Clinical Experience with Californium-252 Seed Assemblies

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Cf-252 シードアッセンブリの臨床的研究

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放射線難治性癌14例に対し，^{252}Cf シード・アッセンブリを用手後充填法を用いて治療した．効果判定可能な12例中6例に一次治癒（2ヶ月後腫瘍消失）を得た．6例中2例は初発皮膚癌，2例は再発舌癌，及び各1例の初発進行乳癌と再発直腸癌であった．全体の治療成績は他の ^{252}Cf 小線源を用いて治療した場合と略々同様であった．

腫瘍治癒線量は 10Gy 以上であり，又副作用は病巣の進行度を考慮すれば堪えられる程度のものであった．

As reported previously[1-5], a series of pilot clinical studies have been conducted at the Cancer Institute Hospital by the use of the first loan of 30 μg of Cf-252 small sources, consisting of 3 applicator tubes, 10 short afterloading cells and 72 seeds from the U.S. Department of Energy in October 1973.

This report describes our clinical attempt made from March 1977 to March 1980 to broaden the indications of brachytherapy by the use of new sources of seed assemblies received as the second loan of 85 μg Cf-252 medical sources in March 1977.

We have applied these sources mainly on a total of 14 radioresistant cancer cases, consisting of 7 primary and 7 recurrent cases. These cases have been considered hitherto to be very radioresistant from clinical and histological points of view and thus conventional radiotherapy is not indicated.

Inventory and Detailed Dimensions of Cf-252 Seed Assemblies

An inventory of Cf-252 seed assemblies is shown in Table 1, and their detailed dimensions are given in Fig. 1.

Fig. 2 shows the external appearance of seed assemblies, their dummy sources and accessories used for implant system, such as implant tube, lead disc, nylon ball and device for cramping lead discs.

Cf-252 seed assembly is provided with a melt-sealed end plug of 3.2 cm in length, which facilitates the safe handling of this radioactive source. A long leader can be easily melt-bounded to the end of the seed assembly by a specially attached device so that the afterloading of this source into a deep-seated tumor is made possible (Fig. 3).

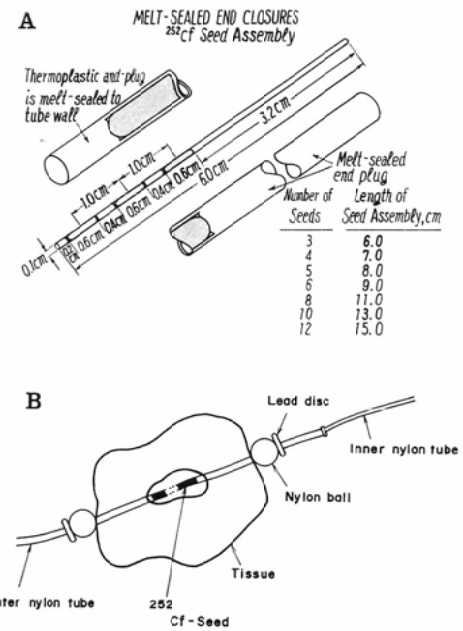

Fig. 1 Various accessories used for Cf-252 seed assembly implant system

(A) The detailed dimensions of seed assemblies with melt-sealed end plug of 3.2 cm in length. Inner diameter of the implant tube is 1.25mm, into which a seed assembly with a diameter of 0.95 mm is inserted with a reasonable clearance.

(B) Implanted tubes are secured by squeezing the buttons with a hemostat against the skin at both ends of a implanted tube where it emerges from the skin.

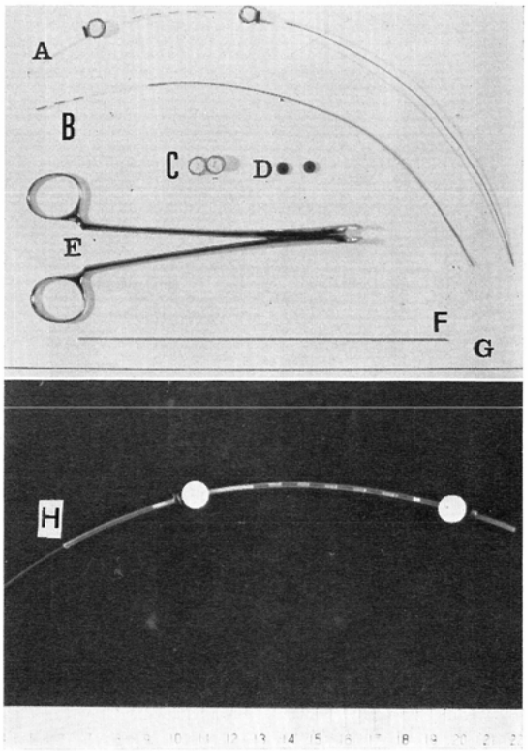

Fig. 2 Various accessaries used for Cf-252 seed assemblies interstitial implant system

A. dummy source and center tube
B. dummy source
C. lead disc
D. nylon ball
E. hemostat (lead disc squeezer)
F. needle
G. mandolin
H. a radioactive source secured by buttons and lead discs in implant tube

Table 1. Inventory of Cf-252 seed assemblies loaned to the Cancer Institute Hospital
(Received: March 1977)

Seed assembly*	Active length mm	External length mm	External diameter mm	Number of seeds	Number of seed assemblies
3-seed	26	60	1.05	0.38 μg* × 3	4
4-seed	36	70	1.05	0.38 μg* × 4	4
5-seed	46	80	1.05	0.38 μg* × 5	4
6-seed	56	90	1.05	0.38 μg* × 6	4

*on September 27, 1976
*7 to 12 seed assemblies at 2 Cf-252 contents of 0.3 and 0.5 μg/seed can be requested to be made.

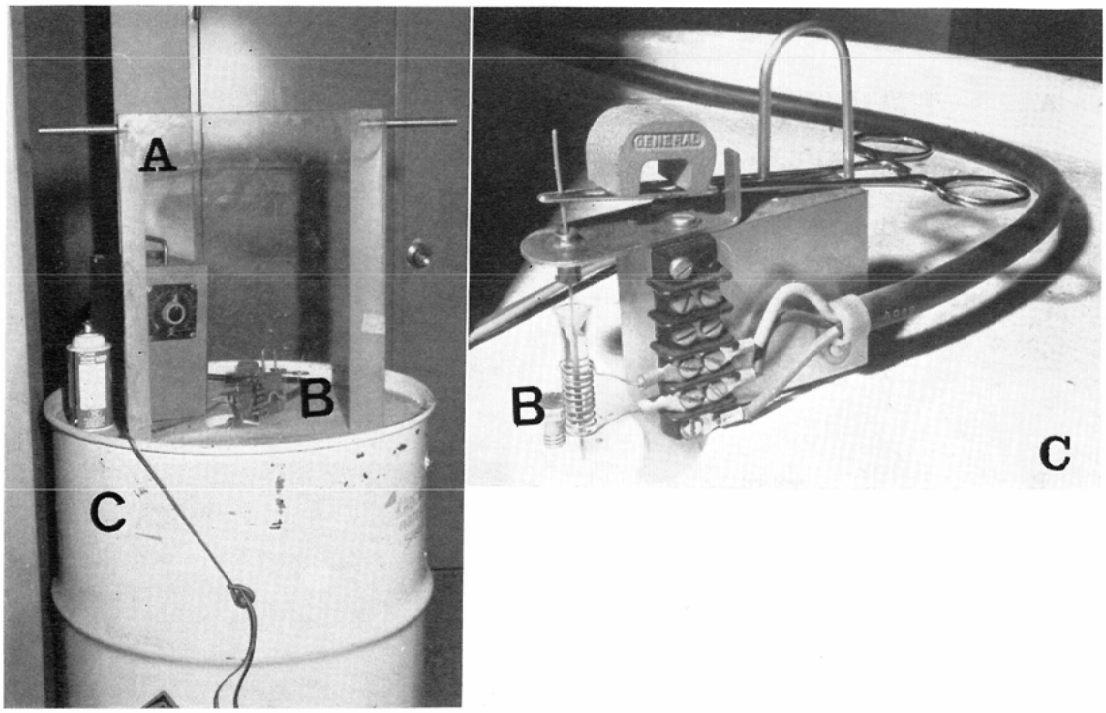

Fig. 3 Butt-welding procedure

(1) Butt-welder (Left)
A eye shield
B butt-welder
C skipping and storage cask
(2) Butt-welding aperation (Right)
A Leader, length optional, is placed over ends to be welded
B Seed assembly receptacle, hold its end plug in upright position
C welding jig

Method of Application

The method of treatment is the same as that of ^{192}Ir brachytherapy, and various methods of application were used. The surface mold was used for superficial lesions and the implant was used in one plane, in two planes or in volume implant according to varying configurations of the volume to be treated.

Three dimensional dose distribution was calculated by our physists' group for individual cases, and the dose to be delivered was determined after considering the tumor size, response, histology, location, previous treatment and conditions of the tumor bed. The delivered dose was given by neutron dose, because the contribution of neutrons is about 6 times greater than that of γ-rays in terms of relative biological effectiveness under low dose-rate neutron irradiation of about 0.1 Gy/hr.

The procedure of its clinical application consists of the following 4 steps[6)-9)].

1. Special implant tubes *(Fig. 1 and 2) are implanted interstitially by the guide of inserted stainless steel needles placed in position in the operation room similar to that of ^{192}Ir wire or seed ribbon implants. For deep-seated or large tumors, it is necessary to implant long nylon tubes to cover the entire affected region by the aid of operation.

2. Next, dummy sources are inserted into implant tubes and verifying films are taken from two perpendicular directions. The dose to be delivered to the target volume is calculated and determined by a computer for each individual case according to a formula developed by our physicists' group[2)3)].

3. The patient is then moved into a special ward provided with various shieldings for personnel radiation protection, where the seed assemblies are inserted into implant tubes and then secured in position by compressing the lead disc. This lead disc is specially provided for ^{192}Ir wire implant**, and both ends of the implanted tube are secured against the skin where it emerges from the skin. The nylon ball is often used as a spacer between the skin and lead disc.

4. The seed assemblies are unloaded after the prescribed dose is delivered by re-expanding the compressed lead disc to enable the inner radiative source to be withdrawn. Finally the implanted tubes are withdrawn.

Advantages of Seed Assemblies

1. Varying active lengths of sources ranging from 3 to 6 cm in length with a specific activity of 0.3 μg/cm are available, which facilitate wide application of this source.

2. The sources are "Tefzel" (ethylenetetrafluoroetylene)-sheathed and rather flexible in strength. The curved or looped arrangement of the source facilitates homogenous irradiation of the tumor with varying configurations.

3. When deep-seated tumors are afterloaded, the source to which a long leader was melt-welded

Table 2. Radiation effect score for tumor control

A:	Early effect score of tumor control (2 mos. later)
	1—Complete disappearance of tumor
	2—Regression, less than half of the original size
	3—Regression, larger than half size of the original
	4—No shrinkage
	5—Growing
B:	Late effect score of tumor control (3 mos. later)
	1—Complete disappearance with no sign of scar
	2—Complete disappearance with scar formation
	3—Residual but non-growing tumor
	4—Residual and slowly growing tumor
	5—Rapidly growing recurrent tumor

* Implant tube is made commercially available from the Alpha-Omega Services, Inc., Califomia, U.S.A.

** Nylon ball and lead disc are made commercially available from the Radiochemical Center, Amersham, England.

Table 3. List of 7 primary cases treated with Cf-252 seed assemblies

Pat. No.	Age and Sex	Primary Site Stage Histology	Previous treatment and Local Condition	Date	Method of Application	Total Neutron dose/hr.	Local and Side Effects Survival Time	Early Effect Score 2 mos. Later	Late Effect Score 3 mos. Later
1. K.S.	44 F	Skin of the head $T_3N_1M_0$ sq. c. ca.	Scar induced cancer, which developed by a trauma to the head 20 years ago. A tumor developed in the center of the scar 12 cm in diameter in Feb. 1977, which grew very rapidly to 6×4.5×1 cm in size in July 1977. The ulcer partly invaded into the skull, and was judged inoperable.	July 1977	Surface mold 0.5 μg cell × 7 3 seed × 4 4 seed × 4 5 seed × 4 6 seed × 4	6 Gy/ 166 hr. at 2 cm	Tumor decreased in size and almost disappeared for 5 mos. Local recurrence developed several times. Died of local recurrence and lymph node metastasis in Aug. 1978.	2	2
2. M.A.	80 F	Skin of the left second and third toes $T_2N_0M_0$ malignant melanoma	Since 2 years a black superficial tumor grew slowly to cover the skin of the whole left second and third toes (acral lentiginous melanoma), without lymph node metastasis.	Oct. 1979	Surface mold 0.35 μg cell × 10 4 seed × 2 5 seed × 4 6 seed × 4	2.16 Gy/ 144 hr. at 0.3 cm	Severe dermatitis developed but subsided with regression of the tumor. Tumor has gradually reduced in size for more than 4 mos.	2-3	2
3. T.K.	73 M	Skin of the right temporal region $T_2N_0M_0$ sq. c. ca.	Burn scar induced cancer after 70 years developed from the right temporal region. Tumor size is 3×4 cm with a ulcer of 1.5×2 cm covered by necrotic membrane.	Jan. 1980	Surface mold 3 seed × 4 4 seed × 3 5 seed × 3 6 seed × 2	10 Gy/ 264 hr. at 0.5 cm	Moderate dermatitis developed. Tumor is well controlled and under observation for 3 mos.	1	1
4. K.N.	70 M	Tongue $T_3N_1M_0$ sq. c. ca.	Large tumor occupying left posterior two-thirds of the tongue and extending to the contralateral side, left anterior pillar and tonsil, with left submaxillary lymph node metastasis and paralysis of the hypoglossus nerve was suspected.	June 1978	Linac x-ray of 40 Gy/20 F/30 d was in effective in May 1978, followed by Cf-252 boost therapy. Loop method: 3 seed × 1 4 seed × 4 5 seed × 3 6 seed × 2	7.2 Gy/ 168 hr.	Slight mucositis developed. Recurred after 7 mos. due to low dose given, and salvaged by Ra implantation of 13 mg. × 125 hr. and RND in Jan. 1979. Ulceration developed but lasted for 14 mos. in Mar. 1980. Surviving with no evidence of recurrence.	1	1
5. N.O.	69 M	Lymph node metastasis sq. c. ca.	Hypopharyngealcancer ($T_2N_3M_0$, postcricoid type) was treated by external Linac x-ray of 7 Gy in Aug. 1976. Left supraclacicular lymph node metastasis developed in Feb. 1977, involving the brachial nerve plexus and caused severe neuralgia.	Apr. 1977	Linac x-ray of 40 Gy rad was ineffective in Feb. 1977, followed by Cf-252 boost therapy. Plain implant: 3 seed × 2 5 seed × 4	16.6 Gy/ 166 hr.	No dermatitis. Neuralgia subsided for 4 mos. Died of metastasis in May 1978.	2	2
6. A.T.	23 M	Tongue $T_2N_0M_0$ acinic c. ca.	Tumor 3.0×3.5×1.5 cm, in size developed from the middledorsal part of the tongue in Sept. 1978. Erosion developed in Nov. 1978.	May 1979	External Co-60 γ-ray of 26 Gy and electron ray of 30 Gy at another hospital ineffective, followed by Cf-252 boost therapy. Loop method: 3 seed × 2 4 seed × 3 5 seed × 4	16.5 Gy/ 168 hr.	Severe mucositis developed which lasted for 3 mos. Tumor decreased in size to 1×0.5 cm. Has been under observation for more than 1 y.	2	2
7. M.M.	51 F	Breast $T_4N_3M_0$ adeno ca.	Advanced breast cancer, 5.3×6.0 cm in size developed 2 years ago from the left upper quadrant, with infiltration and ulceration of the skin. Left axillary lymph node metastasis of 4.5×2.5 cm associated with edema of the left upper extremity is present.	Feb. 1979	Mantle field irradiation of Linac x-ray of 60 Gy/20 F/50 d, and tangential irradiation of 71 Gy/31 F/74 d were given to the primary site. The latter was boosted by Cf-252 2 plain implant. 4 seed × 2 5 seed × 1 6 seed × 4	13.4 Gy/ 336 hr.	Mastectomy was performed in Oct. 1979, due to remaining skin ulcer of 0.5 cm in diameter and suspicious tumor residue. No cancer cell was found in the specimen. Healthy with no evidence of disease in Feb. 1980.	1	1

Table 4. List of 7 secondary cases treated with Cf-252 seed assemblies

Pat. No.	Age and Sex	Primary Site Histology	Site and Local Condition	Previous treatment and Local condition	Date	Method of Application	Total neutron dose/hr.	Local and Side effects Survival time	Early effect score (2 mos. later)	Late effect score (3 mos. later)
8. M.N.	71 F	Tongue sq. c. ca. recurrence	Recurrent tongue cancer of 1.1×2 cm at the mouth floor and left gingiva	Resection of the tongue and gingival leukoplakia with Co-60 irradiation was made in June 1966. IInd recurrence was observed in 1977, but operation was refused.	Apr. 1977	Loop method: 3 seed × 4 4 seed × 4	16.8 Gy/ 168 hr.	Moderate mucositis was seen. Tumor disappeared for 1 year. Removal of the focus of suspected recurrence revealed no cancer remaining. She is healthy for 3 years.	1	1
9. M.T.	45 M	Tongue sq. c. ca.	Residual tumor involving the whole tongue	Ist Ra implant for T_1 tumor developing from the mid-dorsal part of the tongue was made in 1955. Second Ra implant for suspected radiation induced cancer was made in Nov. 1977 after 12 years. III and IV Ra implants were not effective, with residual tumor 6.0 cm in diameter infiltrating into the whole tongue body extending to the mouth floor.	Apr. 1978	Loop method: 3 seed × 4 4 seed × 4 5 seed × 4 6 seed × 4	11.6 Gy/ 144 hr.	Extended radical operation with glossectomy and hemimandibulectomy was made in Oct. 1978, because of tumor extension to the pharyngeal wall. Died of liver abscess in Oct. 1978.	3	3
10. B.Y.	71 M	Tongue sq. c. ca. recurrence and local skin metastasis	Recurrence and metastasis after extended operation at anterior mouth floor and the skin of the chin	Primary tumor of T_1 was treated by 360 mg of Bleomycin for 2 years. Residual tumor, irradiated by x-ray of 50 Gy and β-ray of 50 Gy, could not be controlled. Partial glossectomy was conducted in May 1978, but the tumor growth was activated with skin metastasis.	Jul. 1978	Loop method: 3 seed × 4 4 seed × 4 5 seed × 4 6 seed × 4	10.1 Gy/ 120 hr.	Tumor growth was accelerated. Died of local recurrence in Sept. 1978.	4-5	4-5
11. Y.N.	45 F	Rectum Adeno ca. residual tumor	Residual tumor at the operated site-perineum	Radical operation of a 3×4 cm, I type cancer was made in May 1975. Local recurrence of 10×4×3 cm in size with ulceration was found in Aug. 1978. External x-ray irradiation of 24 Gy combined with Ra needling of 70 Gy was given. Residual tumor of 4 cm in diameter was boosted by Cf-252 to eradiate the disease.	Nov. 1978	Volume implant (One-side method) 4 seed × 4 5 seed × 4 6 seed × 4	11.2 Gy/ 279 hr.	Residual tumor disappeared with partial necrosis but accompanied by moderate epithelitis. Salvaged by reconstructive surgery in Jul. 1979. Brain metastasis developed after 6 mos. Now under follow-up.	1	1
12. S.G.	50 F	Skin sq. c. ca. recurrence	Left lower eyelid recurrence	Tumor of T_1 developed at the left lower eyelid in 1975. Extirpation was repeated 4 times, most recently in July 1979. Recurrent tumor of T_1 size at the inner and lower eyelid was irradiated by 12 MeV β-ray of 62 Gy/20 f/43 d, with residual mass 0.5× 0.9 cm in size remaining in Aug. 1979.	Oct. 1979	Single plain 3 seed × 2 4 seed × 1 5 seed × 2	10.4 Gy/ 216 hr.	Moderate dermatitis. Tumor disappeared without recurrence for 3 mos. A new tumor developed outside of the irradiated field 5 mos. later, which was removed by operation and treated by ^{252}Cf implantation.	1	1
13. T.O.	45 M	Hypopharnx sq. c. ca. residual tumor	Left upper neck lymph node metastasis, suspected residual tumor	Hypopharyngeal tumor of $T_2N_2M_0$ (post-cricoid type) extending to the cervical esophagus (C_3-Th_1 level) was irradiated by external x-ray of 60 Gy/20 f/46 d in Oct. 1976. Left upper neck lymph node metastasis developed in Jan. 1977. Extended radical operation was attempted to remove all affected sites with Cf-252 application to suspected residual tumor in Feb. 1977.	Apr. 1977	Single plain 3 seed × 2 4 seed × 3 6 seed × 1	12.1 Gy/ 121 hr.	Died of metastasis 2 mos. later in Sept. 1977.	–	–
14. K.I.	29 F	Tongue sq. c. ca. residual tumor	Right upper neck lymph node metastasis, suspected residual tumor	Tongue cancer of T_2 at the right border was controlled by Ra needling of 55 Gy in another hospital. Right upper neck lymph node metastasis of N_3 developed in Dec. 1977. RND was performed in Jan. 1977 and Cf-252 for suspected deep residual mass.	Feb. 1978	Single plain 4 seed × 4 5 seed × 1	2.8 Gy/ 120 hr.	Died of metastasis in Oct. 1978, without local recurrence	–	–

is used. Its advantages are two-fold: one is to enable application of the source into the deep region and the other is to reduce the exposure dose to the hospital personnel during manual handling of the radioactive source.

Results

All the cases treated thus far are tabulated with individual course, previous treatment, method of application, delivered tumor dose and tumor response score. The score system used at the National Institute of Radiological Sciences was employed as shown in Table 2.

A total of 14 cases was submitted to clinical trial, consisted of 7 primary and 7 recurrent cancer cases.

(1) Primary cases (Table 3)

a) Neutron therapy only

Two cases of skin cancer (Cases 1 and 3) developing from old burn scar and one case of malignant melanoma (Case 2) of the skin of the left second and third toes were treated by Cf 252 only by surface mold, of which one skin cancer (Case 3, $T_2N_0M_0$) showed good local control of score 1.

b) Neutron boost therapy

Four cases were treated by neutron boost therapy by manual afterloading technique. One case of tongue cancer (Case 4, $T_3N_1M_0$) and one case of advanced breast cancer (Case 7, $T_3N_1M_0$) were well controlled corresponding to score 1. The overall control rate of primary cases was 3/7 (43%).

(2) Secondary cases (Table 4)

Good local control of score 1 was seen in one case of tongue cancer (Case 8), one case of rectal cancer (Case 11) and one case of skin cancer (Case 12) among 7 cases treated by interstitial implant. Two cases (Cases 10 and 11), for which Cf-252 boost therapy was applied to eradicate the remaining tumors after extended radical operation, were excluded as the evaluation of the effect was not possible. Accordingly, the overall control rate of secondary cases became 3/5 (60%).

(3) Overall results:

In 6 out of 12 cases, good local control of score 1 was achieved, that is, 2 each of tongue and skin cancers (squamous cell carcinoma), and one each of breast and rectal cancers (adenocarcinoma).

Table 5. Summary of local tumor response by early effect score 2 months after the completion of therapy

No. of cases assigned		Score 1	Score 2 or 3	Score 4 or 5	Scoring not possible	Total
Primary cancer						
Cf-252 only	Skin	1	1			2
	Malig. melanoma		1			1
Cf-252 boost	Head and neck	1	2			3
	Breast	1				1
Recurrent cancer						
Head and neck		1	1	1	2	5
Rectum		1				1
Skin		1				1
Total		6	5	1	2	14

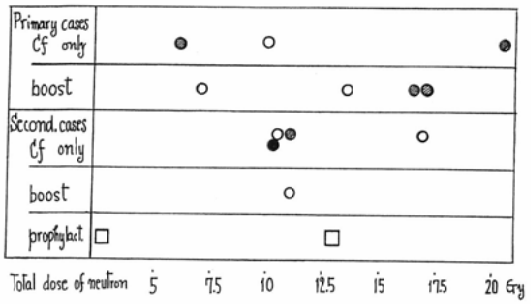

Fig. 4 Relationship between neutron dose and local tumor response by early effect score

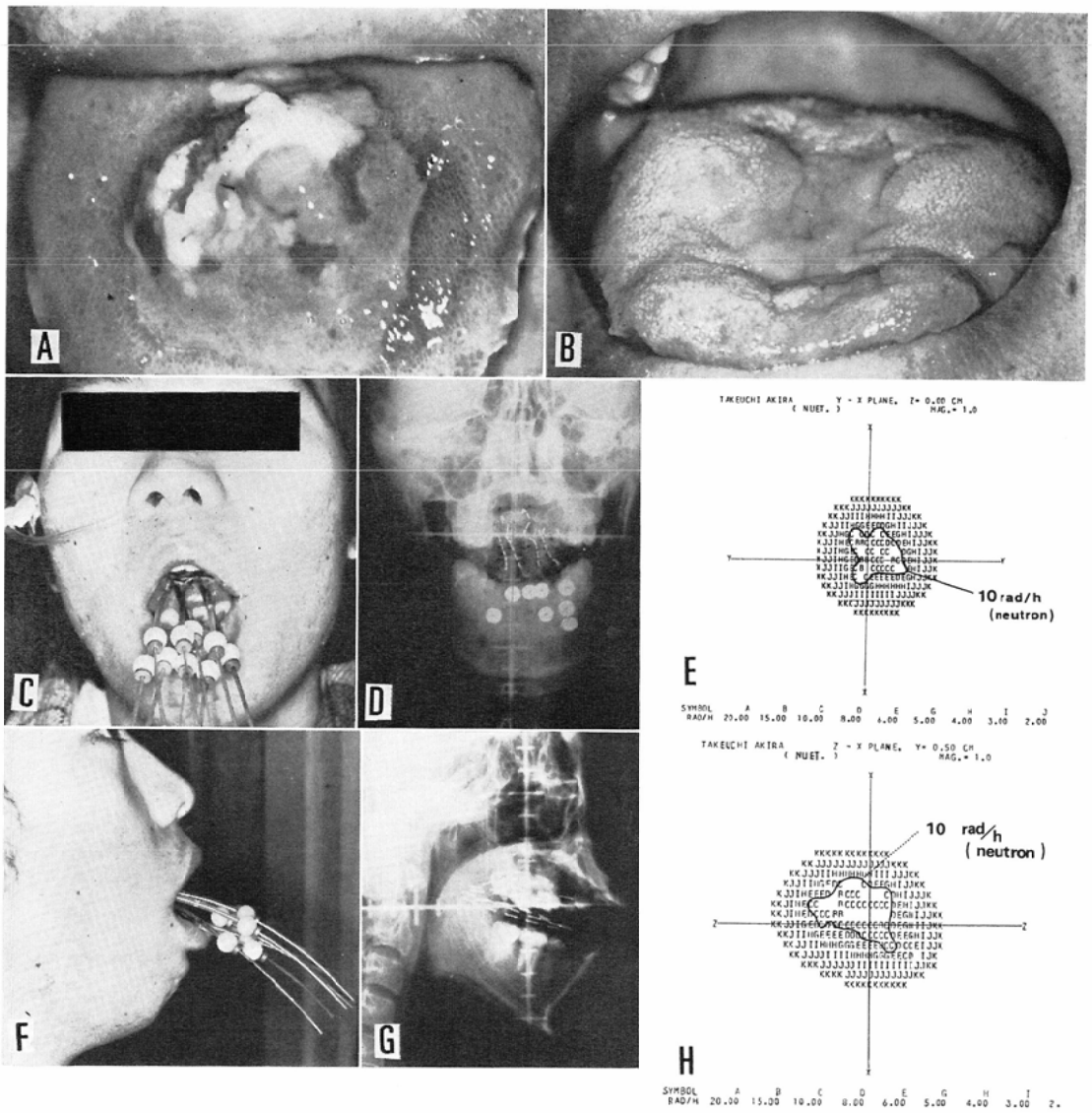

Fig. 5 Case 6

Besides, one tongue cancer (acinic cell carcinoma) with score 2 effect is now under follow-up for more than 1 year. Regarding the complications of the adjacent normal tissues, moderate or severe mucositis or dermatitis were seen in some cases, when this source had been applied as boost therapy. The overall rate of complication is less than 50%, which might be justified considering the advanced stage of the local disease. Neutron dose of above 10 Gy was necessary to control the disease (Table 5 and Fig. 4).

Case Reports

Case 6. A.T. 26 year old male, carcinoma of the tongue, primary case, acinic cell carcinoma (Fig 5).

He was seen with an oval tumor in the middle dorsal part of the tongue, measuring 3.0×3.5×1.5 cm in size, at another hospital in December 1978. External Co-60 γ-ray irradiation of 26 Gy with additional electrons of 30 Gy proved ineffective and therefore boost therapy of Cf-252 was given (A). Cf-252

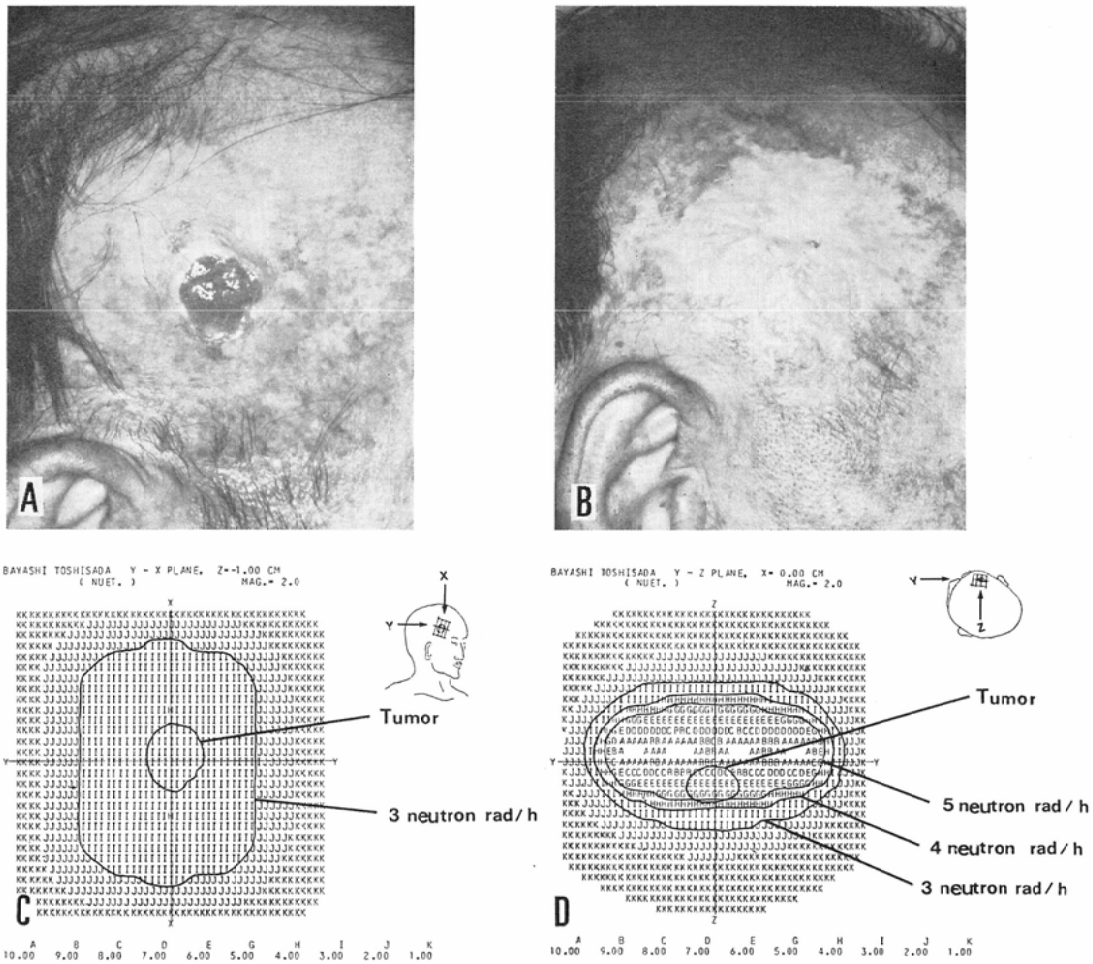

Fig. 6　Case 3

irradiation was applied in May 1979 by arranging the source in 5 loops. Five loops were applied intraorally (C,D,F,G). The total neutron dose of 16.5 Gy was delivered in 168 hours (E,H). The tumor decreased in size to 1.6×1.2 cm after 2 months, while severe mucositis developed, but subsided within 2 months. He is under observation for more than 1 year. The remaining tumor is 1.2×0.6 cm in size for 6 months with no evidence of recurrent growth (B).

Case 3. T.K. 73 year old male, carcinoma of the skin. primary case, sqamous cell carcinoma (Fig. 6)

He sustained a burn at the age of 3 to his right temporal region, which healed with a scar of 4×8 cm. Since a year ago, a tumor of 3×4 cm in size has developed in the center of the scar which was accompanied by a shallow ulcer of 1.0×0.9×0.2 cm in size covered with a necrotic membrane.

This cancer was considered to be a burn scar cancer, having an interval of 69 years, and to be radioresistant (A). This case was rather radiosensitive (B), and was cured by neutron dose of 10 Gy/264 hr(C,D) at a distance of 0.5 cm.

Dose Equivalent to Hospital Personnel

Fig. 7 shows the dose equivalent received by the therapist while loading and unloading ^{252}Cf seed

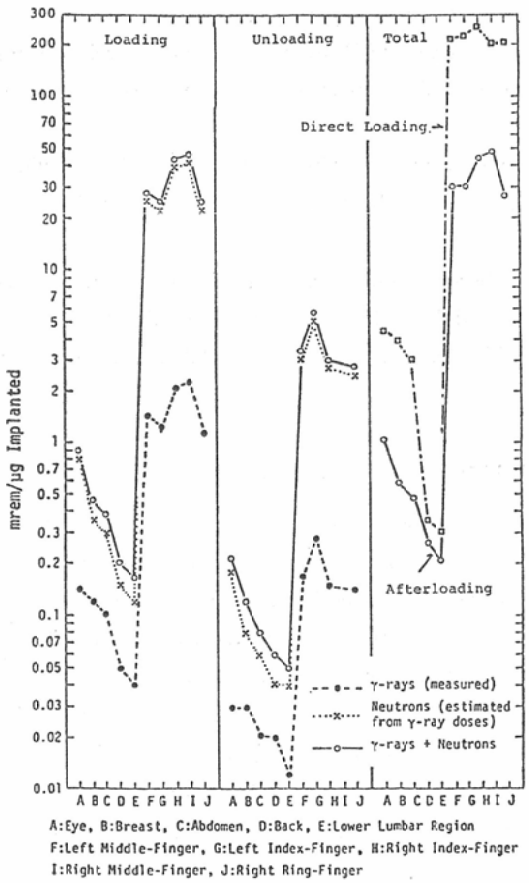

Fig. 7 Dose equivalent received by therapist while loading and unloading Cf-252 seed assemblies

assemblies for patients with tongue, hypopharynx, and lymph node metastatic cancers. Gamma-ray doses to the head (eye), breast, abdomen, back, and lower lumbar region of the therapist were measured with $CaSO_4$: Tm TLDs with compensation filter for photon energy[19] and doses to the fingers with BeO: Na TLDs. These TLDs were insensitive to neutrons[11]. The neutron dose equivalent was calculated by the product of the measured γ-ray dose and the ratio of neutron dose equivalent to γ-ray dose at each position. The ratios used[2][12] for fingers (in air), eye (behind the 10 cm-thick lucite), trunk of the body (behind the bedside shield of 17 cm-thick water tank) were 19, 7.3, and 3, respectively. The dose equivalent received by the eye (behind the eye shield) was 1.15 mrem/μg, while those of the trunk of the body (behind the bedside shield) and the finger were about 0.5 mrem/μg and 30–40 mrem/μg, respectively. The average dose received by the eye or the finger while loading radioactive sources was 5–10 times larger than that received while unloading. By the use of afterloading techniques, the dose equivalents to the eye, breast, abdomen, and fingers of the therapist could been reduced by about a factor of 5 of direct implant technique[2].

Discussion

It is noteworthy that good local control of score 1 was obtained in 6 out of 12 radioresistant cancers, which were considered to be non-curative from our past experience.

In comparison of the results reported in our previous papers[2][3], overall primary control rates were about 50% and to be very similar, although we have applied this source to some cases of larger and deep-seated tumors.

As seed assemblies consist of varying numbers and varying lengths of sources, a wider selection of sources is possible according to varying size and location of the tumor. Various accessories greatly facilitated the use of this source.

The interstitial afterloading device has recently become commercially available to assure the safe use of radioactive sources. The development of interstitial afterloading device adaptable to this source is urgently needed, before verifying the applicability of this treatment modality for randamized clinical trial.

Summary

^{252}Cf seed assemblies were applied to 14 cases of radioresistant cancers by manual afterloading technique. In 6 out of 12 cases (2 cases were excluded as the evaluation of the effect was not possible), good local control of score 1 was obtained regardless whether they were primary or secondary cases. They consisted of 2 primary skin cancers, 2 recurrent tongue cancers, 1 advanced breast cancer and 1 recurrent rectal cancer. The overall results are very similar to those obtained previously by other kinds of Cf-252 small sources. Neutron dose of above 10 Gy was necessary to control the disease. Side effects were tolerable, considering the advanced and radioresistant nature of the disease.

The dose equivalent received by the therapist while loading and unloading Cf-252 seed assemblies was determined to be less the 1/5 of that of direct implant method. They were 1.15 mrem/μg to the eye and 30–40 mrem/μg to the trunk of the body.

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