



## A Contura catheter offers dosimetric advantages over a MammoSite catheter that increase the applicability of accelerated partial breast irradiation

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### ABSTRACT

**PURPOSE:** The purpose of this study was to determine whether a Contura catheter (SenoRx, Inc, Aliso Viejo, CA) can increase the applicability of accelerated partial breast irradiation.

**METHODS AND MATERIALS:** One hundred eighty-two women with early stage breast carcinomas were treated with postlumpectomy brachytherapy using a Contura multilumen catheter ( $n = 45$ ) or a MammoSite single-lumen catheter (Cytyc Corp, Marlborough, MA) ( $n = 137$ ). Hypothetical MammoSite catheter treatment plans were created for the Contura patients. Treatment planning goals were to (1) avoid a radiation “hot spot” in the skin and (2) have only a small air/fluid pocket next to the balloon.

**RESULTS:** The median followup was 16 months. Eighty-nine percent (40 of 45) of Contura plans satisfied both treatment planning goals vs. only 36% (16 of 45) of MammoSite plans ( $p < 0.0001$ ). A Contura catheter did not require explantation in 16% (7 of 45) of patients where balloon-to-skin spacing was only 3–6 mm and 11% (5 of 45) of patients where there was an air/fluid pocket  $>10\%$  of the planning target volume for plan evaluation (PTV\_EVAL). A MammoSite catheter was explanted in 10% of cases where the minimum balloon-to-skin distance was  $<7$  mm and in 13% of cases where there was a large air/fluid pocket next to the balloon. Our incidence rates of acute toxicity with a Contura catheter were similar to those with a MammoSite catheter.

**CONCLUSIONS:** A Contura catheter provides important dosimetric advantages over a MammoSite catheter and does not require explantation in cases where balloon-to-skin spacing is only 3–6 mm or an air/fluid pocket next to the balloon is  $>10\%$  of PTV\_EVAL. © 2009 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

### Keywords:

Contura; MammoSite; Accelerated; Partial; Breast; Irradiation

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### Introduction

In a randomized trial involving 258 early stage breast cancer patients, high-dose-rate (HDR) multicatheter brachytherapy produced 5-year local control, relapse-free survival, and cancer-specific survival rates comparable to those achieved with conventional whole-breast irradiation (1). However, pending the results from large randomized trials such as National Surgical Adjuvant Breast and Bowel Project B-39/Radiation Therapy Oncology Group 0413, whole-breast irradiation remains the standard of care in early stage breast cancer patients (2).

One advantage of accelerated partial-breast irradiation (APBI) over whole-breast irradiation is that the radiotherapy is delivered over 1 week rather than 5–7 weeks (3). Another

advantage of APBI is that the volume of heart and lung irradiated to clinically significant levels is lower than that of whole-breast irradiation (4, 5). In addition, cosmetic results with APBI compare favorably to those with whole-breast irradiation (1).

A closed-cavity placement technique (6–8) and antibiotics (8–10) reduce the risk of acute complications because of APBI. The volumes of breast tissue receiving 150% ( $V_{150}$ ) and 200% ( $V_{200}$ ) of the prescribed dose should be limited to  $\leq 50$  and  $\leq 10$  cc, respectively, to reduce the risk of late complications, such as breast fibrosis or pain, fat necrosis, or rib pain (11, 12).

The United States Food and Drug Administration approved the MammoSite single-lumen balloon catheter (Cytac Corp, Marlborough, MA) for the treatment of early stage breast cancer in 2002 (2). Good-to-excellent cosmetic results have typically been achieved with a MammoSite catheter when balloon-to-skin spacing is  $\geq 7$  mm (3, 7, 13). Balloon-to-skin spacing of only 5–6 mm results in worse cosmetic results because the skin dose may be up to 145% of the prescribed dose. In addition, an air/fluid pocket adjacent to the balloon displaces the 10 mm rind of breast tissue just beyond the lumpectomy cavity that is at greatest risk of harboring residual tumor cells (14). This has the undesirable effect of reducing the radiation dose that is delivered to cancer cells. With a MammoSite catheter, there is no way to remove an air/fluid pocket (12). Balloon-to-skin spacing  $< 7$  mm and poor tissue-balloon conformance limit the use of the MammoSite catheter (15). A MammoSite catheter also delivers relatively high rib doses for carcinomas located deep in the breast (16).

The United States Food and Drug Administration has recently approved a number of APBI catheters that offer increased normal tissue, for example, rib, sparing (17, 18). One of these devices, a Contura multilumen balloon catheter (SenoRx, Inc, Aliso Viejo, CA), offers two important dosimetric advantages over a MammoSite single-lumen balloon catheter: (1) avoidance of a radiation “hot spot” in the skin and (2) reduction of the size of an air/fluid pocket in the planning target volume for plan evaluation (PTV\_EVAL) through the use of a vacuum port. This may allow for APBI in cases where massage of the lumpectomy cavity and adjustment of the balloon volume do not adequately improve tissue-balloon conformance (12).

The purposes of this study are to (1) determine the frequency with which a Contura multilumen catheter can avoid a radiation hot spot in the skin and provide excellent tissue-balloon conformance relative to a MammoSite single-lumen catheter and (2) analyze acute toxicity with Contura and MammoSite brachytherapy.

## Methods and materials

Patient characteristics are presented in Table 1. From February 2003 to March 2009, 182 patients with carcinomas of the breast at least 1 mm from the inked edge of

Table 1  
Patient characteristics

Characteristic	Contura	MammoSite
	Brachytherapy (n = 45)	Brachytherapy (n = 137)
Age, y, median (range)	61 (43–89)	60 (34–91)
Followup, mo, median (range)	3 (1–13)	29 (1–62)
Balloon-to-skin distance, mm, mean (standard deviation)	15 (10)	16 (10)
Balloon volume, cc, mean (standard deviation)	46 (7)	47 (8)
Pathologic T stage		
Tis	31% (14)	10% (14)
Tmic	2% (1)	0% (0)
T1a	2% (1)	7% (10)
T1b	25% (11)	34% (46)
T1c	29% (13)	42% (57)
T2 (maximum size, 30 mm)	11% (5)	7% (10)
Pathologic N stage		
NX	18% (8)	18% (25)
N0	82% (37)	73% (100)
N1mi	0% (0)	1% (1)
N1a	0% (0)	8% (11)
Histology		
Ductal carcinoma in situ	29% (13)	20% (28)
Infiltrating ductal carcinoma	62% (28)	73% (100)
Infiltrating lobular carcinoma	0% (0)	4% (5)
Colloid carcinoma	2% (1)	2% (2)
Tubular carcinoma	5% (2)	1% (2)
Papillary carcinoma	2% (1)	0% (0)
Estrogen receptor		
Positive	78% (35)	70% (96)
Negative	11% (5)	10% (13)
Not assessed	11% (5)	20% (28)
Progesterone receptor		
Positive	69% (31)	61% (84)
Negative	20% (9)	18% (24)
Not assessed	11% (5)	21% (29)
Scharff–Bloom–Richardson grade		
3	7% (3)	2% (3)
4	9% (4)	7% (9)
5	4% (2)	15% (21)
6	44% (20)	55% (75)
7	18% (8)	8% (11)
8	7% (3)	7% (10)
9	11% (5)	6% (8)
Diabetes mellitus	4% (2)	5% (7)

is = in situ; mi = micrometastasis; mic = microinvasion.

the lumpectomy specimen were treated in the supine position with HDR  $^{192}\text{Ir}$  brachytherapy using a Contura catheter (Fig. 1) or a MammoSite catheter (Fig. 2). For invasive carcinomas, an axillary staging procedure was performed. This procedure consisted of a sentinel lymph node biopsy alone if all of the sentinel nodes were negative. If a sentinel node was positive, an axillary dissection was performed and at least six nodes removed. Approval for APBI was obtained from the Western Institutional Review Board and informed consent was obtained from all the patients. The

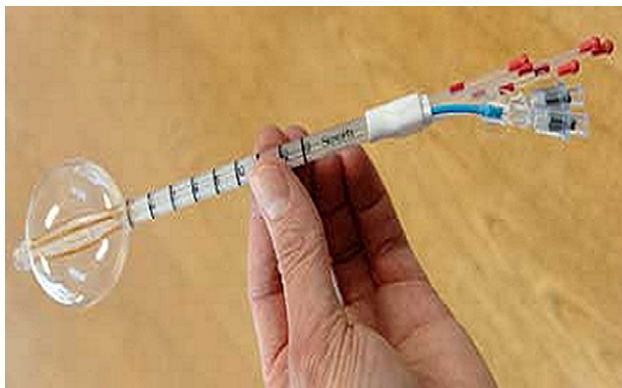


Fig. 1. Contura catheter.

HDR brachytherapy was delivered to a total dose of 34 Gy in 10 fractions twice per day separated by 6 h daily over 5–7 days.

With balloon catheter brachytherapy, PTV\_EVAL is defined as the breast tissue volume bounded by uniform expansion of the balloon radius in all dimensions by 10 mm less than the balloon volume. PTV\_EVAL is limited to 5 mm from the skin surface and by the posterior breast tissue extent. Chest wall and pectoralis muscles are excluded. Dose–volume histogram analysis of target coverage confirmed that  $\geq 90\%$  of the prescribed dose covered  $\geq 90\%$  of PTV\_EVAL.

When determining dose coverage of PTV\_EVAL, the volume of trapped air/fluid next to the balloon was accounted for as follows. The area of trapped air/fluid was contoured on each 5-mm computed tomography slice, a total volume obtained, and the percentage of PTV\_EVAL that was displaced was then calculated. The acceptable percentage of PTV\_EVAL coverage by the prescribed dose of radiation was given by the equation:

$$\begin{aligned}
 &(\% \text{ of PTV\_EVAL coverage}) - \\
 &[(\text{total volume trapped air or fluid} / \text{PTV\_EVAL}) \\
 &\times 100] \geq 90\% \text{ of PTV\_EVAL coverage}
 \end{aligned}$$



Fig. 2. MammoSite catheter.

If the percentage of PTV\_EVAL displaced by trapped air/fluid was  $>10\%$ , then it was not possible to achieve acceptable PTV\_EVAL coverage. At least 90% of PTV\_EVAL received at least 90% of the prescribed dose.

Ideally,  $<60\%$  of the whole-breast volume received  $\geq 50\%$  of the prescribed dose. During brachytherapy, we prophylactically treated patients with an oral antibiotic, such as cephalexin (Keflex, Advancis Pharmaceutical Corp., Germantown, MD) or azithromycin (Zithromax, Pfizer, Inc., New York, NY).

The Contura catheter allows one to load up to five lumens with a radioactive source: four lumens that are offset 5 mm circumferentially from a central lumen (Fig. 3). The ability to choose from multiple lumens allows for greater control over where radiotherapy is delivered (Fig. 4). For example, if the balloon was close to the skin, we loaded only the lumens farthest from the skin with the radioactive source. The Contura catheter also has a sixth lumen through which air/fluid can be removed. Use of this vacuum port improves tissue-balloon conformance (Fig. 5).

Surgeons inflated the balloon to the maximum point where breast comfort remained acceptable. In our experience, breast discomfort because of balloon inflation becomes an issue starting 2 weeks postlumpectomy and worsens with time. Surgeons placed the Contura and MammoSite catheters using a closed-cavity technique between 0 and 68 days (median, 25 days) postlumpectomy. They massaged the lumpectomy cavity and adjusted the balloon volume by 5–15 cc in an effort to improve tissue-balloon conformance (12). With regard to homogeneity of the radiation dose within the breast, the volumes of tissue receiving 150% ( $V_{150}$ ) and 200% ( $V_{200}$ ) of the prescribed dose were limited to  $\leq 50$  cc and  $\leq 10$  cc, respectively.

We created hypothetical MammoSite single-lumen catheter treatment plans using a CT scan of the breast before air/fluid removal. Only the central lumen was loaded for the hypothetical MammoSite plans. Multiple dwell positions were used for all patients to optimize dose delivery.

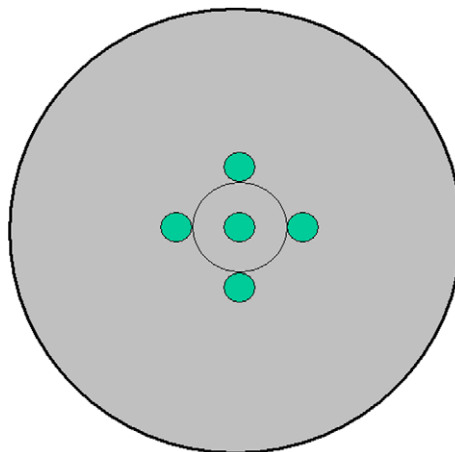


Fig. 3. With the Contura catheter, one can load up to five source lumens. This allows for greater normal tissue, for example, skin or rib, sparing.

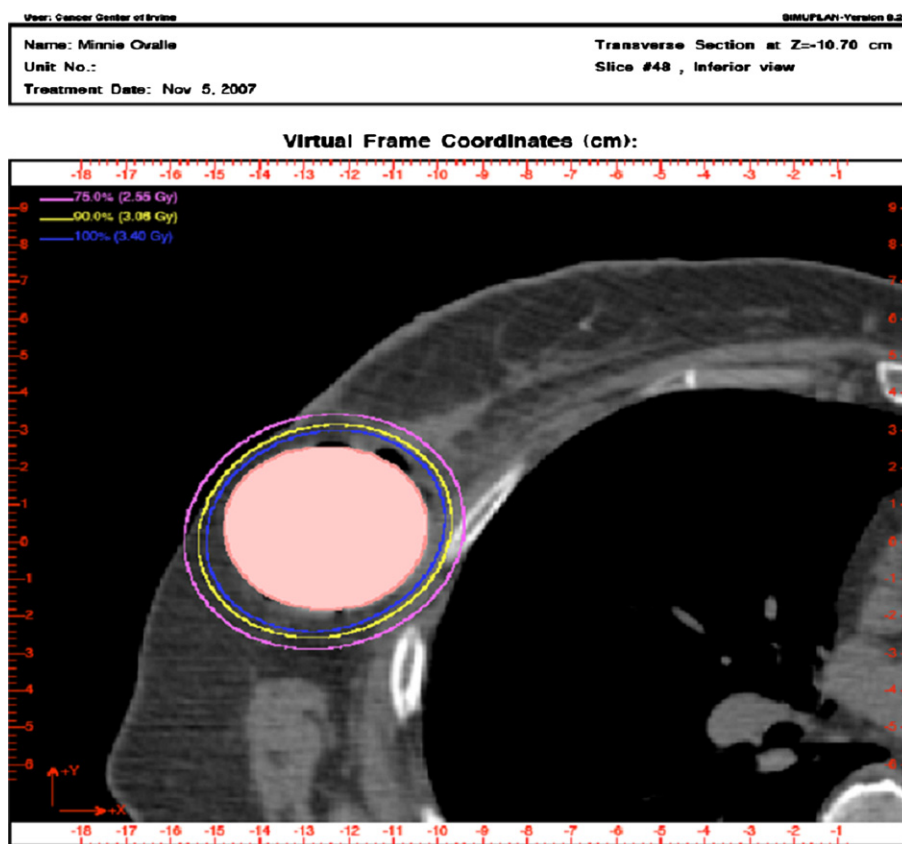


Fig. 4. With the Contura multilumen catheter, one can limit the maximum skin dose to  $\leq 100\%$  of the prescribed dose even when the balloon-to-skin spacing is only 3–6 mm.

The treatment planning goals were to keep the (1) maximum skin dose  $\leq 100\%$  of the prescribed dose and (2) volume of air/fluid next to the balloon  $\leq 3.0\%$  of PTV\_EVAL. Based on the nature of the second treatment planning goal, only patients treated with a Contura catheter were included in the dosimetric study.

We define acute toxicity as toxicity occurring within 90 days of the first day of brachytherapy (19).

We used a Pearson Chi-square test (20) for categorical data and independent groups, a two-sided McNemar test (21) for categorical data and dependent (paired) groups, a two-sided independent-samples *t* test (20) for interval data and independent groups, and a two-sided paired-samples *t* test (22) for interval data and dependent groups.

## Results

The median followup was 16 months. The minimum balloon-to-skin distance was  $< 7$  mm in 16% (7 of 45) of Contura patients and 12% (17 of 137) of MammoSite patients ( $p = 0.78$ ). The maximum skin dose was 100% of the prescribed dose with a Contura catheter vs. 145% of the prescribed dose with a MammoSite catheter. In cases where the balloon-to-skin distance was only 3–6 mm, the maximum skin dose was a median of 90% (range, 89–100%) of the

prescribed dose with a Contura catheter. In contrast, for a balloon-to-skin distance  $< 7$  mm, the maximum skin dose was a median of 100% (range, 70–145%) of the prescribed dose with a MammoSite catheter.

The minimum balloon-to-rib distance was  $14 \pm 8$  mm (mean  $\pm$  standard deviation) for Contura patients and  $16 \pm 10$  mm (mean  $\pm$  standard deviation) for MammoSite patients ( $p = 0.86$ ). Air/fluid next to the Contura balloon was at least partially removed in 71% (32 of 45) of patients. The volume of air/fluid next to the Contura balloon was  $5.0\% \pm 0.7\%$  (mean  $\pm$  standard error) of PTV\_EVAL before suctioning vs.  $1.3\% \pm 0.2\%$  after suctioning ( $p < 0.001$ ). Eighty-nine percent (40 of 45) of Contura plans satisfied both treatment planning goals vs. only 36% (16 of 45) of hypothetical MammoSite plans ( $p < 0.0001$ ).

A Contura catheter did not require explantation in 16% (7 of 45) of patients where balloon-to-skin spacing was only 3–6 mm and in 11% (5 of 45) of patients where there was an air/fluid pocket  $> 10\%$  of PTV\_EVAL on presentation to the radiation oncology department. Use of the vacuum port on the Contura catheter reduced the air/fluid volume to  $\leq 5\%$  of PTV\_EVAL in these cases. In contrast, a MammoSite catheter was explanted in 10% of cases where the minimum balloon-to-skin distance was  $< 7$  mm and in 13% of cases where there was an air/fluid pocket  $> 10\%$  of PTV\_EVAL.

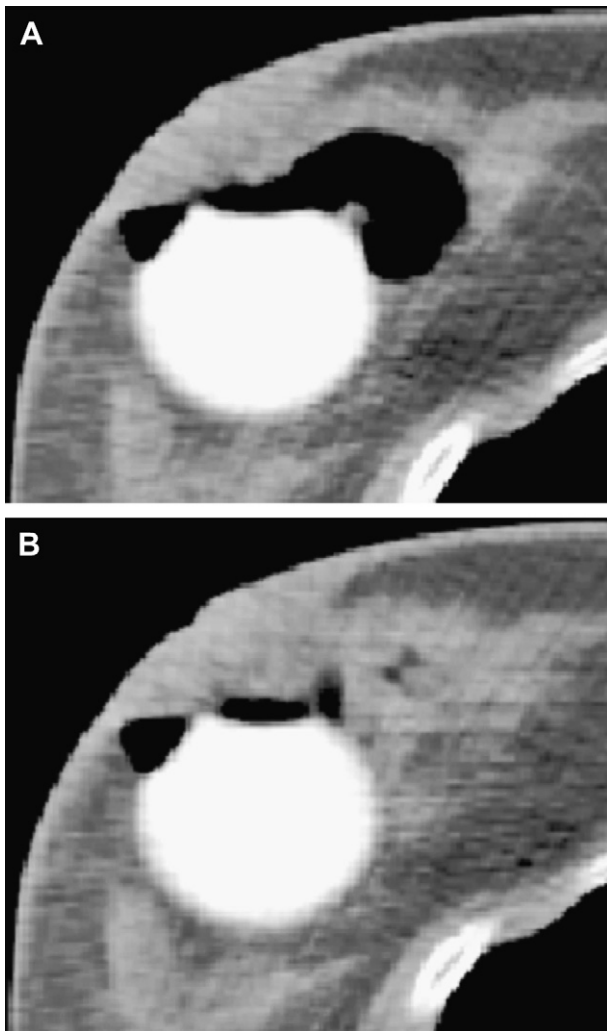


Fig. 5. (A) Before suctioning air (volume of air = 7.7% of planning target volume for plan evaluation [PTV\_EVAL]) and (B) after suctioning air (volume of air = 0.4% of PTV\_EVAL) next to the balloon. Suctioning air/fluid improves tissue-balloon conformance, thereby allowing a higher dose of radiation to be delivered to the breast tissue at greatest risk of harboring residual tumor cells.

In terms of acute complications, 11% (5 of 45) of Contura patients developed a National Cancer Institute Common Terminology Criteria for Adverse Events Grade 2 seroma that was symptomatic and required simple aspiration. Eight percent (11 of 137) of MammoSite patients developed a Grade 2 seroma. Two percent (1 of 45) of Contura patients developed a Grade 3 infection that was not life threatening. This individual was a poorly controlled, insulin-dependant diabetic who was noncompliant with an oral antibiotic and had to be admitted for intravenous antibiotics and abscess drainage. Four percent (6 of 137) of MammoSite patients developed a Grade 2 infection. There was limited drainage around the catheter in five of these cases. After 15-mm rather than 12-mm incisions were made to facilitate drainage around the MammoSite catheter, there have been no more infections over the past 2 years. Two percent (1 of 45) of Contura patients complained of Grade 1 breast pain that was mild

and did not interfere with function. Four percent (5 of 137) of MammoSite patients complained of Grade 1 breast pain. None of the Contura patients and 1% (1 of 137) of the MammoSite patients experienced Grade 2 breast induration where there was a marked increase in density and firmness on palpation. None of the Contura patients and 1% (1 of 137) of the MammoSite patients complained of Grade 2 rib pain. There was no significant difference in acute toxicity by treatment group.

## Discussion

The Contura catheter provided important dosimetric advantages over a MammoSite catheter. Eighty-nine percent (40 of 45) of Contura plans satisfied both treatment planning goals vs. only 36% (16 of 45) of hypothetical MammoSite plans ( $p < 0.0001$ ).

Even though balloon-skin spacing was only 3–6 mm in 16% of our Contura patients, the Contura multilumen catheter never needed to be explanted because of concerns regarding a radiation hot spot in the skin. In addition, the Contura catheter did not have to be explanted in 11% of patients who presented for APBI with air/fluid next to the balloon measuring >10% of PTV\_EVAL because use of the vacuum port dramatically improved the tissue-balloon conformance. Other groups have reported that MammoSite single-lumen catheters have been explanted in 4–39% of patients because of inadequate skin spacing (15, 23) and in 13% of patients because of suboptimal tissue-balloon conformance (15). In our study, a MammoSite catheter was explanted in 10% of cases where the minimum balloon-to-skin distance was <7 mm and in 13% of cases where there was a large air/fluid pocket.

Our incidence rates of acute toxicity with a Contura catheter are in accordance with those reported in the literature (7, 9, 13). Although a Contura catheter was used to treat patients with a balloon-to-skin distance as small as 3 mm, there was no difference in acute toxicity between Contura and MammoSite brachytherapy. Patients will be followed up long term to determine whether the dosimetric advantages offered by a Contura catheter translate into a reduction in late toxicity, such as rib pain.

## Conclusion

A Contura catheter obviates the need for explantation in cases where breast cancer patients present to a radiation oncology department with (1) a balloon-to-skin spacing of only 3–6 mm or (2) an air/fluid pocket measuring >10% of PTV\_EVAL.

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