



Princess Margaret Hospital

University Health Network

Informed Consent Form
(For Participation in a Clinical Research Study)

**Validating the Accuracy of a Relocatable Frame for PERFEXION™
Based Stereotactic Radiotherapy
Part 2**

Principal Investigator: Dr. David Jaffray (416) 946-2387

Introduction

You are being asked to take part in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation describing the purpose, procedures, benefits, discomforts, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study doctor or study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

Background

Stereotactic radiotherapy (SRT) is a highly precise and accurate technique commonly used to treat lesions of the brain and eye. SRT involves splitting the radiation dose into multiple fractions. Only one fraction is treated per day, and the number of fractions (days) can range from 5 to 35. Currently, SRT is performed using a linear accelerator (L-SRT) machine to deliver the treatment. For each treatment fraction, patients are set up using a rigid frame (like a box) attached to the teeth and head. This frame can be removed every day between treatments. The frame is needed to set patients up in the same place every day and to prevent them from moving during the treatment.

A new radiation machine, named Perfexion™ (PFX), has recently been installed at Princess Margaret Hospital. The machine contains 192 radioactive sources located around a cylinder. The beams of radiation from each source intersect at a centre point (isocenter) where the radiation

dose is concentrated. In this way, radiation delivery can be very precise. This new machine has more space and is quicker and more flexible than previous models made by the same manufacturer. We now plan to develop techniques for SRT using this new machine.

Purpose

The purpose of this study is to measure the accuracy of a new relocatable frame designed for SRT with the PFX machine. We expect the new frame to be as accurate or even better than the standard frame currently used for SRT with the linear accelerator machine.

There are 2 parts to this study. In the first part, the frame will be tested in a group of healthy volunteers. In part 2, patients receiving SRT on the linear accelerator machine will be immobilized with this new frame. You have been asked to consider participating in Part 2 of the study.

Procedures

You will undergo **standard radiotherapy planning procedures**. You will attend a 1-hour teaching session with a radiation therapist prior to radiation planning. The primary difference between this technique and standard technique is the use of a new relocatable frame. The frame being used in this study is a prototype device similar to the commercially available Headfix frame, which is often used in other centers. The specific procedures are as follows:

Initial fitting of relocatable frame

First, an impression of your teeth and upper palate will be made. Once the impression has hardened, it is attached to the mouthpiece of the frame. While biting down on the mouthpiece, a vacuum seal will be activated to secure the mouthpiece to your upper palate. You will then be positioned on the couch such that the mouthpiece fits with the frame. Your head will be adjusted until a comfortable position is achieved. The mouthpiece will then be locked in position, and used for your subsequent setups. This mouthpiece is specific to you, and will not be used with other subjects. A plastic bubble will be attached to the frame over your head in order to measure the initial position of your head relative to the frame.

CT Planning

As per standard care procedures, you will have a CT scan performed, which is used to plan your radiation treatment. For the CT scan, you will be positioned and immobilized in the relocatable frame. The plastic bubble measurements will be repeated to make sure that you are in exactly the same position as during the fitting procedure.

Treatment

As per standard care, you will be undergoing multiple radiation therapy sessions. As in the frame-fitting session, you will bite down on the mouthpiece and be positioned and immobilized within the frame. Plastic bubble measurement will be done to detect any differences between the initial frame fitting and each setup. If differences are too large, you may be repositioned up to three times within the same session. A CT image will be acquired to verify that your position is accurate. If it is not accurate, we will correct your position based on the CT scan prior to your treatment. You will be asked to lie very still for the duration of the treatment. The bubble measurements and CT will be repeated at the end of the treatment, before the frame is removed, to make sure that your head has not moved during the treatment.

Optical monitoring

A digital camera in the room will be monitoring markers placed on your skin and on the frame. The images taken from the camera will monitor the movement of your head and of the frame during the treatment.

Questionnaire

You will be asked to complete a questionnaire at the time of your first initial fitting and at the end of your treatment, to provide your general impression and evaluate any discomfort you may feel.

Potential Risks

There is minimal risk or added discomfort posed to you as a result of participation in this study. The use of a vacuum seal to secure the mouthpiece to your palate has never been reported to cause any harm. However, you may feel mild discomfort while you are immobilized in the frame. Please inform the study personnel if you feel any discomfort.

There is a very small risk that the new frame will not work as accurately as the standard frame in keeping your head perfectly still during treatment. We will be measuring for this every day. If we find that your head is able to move while you are immobilized in the new frame, your doctor will be informed, and your treatment will be adjusted to account for this as needed.

Benefits

You may or may not directly benefit from participation in this study. If the new frame is found to be more accurate than the standard frame, your treatment may be delivered more accurately. Information learned from this study may also benefit other patients in the future with your type of disease.

Alternatives to Participation

You may choose not to participate in this study. If you do not choose to participate, or participate and subsequently withdraw, your care at Princess Margaret Hospital will not be affected.

Confidentiality

Every effort will be made to keep your personal information confidential.

Qualified representatives of the following organizations may inspect your medical records (relating to the study) and study records and receive information from your medical/study records for quality assurance and data analysis:

- The University Health Network research ethics board that oversees the ethical conduct of this study in your hospital/clinic
- Health Canada (because it oversees the use of new drugs in Canada)

This information may include test results; reports of operations, x-rays or other body scan reports relating to the study.

The organizations listed above will keep information about you confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports, publications or presentations about the study
- You will be identified only by a study code
- Identifying information will be kept behind locked doors and will not leave the Princess Margaret Hospital (PMH)

All information obtained during the study will be held in strict confidence. Your medical records will be reviewed during the study to obtain information important to this study.

The images and data obtained in this study may be stored and used in the future to study new scientific questions similar in nature to this study.

Participation

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Deciding not to take part or deciding to leave the study later will not result in any penalty or any loss of benefits to which you are entitled.

Should you choose to leave the study, we would like to be able to collect additional information from you/your medical records for study follow up purposes. This decision, however, is your choice; you will be asked at that time if we may continue to collect information about you for the study purposes. If you decide to leave the study, the study data collected prior to that time will still be used for study purposes.

Fractionated Perfexion

It may become necessary to suspend your participation at any time by the study doctor with or without your consent. You could be withdrawn if your symptoms worsen or if you experience serious unforeseen side effects. You could also be withdrawn if the study is prematurely stopped for whatever reason.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

You will be given a copy of this signed and dated consent form.

Compensation

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form..

Questions

If you suffer any side effects or other injuries during the study, or if you have any general questions about the study, please call the doctor in charge of this study:

Dr. Cynthia Ménard at (416) 946-2230

If you have any questions about your rights as a research participant, please call:

Dr. Ronald Heslegrave, Chair of the University Health Network Research Ethics Board
(416) 340-4557.

This person is not involved with the research project in any way and calling him will not affect your participation in the study.

Consent

- I have had the opportunity to discuss this study and my questions have been answered to my satisfaction.
- I consent to take part in the study with the understanding that I may leave the study at any time without affecting my medical care.
- I voluntarily consent to participate in this study.

Study Participant signature

Date

Study Participant name: printed

Person obtaining consent: signature

Date

Person obtaining consent: printed

If this consent has been verbally translated:

I confirm that I have verbally translated this consent form for the study participant noted above, and in my opinion the study participant has understood what I have explained to them.

Name of Translator

Signature

Date

Language of Translation

Relationship to Study Participant (if applicable)