

10 Thirty-Nine Month Results with the MammoSite Brachytherapy Applicator: Details Regarding Cosmesis, Toxicity and Local Control in Partial Breast Irradiation

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Purpose/Objective: Update the original cohort of MammoSite breast brachytherapy patients by presenting the 39 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. Two patients not enrolled in the long term follow-up study are censured.

Results: With a median and mean follow-up of 38.5 months and 39 months respectively (12 to 54 mos.), 85% of patients were reported to have a good/excellent cosmetic result. Of the 38, and 29 patients followed >2, and >3 yrs., 84%, and 86% had good/excellent results respectively. An analysis was performed of factors associated with a good/excellent cosmetic result. Variables examined included skin spacing, implant timing, balloon volumes, breast size, chemotherapy, and age. Median skin spacing continues to be significantly different in the excellent, good, and fair cosmetic groups ($p=0.005$). Skin spacing is associated with a statistically significant improved cosmetic result at cutoffs of 7, and 8 mm in separate 2 by 2 analyses ($p=.05$, and $p=.005$ respectively) as well in a continuous variable analysis ($p=0.005$). Cosmetic results in patients with skin spacing greater than or equal to 7 mm versus 5–6 mm were excellent/good in 91% and 57% of the patients respectively ($p=0.05$). In patients with skin spacing greater than or equal to 8 mm versus 5–7 mm were excellent/good in 97% and 58% of the patients respectively ($p=.005$). Three patients have experienced fat necrosis (4.9%); none symptomatic or requiring treatment (radiographic findings only). No patients developed adverse sequelae statistically associated with any variable examined. Telangectasias occurred more frequently in patients that had skin spacing of 5–7 mm (58%) vs. greater than 7mm (32%) ($p=.03$). The median skin spacing of patients with and without telangectasias was 0.75 cm and 1.28 cm respectively. ($p=0.001$) Local breast tissue retraction was noted in 5 patients in whom median skin spacing was 0.72 cm vs. 1.15 cm in those patients not developing retraction ($p=0.04$). Skin spacing as a continuous variable was also statistically significant with spacing of 5–7 mm more frequently associated with local breast tissue retraction (25%) than in patients with greater than 7mm of skin spacing (7%) ($p=.05$). Despite focal cosmetic issues, patients rated satisfaction excellent/good 100% of the time. No local failures have occurred.

Conclusions: 39 month cosmetic outcomes with the MammoSite balloon breast brachytherapy applicator were good-to-excellent in 85% 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. No ipsilateral breast failures have occurred.