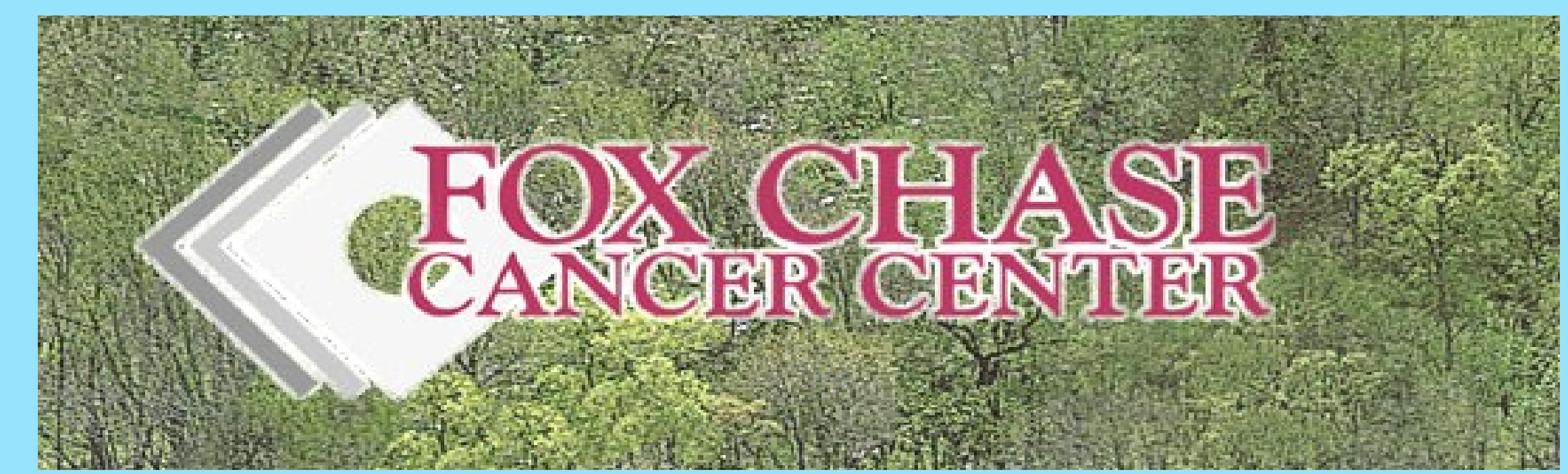


# A PHASE II STUDY OF FOUR-WEEK RADIATION FOR BREAST CANCER USING HYPOFRACTIONATED INTENSITY MODULATED RADIATION THERAPY (IMRT) WITH AN INCORPORATED BOOST

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**Purpose:** The goals of this phase II trial of a 4-week course of RT for early stage breast cancer were to reduce treatment length 1) without increasing acute toxicity and 2) without decreasing cosmesis and quality of life compared to conventional RT.

**Methods and Materials:** Eligibility included age  $\geq 18$ , Tis-T2, any N, M0, and breast-conserving surgery. Using IMRT and an incorporated electron boost, the whole breast received 45 Gy and the tumor bed 56 Gy in 20 treatments (Figure 1). The IMRT used 2 tangential beam directions, an inverse-planned iteration method for optimization, and a step-and-shoot delivery using multi-leaf collimation. Acute toxicity was scored using common terminology criteria (CTC, Table 1). Physician-reported cosmesis was assessed using the EORTC breast cancer rating system. Patient-reported outcomes were assessed using the Breast Cancer Treatment Outcome Scale (BCTOS). Wilcoxon non-parametric test was used to determine significance of differences in mean scores.

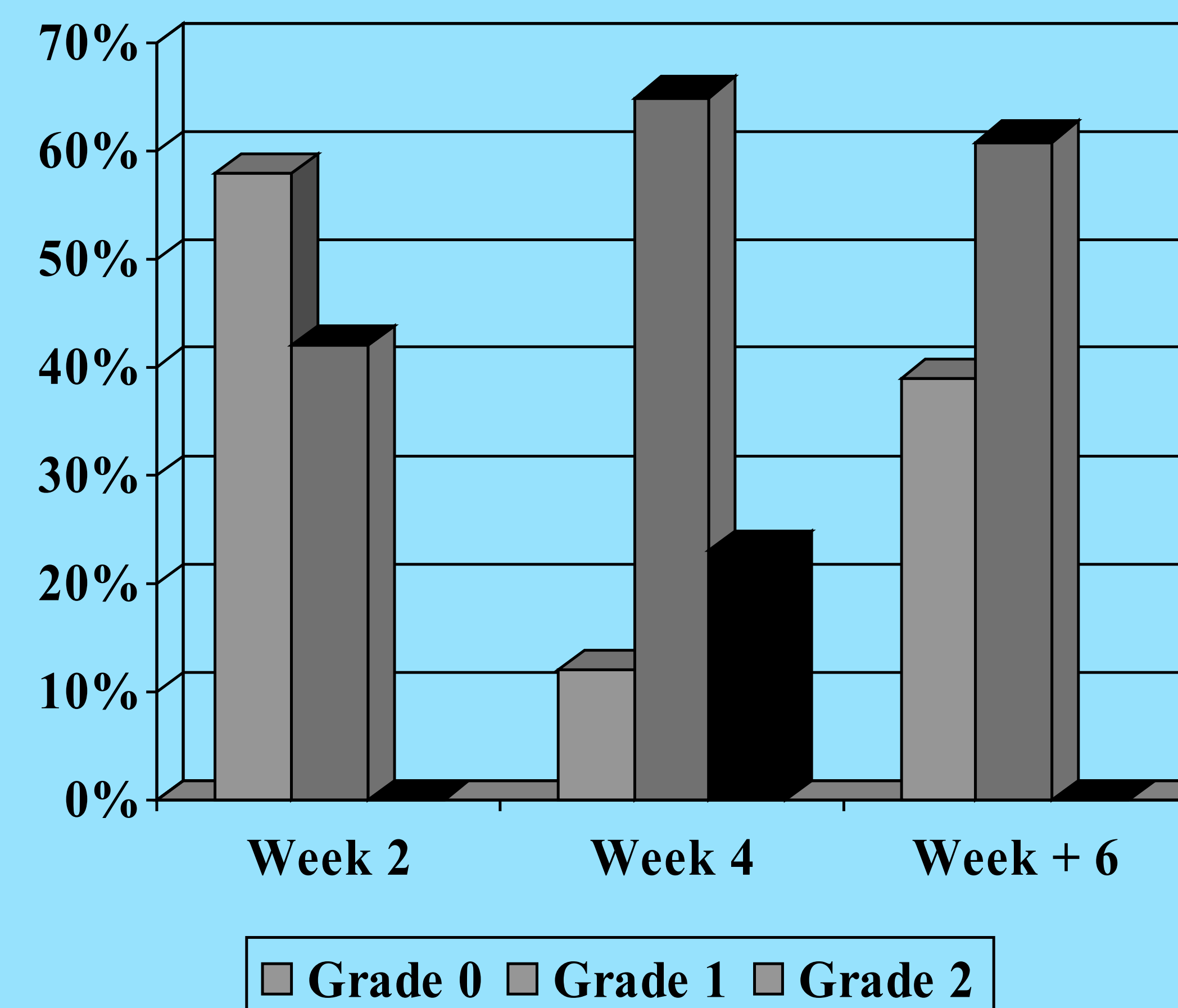
Characteristics	75 pts	%
Race		
White	71	96
Hispanic	2	3
African-American	1	1
Tumor size		
Tis	11	15
T1	50	67
T2	14	19
Bra Size		
32, 34A, B; 36 A	12	16
34C; 36B, C; 38 A, B, C	35	47
Any D or 40 +	23	31
Unknown	5	6
Node status		
N0	53	71
N1	13	17
NX	9	12
Side		
Left	33	44
Right	42	56
Chemotherapy prior to XRT		
Yes	33	44
No	42	56
ER status		
Positive	52	69
Negative	19	25
Unknown	4	5
Histology		
Invasive ductal	55	74
DCIS	13	17
Other	7	9

Grade	Description
1	Faint erythema or dry desquamation
2	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema
3	Moist desquamation other than skin folds and creases; bleeding induced by minor trauma or abrasion
4	Skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site
5	death

**Results:** 75 patients (median age 52 years; range 31-81) completed treatment (Table 2).  
 1) **Acute Dermatitis.** The acute dermatitis is shown in Figure 2. There was no grade 3 skin toxicity. All dermatitis had resolved to grade 0-1 by 6 weeks after radiation. The acute dermatitis is compared to controls in studies of conventional RT or IMRT in Table 3.  
 2) **Quality of Life.** The mean patient-reported BCTOS scores are shown in Table 4 (1 = no difference with the untreated side, 2 = mild difference, 3 = moderate and 4 = severe). Mean cosmesis and function scores were no different after treatment. Mean pain scores were higher at 6 weeks versus baseline ( $p=0.014$ ).  
 3) **Physician-rated cosmesis.** The mean physician-reported cosmesis (0 = excellent, 1 = good, 2 = fair) did not worsen after treatment from  $0.40 \pm .60$  baseline to  $0.38 \pm .59$  at 14 months. The mean physician-reported cosmesis agreed with patient-reported scores at baseline ( $p=0.024$ ), but post-treatment there was no significant relationship between them.

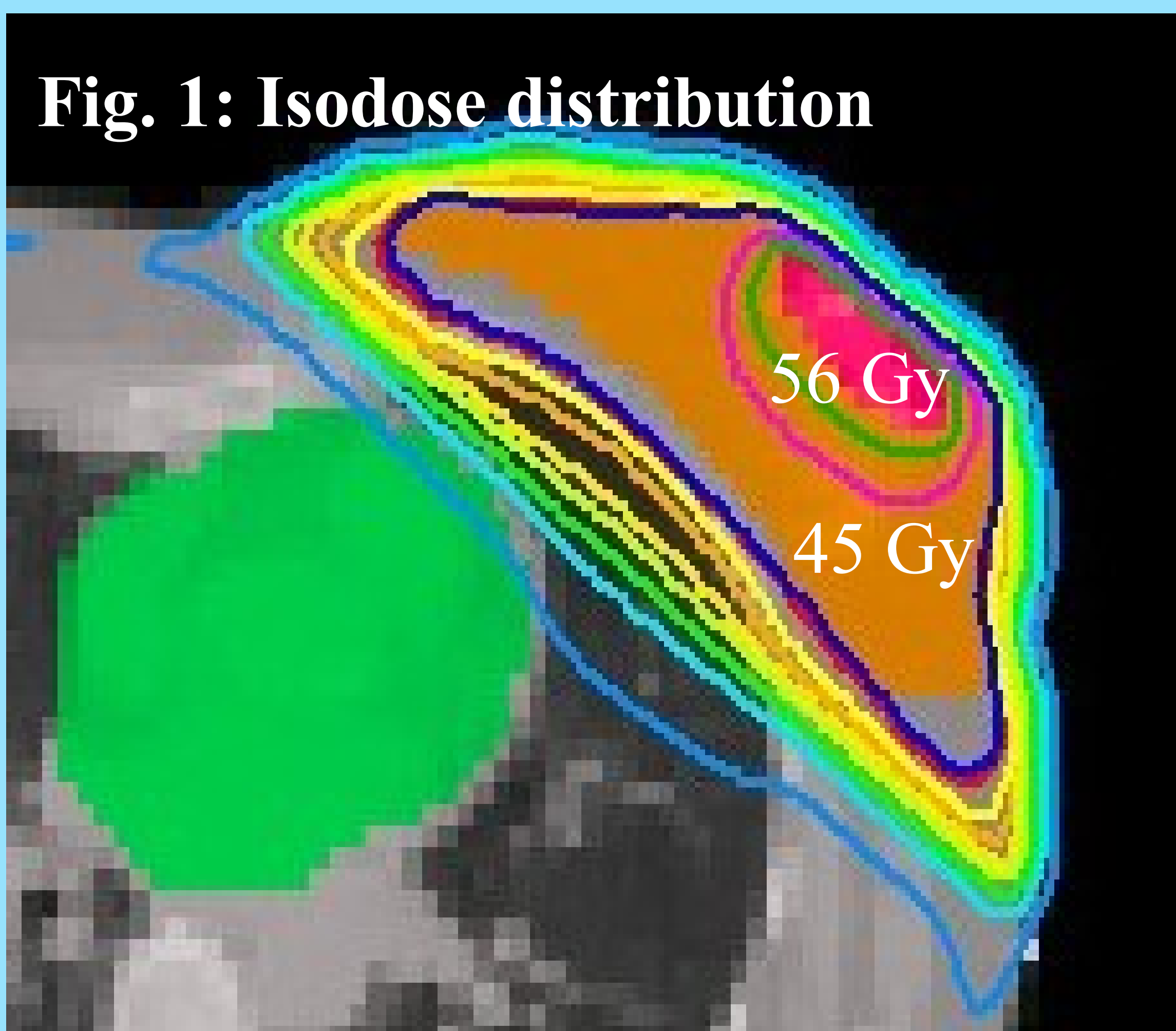
Type of RT	RTOG 97-13 Conventional	Current Study Hypofractionated IMRT	William Beaumont IMRT	FCCC IMRT
Patient #	140	75	281	73
Grade 0	8%	12%	--	0%
Grade 1	54%	65%	56%*gd 1+2	30%
Grade 2	36%	23%	43%	70%
Grade 3	1%	0	1%	0%

**Figure 2:** Acute Dermatitis



BCTOS scores	Time from XRT	Cosmesis Mean $\pm$ STD	Pain Mean $\pm$ STD	Function Mean $\pm$ STD
67 pts	Pre-treatment	$1.64 \pm 0.54$	$1.64 \pm 0.73$	$1.28 \pm 0.44$
55 pts	6 weeks after	$1.67 \pm 0.49$	$1.82 \pm 0.78$	$1.30 \pm 0.56$
41 pts	8 months after	$1.64 \pm 0.44$	$1.81 \pm 0.80$	$1.22 \pm 0.43$
21 pts	14 months after	$1.52 \pm 0.53$	$1.75 \pm 0.86$	$1.21 \pm 0.42$

**Conclusions:** This 4-week course of RT is associated with acute toxicity, cosmesis and quality of life comparable to 6-7 week fractionation. There was good correlation between physician and patient-reported cosmetic scoring only before radiation. Further study by means of a randomized clinical trial is justified.



**Fig. 1:** Isodose distribution