Contura) were estimated when the body surface was conformed to the shape of a balloon applicator. These are still unacceptable values, but realistically lower values than the ones reported for case #2 in Table 1.