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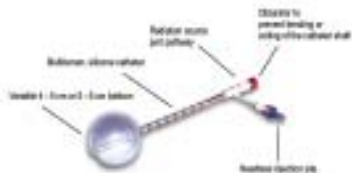
Thirty Month Results with the MammoSite® Breast Brachytherapy Applicator: Cosmesis, Toxicity and Local Control in Partial Breast Irradiation

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INTRODUCTION

We present the 30 month cosmetic outcome, toxicity and local control using the MammoSite balloon breast brachytherapy applicator to deliver accelerated partial breast irradiation (APBI).



MATERIALS AND METHODS

Forty-three patients enrolled and treated in a multi-center prospective trial from May 2000 to October 2001 testing the applicator for safety and performance for FDA approval constitute the study population. A dose of 34 Gy was delivered in 10 fractions over 5 days prescribed to 1 cm from the applicator surface using ¹⁹²Iridium high dose rate brachytherapy. Cosmesis was prospectively assessed by investigators using Harvard criteria. Toxicity was assessed using the FDA COSTART Terminology.

RESULTS

With a median and mean follow-up of 29 months and 27 months respectively (range 1 to 41), 84% of patients (36/43) were reported to have a good/excellent cosmetic result. Of the 32 patients followed > 2 years, 78% had good/excellent results. Of the 20 patients followed > 2.5 years, 75% had good/excellent cosmetic results. Of the 8 patients followed > 3 years, 75% have experienced good/excellent cosmetic results.

Two patients experienced fat necrosis (4.9%). None were symptomatic or required treatment. No patient has developed adverse sequelae requiring surgical correction or chronic analgesics. Twelve (12) patients (28%) had local telangiectasis and 14 patients had localized fibrosis (32%). Patient satisfaction was rated excellent or good 98% of the time. No local failures have occurred.

ANALYSIS

An analysis was performed of factors associated with a good/excellent cosmetic result. Variables examined included skin spacing (cutoffs 6, 7, and 8 mm), median skin spacing by cosmesis, implant timing (closed cavity versus open cavity), balloon inflation volumes, the use of systemic chemotherapy, and patient age. Median skin spacing was significantly different in the excellent, good, and fair cosmetic groups (p=0.004). Skin spacing is associated with a statistically significant improved cosmetic result at cutoffs of 6, 7 and 8 mm in separate 2x2 analyses (p=.015, p=.019, and p=.04 respectively). Linear regression analysis was performed and shows a continuous improvement in cosmesis with increasing skin spacing (p=.03).

COSMESIS

Cosmesis over time for patients with > 6 mm of skin spacing were examined. In patients with follow up greater than 1 year and skin spacing greater than 6 mm, cosmetic results in patients were excellent/good in 90% (n=29). In patients with follow up greater than 2 years and skin spacing greater than 6 mm, cosmetic results in patients were excellent/good in 91% (n=22). In patients with follow up greater than 3 years and skin spacing greater than 6 mm, cosmetic results were excellent/good in 100% (n=7).

Changes in cosmesis over time were examined in more detail. In the entire group forty four percent (44%) of patients had no change in status from first to last observation (19/43). Patients with changes in cosmesis over time both worsened (35%), and improved (21%).

Changes in cosmesis over time for the group with skin spacing greater than 6 mm were also examined. From one year onward, only 3/29 (10%) changed status downward from good to fair cosmesis, and 2/29 (21%) changed status downward from excellent to good cosmesis and 10/29 (34%) of patients improved from good to excellent cosmesis.

Patient	Device Depth (mm)	Examples of Cosmetic Outcome Over Time		
		Time Point 1	Time Point 2	Time Point 3
1	12	3 mo. Good	24 mo. Excellent	37 mo. Excellent
		1 mo. Good	5 mo. Good	37 mo. Good
2	12	15 mo. Excellent	31 mo. Excellent	34 mo. Excellent
		1 mo. Good	15 mo. Excellent	31 mo. Excellent
3	11	5 mo. Excellent	10 mo. Excellent	29 mo. Excellent
		3 mo. Good	24 mo. Good	37 mo. Good
4	10	9 mo. Good	30 mo. Fair	37 mo. Good
		1 mo. Fair	12 mo. Fair	39 mo. Fair
5	9	5 mo. Good	9 mo. Good	34 mo. Fair
		1 mo. Good	7 mo. Good	31 mo. Good
6	7	1 mo. Good	7 mo. Good	19 mo. Good
		1 mo. Good	7 mo. Good	31 mo. Good

CONCLUSION

30 month overall cosmetic outcome with the MammoSite® balloon breast brachytherapy applicator was good to excellent in 84% of patients. Skin spacing correlates strongly with cosmesis. Patients with at least 7 mm of skin spacing appear to have stable cosmesis out to 3 years. Toxicity at this evaluation remains minimal. Patient acceptance is excellent. No ipsilateral breast failures have occurred.