Senior Design Project Description

Company Name	Atrium Health – Cabarrus	Date Submitted	7/30/2020
Project Title	Cryotherapy to Prevent Radiation- Induced Dermatitis and/or Alopecia (AH_CRYO)	Planned Starting Semester	Fall 2020

Personnel

Typical teams will have 4-6 students, with engineering disciplines assigned based on the anticipated Scope of the Project.

Please provide your estimate of staffing in the below table. The Senior Design Committee will adjust as appropriate based on scope and discipline skills:

Discipline	Number	Discipline	Number
Mechanical	3	Electrical	1
Computer	1	Systems	
Other (

Company and Project Overview:

Levine Cancer Institute (LCI) is part of the Atrium Health organization. The technical supporters for this project work in the department of radiation oncology at LCI-Cabarrus, primarily as clinicians but also with a focus on clinical research. This engineering collaboration is a first of its kind for LCI-Cabarrus. Cryotherapy (cooling) solutions have been developed (see DigniCap, for example: https://dignicap.com/) to prevent chemotherapy-induced hair loss for cancer patients, and we aim to explore whether cooling can also prevent radiation-induced hair loss and skin irritation. However, the DigniCap solution is incompatible with radiation due to the way the material interacts with the X-rays used in radiation therapy. We hope to develop a technology that will allow us to cool the skin during radiation treatment without interfering with the delivery of radiation to the target, itself.

Project Requirements:

We ultimately aim to run a clinical trial to test whether cooling the skin over the irradiated target (breast or skull) can prevent radiation-induced skin irritation or hair loss, respectively. The hypothesis will be that cooling target skin to 3°C during the delivery of radiation therapy will achieve the desired protective effect. This target temperature is derived from the studies done on preventing chemotherapy-induced hair loss with a cooling cap. A unique solution is needed for applying this concept to radiation therapy, however, as the "cooling cap" approach used for chemotherapy relies on a circulating coolant solution that is incompatible with radiation, as any material layered on the treated skin with thickness of 3 mm or greater and density of water or greater will interact with the treatment X-rays and, thereby, actually increase the dose of radiation delivered at the skin.

Other forms of cooling technology are in widespread use for other applications within medicine, some of which utilize liquid nitrogen-based vapor to cool the skin (so-called "cryotherapy"). These commercially-available devices are not applicable to our problem, however, as they are intended to treat small areas of skin with intense coldness. We aim to apply this general technique, though, and adapt it to treat larger areas of skin to mild coldness.

Based on the current design of cryotherapy units, then, we envision designing a liquid nitrogen-based cryotherapy unit that will fuel our cooling treatment. As is done with existing systems, we envision delivering the cooled vapor to the skin via attached hoses. However, instead of a single hand-held hose, we will need an array of 4 connected hoses that can be arranged at corners surrounding the target. In that way, they will need to be flexible but semi-rigid, and should have an attachment point for being positioned onto the treatment "table" the patient rests upon.

Finally, regulation of the cooling system will be critical. Infrared thermometers should be able to monitor the surface temperature of the target skin. Ideally, each of the 4 cooling "arms" would be attached to one such thermometer, and the vapor delivery would be regulated by the recorded temperature.

Expected Deliverables/Results:

- A proof of concept, cryotherapy unit, cooled by liquid nitrogen
- A regulator for the cryotherapy unit, coupled to an infrared thermometer, to allow the unit to run automatically while keeping the target skin at the desired temperature
- A 4-way flexible but semi-rigid hose system that can be secured to the radiation therapy table through which the cooled vapor can be directed towards the target

Disposition of Deliverables at the End of the Project:

We hope to use the system developed during this project as part of a clinical trial at LCI-Cabarrus to test its efficacy, so anticipate delivery to our clinic at the end of the project.

<u>List here any specific skills, requirements, specific courses, knowledge needed or suggested (If</u> none please state none):

- Experience and/or interest in biomedical engineering would be helpful
- Experience and/or interest in heat/mass transfer would be helpful
- In the event that IP is created, Atrium Health will have exclusive ownership rights to the IP. Any student working on this project must agree to this condition.