Photodynamic Therapy Light Delivery System

ApolloTech Team
Jon Casali, Greg Dwyer, Brandon Poulin
Bryce Wilson, Josh Zastrow

Design Advisor
Prof. B.K. Jaeger

Abstract
Photodynamic Therapy (PDT) is a medical treatment that uses light-sensitive pharmaceuticals, known as photosensitizing agents (PSAs), activated by light of a specific wavelength. When activated, these drugs cause a chemical reaction that destroys targeted cells. PDT has been proven to be effective at combating a variety of forms of cancer. Experimental PDT treatments using low intensity light for a long duration have been shown to treat breast cancer; however, a light delivery system intended for such use does not currently exist. All light delivery systems currently in use are large, stationary, and intended for use in hospitals or clinical settings. The duration and frequency of the required treatment (12 to 24 hours several times per week) place a burden on the patient to spend such a large amount of time in a hospital. Our team ApolloTech is innovating a new light delivery device for treating breast cancer—called The Chariot—that is battery-operated, ambulatory, lightweight, comfortable, and usable in the home, providing greater flexibility for the patient. The project scope is to design, build, and test a working prototype to show that the ApolloTech Chariot can effectively deliver prescribed light levels into the skin at depths necessary to reach breast cancer tumors.

For more information, please contact: bkjaeger@coe.neu.edu
The Need for Project

Breast cancer is a disease in which cancerous cells form in the tissues of the breast. Nearly 1 in every 8 women in the United States will develop invasive breast cancer over the course of their lifetime. It is the most commonly diagnosed cancer in women and the second leading cause of death among women. This year it is estimated that over 220,000 women in the U.S. will be diagnosed with breast cancer and it will kill more than 40,000 women. Most local recurrences of breast cancer happen within the first 5 years after treatment and the chance of local recurrence can range from 6 to 26 percent (Ref 6).

Photodynamic therapy, a medical treatment that uses pharmaceuticals activated by light of a specific wavelength, has been demonstrated to be an effective method to combat breast cancer in studies by Gary Rogers, M.D. of Tufts Medical Center. The treatment he outlines in his paper Continuous Low-Irradiance Photodynamic Therapy: A New Therapeutic Paradigm is most feasible if the patient is exposed to the light for long durations, as much as 12 to 24 hours. The experimental procedures performed by Dr. Rogers and other researchers thus far use light sources modified to perform the function; no commercial light delivery system is currently marketed for this application. Moreover, no portable light delivery device designed to reach sub-dermal tumors has ever been created. Providing patients the flexibility to pursue this treatment in the home would cause minimal disruption to their day-to-day living and allows the patient to minimize the amount of time spent in and traveling to healthcare facilities.

The Design Project Objectives and Requirements

The device must be feasible, functional, portable, safe, modular and affordable to the target audience. Design and build a battery-operated, ambulatory, lightweight and ergonomic light delivery device that can be used in the home –under a physician’s care– to manage breast cancer through Photodynamic Therapy in conjunction with traditional treatments. The design goals are that the device must be feasible, functional, portable, safe, modular, and affordable. The light must be able to penetrate to tumor depths of 17mm under the skin. It also should meet a baseline level of comfort and user acceptance for the patients.
Design Concepts Considered

A variety of concepts were conceived along the path to a final design.

Modular LED Patch

The first design concept was a Modular LED Patch and is shown in the side figure. The first part is an adhesive Tegaderm® piece that is secured to the patient’s skin above the target area. This allows for a secure biocompatible fit to the skin that can be placed on different parts of the body. There is a clear section found in the middle of the adhesive patch for the light to penetrate the skin. The second part of this device is the light housing that attaches to the Tegaderm® and directs the proper wavelength light into the target area. The light housing is connected by a cord to the patient interface, which is the third part of the device holding the battery.

LED Undergarment Insert

The group named this second concept the LED Undergarment Insert. This device uses a red light LED array that can be comfortably inserted into the patient’s bra. Due to the insert fitting in the patient’s bra, the patient will still be able to move freely making sure the treatment non invasive to their lifestyle. The device’s LED array is flexible and would conform to the surface contours of the patient.

Recommended Design Concept

Our design houses all components in a light-weight and compact design.

Design Description

Our device is a compact light engine that holds all of its components in a low-profile housing. The device is portable, safe, modular, and affordable. The design of our wearable PDT device will use a high powered Light Emitting Diodes (LED) light source. Because skin acts a red band pass filter, a red light (660 nm wavelength) will be used to ensure skin tissue penetration. Human skin tissue has a high optical scattering coefficient, which means the light is quickly dispersed when it enters the skin. The directionality of the LED light compensates for this.

Battery Pack

Based on the drive current of the LED board (350mA Test), disk batteries would not provide enough capacity to keep the LED powered for the duration of the treatment. The best solution is a Lithium Poly-Ion Battery with a voltage of 3.7V. The design involves relatively simple circuitry.
Additional Components and Housing

The housing has been designed to accommodate additional components and was realize a seamless geometric interface. It has been 3D printed which has allowed us to rapidly prototype. One notable component added to the system is an Arduino-based microcontroller for “smart” LED functionality. The goal is to use Pulse Width Modulation (PWM) to rapidly turn the LED on and off. This can be used to control brightness/intensity, as well as preserve battery life. Appropriate switch mechanisms were researched and purchased for digital power control, and a more advanced charging breakout board was purchased for micro-USB charging of the battery pack (Ref. Figure 18). The design will also include an aluminum heat sink to overheating and dissipate heat created by the LED and battery away from the patient.

Human Factors

This protocol looks specifically at the three areas of user machine interaction: Doctor to Machine, Clinician to Machine, and Patient to Machine. The doctor will have the highest level of control over the system, being able to order a device with specific power and wavelength LED depending on the most appropriate treatment regiment for the individual patient. A qualified non-MD clinician will have ability to modify the duration limits of the operation of the device and train the patient. This ensures that patients cannot overtreat themselves inadvertently or intentionally. While the patient will have less control than the doctor and the clinician, their main responsibility is the proper use of the device. In the event that the patient feels pain or experiences extreme discomfort, it is important the patient immediately stop treatment by turning off the device or removing it from their body.

Analytical Investigations

Correctly modeling the properties of human breast tissue is essential for the ApolloTech Team to better understand photon propagation in breast tissue as a function of radius and depth. To verify that the ApolloTech Chariot will be capable of delivering enough light to the depths needed to reach breast tumor cells, the team ran a Monte Carlo Multi-Layer (MCML) simulation. Monte Carlo Multi-Layer is a stochastic modeling technique that works by simulating the random walks photons make as they travel through tissue; the program performs this photon simulation by propagating many photon paths and
taking their net distribution to yield a realistic approximation. It reads in parameters such as scattering coefficients and absorption coefficients for layers of tissue, and creates an output file which lists the average light in joules per square centimeter at each depth. This simulation technique is made available by the Oregon Medical Laser Center (Ref. 17).

**Experimental Investigations**

To validate that the device will be able to deliver enough light to the necessary depths, the ApolloTech team will conduct optical testing using the Chariot prototype. The results of this physical testing will be compared with the Monte Carlo simulation. The team created a skin phantom from whole milk and India ink. The suspended fat molecules found in whole milk scatter light similar to the suspended fat molecules found in human flesh. The India ink added to the milk simulates light absorption by blood vessels. This testing will tell the ApolloTech team how deep light from the LED source chosen will penetrate the target tissue, and how much light will be present at given depths. Comparing both the data from this experiment and the Monte Carlo simulation will help give credibility to the Chariot’s design.

**Key Advantages of Recommended Concept**

The key advantages of a design such as ours include both ability to use the device in an outpatient setting and the low profile design which allows the user to “hide” their ailments from others. This compact design fills a major gap in a potentially growing market.

**Financial Issues**

Due to rising health care costs in the US, there is a financial advantage to outpatient treatments compared to hospital and clinic visits. The total cost of the major components of the prototype was $90.50. If this item were to be mass-produced, economies of scale would reduce the cost per unit to around $55. Operating the device is virtually free, as the battery is rechargeable. The patients and/or their insurance companies would of course have to pay for the supply of photosensitizing agents (the light-sensitive pharmaceuticals), however estimating this cost is outside of the scope of the project.

Overall, photodynamic therapy will save patients and insurance companies a great deal of money compared to other cancer treatments such as chemotherapy, radiation therapy, or surgery. This is because PDT reduces the time spent in the hospital. The patient may check in with doctors and clinicians on a weekly or bi-weekly basis. A system
design around treatment on the patient’s terms represents a significant savings compared to status quo cancer treatments.

**Recommended Improvements**

The improvements that could be made to the Chariot include a touch screen so that the patient has an easy to use interface when controlling the device. The device could also possibly be made with smaller components to have a smaller, slimmer profile that was more comfortable and aesthetically pleasing. After completing more research on components and through economies of scale, the device could be designed to be manufactured for a lower price. Additional, more research and design must be focused toward the wearable aspects of the device. The team has begun to survey the target audience to choose the best wearable design interface. Finally, computer programming and connectivity will allow the oncology-care physician to (1) configure the settings such as frequency, intensity, and duration for each treatment protocol (including usage controls), (2) monitor the usage profile of the patient, (3) make any adjustments to treatment plans or settings to suit each patient’s condition, and finally (4) generate clinical research databases for analysis of the settings, tolerance levels, compliance levels, and clinical outcomes.