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Radiation Therapy Utilizing Fast Neutrons For Head and Neck Cancer - The Fermilab Experience

Parvathy D. Kurup, M.D., JoAnne Mansell, R.N., P.A.,

Frank R. Hendrickson, M.D., Lionel Cohen, M.D.,

Miguel Awschalom, Ph.D., Ivan Rosenberg, Ph.D.,

Randall K. Ten Haken, Ph.D.

Fermilab Neutron Therapy Facility, P.O. Box 500, Batavia, IL 60510

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Abstract From September 1976 to December 1980, 249 previously untreated patients with locally advanced epidermoid carcinoma of the various head and neck regions were treated with definitive radiotherapy at the Fermilab Neutron Therapy Facility and/or at the referring institutions. Of these, 29 patients received neutrons alone 2-3 times per week, 51 patients received mixed beam therapy (RTOG 76-10, 3 times per week photons and 2 times per week neutrons) and 87 patients received neutron boost after 5 - 5-1/2 weeks of photons (RTOG 78-08). The other 82 patients constitute the control group who received photons only at the referring institutions according to RTOG protocol 76-10 or 78-08. Local control, survival and morbidity are analyzed.

The mixed beam and neutron boost group patients are compared with the randomized photon controls. By actuarial analysis, no advantage is demonstrated by any modality in local control or survival. Patients who received neutrons alone had more advanced disease compared to other groups. Data is analyzed to study the influence of initial stage and site of origin of tumor. Actuarial analysis shows very similar results in terms of local control and survival in comparable groups of patients. Morbidity analysis reveals some increase in major morbidity in the group treated with neutrons alone.

Key Words: Fast neutron therapy, mixed beam, neutron boost, photons, epidermoid carcinoma head and neck.

Introduction

Even with high doses from supervoltage machines, conventional radiotherapy has yielded poor results in locally advanced head and neck cancer. Most of these tumors are beyond the possibility of radical surgery even at the cost of considerable functional and cosmetic impairment. Several alternatives have been tried in recent years including neutron irradiation, chemotherapy,[13] radiosensitizers,[25] hyperbaric oxygen[14] and hyperthermia[21]. Catterall et al.[6,7] first reported encouraging results with fast neutrons in a controlled clinical trial on locally advanced head and neck cancer.[6,7]

Several other neutron therapy centers have published similar studies with varying results.[4,12,15,16,18,19] alone and in combination with photons, for head and neck carcinoma at Fermi National Accelerator Laboratory, near Chicago.

Materials and Methods

From September 1976 to December 1980, 308 patients with locally advanced head and neck carcinoma were treated with definitive radiotherapy at Fermilab Neutron Therapy Facility Informed consent[26] was received from all patients after the nature of the treatment program was fully explained to them. Fifty-nine patients are excluded from the present analysis (50 - previously treated with radical surgery or radiation therapy, 9 - non-epidermoid carcinoma). The 249 previously untreated patients with epidermoid carcinoma of various head and neck regions are grouped as follows:

1. Neutrons only - 29 patients.

2. Neutrons and Photons - 51 patients.
   ("Mixed Beam", RTOG 76-10)

3. Photons and a neutron boost - 87 patients.
   (RTOG 78-08 - 35 patients)

4. Photons only - 82 patients.
   (Control group, RTOG 76-10 and 78-08).

Treatment Policy and Techniques

Neutrons Only

The fast neutron beam at Fermilab is produced by bombarding a 22 mm thick beryllium target with 66 MeV protons from a linear accelerator.[8] The relative biological effectiveness as compared to high energy photons (RBE) of this beam is approximately 3.[20,22] The skin sparing and depth dose characteristics are similar to those of megavoltage x-rays from a linear accelerator.[3,23,24] See also Figures 1, 2, and 3. Patients are treated in a sitting position in an adjustable chair. Immobilization of the head is achieved with individually made "Light Cast" molds.[17] The neutron beam is fixed horizontally. However, all the relative movements provided by conventional isocentric therapy can be achieved with the chair, since it moves in three dimensions and rotates about a vertical axis. The point of intersection of the vertical axis of rotation and central axis of beam is defined as the isocenter, which is at 190 cm from the target. Four intersecting laser beams help in proper alignment of the patient.[2]

X-rays for planning are done with the patient in the same chair. Treatment plans are individualized for each patient according to the site of origin of tumor and involvement of lymph nodes in the neck. The target volume consists of gross tumor with at least a 1 cm margin. The neutron doses reported are "target absorbed doses" including the gamma component.[10] Doses were usually prescribed in terms of minimum target volume doses which varied from 20 Gy to 24 Gy; nominal target absorbed doses were generally 10% higher. The regional lymph node areas at risk were treated to a dose of 14 - 15 Gy, limiting the spinal cord dose to less than 12.5 Gy. A typical treatment plan is shown in Figure 4. The treatments were given 2 or 3 times every week for 6 or 7 weeks. Multiple fields, including posterior oblique fields, wedges and bolus were used as needed.

Mixed Beam

All mixed-beam patients were treated according to RTOG protocol 76-10 with 5 treatments per week (3 photons, 2 neutrons) for 7 weeks. The photon part of treatment was given at various referring institutions. The dose in mixed beam therapy is prescribed in terms of the total equivalent dose consisting of the sum of photon dose plus neutron dose plus x 3. The neutron dose was delivered to areas of gross disease bringing the equivalent dose in the primary target volume to 66 - 72 Gy. The regional areas at risk received photon or electron irradiation up to 50 Gy. The target volume definition and treatment planning were as described in the neutron only group. Spinal cord dose is limited to less than 50 Gy equivalent assuming an RBE of 4 for CNS [D(spinal cord) = D(photon) + 4D(neutron)].[2]

Neutron Boost

This group of patients received an initial 45-50 Gy with photons to the gross disease and regional drainage areas at risk at the referring institutions. The subsequent neutron boost was given to the gross disease with a 1 cm margin. The neutron dose consisted of 7.5 - 9 Gy in 2-1/2 weeks, bringing the total equivalent dose up to 66 - 72 Gy (photon dose + neutron dose x 3). Treatment planning was individualized for each patient according to the site of origin of tumor and involvement of regional lymph nodes. Spinal cord dose limitation was similar to that of mixed beam. Of these 35 patients were actually entered in the RTOG protocol 78-08;
the rest were not randomized but were treated as per protocol.

Photons Only

This group constitutes the control group from RTOG protocols 76-10 (mixed beam) and 78-08 (boost). The target volume definition and treatment planning were individualized for each patient at the referring institutions. The dose to gross disease was 66 - 72 Gy. Regional drainage areas and other areas at risk were treated up to 45 - 50 Gy, again limiting the spinal cord dose below 50 Gy. Megavoltage equipment was utilized and multiple fields with wedges were used if necessary.

All patients except the control group (photon only) were seen at Fermilab at 2 - 3 month intervals for follow-up. Any necessary diagnostic work-up was done at referring institutions. For most of the control group of patients follow-up information was available from the referring physicians.

Results

Patients treated up to December 1980 are included in this analysis which was done in December 1981. Median follow-up for all living patients is 20 months. All patients had epidermoid carcinoma. The staging is per AJCC system (1980).[1] The distribution of patients by initial staging and treatment is shown in Table 1. The neutron only group consisted of mainly stage IV patients.

The listing by tumor site and treatment is shown in Table 2. As can be seen, oral cavity and oropharyngeal tumors constitute the majority in all treatment groups.

Local Control

Complete absence of tumor in the primary site and regional lymphatic drainage areas is considered as local control. Patients who died within 3 months are counted not evaluable for this part

~~of the analysis~~. There is a 10% difference in local control between the neutron only group and conventional treatment. The mixed beam and neutron boost group analysis reveals somewhat inferior results. Local control for different stages according to the treatment groups is shown in Table 3. Local control for tumors arising from different sites according to treatment groups is listed in Table 4. In general, oral cavity lesions did not do well in this series.

Actuarial analysis[5] for local control was done for comparable groups of patients and has yielded very similar results [Figure 5(a), 6(a), 7(a)]. For the mixed beam and neutron boost groups the control arm consists of photon treated patients from the corresponding randomized studies (RTOG 76-10, 78-08). In Figure 7(a) only stage IV patients are included. Mixed beam and neutron boost group are plotted together and compared with their combined control group treated with photons. The third curve represents neutron only group patients (not randomized into the studies).

Survival

Actuarial disease-free survival analysis[5] was done for a comparable group of patients from different treatment arms. [Figure 5(b), 6(b), 7(b)]. The curves are almost identical. Again Figure 5(b) and 6(b) show the comparison between mixed beam and neutron boost group patients with their corresponding controls treated with photons in the randomized studies (RTOG 76-10, 78-08). Figure 7(b) compares stage IV patients from mixed beam and neutron boost groups to the combined control groups and also to the neutron treated group. The three curves are similar in characteristics. Thus, actuarial analysis has failed to demonstrate any survival difference between the different treatment groups.

Morbidity

Major morbidity from treatment is analyzed in different treatment groups according to the type of mordibity. Table 5 summarizes the results. Soft tissue necrosis at the site of, and in association with, persistent tumor is scored as a treatment failure and not as a complication. Patients who died within 5 months of treatment are considered ineligible for morbidity analysis. Treatment with neutrons only has resulted in more morbidity compared to other groups. One patient died as a result of complications. He was treated for a hypopharyngeal lesion and died 10 months later with severe soft tissue and laryngeal necrosis. Autopsy revealed no evidence of residual tumor. The only patient with eye problems in the neutron only group had stage IV disease of maxillary antrum and the eye had received maximum dose of 2668 neutron rads (minimum tumor dose 2400). He developed an abscess that necessitated enucleation, and died 1 year after treatment with pneumonitis. The tumor was still under control. In the mixed beam group, one patient has developed minimal radiation myelopathy. She had a T2N3 oropharyngeal tumor and received a total equivalent dose of 75.6 Gy to the gross disease. Forty-four months after the therapy she is alive without disease, but has right sided motor and left sided sensory deficits. The maximum equivalent dose to the spinal cord was recalculated and found to be 51.8 Gy. In most patients who developed bone necrosis the event was precipitated by tooth extraction, and all were successfully treated by conservative management or surgical excision.

Discussion

This analysis failed to show a significant improvement in local control or survival in the randomized studies involving mixed beam and neutron boost treatment for previously untreated epidermoid carcinoma of the head and neck. Patients treated with neutrons only were fewer in number and were not randomized. This group is not fully comparable with the control groups even when classified by stage or site of origin. The marginal gain in local control is apparently masked by the increase in major morbidity for this group. None of the neutron-treated groups has any clear advantage over photon controls.

A comparison of local control results with fast neutrons at different centers in locally advanced head and neck carcinomas is shown in Table 6.[6,7,12,18,19] With the exception of the significant improvement in local tumor control shown by Catterall et al.,[6,7] all these results are comparable with our results.

The reports from M. D. Anderson Hospital[18,19] mention the inclusion of non-epidermoid carcinomas and they feel that since the numbers are very few it is unlikely this would have affected the ultimate results. EORTC[12] and our group of patients all had epidermoid carcinomas only. Catterall et al.[6,7] probably included some non-epidermoid carcinomas since the report does not specify histology. Here again, the numbers may or may not be significant enough to change the overall results. In our analysis, the results in the neutron only arm appeared somewhat better when non-epidermoid carcinomas were included (Table 7). We have elected to evaluate only epidermoid carcinomas in this paper. All neutron treated patients including those with recurrent disease, will be analyzed in detail in a future publication.

Survival advantage has not been shown from any of the centers so far. Even the significant local tumor control advantage in the Catterall et al.[6,7] study has failed to show a survival advantage in head and neck carcinomas. This reflects the problems of intercurrent disease as well as deaths from disease outside of the treated area.

The increased occurence of major morbidity in the neutron group has been reported by other authors also.[11,16,18,19] There have been suggestions that this may be due to the equivalent or biological dose from neutrons being higher than estimated or to the dose response curve being steeper for neutrons than for photons. A comparison of normal tissue and tumor responses in patients treated with Fermilab neutron beam and photon controls was done by one of the authors.[9] No demonstrable therapeutic gain factor is suggested for neutrons relative to photons since RBE of neutrons relative to photons is the same for normal tissue and tumor. The optimal dose with either modality yields an estimated probability of uncomplicated control of no more than 45%. New studies involving neutrons for head and neck tumors are being designed to evaluate different neutron doses, with a shorter overall treatment time (in 4 to 4-1/2 weeks compared with 6 to 7 weeks). There may also be some potential for improving results by achieving uniformity of dosage distribution in the target volume.[9]

Conclusion

The preliminary results of this analysis fail to demonstrate any gain factor for fast neutrons over conventional radiation in head and neck carcinomas, in the doses and combinations utilized.

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Figure Captions

Figure 1 - Comparison of central axis depth dose distributions for 10x10 cm^2 therapy beams.[24] The beam qualities are given in the figure. The numbers in parentheses are the SSD at which the measurements were made.

Figure 2 - Comparison of off axis ratios for 10x10 cm^2 beams.[24] The beam qualities are given in the figure. The numbers in parentheses are the SSD at which the measurements were made.

Figure 3 - Comparison of dose build-up distributions for a 10x10 cm^2 beam.[24] The beam qualities are given in the figure. The numbers in parentheses are the SSD at which the measurements were made.

Figure 4 - Typical head and neck treatment plan using Fermilab fast neutrons. There is unilateral node involvement.

Figure 5a - Comparison of mixed (n + x-rays) beam and photon only results for local control.

Figure 5b - Comparison of mixed (n + x-rays) beam for photon only results for disease free conditions.

Figure 6a - Comparison of neutron boost and photon boost results for local control.

Figure 6b - Comparison of neutron boost and photon boost results for disease free conditions.

Figure 7a - Comparison of (i) mixed and neutron boost, (ii) neutrons only, and (iii) photon only results for local control.

Figure 7b - Comparison of (i) mixed and neutron boost, (ii) neutrons only, and (iii) photon only results for disease free conditions.

Table 1

Radiation Therapy Utilizing Fast Neutrons
for Head & Neck Cancer - The Fermilab Experience

Distribution of Patients According to Stage and Treatment Group.

Rx Group / Stage*	Neutron Only	Neutron + Photon (Mixed)	Neutron + Photon (Boost)	Photon Only
II	4	3	18	13
III	4	13	23	23
IV	21	35	46	46
TOTAL	29	51	87	82

*AJCC Stage Grouping, 1980.[1]
Stage I - T1 N0 M0
Stage II - T2 N0 M0
Stage III - T3 N0 M0, T1 or T2 or T3 N1 M0
Stage IV - T4 N0 or N1 M0, Any T N2 or N3 M0, Any T Any N M1

Table 2

Radiation Therapy Utilizing Fast Neutrons
for Head & Neck Cancer - The Fermilab Experience

Distribution of Patients According to Site and Treatment Group

Rx Group / Site of Origin	Neutron Only	Neutron + Photon (Mixed)	Neutron + Photon (Boost)	Photon Only
Oral Cavity 68	6	13	22	27
Oropharynx 100	8	20	38	34
Larynx 32	4	9	9	10
Hypopharynx 38	7	9	11	11
Other* 11	4	-	7	-
TOTAL 249	29	51	87	82

*Nasal cavity, paranasal sinuses, nasopharynx, 1 unknown.

Table 3

Radiation Therapy Utilizing Fast Neutrons
for Head & Neck Cancer - The Fermilab Experience

Local Control By Stage and Treatment Groups.

Type of Rx / Stage	Neutron Only	Neutron + Photon (Mixed)	Neutron + Photon (Boost)	Photon Only
II	3/3	2/3	6/17	7/11
III	2/4	6/13	6/22	9/23
IV	8/19	9/34	11/44	16/45
TOTAL	13/26 (50%)	17/50 (34%)	23/83 (28%)	32/79 (40.5%)

Not evaluable: N - 3, Mixed - 1, Boost - 4, P - 3

Table 4

Radiation Therapy Utilizing Fast Neutrons
for Head & Neck Cancer - The Fermilab Experience

Local Control By Site of Origin of Tumor and Treatment Groups

Rx Group / Site	Neutron Only	Neutron + Photons (Mixed)	Neutron + Photons (Boost)	Photon Only	Total
Oral Cavity	0/6	3/13	2/22	8/26	13/67
Oropharynx	4/7	8/19	10/36	13/33	35/95
Larynx	3/4	4/9	6/9	6/9	19/31
Hypopharynx	5/6	2/9	3/9	5/11	15/35
Other*	1/3	-	2/7	-	3/10
TOTAL	13/26 (50%)	17/50 (34%)	23/83 (28%)	32/79 (40.5%)	85/238

Not evaluable N - 3, Mixed - 1, Boost - 4, P - 3

Table 5

Radiation Therapy Utilizing Fast Neutrons
for Head & Neck Cancer - The Fermilab Experience

Analysis of Major Morbidity By Treatment Groups

Rx Group / Morbidity	Neutron Only	Neutron + Photons (Mixed)	Neutron + Photons (Boost)	Photon Only
Soft-tissue necrosis, fistula	1	1	2	2
Bone necrosis	2	-	3	2
Laryngeal edema, cartilage necrosis	1	1	1	-
Severe symptomatic fibrosis	1	1	2	-
Spinal cord	-	1	-	-
Eye	1	-	-	-
TOTAL	6/24 (25%)	4/42 (9.5%)	8/72 (11%)	4/74 (5.5%)

Table 6

Radiation Therapy Utilizing Fast Neutrons
for Head & Neck Cancer - The Fermilab Experience

Local Control By Treatment Groups-Results from Different Neutron Centers.

Facility	Neutron Only	Neutron + Photons (Mixed)	Neutron + Photons (Boost)	Photon Only
Hammersmith* (Ref. K3,K4)	53/70 (76%)			12/63 (19%)
Houston (Ref. K10,K11)	23/49 (47%)	26/54 (48%)		18/41 (44%)
EORTC* (Ref. K7)	48/100 (48%)			41/95 (43%)
Fermilab	13/26 (50%)	17/50 (34%)	23/83 (28%)	32/79 (40.5%)

EORTC - European Organization of Radiation Therapy Centers.
*Randomized studies.

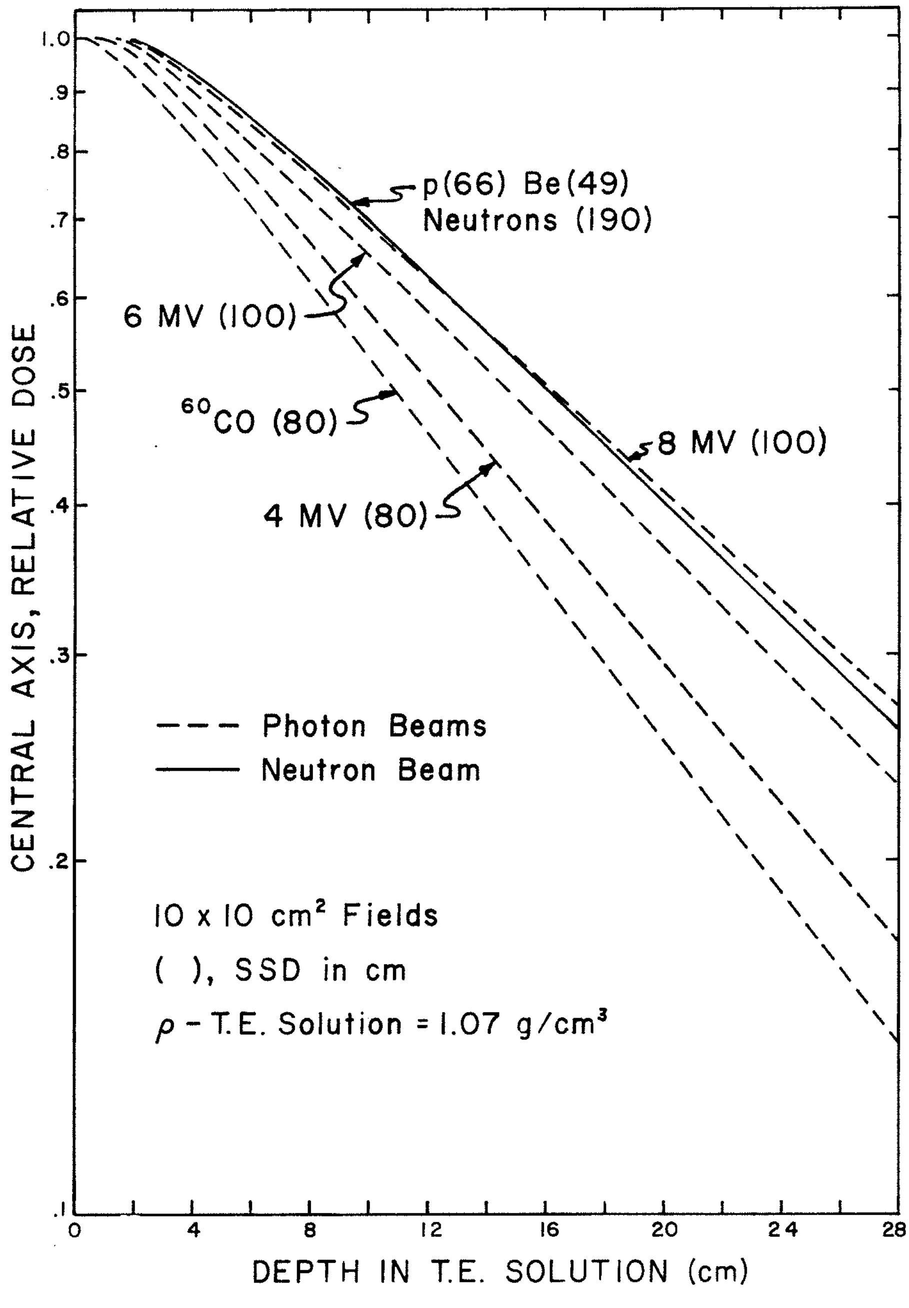
Table 7

Radiation Therapy Utilizing Fast Neutrons
for Head & Neck Cancer - The Fermilab Experience

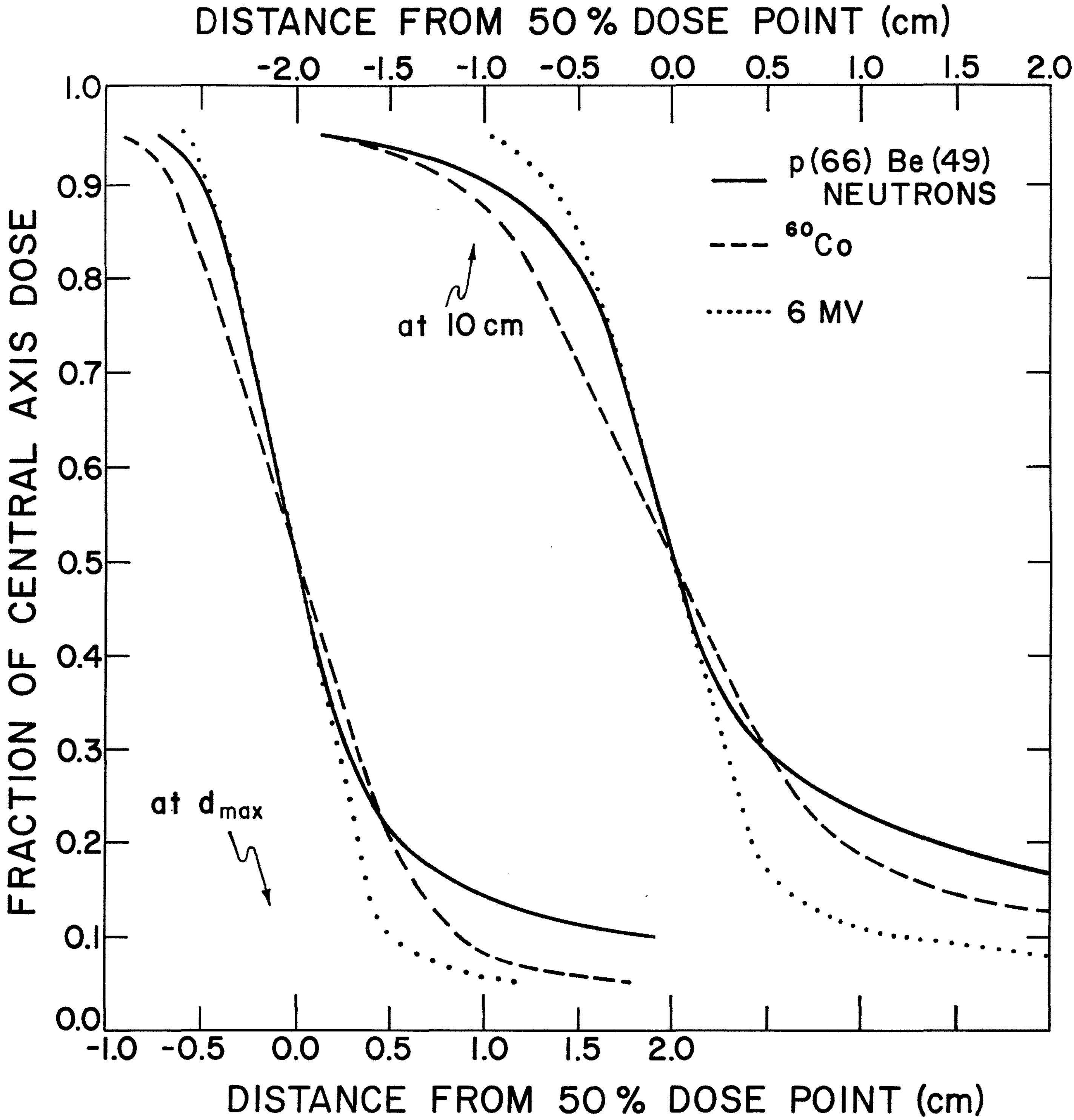
Local Control in Neutron Only Group By Histology & Previous Treatment

Histology / Previous Rx	Epidermoid Carcinoma	Non-epidermoid* Carcinoma
None	13/26	3/6
Surgery	4/8	8/10
TOTAL	17/34 (50±9%)	11/16 (69±11%)

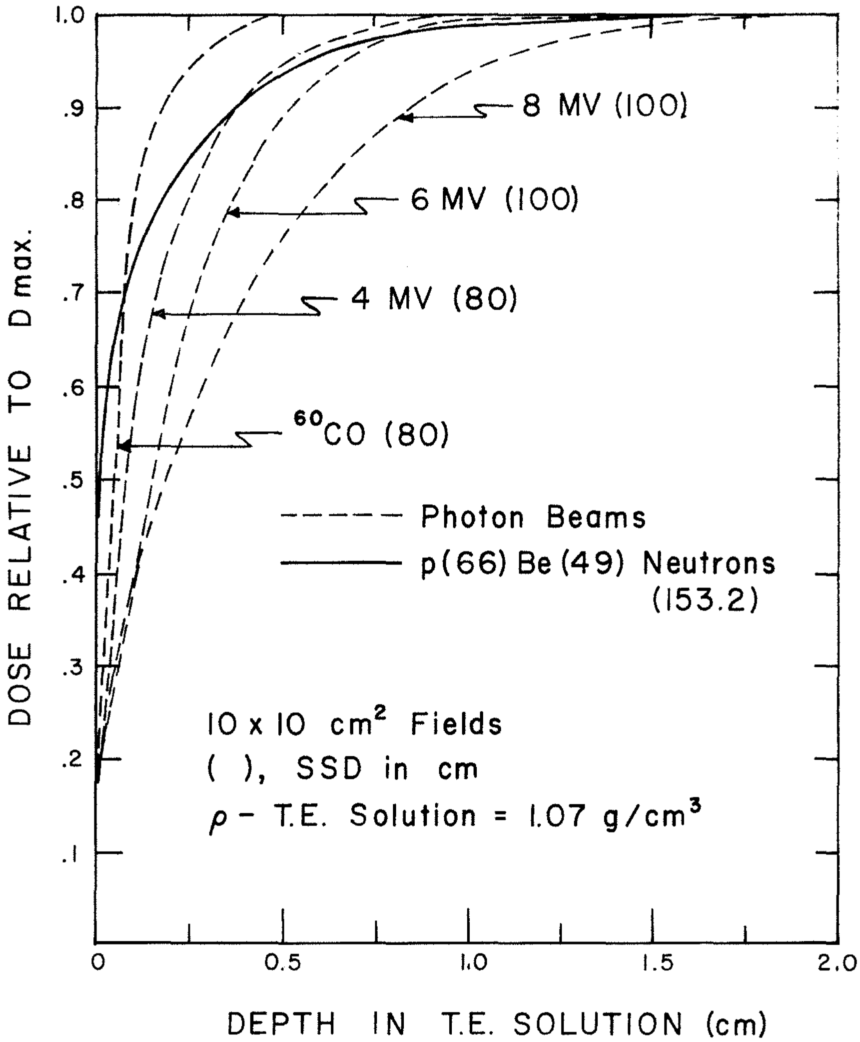
*Adenocystic, mucoepidermoid, adenocarcinoma.

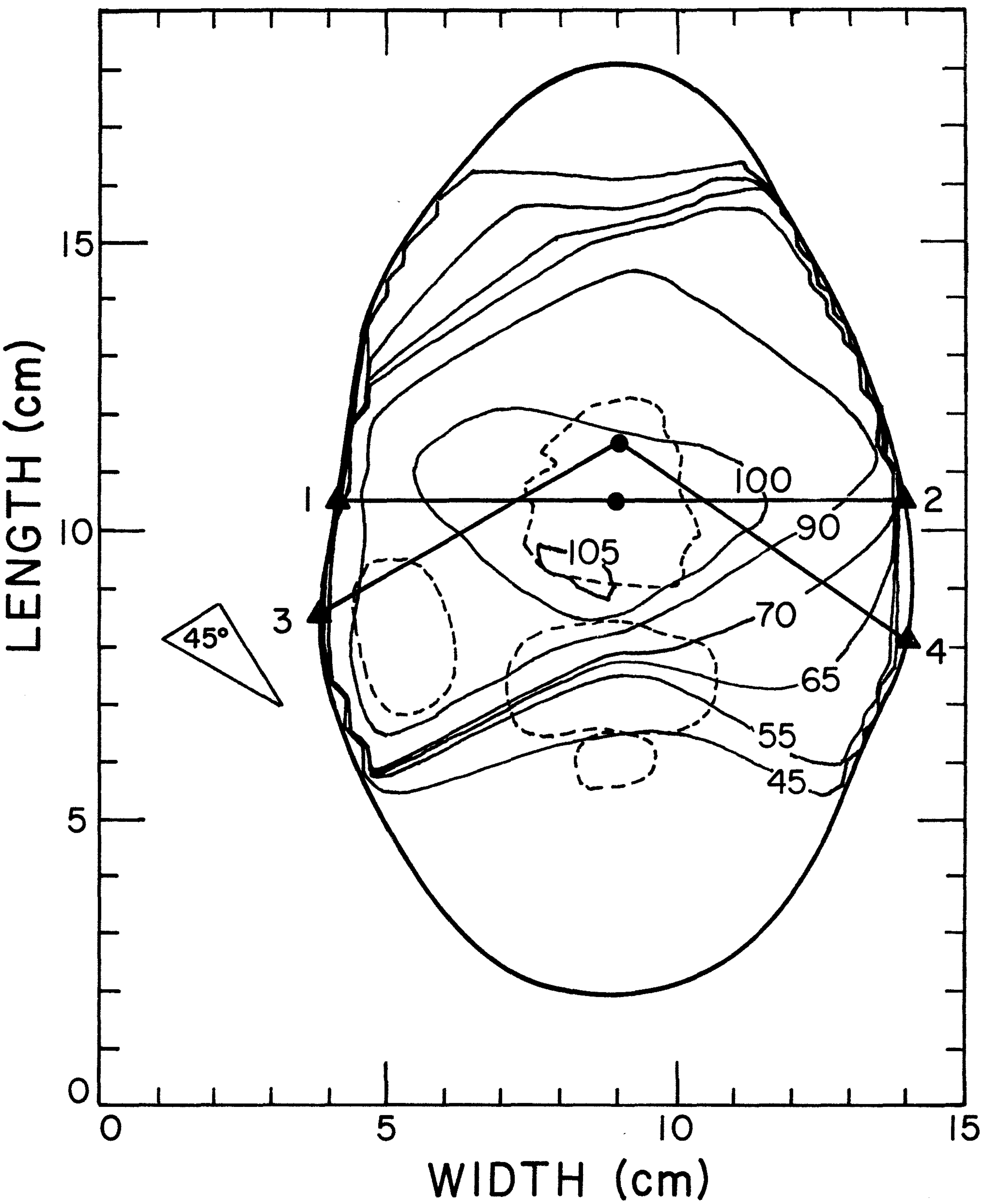


p(66) Be(49)
Neutrons (190)
6 MV (100)
60CO (80)
8 MV (100)
4 MV (80)
Photon Beams
Neutron Beam
10 x 10 cm² Fields
( ), SSD in cm
ρ - T.E. Solution = 1.07 g/cm³
CENTRAL AXIS, RELATIVE DOSE
DEPTH IN T.E. SOLUTION (cm)
1.0
.9
.8
.7
.6
.5
.4
.3
.2
.1
0
4
8
12
16
20
24
28



DISTANCE FROM 50% DOSE POINT (cm)
-2.0
-1.5
-1.0
-0.5
0.0
0.5
1.0
1.5
2.0
FRACTION OF CENTRAL AXIS DOSE
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
p(66) Be(49) NEUTRONS
^{60}Co
6 MV
at 10 cm
at d_{max}
-1.0
-0.5
0.0
0.5
1.0
1.5
2.0
DISTANCE FROM 50% DOSE POINT (cm)


1.0
.9
.8
.7
.6
.5
.4
.3
.2
.1
DOSE RELATIVE TO D max.
8 MV (100)
6 MV (100)
4 MV (80)
^{60}CO (80)
Photon Beams
p(66) Be (49) Neutrons
(153.2)
10 x 10 cm^2 Fields
( ), SSD in cm
ρ - T.E. Solution = 1.07 g/cm^3
0
0.5
1.0
1.5
2.0
DEPTH IN T.E. SOLUTION (cm)



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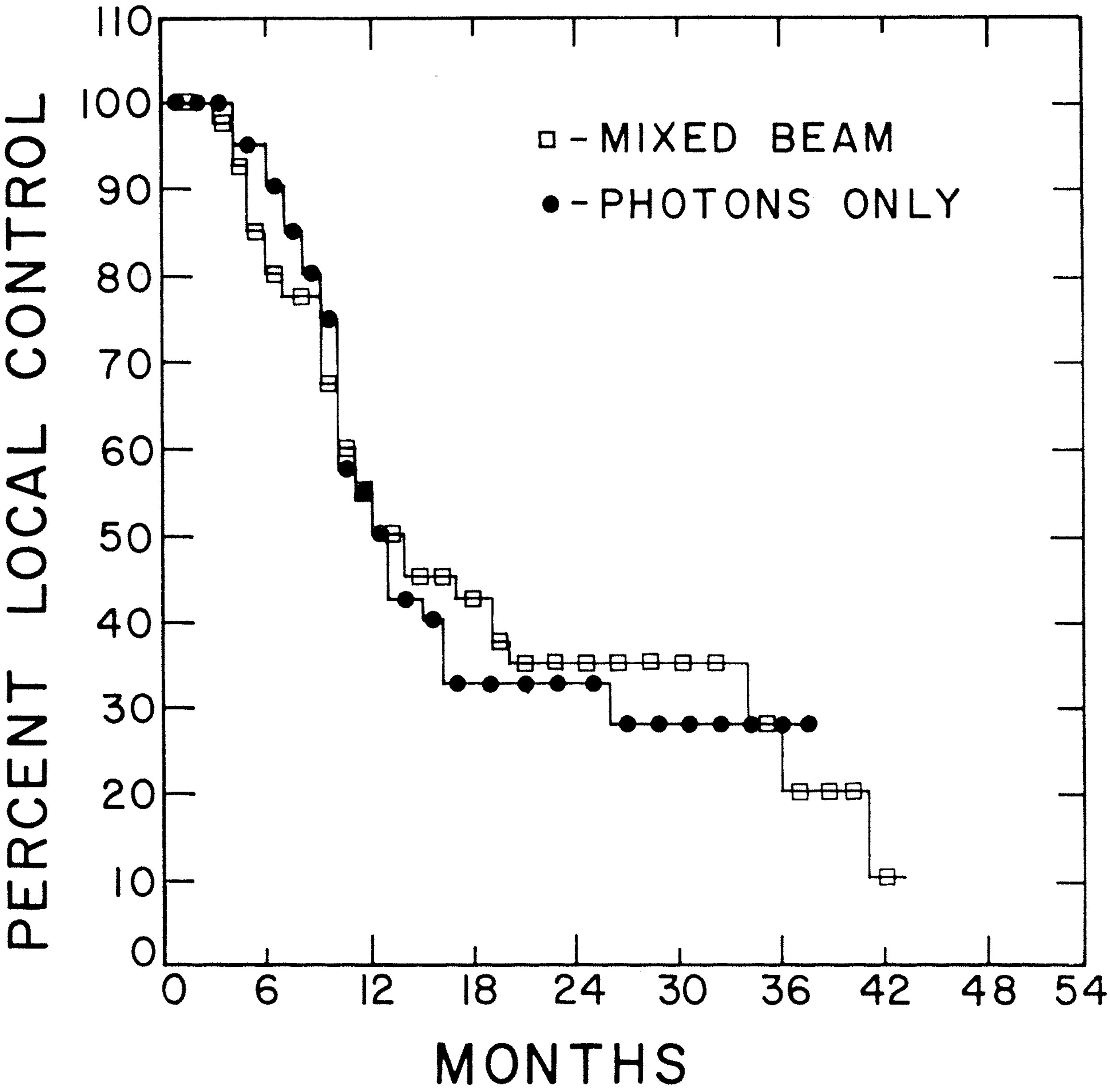

□ - MIXED BEAM
● - PHOTONS ONLY
PERCENT LOCAL CONTROL
0
10
20
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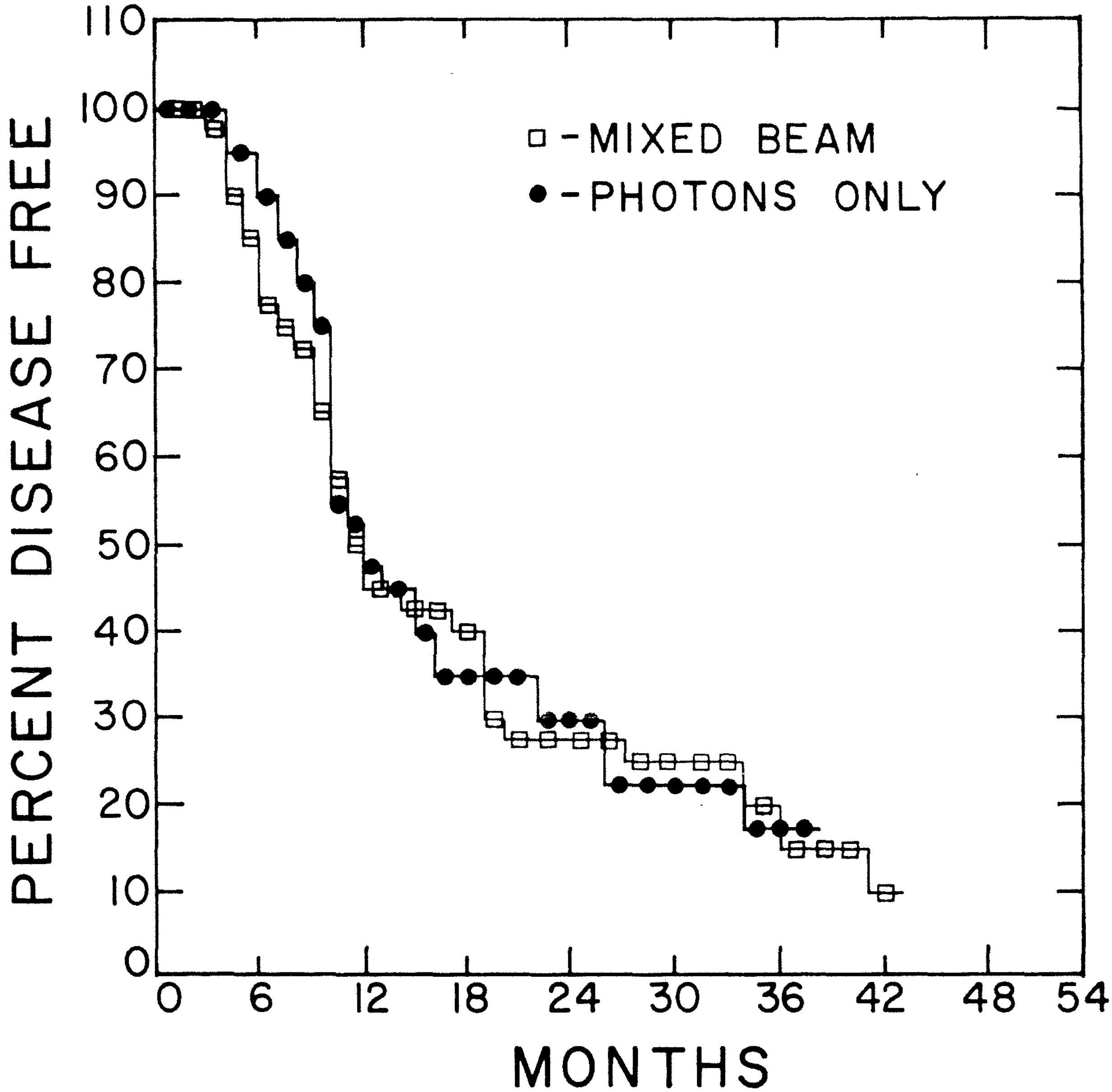
42
48
54
MONTHS



PERCENT DISEASE FREE
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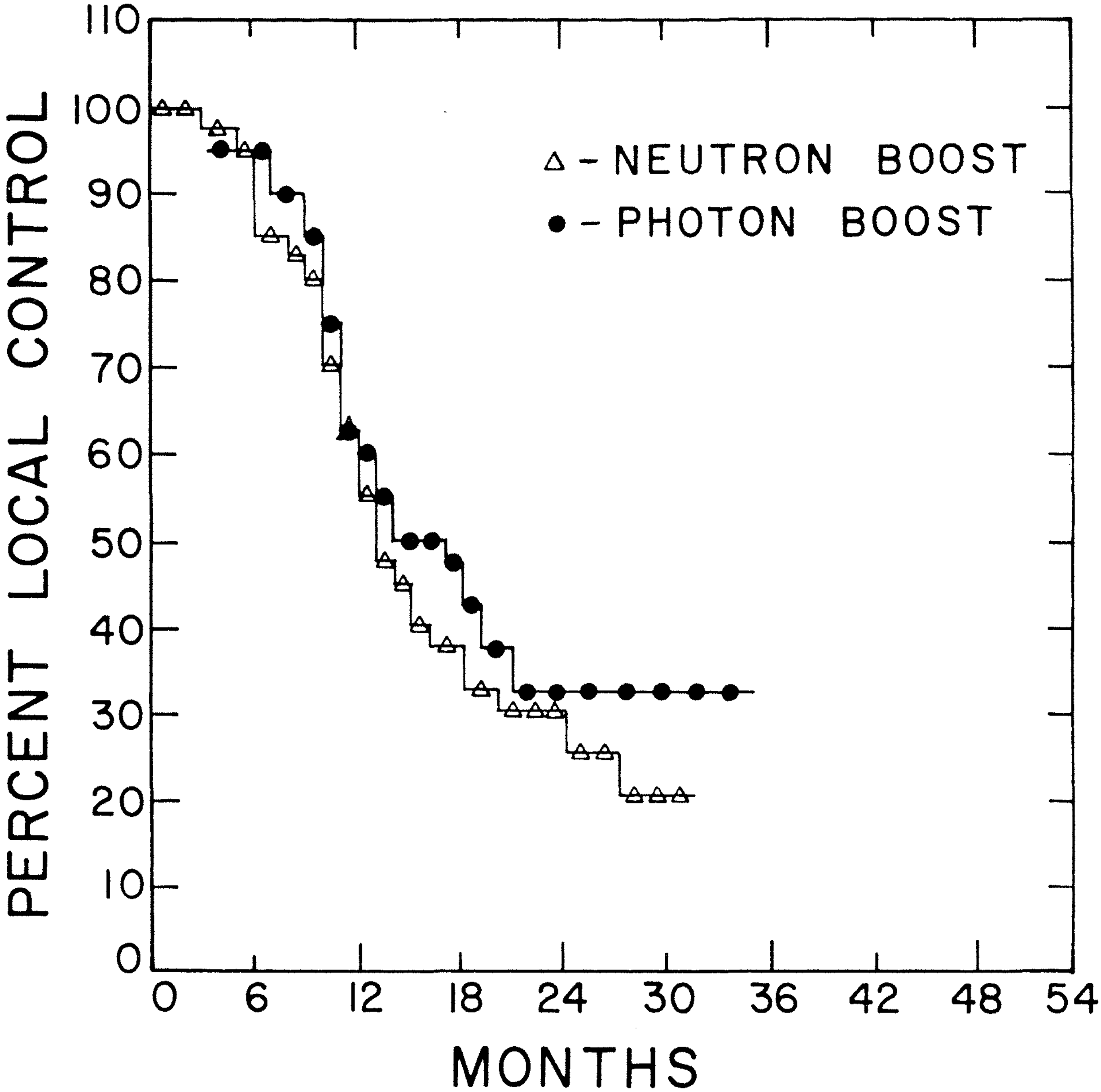
MONTHS



PERCENT LOCAL CONTROL
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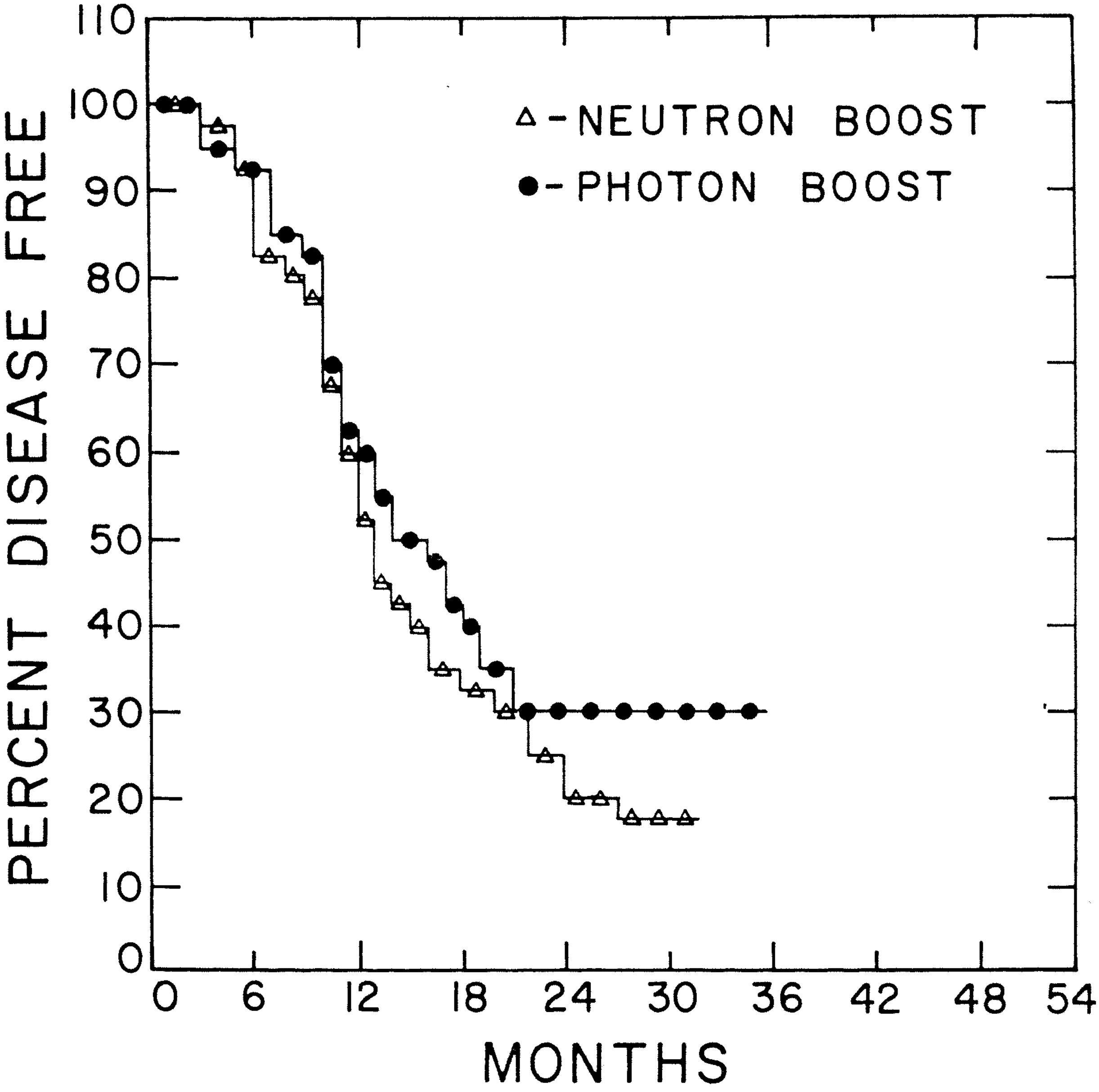
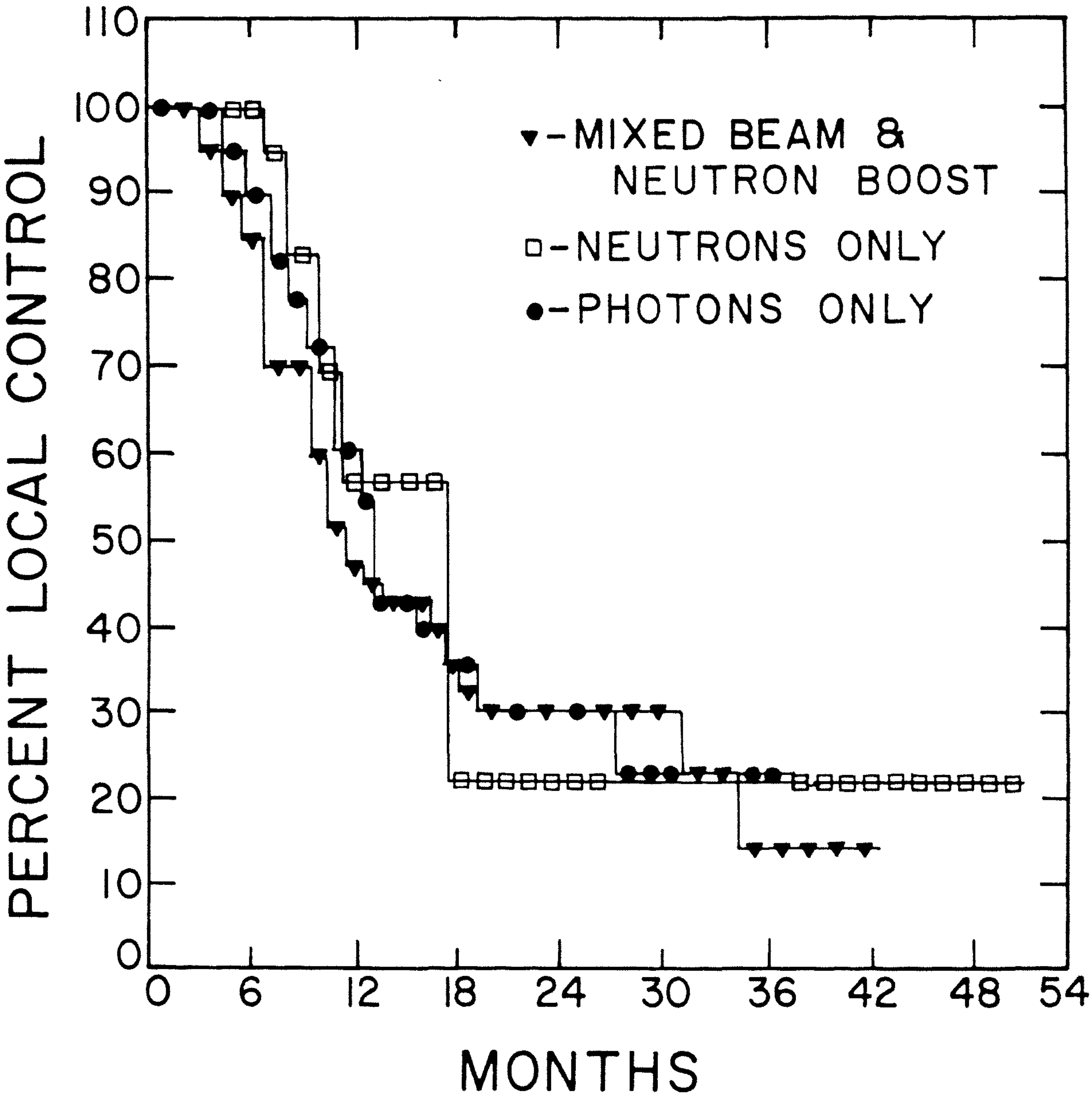
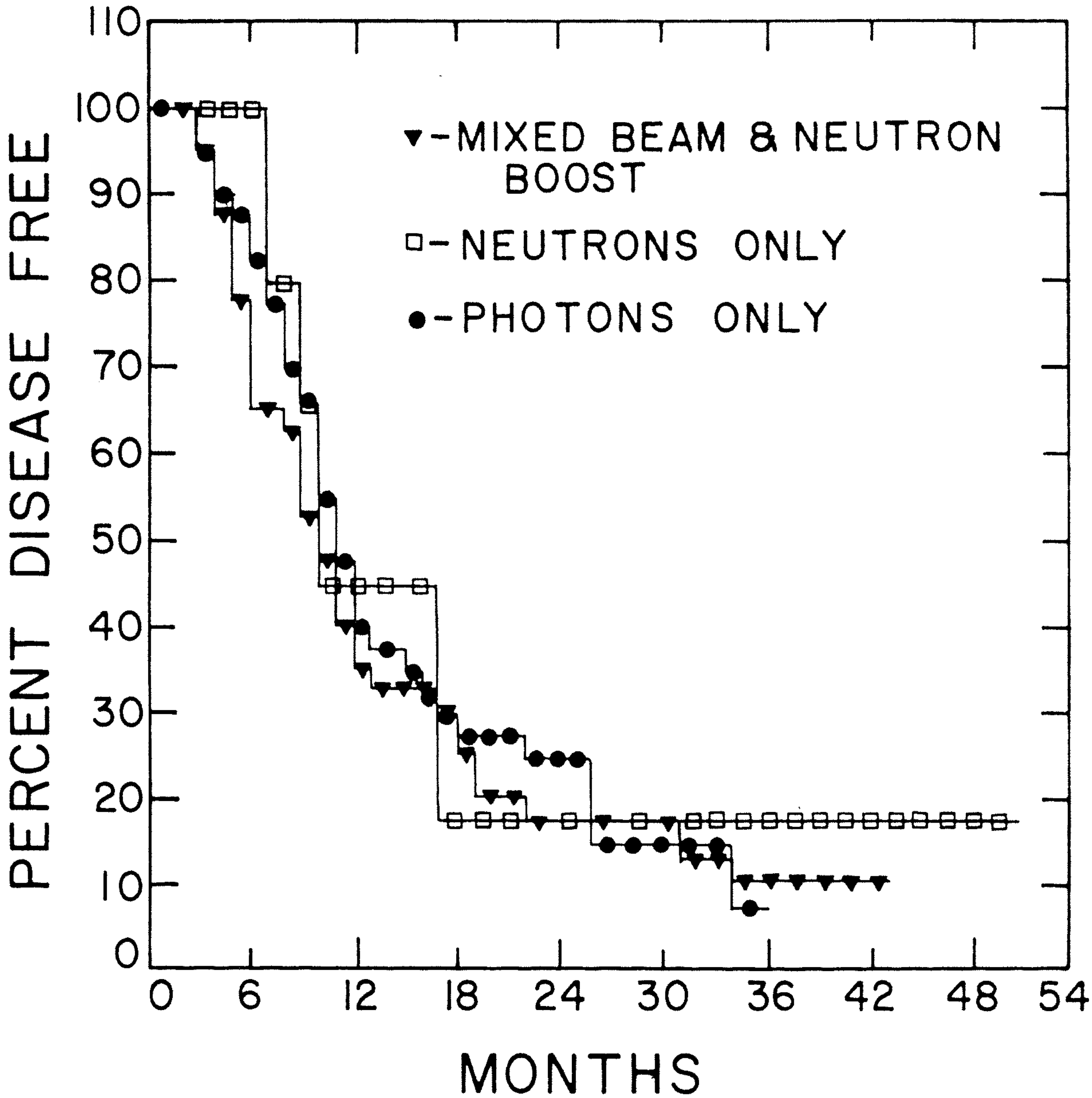
36
42
48
54
MONTHS
△ - NEUTRON BOOST
● - PHOTON BOOST



PERCENT DISEASE FREE
110
100
90
80
70
60
50
40
30
20
10
0
0
6
12
18
24
30
36
42
48
54
MONTHS
△-NEUTRON BOOST
●-PHOTON BOOST



▼-MIXED BEAM & NEUTRON BOOST
□-NEUTRONS ONLY
●-PHOTONS ONLY
PERCENT LOCAL CONTROL
MONTHS
0
10
20
30
40
50
60
70
80
90
100
110
0
6
12
18
24
30
36
42
48
54



PERCENT DISEASE FREE
MONTHS
▼-MIXED BEAM & NEUTRON BOOST
□-NEUTRONS ONLY
●-PHOTONS ONLY
110
100
90
80
70
60
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40
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