APPARATUS FOR COOLING IRRADIATED SKIN AREAS

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Fig. 1

Fig. 2

Fig. 3

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This invention relates to reducing the harmful effects of irradiation on externally irradiated skin areas of human patients and is more particularly directed to new and improved apparatus for reducing such harmful effects on skin areas of irregular contour, such as the head and neck, by regional cooling of the skin area during irradiation thereof.

Heretofore, difficulty has been encountered in the use of roentgen irradiation in radiotherapy treatment of humans with conventional 200–400 kv. voltage roentgen and electron beam irradiation machines, because of the harmful side effects caused by irradiation to the irradiated skin area of the patient. For example, the irradiation dosages now generally employed in irradiation therapy for cancer usually result in severe erythema, desquamation, atrophy or necrosis of the irradiated skin area. It is also known that certain drugs, for example, Actinomycin D, may enhance the skin reaction of patients undergoing irradiation treatment. These harmful effects to the skin caused by irradiation present in particularly severe problem in irradiation treatment of patients where the irradiated skin overlies soft tissue tumors undergoing the irradiation treatment, and, as is well known, young patients having undergone adequate irradiation treatment are more likely to develop pronounced skin changes during the long follow-up period of such therapy.

Because of such side effects to the irradiated skin area, radiology departments in hospitals, clinics and the like have preferred to employ conventional super-voltage machines for irradiation treatment, as these machines do not produce such side effects to the irradiated skin areas. Consequently, in such radiology departments having both 200–400 kv. voltage and super-voltage irradiation machines, the super-voltage machine is used in the treatment of patients in preference to the conventional 200–400 kv. X-ray or electron beam machines, with the result that the super-voltage machine has excessive use, while the conventional 200–400 kv. X-ray or electron beam machines stand idle. In less adequately equipped radiology departments, a super-voltage machine may not be available, and, consequently, the patient is required to either submit to treatment with a conventional 200–400 kv. voltage machine with the attendant harmful side effects to the skin or seek treatment elsewhere.

The aforementioned problems and difficulties of the prior art are substantially overcome with the present invention by the provision of apparatus for controlled cooling of the irradiated skin area of human patients during external irradiation treatment thereof with 200–400 kv. X-ray or electron beam machines. Such apparatus is capable of cooling irradiated skin areas of irregular contour to thereby minimize the harmful side effects to such irradiated skin areas attendant irradiation treatment with 200–400 kv. X-ray or electron beam roentgen irradiation machines, without causing additional discomfort to the patient other than the discomfort of the sensation of cooling.

It is, therefore, an object of the present invention to provide new and improved apparatus for cooling the skin area of a human patient undergoing roentgen irradiation with 200–400 kv. X-ray or electron beam irradiation machines.

Another object of the present invention is to provide adjustable apparatus for cooling irradiated skin areas of a human patient undergoing irradiation treatment with 200–400 kv. X-ray or electron beam irradiation machines.

Still another object of the present invention is to provide adjustable apparatus for cooling irregularly contoured irradiated skin areas of human patients undergoing irradiation treatment with 200–400 kv. X-ray or electron beam irradiation machines.

A further object of the present invention is to provide new and improved apparatus for cooling irregularly contoured irradiated skin areas of human patients undergoing irradiation treatment with conventional 200–400 kv. X-ray or electron beam irradiation machines.

A still further object of the present invention is to provide apparatus for directly cooling the irradiated skin area of a human patient undergoing irradiation treatment for cancer with conventional 200–400 kv. X-ray or electron beam irradiation machines.

Another object of the present invention is to provide new and improved apparatus for cooling the irradiated skin area of a human patient undergoing irradiation.
treatment for cancer with conventional 200-400 kV.
X-ray or electron beam irradiation machines, which is simple and compact in construction and efficient in operation.

These and other objects, features and advantages of the present invention will become readily apparent from a careful consideration of the following detailed description, when considered in conjunction with the accompanying drawing, illustrating preferred embodiments of the present invention, wherein like reference numerals and characters refer to like and corresponding parts through the several views, and wherein:

FIG. 1 is a schematic view of a skin cooling assembly constructed in accordance with the principles of the present invention;

FIG. 2 is a front view in elevational view in partial section of the cooling assembly of FIG. 1;

FIG. 3 is a view in partial section taken along line 3—3 of FIG. 2;

FIG. 4 is a schematic view of another embodiment of a cooling assembly incorporating the principles of the present invention;

FIG. 5 is a view in partial section illustrating the details of the cooling assembly of FIG. 4;

FIG. 6 is a view taken along line 6—6 of FIG. 5;

FIG. 7 is a view of the assembly of FIG. 5 taken along line 7—7 of FIG. 4, and

FIG. 8 is a view in partial section of another embodiment of a cooling assembly.

Although the present invention has a variety of applications, one embodiment thereof is illustrated in FIG. 1 and comprises a skin cooling assembly, generally indicated by the numeral 11, which is mounted, as by a support bracket 12, to a conventional 200-400 kV. X-ray or electron beam irradiation machine, generally indicated schematically in FIG. 1 and by the numeral 14.

The direct cooling assembly 11 comprises, as appears in FIGS. 2 and 3, four right-angled sections 17, 18, 19, and 20 defining therebetween a rectangular opening 15.

The sections 17 and 19, which are diagonally opposite to each other, have their ends telescopically disposed in the diagonally opposite sections 18 and 20, as appears in FIG. 2. The section 17 has one leg 22, as indicated by the dotted lines in FIG. 2. disposed in the corresponding leg 23 of the section 18, and the section 17 has its other leg 24, as indicated by the dotted lines in FIG. 2, disposed in the corresponding leg 26 of the section 20. Similarly, the section 19 has one leg 28, as indicated by the dotted lines in FIG. 2, disposed in the corresponding leg 29 of the section 18 and its opposite leg 30 disposed in the corresponding leg 31 of the section 20. The legs of the sections 17 and 19 are slidably disposed in the corresponding legs of the sections 18 and 20 for separately varying the area dimensions of the opening 15. Set screws 32, 34, 36 and 38 are provided to permit adjustment of the sections relative to one another and holding of the sections 17-20 of the assembly 11 in predetermined positions.

The mounting bracket 12 is secured to the section 20, as by screws 39, and the bracket 12 is preferably provided with slots for the screws to permit lateral adjustment of the assembly 11 away from or towards the machine 14.

Each of the sections 17, 18, 19 and 20 is rectangular in cross section and each section defines a rectangular coolant fluid flow chamber. In FIG. 2, the rectangular flow chamber of section 17, the rectangular flow channel 42 of section 18 and the rectangular flow channel 46 of section 20 are shown. FIG. 3 illustrates the rectangular flow channel 44 of section 19 and channel 46 of section 20. These channels 40-46 are in communication with each other, and, as appears in FIG. 2, the channel 42 is in communication with an inlet conduit 48 and the channel 46 is in communication with an inlet conduit 50. The conduits 48 and 50 are connected by means (not shown) to a source of refrigerant liquid, which in this modification uses gases or known gas-phase refrigerants, preferably air or Freon, rather than liquids as used in a modification discussed below, for the supply of the coolant fluid to the channels 40-46.

Each of the channels 40-46 is provided with an outlet slot formed in the inner surface of each leg thereof for supplying the fluid coolant at an angle, as indicated by the arrows in FIG. 1, onto the pre-selected irradiated skin area of a patient, indicated by the numeral 54 in FIG. 1.

In FIG. 3, the outlet slot 56 of the assembly section 17 is shown as defined by inwardly directed and spaced angle flanges 58 and 60 and the corresponding slot 62 of the assembly section 18 is shown as defined by a pair of inwardly directed and spaced angle flanges 64 and 66. It will be observed that the flanges 61 and 66 are disposed in the slot 56 and are preferably in engagement with the flanges 58 and 60 to facilitate adjustment of the sections relative to each other to vary the width of the opening 15.

The slots 56 and 62 extend along each leg of each of the sections 17 and 18. Similarly, each of the sections 19 and 20, as appears in FIG. 3, is provided with a slot communicating with the corresponding channel. Section 19 is provided with a slot 68 defined by inwardly directed and spaced angle flanges 70 and 71, and the section 20 is provided with a slot 72 defined by flanges 74 and 76. The flanges 74 and 76 are disposed in the slot 68 and are in engagement with the flanges 70 and 71 to guide the legs of the sections 19 and 20 during adjustment of the width of the opening 15. The slotted telescoping ends of the legs 24 and 25 of the sections 17 and 19 permit adjustment of and variation in the height of the opening 15 (FIG. 2). It will also be appreciated that engagement of the angle flanges of the sections 17-20 tends to rigidize the cooling assembly 11 in addition to providing guide means as the area of the opening 15 is varied.

The slots 56, 62, 68 and 72 direct the flow of the coolant fluid, such as cool air, in a predetermined converging flow pattern irrespective of the area dimensions of the opening 15 and at an angle to and against the skin area of the human patient undergoing irradiation treatment to cool the irradiated skin area to a predetermined temperature. It will be observed that the cooling assembly 11 is preferably maintained in spaced relation to the skin area of the patient in order to prevent the pre-selected skin area without causing the discomfort to the patient which might otherwise be caused by contact of the assembly 11 with the skin. It will also be observed that in FIG. 1 the head area of the patient, which is, of course, of the opposite contour, is being directly cooled with the assembly 11. The direction of flow and flow of the coolant air from the slots 56, 62, 68 and 72 and area of the opening 15 will depend upon such factors as the skin area to undergo irradiation and are critical only to the extent that the skin area undergoing irradiation and the surrounding area of the skin is cooled.

With the assembly 11, the harmful side effects of irradiation, such as erythema and desquamation, normally resulting from use of 200-400 kV. X-ray and electron beam irradiation machines, have been substantially minimized, and particularly such side effects to irregularly contoured areas of the patient undergoing irradiation treatment. In addition, there is not interposed between the irradiation machine and the skin of the patient a material which would cause large scattering or absorption of the electrons or X-rays. Moreover, cooling may be controlled during irradiation treatment. The result is that patients who have been treated experienced no discomfort during treatment and irradiation side effects have not been encountered.

The following examples are given as Table I by way of illustration, and not by way of limitation, to illustrate the reduction in side effects to the irradiated skin area by the use of the present invention in conventional X-ray irradiation or electron beam therapy.
The "Remarks" section of Table I indicates the total roentgen dosage (r) given the patient, the period of time over which the treatments were given, the number of times the treatment was given (Rx's), the average roentgen dosage given the patient per day of treatment, and the skin effects observed during treatment.

The following procedures were employed in the tests of Table I.

The conduits 48 and 50 of the assembly 11 were connected to the outlet lines of a conventional refrigeration machine (not shown) of cooling apparatus consisting of a three-fourths ton compressor (Frigidaire) which circulated a compressed gas, Freon 12. This compressor was connected to a three-pass chilling coil system connected to conduits 48 and 50. Compressed air flowing through the conduits 48 and 50 was measured with a Fischer-Porter Flow Meter. The cooled air from the refrigeration device flowed through the slots 56-72 at an angle to the vertical axis of the assembly 11 (FIG. 1) and impinged directly on the skin area of the patient 54 undergoing irradiation, the electron beam of the irradiation field being indicated by the numeral 70 in FIG. 1.

In order to obtain multiple temperature readings, five thermocouples (not shown) were attached to the skin area to be irradiated. The thermocouples employed were copper, constantan elements and an additional reference thermocouple was placed in a Dewar flask (thermos) containing ice chips and water. The thermocouples were attached to an electronic potentiometer (Minneapolis-Honeywell-Brown Instrument) (not shown) which had a range of voltage up to 70 millivolts. Temperature readings were made at 1, 3, 5, 7 and 10 minutes, as indicated in Table I, after the cooled air stream was applied to the skin area.

The electron beam of a 23 m.e.v. betatron (Allis Chalmers) was used for irradiation. The electrons were extracted at 10 m.e.v.'s, 15 m.e.v.'s and 21 m.e.v.'s, depending on the nature and the depth of the lesion to be treated, e.g., cervical metastatic lymph nodes, carcinoma of the larynx, or carcinoma of the tonsil. In this connection, perhaps I should state that although the units "r" or "roentgens" are more correctly applied to X-ray radiation than to electron beam radiation, these units are also used in clinical work with the electron beam machines. Thus, an electron beam clinically comparable to an X-ray beam of a certain intensity is described by the same roentgen number.

Approximately three minutes of air cooling of the skin area prior to irradiation treatment was necessary to achieve a uniform temperature at all points where the thermocouples were attached.

It was found that, to minimize the harmful side effects to the skin area undergoing irradiation, the temperature of the skin area undergoing irradiation and adjacent thereto should be reduced to a temperature falling within the range of from about 25° F. to about 60° F., preferably within the range of from about 38° F. to about 44° F. and that, in most cases, a mean temperature of 50° F. produces good results in reducing the harmful side effects to the irradiated skin area.

The assembly 11 of FIG. 1 gives a substantially uniform reading of the five thermocouples distributed over the skin area being irradiated, and Table I, column 6, presents some of the readings obtained in 16 cases of human patients in which the skin area was cooled by means of the assembly of FIG. 1. The cooling air stream was continuously in operation to cool the skin area during irradiation treatment of the patient. As indicated in Table I, thermocouple readings were made of five patients in the inner buccal mucosa, the outer skin of which was air cooled with the assembly 11. While the skin mean temperature readings of the thermocouples was 94° F., the buccal mean temperature was 94° F. Thus, it would appear that the effective cooling of the air stream emitted from the assembly 11 of FIG. 1 is superficially confined to the dermis.

The temperature of the air issuing from the slots 56, 62, 68 and 72 for distribution over the skin area was recorded to a mean of minus (—) 50° C. or —22° F. The skin temperature readings of the patients obtained prior to cooling of the skin area ranged from 86 to 90° F. (mean 88° F.). Thus, the effective lowering of the skin temperature accomplished with the assembly 11 was a mean 38° F. The area of the space 15 in each of these cases is indicated in Table I, column 5. The patients indicated no discomfort at the cooling temperatures set forth in the table. Moreover, lowering of the skin temperature of a small area of the patient undergoing irradiation treatment was tolerated with no attendant harmful side effects.
With employment of the assembly 11, the irradiated skin area evidenced lessening of the marked skin changes normally shown with normal irradiation dosage treatment. For example, the moist desquamation normally seen with irradiation is less commonly seen with irradiation treatment employing the assembly 11 of FIG. 1. It will be appreciated, therefore, that the harmful side effects of irradiation on skin area of burn 13 patients may be substantially minimized with employment of the present invention with low voltage or electron beam irradiation machines, that skin areas of irregular contour may be easily and uniformly cooled during irradiation, and that apparatus for directly cooling the irradiated skin area may be simply and economically manufactured.

The assembly 11 of FIG. 1 may be readily employed with electron beam therapy, since no material other than a cool gaseous fluid is interposed between the beam and the skin area, and, thus, there is eliminated the problem associated with employment of such interposed material which would cause electron scatter or absorption. Thus, the assembly 11 may be employed especially in electron beam therapy, since cooling of the skin areas may be maintained throughout the irradiation treatment, irregular contours may be readily cooled, and electron scatter is minimized as a problem.

Referring to FIGS. 4–7, there is disclosed another embodiment of a cooling assembly 90 constructed in accordance with the present invention. This embodiment has particular application to relatively large skin surface areas of gradually curved contour, such as the lower abdomen and buttocks, and is eminently suitable for reducing the skin temperature of large curved skin areas undergoing irradiation with conventional 200–400 kv. X-ray or electron beam machines.

As appears in FIG. 4, the conventional 200–400 kv. X-ray irradiation machine 92 has mounted thereon the assembly 90 which includes a hollow cone 94 constructed of "Lucite" or other plastic material. The cone 94 carries at its larger end adjacent the lower abdomen of a patient 96 outlined in FIG. 4 a cooling fluid chamber 98 (FIG. 5) which closes the end of the cone 94 and which closes the end of the cone 94 and which is defined by an inverted channel shaped member 102 closed at the bottom thereof by a flexible gasket member 104. The member 102 has a body portion 106 and a rectangular flange 108. The cone 94, as appears in FIG. 5, terminates in a rectangular flange 110. The flexible member 104 may be constructed of material, such as rubber, which has an end 112 thereof trapped between the flange 108 of the member 102 and flange 110 of the cone 94. The body portion 114 of the flexible member 104 spans the open side of the channel member 102 to define the bottom of the flow chamber 98. Means, such as screws 116, may be employed to hold the flexible member 104 and channel member 102 secure to the cone. The chamber 98 is provided for a circulating coolant fluid, which in this embodiment can include liquids, as well as gases, such as water, a water-alcohol mixture, or cooled air, which is circulated from a source (not shown) through a conduit 120 and through a coupling 122 to the chamber 98 and from the chamber 98, as indicated by the arrow in FIG. 5, through a coupling 124 connected to a conduit 126 for return to the source. The cone 94 is mounted by means (not shown) to the machine 92, so that the electron beam 128, indicated by the dotted lines in FIGS. 4, 5 and 7, emitted from the machine 92, flows substantially through the cone 94.

In FIG. 7, it will be observed that the body portion 114 of the flexible member 104 engages the body of the patient 96 and conforms to the general contour of the body area so engaged. In this manner the skin area to be irradiated and cooled is effectively cooled by the coolant fluid circulating through the chamber 98.

FIG. 8 illustrates another form of a cooling assembly found useful in the practice of the present invention. The cooling assembly 130 of FIG. 8 comprises a rectangular chamber having a first flexible member 132 and a second flexible member 133. Each of the members 132 and 133 has a flexible annular flange, flanges 134 and 135, respectively, secured to the inner wall of the end flange 110 of the cone 94 as by bolts 116. The inlet conduit 120 (not shown) communicates with the chamber 98 defined by the members 132 and 133. A flexible tube is inserted into the conduit 126 for return and re-circulation through the source (not shown) of the coolant fluid.

The patient contact end of one cone 94 had an area of 8 x 5 cm. A cooling unit consisting of a refrigeration unit (not shown), was employed to cool the water circulated through the chamber 98 and to maintain the skin temperature of the patient within predetermined limits. Preliminary temperature readings of the skin of the patients tested, and of the cone before, during and after irradiation treatment, were made with a thermistor device sold by Tele-Thermometer Yellow Springs Instrument Company. In order to obtain multiple readings almost simultaneously of the outer surface 140 (FIGS. 5 and 8) of the chamber 98 in contact with the skin of the patient, thermocouples which were copper, constantan elements were employed. Five thermocouples were then attached to the surface 140 of the members 104 and 133 in such a manner that the thermocouples were interposed between the surface 140 and the skin of the patient. One thermocouple, as a reference thermocouple, was placed in a Dewar flask (Thermos) containing ice chips and water. The thermocouples were then attached to an electronic potentiometer sold by Minneapolis-Honeywell-Brown Instrument which had a range of up to 70 millivolts.

Of eight patients treated with cooling apparatus corresponding to the apparatus of FIG. 4, the skin area undergoing irradiation showed less harmful side effects than patients undergoing irradiation without the cooling apparatus. The skin temperatures of the patients were reduced to between 50 and 55°F. before irradiation treatment was begun. Preferably, the temperature of the skin area to be irradiated is reduced to between 40°F. and 44°F.

To adequately reduce the effects of irradiation on the skin, it is preferable to cool an area at least about one and a half to two times the size of the actual radiation field. It was observed that the normally encountered increased skin changes resulting from combining Actinomyein C and radiation therapy is lessened by cooling. It was also observed that additional irradiation dosage could be given to the skin areas which showed good skin sparing effects. The dosage that can be given, it will be noted, will vary from patient to patient, depending on the effectiveness of cooling and the irradiation tolerance of the patient. It was observed that 1,200 r. can be given to a routine patient and that about 2,000 r. can be given occasionally with some evidence of reduced skin changes being observed. It will be appreciated that with the use of large irradiation fields, e.g., in the region of the pelvis, the conventional depth dosage value at 10 cm. is 3%. In other words, because of absorption and scattering of the applied rays, only 38% of the applied dosage reaches the restricted 10 cm. below the skin surface. Thus, if the applied dosage can be increased from 1,200 to 2,000 r., because the skin area has been cooled in accordance with the present invention, the depth dose is increased from 456 to 760 r. This increased value could be obtained by reducing the depth dose at 10 cm. obtainable from cobalt irradiation.

The average external irradiation treatment time is between 5 to 6 minutes after the skin area has been cooled to a temperature within the ranges above set forth.

Thus, it will be appreciated that with the present invention, there is provided simple and effective means for reducing the harmful skin changes which normally occur as a result of treatment with irradiation.

Although various minor modifications and alterations of the present invention will be readily apparent to those
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versed in the art, it should be understood that what is desired to be embodied within the scope of the patent grant sought, are all such embodiments as reasonably and properly fall within the scope of the contribution to the are hereby made.

1. In apparatus for treatment of a human patient with a source irradiation machine located externally of the patient, the improvement comprising: a cooling assembly for cooling the skin area undergoing irradiation, said assembly including a rectangular frame of channel members having a pair of opposed side members joined to a top member and to a bottom member, said frame defining and surrounding an opening, each of said frame members being formed with an internal fluid flow channel in communication with the fluid flow channels of the adjacent members, a longitudinal slot formed in each of the facing inner surfaces of the side members and in each of the facing inner surfaces of the top and bottom members, each of said slots communicating the corresponding fluid flow channel with said opening, at least one inlet communicating said channels with a source of coolant fluid, means for directing flow of fluid means for supplying a coolant fluid to said inlet, and from said slots through said opening and for distributing said fluid directly against said skin area of the patient.

2. The improvement of claim 1 wherein said means for directing the fluid flow includes flange members disposed at an angle to the vertical axis of the frame.

3. The improvement of claim 1 wherein said means for directing flow comprises a plurality of inwardly directed and angled flanges for directing the flow therefrom in a converging flow pattern.

4. The improvement of claim 1 including means for adjusting the size of said opening.

5. The improvement of claim 1 wherein each of said frame members has two right-angled legs, each of two of said members having its end portions slideably disposed in the channels of the remaining two members, said members being slideably adjustable relative to each other for varying the size of the opening, and including means for releasably securing the members in a plurality of relative positions.

6. An assembly for cooling the skin area of a patient undergoing irradiation treatment from a source irradiation machine located externally of the patient comprising: a rectangular frame having a pair of opposed side members joined to a top member and to a bottom member, said frame defining an opening, each of said frame members being formed with an internal fluid flow channel in communication with the fluid flow channels of the adjacent members, a longitudinal slot formed in each of the facing inner surfaces of the side members and in each of the facing inner surfaces of the top and bottom members, each of said slots communicating the corresponding fluid flow channel with said opening, at least one inlet communicating said channels with a source of coolant fluid, means for directing flow of fluid means for supplying a coolant fluid to said inlet, and from said slots through said opening and for distributing said fluid directly against said skin area of the patient.

7. In apparatus for treatment of a human patient with a source irradiation machine located externally of the patient, the improvement comprising: a cooling assembly for cooling the skin area undergoing irradiation, said assembly including a fluid flow channel which is rectangular in shape and comprises four right-angle channeled sections two of which have their end portions slideably disposed within the end portions of the remaining two sections, means for releasably securing the sections in a plurality of positions relative to each other for varying the size of the opening, means for supporting said channel in spaced cooling relation to said skin area, means for supplying a coolant fluid to said channel member, and an outlet in each of said sections for delivering the coolant fluid onto said skin area of the patient.

8. A cooling assembly for cooling the irradiated skin area of a patient undergoing irradiation treatment from a source irradiation machine located externally of the patient, said assembly including a frame member for supplying a coolant fluid against the skin area of the patient undergoing irradiation, said frame member having an aperture passing through it for the passage of the irradiation emitted from said machine, means for connecting said frame member to a source of coolant fluid, a plurality of outlets in said frame member for discharging said fluid through said opening and against said skin area, means for supporting said frame member between the patient and the irradiation machine, and means for adjusting the size of said frame member and the size of said aperture to vary the size of the skin area being cooled by the coolant fluid supplied therefrom.

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