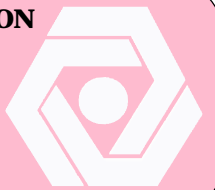




A CONTURA™ CATHETER PROVIDES DOSIMETRIC ADVANTAGES OVER A MAMMO SITE™ CATHETER FOR ACCELERATED PARTIAL BREAST IRRADIATION



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PURPOSE/OBJECTIVES

The new Contura™ Multi-Lumen Balloon (MLB) catheter (SenoRx, Inc, Aliso Viejo, CA) offers 2 dosimetric advantages over a MammoSite™ catheter: 1) avoidance of a radiation “hot spot” in the skin which may produce better cosmetic results, and 2) reduction of the size of an air/fluid pocket in the planning target volume for plan evaluation (PTV_EVAL); this may improve local control by bringing the 1 cm rind of breast tissue outside of the balloon, which is at greatest risk of harboring residual tumor cells, closer to the radiation source inside of the balloon. The purpose of this study was to determine the frequency with which a Contura catheter can satisfy the above 2 treatment planning goals relative to a MammoSite catheter.

CONTURA MULTI-LUMEN BALLOON CATHETER



MATERIALS/METHODS

From October 2007 to November 2008, 37 patients between the ages of 43 and 89 years (median, 59 years) with unifocal AJCC pathological T0, T1, or T2 (maximum, 3.0 cm; median, 1.0 cm), NO ductal, papillary, or tubular carcinomas of the breast at least 1 mm from the inked edge of the lumpectomy specimen were treated with high-dose-rate iridium-192 brachytherapy using a Contura catheter. Seventy-eight percent of the cancers were estrogen-receptor positive. Brachytherapy was delivered to a total dose of 34 Gy in 10 fractions bid over 5-7 days. We prescribed the dose to a depth of 1.0 cm from the balloon surface. The Contura applicator allows one to load up to 5 lumens: 4 lumens that are offset 0.5 cm circumferentially from a central lumen. The ability to choose from multiple lumens allows for greater control over where radiotherapy is delivered. The Contura

catheter also has a sixth lumen through which air/fluid can be removed from around the balloon. Suctioning helps to improve tissue-balloon conformance. The minimum balloon-to-skin distance was 0.3 cm. In 38% of patients, the balloon-to-skin distance was 0.3-0.9 cm. The balloon volume was 30-58 cc, V150 was £ 43 cc, and V200 was £ 10 cc. Hypothetical MammoSite treatment plans were created using a CT scan of the breast prior to air/fluid removal. Only the central lumen was loaded for the hypothetical MammoSite plan. The 2 treatment planning goals were to keep the: 1) maximum skin dose £ 100% of the prescribed dose, and 2) volume of air/fluid next to the balloon £ 3.0% of PTV_EVAL. A 2-sided McNemar test was used to compare the % of Contura plans that satisfied both treatment planning goals vs the % of MammoSite plans that satisfied both goals.

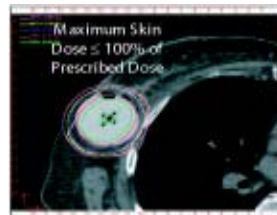
RESULTS

The maximum skin dose was 100% of the prescribed dose with a Contura catheter vs 145% of the prescribed dose with a MammoSite catheter. The volume of air/fluid next to the Contura balloon was 4.6% ± 0.8% (mean ± standard error) of PTV_EVAL prior to suctioning vs 1.1% ± 0.2% after suctioning. Ninety-two percent of Contura plans satisfied both treatment planning goals vs only 41% of MammoSite plans (p=0.01). There have been no relapses, though follow up is short. Cosmetic results were excellent. Three patients (8%) developed an NCI CTCAE v3.0 grade 2 seroma. One patient (3%) developed an NCI CTCAE v3.0 grade 3 infection. This patient was poorly-controlled, insulin-dependant diabetic who was non-compliant with oral antibiotics and had to be admitted for I.V. antibiotics and abscess drainage.

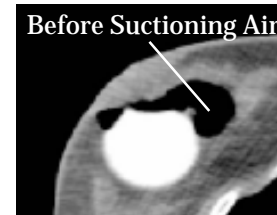
CONCLUSIONS

The Contura MLB catheter provided excellent local control and cosmetic results and was well-tolerated. This multi-lumen catheter provides important dosimetric advantages over a single-lumen MammoSite catheter. Contura patients will be followed long-term in order to determine their local control, disease-free survival, cosmetic results, and treatment-related

MAIN ADVANTAGES TO USE A CONTURA CATHETER FOR ACCELERATED PARTIAL BREAST IRRADIATION:



1) Avoidance of a Radiation Hot Spot in the Skin



2) Suctioning of Air/Fluid Outside of Balloon Brings Breast Tissue at Greatest Risk of Harboring Residual Tumor Cells Closer to Radiation Source Inside of Balloon

