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**TITLE:**

**Forty-Eight Month Results with the MammoSite Brachytherapy Applicator: Details Regarding Cosmesis, Toxicity and Local Control in Partial Breast Irradiation**

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**ABSTRACT BODY:**

**Purpose/Objective:** Update the original cohort of MammoSite breast brachytherapy patients by presenting the 48 month cosmesis, toxicity, and local control data in accelerated partial breast irradiation (APBI).

**Materials/Methods:** Forty-three patients originally treated in a multi-center prospective trial testing the applicator for FDA approval constitute the study population. A dose of 34 Gy in 10 fractions over 5 treatment days was prescribed to 1 cm from the applicator surface using Ir192 HDR brachytherapy. Cosmesis was assessed using Harvard criteria. Toxicity was assessed using the FDA COSTART Terminology. Three patients not enrolled in the long term follow-up study are censored.

**Results:** With a median and mean follow-up of 48 months and 45.6 months respectively (28 to 62 mos.), no local failures have occurred. 80% of patients were reported to have a good/excellent cosmetic result at their last follow-up. Of the 35 and 21 patients followed >3 and >4 yrs., 83%, and 76% had good/excellent results, respectively.

An analysis was performed to examine whether there were any factors associated with a good/excellent cosmetic result. Variables examined included skin spacing, implant timing, balloon volumes, breast size, chemotherapy, and age. Skin spacing continues to be significantly different in the good/excellent vs. fair cosmetic groups ( $p= 0.03$ ), while none of the other factors examined exhibited any trends for differences in the cosmetic result. Additional analyses of the effect of skin spacing at the time of treatment on the cosmetic result using categorical skin spacing cutoffs of 7 mm and 8 mm in separate 2 by 2

analyses exhibited trends for improved cosmesis with increased skin spacing. Cosmetic results in patients with skin spacing greater than or equal to 7 mm were good/excellent in 85% of the patients versus 57% in the patients with skin spacing between 5-6 mm (p=0.13). In patients with skin spacing greater than or equal to 8 mm, 89% reported a good/excellent cosmetic result, versus 58% in the patients with a skin spacing from 5-7 mm (p=0.04).

Three patients have experienced fat necrosis (8%); none symptomatic or requiring treatment (radiographic findings only). No patients developed adverse sequelae requiring intervention. 16 patients (40%) had local telangectasias; 14 patients had localized fibrosis (35%). Fibrosis was not statistically associated with any variable examined. Telangectasias occurred more frequently in patients that had skin spacing of 5-7 mm (67%) vs. greater than 7mm (29%) (p=0.04). The median skin spacing of patients with and without telangectasias was 7.5 mm and 11.5 mm respectively (p=0.0009).

Local breast tissue retraction was noted in 5 patients (12%) in whom median skin spacing was 7.0 mm vs. 10.0 mm in those patients not developing retraction (p=0.05). Skin spacing as a categorical variable was not statistically significant, but skin spacing of 5-7 mm more frequently associated with local breast tissue retraction (25%) than in patients with greater than 7 mm of skin spacing (7%) (p=0.15). Despite focal cosmetic issues, 100% of patients rated satisfaction with the use of the treatment when asked whether they would use the MammoSite RTS treatment again and if they would recommend the MammoSite RTS to a friend or family member.

Conclusions: 48 month cosmetic outcomes with the MammoSite balloon breast brachytherapy applicator were good-to-excellent in 80% of patients. Skin spacing remains strongly correlated with cosmesis. Telangectasias over a small area of skin is the most common reason for decreased cosmesis, followed by local breast tissue retraction. Both toxicities are strongly correlated with skin spacing. Serious toxicity requiring intervention remains absent. Patient acceptance is excellent. At 4 years median follow-up, no ipsilateral breast failures have occurred.

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