Partial breast irradiation

Clinical implementation of a new HDR brachytherapy device for partial breast irradiation

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Purpose: To present the clinical implementation of a new HDR device for partial breast irradiation, the Strut-Adjusted Volume Implant (SAVI), at the University of California, San Diego.

Methods and materials: The SAVI device has multiple peripheral struts that can be differentially loaded with the HDR source. Planning criteria used for evaluation of the treatment plans included the following dose volume histogram (DVH) criteria: V90 >90%, V150 <50 cc and V200 <20 cc.

Results: SAVI has been used on 20 patients to date at UC San Diego. In each case, the dose was modulated according to patient-specific anatomy to cover the tumor bed, while sparing normal tissues. The dosimetric data show that we can achieve greater than 90% coverage with respect to V90 (median of 95.3%) and also keep a low V150 and V200 dose at 24.5 and 11.2 cc, respectively. Complete treatment can be done within a 30-min time slot, which includes implant verification, setup, and irradiation time as well as wound dressing.

Conclusion: SAVI has been implemented at UC San Diego for accelerated partial breast irradiation with excellent tumor bed conformance and minimal normal tissue exposure. Patient positioning is the key to identifying any inter-fraction device motion. Device asymmetry or tissue conformance has been shown to resolve itself 24 h after the device implantation. The device can be implemented into an existing HDR program with minimal effort.

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Breast conservation therapy (BCT), lumpectomy plus radiation therapy, has been used as a treatment regime for over two decades in patients with early-stage breast cancer. Data suggest that in properly selected patients there is no need for whole breast irradiation and accelerated partial breast irradiation (APBI) is acceptable [1–10]. APBI has been performed using multiple methods, including multi-catheter brachytherapy, MammoSite brachytherapy, and 3D conformal external beam teletherapy [11–29]. Traditionally, multi-catheter brachytherapy has been performed with interstitial implantation; however, this technique requires trained physicians with specialized technical skills. MammoSite brachytherapy has been widely accepted, and is technically much easier to perform, but a major disadvantage is the spherically symmetric dose distribution. A single source gives rise to a spherical dose distribution, whereas multiple dwell positions cumulatively add to the total dose and allow shaping of the dose distribution to patient anatomy. Additionally, in early reports, up to 20% of catheters were removed due to concerns about poor breast tissue conformance, balloon asymmetry, or inadequate balloon to skin distance [18,26–29]. Recently, there have been several devices developed to adopt the advantages of both methods, blending the versatility of interstitial brachytherapy with the convenience and aesthetics of a single-entry device. The Strut-Adjusted Volume Implant, SAVI (Cianna Medical, Aliso Viejo, California), is a marriage of these two techniques that uses multiple peripheral struts, which can be differentially loaded to maximize tumor bed dose and minimize normal tissue dose. Besides the SAVI, another example of a recent device on the market that offers a single entry with multiple struts is the Contura device (SenoRx, Inc., Aliso Viejo, CA, USA).

The SAVI is intended to be used in the same dose and fractionation scheme as a MammoSite balloon. After Arizona Oncology Services, the University of California, San Diego (UC San Diego) was the second location in the United States to implement the SAVI in its APBI program. In this article, we present data from the first 20 patients treated at UC San Diego. Since treating our first patient; patient setup, clinical planning criteria and quality assurance (QA) guidelines have evolved with increasing dosimetric data and experience. The purpose of this work is to present the evolution of the clinical implementation and current procedures for implant verification, treatment planning and QA.

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Materials and methods

The SAVI device

The SAVI device is shown in Fig. 1 and consists of a central strut surrounded by 6, 8, or 10 peripheral struts, depending on the size of the device. The size specifications of the device and guidelines for use (SAVI size vs. cavity dimensions and volume) are displayed in Fig. 2 (chart courtesy of Cianna Medical). The multiple strut configuration allows one to differentially load the struts for dose modulation in an effort to optimally treat the lumpectomy cavity and conformally avoid normal tissues. The primary advantage of this device is patient-specific three-dimensional dose optimization from the multiple dwell positions in each strut to minimize dose to normal tissues, including skin, chest wall, and lung. There is a fixed hub located near the base of the implant and an expansion tool that slides over the central strut and is used to expand the device once inside the lumpectomy cavity and collapse the device for removal. The device is inserted in the collapsed position (Fig. 1A), and clockwise rotation of the knurled knob, at the proximal end of the expansion device, expands the peripheral struts (Fig. 1B). The peripheral struts of the device are expanded into the surrounding tissue of the cavity thus providing a pressure fit. The outward pressure exerted by the expanded struts pushes against the cavity walls securing the struts in place. Some tissue invagination between the struts has been observed during the course of the treatment. The device does not move independently to the body or breast with patient/breast motion due to the pressure fit with the surrounding tissue. Therefore, the expansion tool is removed after insertion. This allows for more flexibility of the SAVI device, since it will protrude from the patient’s skin for a minimum duration of 5 days. For safety purposes, the expansion tool is reinserted prior to each treatment, which allows a quick collapse and removal of the implant in the event of an emergency.

Radio-opaque markers are present on three of the peripheral struts (numbers 2, 4, and 6) for identification during the reconstruction process, and are shown in Fig. 3. The number 2 strut has a small-sized marker located at the distal end of the device, closest to the tip of the implant. The number 4 strut has a medium-sized marker located midway along the length of the device and the number 6 marker is the largest in size and located proximally.

Patient selection and surgery

Patients eligible for a SAVI implant at our institution are those patients diagnosed with non-invasive or T1,2 (≤3 cm) breast tumors, axillary lymph nodes (N0), no distant metastases (M0), with negative margins and also identified within 6 weeks of surgery. Approximately one week prior to SAVI implant, a pre-operative CT scan is taken for the patient for the evaluation of the cavity size and for surgical entry into the cavity. The implant surgery is a closed cavity, post-operative (lumpectomy) technique. The SAVI device is surgically implanted on an outpatient basis by the treating radiation oncologist using ultrasound guidance with the patient under local anesthesia. The majority of patients are given prophylactic antibiotics prior to surgery.

After appropriateness for brachytherapy is established, the post-operative tumor bed is evaluated with either a computed tomography scan or ultrasound. The size, symmetry and long axis of the cavity are determined. The angle of entry of the device, as well as the SAVI size is established. Approximately a third of the patients had the device placed by opening a lateral portion of the existing lumpectomy scar. The remainder had a new incision placed in the skin after intradermal injection of 45% lidocaine with epinephrine, 45% bupivacaine, and 10% sodium bicarbonate (4.5:4.5:1). After the skin is numbed, 2–3 cc of the solution is placed in the tumor bed as well as in the distal portion of the tumor bed under ultrasound guidance. A 1 cm incision is made with an 11-blade scalpel, and either a straight Kelly or a trocar is used to enter the cavity. The appropriate-sized SAVI is then inserted assuring that the white band just distal to the expansion portion of the device is beneath the skin (this ensures that the expansion portion is well within the cavity to allow unhindered expansion). Using gentle forward pressure the expansion tool is then turned until full expansion. The patient is then transported to the CT scanner for planning. The patients are moved from the gurney to the CT table for the treatment planning CT scan. Patient positioning for the scan is described in detail below.

Imaging for treatment planning

It is important to verify that the SAVI implant is in the same position as it was for the original treatment planning CT scan prior to each fraction. A CT scan is acquired immediately following the implant surgery both for the verification of the proper deployment of the device and for treatment planning. Reproducibility of the patient setup is important for implant verification because the patient should be treated in the same position as planned and also movement of the body or breast, relative to the post-operative CT scan, can appear as movement of the device. For example, if the patient is slightly rotated then the device might be mistakenly assumed to have rotated when compared to the images from the initial deployment. However, this would not be the case as the

Fig. 1. The size 6 SAVI device. (A) The device in the collapsed position as it would be prior to insertion. (B) The device in the expanded position as it would appear in the lumpectomy cavity. The radio-opaque markers, hub, and expansion tool are labeled in the figure.
patient’s entire body was in fact rotated relative to the initial planning scan. Therefore, care must be taken in ensuring reproducible patient setup. Although the device does not move independently to the body, as stated previously, one should always try to attain a position as close to the planned patient position due to breast deformation. For example, one would not want to position, image and plan a patient supine and then treat prone. A large, pendulous breast would have an entirely different shape and the calculated plan would not be what was actually treated. Therefore, if you are treating multiple fractions over multiple days, reproducible patient positioning is required to ensure that treatments coincide with the treatment plan. Several methods of patient setup have been attempted (listed chronologically) to get reproducible patient positioning. These include using no immobilization device, foam wedges and pillows, Vac-lok alone, Vac-lok with the patient holding a strap around her feet, and finally a breast board. The breast board has been the most successful for ease of setup and reproducibility.

After SAVI insertion, a CT scan of the treatment area (typically 12.5 cm superior-inferior distance centered about the implant) is taken immediately following the implant surgery and is used for the treatment plan. The CT scanner used at UC San Diego is a GE Lightspeed, large-bore, 4 slice CT scanner (GE Medical Systems, Waukesha, Wisconsin). X-ray markers ("dummy seed" strands) are placed in the central and peripheral struts prior to the CT scan in order to aid in first source position visualization. The CT scan utilizes a slice thickness of 1.25 mm in order to get a higher quality reconstructed image for treatment planning, which helps with strut identification and reconstruction. The typical number of images for a scan with 1.25 mm slice thickness is around 99 slices. Finer slice thickness (0.625 mm) is probably not necessary as the 1.25 mm scan width, with a breath-hold technique (described below), has yielded high quality images with easy strut identification. We employ a breath-hold during the CT scan and this has been found to greatly reduce artifact (blurring or streaking) previously present in the scans, presumably due to the respiratory motion.

**Fig. 2.** The three SAVI sizes and their corresponding dimensions along with two sizing charts relating the cavity dimensions to the size of the SAVI. Chart courtesy of Cianna Medical.

**Fig. 3.** AP and lateral CT scout film that can be checked for rotational motion with reference to the radio-opaque markers on the peripheral struts and anatomical landmarks. The large arrows indicate the distance between the two struts that are furthest apart. This distance is checked prior to each treatment for indication of strut collapse. The dashed arrows point to the radio-opaque markers present on the 2, 4, and 6 peripheral struts.
of the patient [30]. The CT images are then used for the treatment planning as described below. Daily verification of the implant placement and strut expansion is obtained through post-operative anterior and lateral X-ray images (CT scout views) that are compared to the original images obtained post-operatively. Additionally, prior to treatment of each fraction, the device is checked for in-and-out displacement by measurement of the skin to hub distance.

**Treatment planning**

The CT images are sent to a Plato treatment planning system (Nucletron, Columbia, Maryland), which includes three-dimensional reconstruction of the SAVI device. The radio-opaque markers present on three of the peripheral struts are used for identification. Multi-planar reconstruction within the planning system makes reconstructing the catheters straightforward, regardless of anatomical orientation.

Planning is performed once, immediately following the implant surgery, and re-planning is usually not necessary prior to each fraction. Re-planning is only needed if there is any in-out or rotational motion of the device, if there are any air gaps that appear or disappear, or if there is any change in the device, such as struts changing their proximity to one another. It is usually predictable when a re-plan will be necessary. Predictable re-plans include those plans with air gaps between the strut(s) and tissue or if the device has splayed struts.

Treatment planning is slightly more time-consuming than a MammoSite balloon as multiple struts need to be digitized and optimized. There are 6, 8, or 10 additional struts to digitize compared to a MammoSite, but the optimization process is comparable in time and therefore negligible. Once the images are imported into the treatment planning software, the physician draws the lumpectomy cavity. This is followed by a 1 cm uniform expansion of the cavity volume. The planning target volume (PTV) is defined as the difference between the expanded volume and the cavity volume. It is recommended that the physician either perform the 1 cm volume expansion or be present for consultation while the physicist creates the expansion to review and modify the volume clinically. Since the dose can be modulated, the PTV should be conformed to the patient’s anatomy and contoured to stay 5 mm from the skin and outside of the pectoralis muscle (no margin). This is the same procedure for definition of the PTV as with the MammoSite; however, the difference is that the dose can conform to this irregularly shaped PTV. The PTV is analyzed by the physician to ensure that there is adequate tumor bed coverage as well as normal tissue sparing.

Patients are treated in 10 fractions of 340 cGy per fraction over the course of 5 days, with a minimum treatment separation time of 6 h. Once the aforementioned planning has been accomplished, the prescription can be applied and a 3D dose can be calculated and optimized appropriately. The skin and lung doses are visually checked with the isodose curves on each axial slice. The planning criteria (maximum) for skin and lung dose are shown in Table 1. Skin dose is kept below 100% of the prescribed dose and, although there is no published data for lung or chest wall dose criteria, the maximum lung dose is kept to 75% of the prescribed dose. The PTV dose volume histogram is analyzed by examining V90, V100, V150 and V200, where Vxx represents the volume (cc) covered by xx% of the dose. The planning criteria guidelines, with respect to the DVH values, for multi-catheter, MammoSite and SAVI breast brachytherapy are shown in Table 1.

**Results and discussion**

**Implant verification**

As previously discussed, AP and lateral CT scout films are acquired to check for any rotational motion or strut collapse as shown in Fig. 3. In our experience, there have been five cases where there was a significant difference between scout films acquired immediately after the implant and those acquired prior to the first fraction. In these five cases, the old plan was cast on the new CT for evaluation of the implant dosimetry. In only one instance was the dose distribution sufficiently changed to warrant re-planning. In this patient, the V90 dropped below 90% and re-planning restored

<table>
<thead>
<tr>
<th>Technique</th>
<th>V90 (%)</th>
<th>V150 (cc)</th>
<th>V200 (cc)</th>
<th>Skin dose (%)</th>
<th>Lung dose (%)</th>
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<tr>
<td>Multi-catheter</td>
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<td>&lt;70</td>
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<td>–</td>
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<tr>
<td>MammoSite</td>
<td>&gt;90</td>
<td>&lt;50</td>
<td>&lt;10</td>
<td>&lt;145</td>
<td>–</td>
</tr>
<tr>
<td>SAVI</td>
<td>&gt;90</td>
<td>&lt;50</td>
<td>&lt;20</td>
<td>&lt;100</td>
<td>&lt;75</td>
</tr>
</tbody>
</table>

**Fig. 4.** Original CT scan showing a gap between tumor bed and the SAVI struts (A) and a second CT scan showing closure of the gap over a 24-h period (B).
the V90 near to its original value. These five cases are out of the 20 total cases, so this represents 25% of the total patient population. More importantly, we have found, on a fraction-to-fraction basis, the inter-fraction movement of the device only occurs 2.5% of the time (5 fractions of 200 total fractions). Despite the rotational motion of the device between the implant and the first fraction, there was no subsequent motion of the device between the remaining fractions. This means that the early stages of the implant are the most sensitive to motion but once the device remains in the patient for 24 h or more, the device is very stable. Therefore, pre-planning evaluation of the device position will minimize the probability of re-planning.

There are several telling signs as to whether there is an increased chance of motion in the early stages of the implant. Four of our five re-plans were expected as three were due to the implant deployment in a patient with a small cavity, close to the skin, and the struts were splayed on the anterior side of the device and the fourth was one in which air gaps closed prior to the first fraction. The case with air gaps between the strut(s) and tissue is shown in Fig. 4A. In both cases, the device should be left in place and a re-scan scheduled approximately 24 h later. The splayed struts will most likely return to their proper position and open to a more symmetric shape and the air gaps will most likely close (Fig. 4B). Therefore, we recommend that treatment be postponed and a re-scan scheduled if there is strut asymmetry immediately following the implant. The one unpredicted re-plan occurred in a patient where there was slight (few degrees) rotation of the device between the simulation/planning day and the first treatment fraction. The rotation was seen on the scout films and a CT scan confirmed the rotation. Therefore, a daily CT scan is not necessary and hence reduces the overall radiation exposure of the patient. Limiting radiation exposure is a topic that has recently received considerable attention in regard to CT exposure raising overall lifetime cancer risks [31], and could be important especially for patients who are young and otherwise healthy individuals. Measurement of the distance between the maximally displaced peripheral struts on the CT scouts (Fig. 3) prior to each fraction ensures that there has not been any collapse of the struts. One can also measure the distance between each of the peripheral struts to check for relative motion between each of the struts (inter-strut motion). Finally, a

Fig. 5. Comparison between the cavity and PTV drawn, as well as the isodose distribution, with a CED (A), mimicking a balloon device, and with a SAVI (B). Moving from the periphery in, the outer most line is the 50% isodose line, the next two lines are the 100% isodose line and PTV, followed by the 150% isodose line, 200% isodose line, and the cavity.
post-operative evaluation form is filled out by the therapists that has the skin to hub distance and also a list of the SAVI struts numbers in a tabular form such that each strut can be associated with an orientation (e.g., Strut 3–12 o’clock), which serves as a check for gross rotation.

Dosimetry

A cavity expansion device (CED) placed in the lumpectomy cavity after the surgery and changed out for a treatment device at a later date is typically used prior to a MammoSite implant. This has not been routinely used at our institution for the case of the SAVI. However, one patient was implanted with a CED that was later swapped out for the SAVI. This allowed a comparison of the cavity and planning target volumes on the same patient with a CED (Fig. 5A), mimicking a balloon, and with the SAVI (Fig. 5B).
The 100% isodose line is seen to extend outside the body in Fig. 5A. However, because the SAVI allows for patient-specific conformal dose distribution, the 100% isodose line conforms to the PTV (Fig. 5B). The 100% isodose line is seen to extend outside the body in Fig. 5A. Since there are multiple peripheral struts and a central strut that can be loaded with the HDR source, this allows the option of not loading those struts close to the skin surface thus allowing for a reduced dose to the skin but full dose to the remaining PTV.

Dosimetric data from the first 20 patients treated at our institution are shown in Table 2. The table shows that our median for cavity size is 24.1 cc, PTV volume is 57.8, V90(PTV) is 95.3%, V150(PTV) is 24.5 cc, and V200(PTV) is 11.2 cc. We found that the V150 criteria can be reduced to that of the MammoSite criteria of V150 <50 cc, while the V200 criteria is maintained at <20 cc.

Quality assurance

There are several aspects of quality assurance related to the SAVI device in addition to the usual daily and monthly HDR QA. The associated distance used in the treatment plan for each catheter is the first aspect addressed. This is followed by pre-treatment and post-treatment procedures, including safety protocols.

Each device connected to the HDR afterloader machine has a predetermined treatment length, which is the maximum distance the source will run from its zero position at the treatment machine. The distances should be checked for each SAVI device prior to the first treatment. There should be little to no variation in these distances, however, due to manufacturing processes we have found a tolerance of approximately ±1 mm. Therefore, a source simulator should be used to accurately determine the distance used for each device in the treatment planning system. The distances associated with the SAVI device, for the Nucletron microelectron-HDR unit with six French transfer tubes, are 1255 mm for the central strut and 1210 mm for the peripheral struts (it should be noted that UC San Diego uses a Nucletron HDR unit; however, the SAVI device is also compatible with Varian Varisource and GammaMed Plus machines). Pre-treatment procedures include the skin to hub measurement and the rotational motion/strut integrity check discussed previously. Prior to connection of the HDR machine to the device, the expansion tool should be inserted over the central device strut. This assures that if the source were to be left in one of the struts, the device could be quickly collapsed, removed from the patient and placed in a lead storage container. The transfer tubes from the machine to the device can be placed interchangeably on the device struts, so it is extremely important that second checks are in place to make sure that the guide tubes are connected to the proper device strut. Our method is for the physicist to hand the therapist a transfer tube while calling out its number, which the therapist checks; then the therapist connects the transfer tube to the device while the physicist observes and checks for the correct assembly.

Post-treatment procedures include the survey of the patient to assure that the source has been completely removed from the patient. The machine transfer tubes are then disconnected from the device, expansion tool removed and the patient is bandaged, returning later for their next treatment. Finally, the transfer tubes are cleaned at the device connection end with an isopropyl alcohol-based disinfectant wipe between each use.

Conclusions

The clinical implementation of SAVI and the subsequent treatment of the first twenty patients at UC San Diego have been described. We have found that the ability to modulate the dose allows for conformal tumor bed coverage, while minimizing normal tissue exposure. Procedures evolved with increasing experience and the significant recommendations are as follows. It was found that reproducible patient positioning was key for assessing inter-fraction motion of the device and a breast board was the best device for this purpose. Additionally, a breath-hold during the CT scan was found to greatly reduce artifact and lead to better planning images. Our experience has shown that asymmetry in the device (splays), or air gaps between tissue and struts, immediately after deployment, will usually resolve itself within 24 and it is best to delay planning for 24 h, then re-scan and plan. Overall, APBI via the SAVI device was straightforward to implement into our existing HDR program, and we expect this experience would be generally applicable to other institutions.

Acknowledgements

The authors thank Prof. Steve Jiang and Dr. Mitchell Kamrava for their thoughtful discussions and input.

References


Table 2

Table displaying the dosimetric data obtained from our first 20 patients including cavity volume, PTV volume, V90, V100, V150 and V200, where Vxx represents the volume covered by xx% of the dose.

<table>
<thead>
<tr>
<th></th>
<th>Cavity (cc)</th>
<th>PTV</th>
<th>V90 (%)</th>
<th>V100 (%)</th>
<th>V150 (%)</th>
<th>V200 (%)</th>
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<td>Median volume</td>
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<td>49.9</td>
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<tr>
<td>Min volume</td>
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<td>19.8</td>
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<td>10.8</td>
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