Skin Applicator

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Abstract

During the past two semesters we were charged with the task of designing an applicator device for a topical drug solution. The motivation for this design comes from our client, Dr. Bill Fahl, who—along with his associates—has developed a drug for the prevention of radiation-induced burns. Our client had a few main requirements for this design, and over the course of this year we sought to create a prototype which conformed to these standards. In the end, we came up with a device which we believe has unique and redeeming qualities over current devices on the market. In the future, our client would like to produce this device on a larger scale for clinical testing.

Background

- Radiation burns (dermatitis) are a major side effect experienced by cancer patients undergoing radiation therapy [1]
- Currently no sufficient method exists for preventing radiation burns from occurring as a result of radiation therapy [2]
- The high-energy electron beam used in radiation therapy creates oxygen free radicals which damage the surrounding tissue
- Our client has developed a drug solution incorporating norepinephrine to prevent radiation burns from occurring as a result of radiation therapy

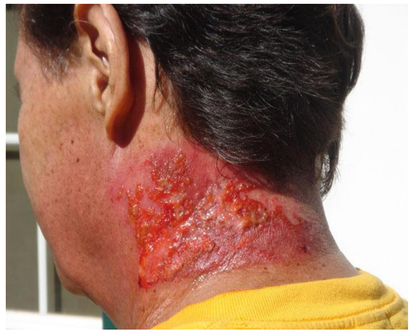


Figure 1: A patient exhibiting radiation-therapy-induced dermatitis.
(Source: http://www.cancer-throat.com/index.php?s=lubricate)

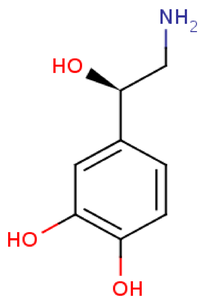


Figure 2: Norepinephrine, the drug used in the client's trials.
(Source: http://www.bmrb.wisc.edu/metabolomics/mol_summary/?molName=Norepinephrine)

Motivation

•The client's drug solution, a 70:30 ethanol:water mixture containing norepinephrine, requires an effective method to deliver this drug topically to radiation-therapy patients
•The client is preparing to commence a relatively large-scale clinical trial which would benefit from an effective application method

Client Requirements

- The device should apply 8.0 mL of the drug solution to approximately 225 cm^2 of skin
- The device should be disposable (i.e. single-use)
- The device should be relatively light-weight and handheld
- The drug solution must be contained in a glass ampoule

Final Design

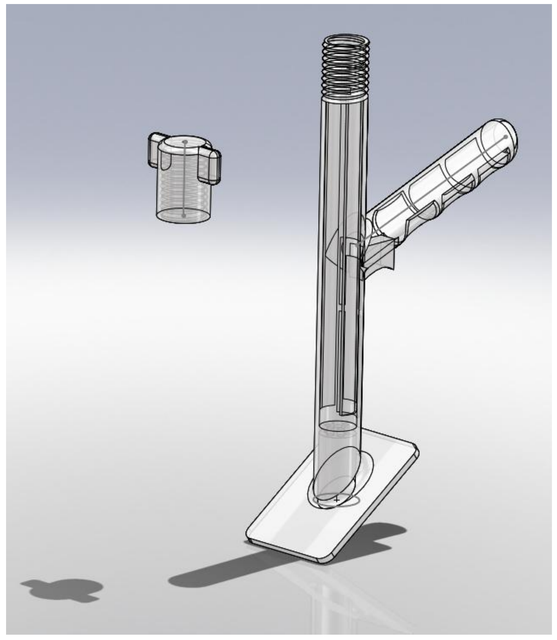


Figure 3: The final design

Key Features of the Final Design:

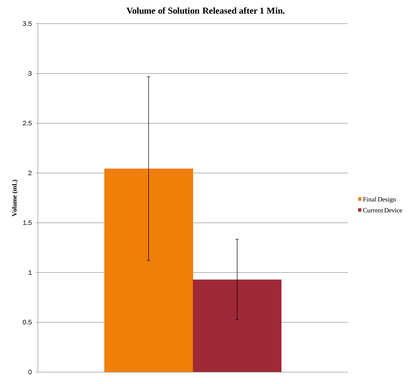
- Ergonomic handle for reduced stress to hand and forearm during application
- Drug is stored in a crushable glass ampoule placed inside of the chamber of the device
- Designed to store and release 13 mL of ampoule-contained drug solution
- Torque applied to the cap causes a compressive stress which fractures the bottom of the glass ampoule
- The drug solution is released through the bottom of the shaft and diffuses through a reticulated polyurethane foam pad attached to the bottom of the shaft
- Once the released drug solution has been allowed to sufficiently saturate the foam (i.e., after approximately ten seconds), it can be applied topically to the patient prior to radiation therapy

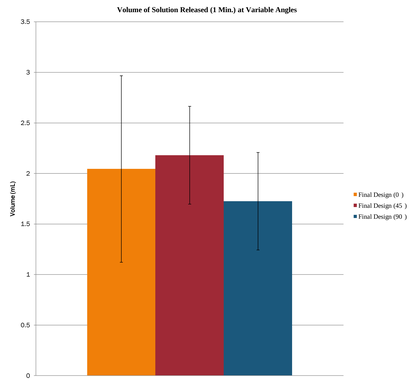
Testing/Calculations

•Through the course of our testing process, we attempted to demonstrate that our device's functionality is comparable or even superior to that of current devices on the market.

- Test 1: Comparison of volume of solution delivered after one minute of application (0 with respect to horizontal)

- Test 2: Volume of solution delivered on variably oriented surface after one minute of application (45 with respect to horizontal)





Prospective Modifications

- Develop a mold for mass production via injection molding
- Integrate device into the clinical trials
- Modify and refine design as needed following clinician feedback prior to, during, and after clinical trials

References

1. Prat, M., Bey, E., Brachet, M., Trompier, F., Ernou, I., et al. (2008). New therapeutic approach in the treatment of severe radiation burn: Surgery and local stem cell therapy. *Wound Repair and Regeneration*, *16*(6), A78.

2. Lataillade, J., Doucet, C., Bey, E., Carsin, H., Huet, C., et al. (2007). New approach to radiation burn treatment by dosimetry-guided surgery combined with autologous mesenchymal stem cell therapy. *Regenerative Medicine*, *2*(5), 785-794.