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THE FERMILAB CANCER THERAPY FACILITY: STATUS REPORT AFTER 2.5 YEARS OF OPERATION*

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Summary

This research facility has been treating cancer patients for 2.5 years. The original physical plant, controls and treatment room planning were adequate. Improvements have been natural system evolutions to simplify operations and reduce the time to set-up patients, thus increasing patient throughput. Linac changeover from p's to H^-'s nearly trebled the dose rate. During the first half of this period most patients were pilot study cases while in the second half, they were mostly protocol cases. Major problems remaining are: 1. patient accession, and 2. lack of ancillary resources normally found in hospitals. One hundred and thirty patients have been entered into a randomized clinical trial from a group of four hundred and forty entered in the study. Descriptions of system improvements and medical research activities are given.

Introduction

The Fermilab Cancer Therapy Facility, (CTF), is located in the gallery of the 200 MeV linac. It has been operating compatibly and harmoniously with the requirements of the high energy physics research program since September 7, 1976. Four hundred and forty patients have been referred to it as of the end of February, 1979. The facility, target optimization studies, and other technical data have been published elsewhere.[1-7] This facility was built with private funds.

Technical Improvements

The average beam current in the Linac for the CTF was increased when the new ion source for H^- operation was installed. The average dose rate was increased from 10 to 30 rads/min. This larger average dose rate has made it practical to increase the source axis distance (SAD) without drastically increasing the patient irradiation times. The increased SAD will allow us to position the patient farther from the end of the collimator. The patient's anatomy, the collimator, beam modifiers and our immobilization fixtures should no longer interfere with each other during rotation from one treatment position to the next. The new isocenters for set-up at the x-ray level and for treatment at the neutron level will be on the same vertical line. This will allow us to leave the chair and patient at one position on the chair rails, see figure 1, requiring only a 180° rotation from the verification to the treatment positions and the lowering of the floor.

A new collimator system has been developed to reduce the weight of the individual collimators and to increase the speed with which they can be handled. The new system has three sets of collimators and two inserts versus two and one respectively of the original system. The heaviest of the old small collimators weighed 60 lbs. (27 kg.) while the new design brings the heaviest medium size collimator weight down to less than 30 lbs. (13 kg.) which is much more manageable by radiotherapy technologists. In addition, the new collimator system will allow remote motor driven angulation of the collimator and the easy placement of tungsten blocks and the other beam modifiers such as wedges in the beam.

A new and improved chair base has been put into operation. The base slides toward and away from the target on ball bushings and cylindrical rails aligned parallel to the beam central axis, and locks so that the vertical axis of rotation of the base is at a fixed distance from the target. On the base, two plates can translate the chair in orthogonal directions, bringing the axis of rotation through elective points in the patient. The chair base has an encoder coupled to its shaft to allow remote read out of the chair position. This will allow the microcomputer to check the chair position. In the future the microcomputer will set the chair angle. Eventually, this will also allow continuous rotation therapy. A false floor has been installed for technologists safety to avoid their tripping on the rails. The displacement of the chair with respect to the axis of rotation is made with battery powered motors. These motions will soon be under digital control.

The "chair" has been designed in such a way that a patient may be immobilized in several different positions and such that the chair fixtures do not intercept the neutron beam during treatment. Patients either sit or stand and the fixtures support and immobilize the patient during treatment. The chair frame has a removable seat and presently three types of supports attach to the back of the frame. First, two posts which are used to support standing patients or where large posterior fields are needed. A rectangular "tennis racket" can be slid over the two posts as well as arm rests. The other two supports are used to immobilize head and neck cancer patients. The "dipole" has two posts about 20 cm. apart to which a sliding plate is attached. A mask molded out of "Litecast"^{R}, a UV setting plastic impregnated fiberglass material, is attached to the sliding plate to immobilize the patient's head. If the "dipole" will interfere with one of the treatment portals, then a "monopole" fixture can be used which obscures less space behind the patient than the dipole.

Software has been developed for the microprocessor which controls the beam on and off sequence for each patient. The "patient treatment" display contains information about the patient and his individual treatment for each portal. Information such as name, name of portal, size and description of portal, chair angle, collimator angle, blocks, wedges

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and number of monitor units required are entered by the technologists. At the completion of a treatment portal the display is printed out on a hard copy unit for permanent record. In addition to a patient treatment program, others have been developed for the daily calibration procedure which record all of the necessary parameters such as ion chamber correction factor, temperature and pressure correction, number of rads per monitor unit, and various beam line parameters.

To minimize the probability of human errors, software has been written that will allow the microcomputer, using a light pen and coded labels, to check the identity of the collimators, wedges, patients' identification number and, using shaft encoders, angulations of the collimators, chair and wedges. The check will be made against the nominal values entered into the microcomputer manually by the technologists and later via a floppy disk.

A computerized patient data base has been developed so that retrieval of all necessary information can be simplified. The data base contains information about the patient's disease before treatment, during treatment, and after completion of treatment, as well as information about the treatment parameters.

In order to ease the patient's anxiety on entering and remaining alone in the treatment room an intercom system, closed circuit T.V. system and taped background music have been installed.

Support Activities for Medical Research

In any research involving human subjects it is necessary to obtain an informed consent from the patient. As simple as this sounds it is not always easy to get. First, the informed consent procedures and documents had to be approved by the institutional review board (IRB) at Fermilab and each referring institution. The procedures cover explanations about the medical research program when the patient is invited to participate in it, brochures about radiation therapy, potential side effects and complications, as well as the actual informed consent form. These procedures allow the patient at least 24 hours to review the written information and to consider the alternatives presented him by the physician on his first visit to Fermilab.

Since Fermilab is not a hospital based facility it was necessary to develop a referral network for patient accession. This was done by lectures to radiotherapists and surgeons at users' meetings and local medical society gatherings, by developing and sending out a newsletter, and by site visits by a Fermilab team of physicians, physicists and nurses to the referring hospitals' tumor board meetings and radiotherapy departments. Local radiotherapists are encouraged to actively participate in the treatment of patients at Fermilab. In this way a network of referring institutions and radiotherapists has been slowly developed.

During the early days of neutron treatment at Fermilab a large variety of patients with advanced disease were accepted to evaluate the effect of neutrons versus photon treatment. Particularly, the acute response of tissues and organs was studied. As time progressed protocols including photon plus neutron treatment versus photon were developed and implemented.

The photon treatments are delivered at a number of referring institutions. This requires institution of quality control of the delivery of the photon treatments as well as the very careful definition and agreement on treatment practices. It must be recalled that the results of the Hammersmith neutron trials in England have not been duplicated in the United States and that one criticism of those studies has been that there was no quality control of the photon arm by the Hammersmith team.[8] A quality control program has been instituted here which will check the basic physical dose parameters of the photon machines, that the prescribed dose meets the protocol requirements, and that it is delivered to the same target volume. It is absolutely necessary when reviewing the final data to be sure that all the patients in approved protocols be treated in the manner specified in them, otherwise meaningful comparisons will not be possible between neutron, photon and mixed beam (photon and neutron) therapies.

It was also found that a certain amount of financial support was needed for medically indigent patients. Funds were secured from the National Cancer Institute to assist with transportation and housing costs. Local community organizations and the American Cancer Society provide funds and transportation from train stations to Fermilab. Other volunteers provide housing and meals.

Controlled Medical Research

The Radiation Therapy Oncology Group (RTOG) is a national cooperative group whose function it is to gather and analyze patient information nationally on patients treated according to the protocols developed by RTOG. A protocol is a document describing not only the rationale for carrying out a certain experiment but also describes in fine detail how the experiment is to be performed. It specifies clearly what will be the new and the reference therapies. For each RTOG protocol patient there are at least ten forms to be filled out by the institution treating the patient.

Several protocols are now active at Fermilab. The RTOG protocols now active include: squamous cell carcinoma of cervix, head and neck with surgery, head and neck - radiation only, head and neck - radiation only/boost, glioma, prostate, bladder, esophagus and lung. Local studies involve fewer patients and have fewer restrictions. Currently the local studies are: pancreas, salivary gland, melanoma, sarcomas, and selected adenocarcinomas.

Patient accession into our studies has been gratifying considering the number of other ongoing studies available to referring physicians. Patient accrual has constantly increased since the beginning of the project. At the present time the CTF is contributing 40% or more of all new patients entered into the national neutron studies.

Analysis of the patient information is beginning. However, cancer is multifaceted and results depend on long term survival (5

years or more). Therefore it is too early for all but the most preliminary assessments. Our failures are obvious because these occur fairly early (6 months to one year after treatment), but long term positive results will require at least 5 years of patient follow-up for initial results and after that, patient follow-up until death to determine the real results. A measure of the Fermilab contribution to the national cooperative neutron therapy trials is given in figure 2. The dotted lines indicate the number of cases needed to complete each study. The solid lines show the number of cases already accessed and the solid areas are the Fermilab's contributions.

In summary it has been our experience that the physics "hardware" (beam line, target, neutron spectrum, dosimetry and controls) is not the most difficult part of this type of research project. The medical and human aspects of the project are much more difficult and require a revision of the hard "black and white" ideas of data acquisition which are commonplace in physics and engineering.

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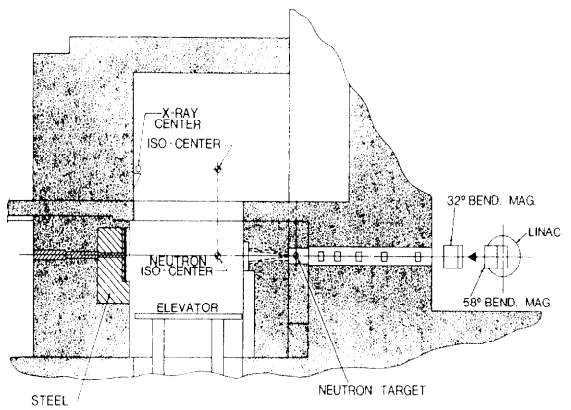

Figure 1. Treatment room elevation.

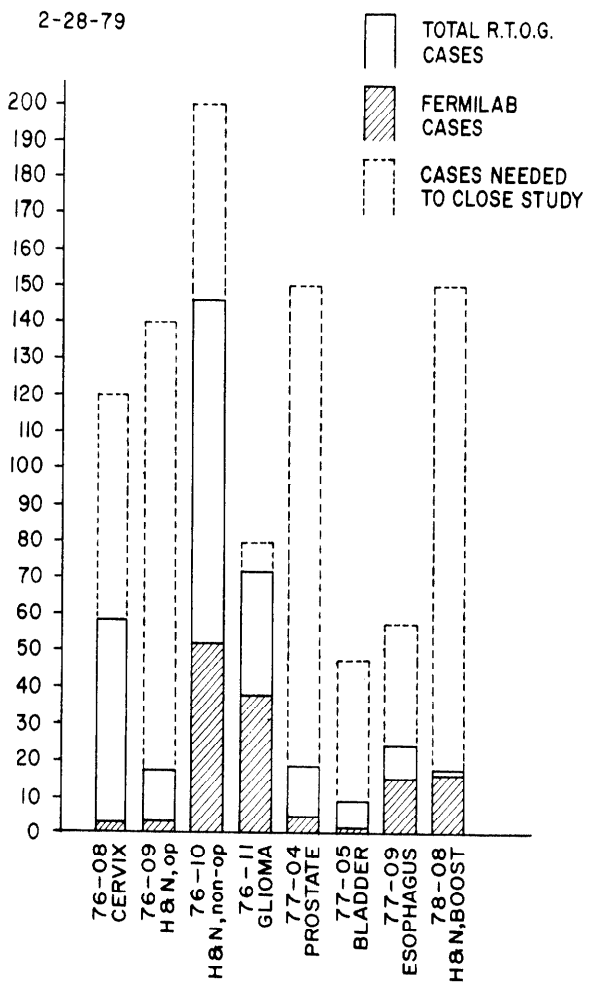

Figure 2. Case accession statistics.