

Skin Applicator

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Client: Dr. Bill Fahl

Outline

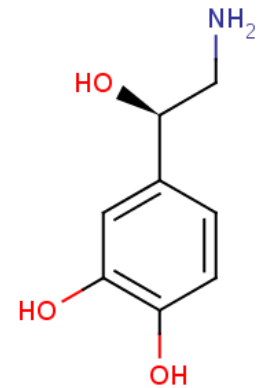
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Problem Statement

- A disposable applicator
- Will disperse 10 ml of solvent (70:30, ethanol:water) containing drug
- Drug applied to cancer patient receiving radiotherapy for 30 days
- Device will provide cost-effective alternative to current devices

Background

- The drug will be administered to an area of skin on the patient immediately prior to radiation therapy
- The drug is designed to prevent dermatitis (radiation burns) in these patients
- The drug itself is the well known neurotransmitter, Norepinephrine
- The drug vehicle, as previously mentioned, is a 70:30, ethanol:water solution



Norepinephrine

Source:
[http://www.bmrb.wisc.edu/
metabolomics/mol_summary
/?molName=Norepinephrine](http://www.bmrb.wisc.edu/metabolomics/mol_summary/?molName=Norepinephrine)

Background

- The cause of dermatitis:
 - Radiotherapy directly damages tissues by creating oxygen-based free radicals via high energy electron beam
 - Much of this energy is dissipated in the 1st mm of skin
 - Free radicals are formed from the bloodstream, which damage the surrounding tissues
 - e^- (electron beam) + oxygen containing species (H_2O , O_2 , etc.) \rightarrow Reactive Oxygen Species \rightarrow Tissue Damage
 - Radiation burns/dermatitis occurs



Severe dermatitis from radiation targeting throat cancer.

Source: <http://www.cancer-throat.com/index.php?s=lubricate>

Background

- How the drug will work:
 - The drug, norepinephrine, is a vasoconstrictor
 - By restricting blood supply to the treated area, oxygen is removed
 - Free radical formation is limited and (hopefully) dermatitis/radiation burns are avoided
 - Drug trials are underway, and a more efficient and cost-effective means of application is required

Client Requirements

The device should...

- apply 10 mL of drug solution to an area of 225 cm²
- improve upon problems with similar devices on the market
- deliver the drug solution in a controlled, consistent manner
- be disposable (i.e. one-time use)
- not cause the patient any excessive discomfort or harm
- have a per-unit cost of \$5

Current Devices on the Market

- Current devices are the ChloroPrep[®] skin applicators
- Applicators apply an antimicrobial/antibacterial drug pre-surgery and come in a variety of sizes
- The devices all use crushable glass ampoules as the mechanism for drug containment and delivery
- Current design could be modified to contain and apply our drug of interest, but there are cost-related concerns
- Other concerns with these devices include:
 - Lack of a controlled drug-release mechanism
 - Possible waste of drug solution
 - Lack of an abrasive application surface

Current Devices on the Market

- Examples of current devices
 - The 1.5 mL applicator:
 - Squeeze wings, release drug
 - Apply via polyurethane foam
 - Simple, creative design
 - No control of drug release
 - The 10.5 mL applicator:
 - Squeeze wings, release drug
 - Apply via polyurethane foam
 - Simple, creative design
 - No control of drug release



Source:
<http://www.chloraprep.com/fr/epp>



Source:
<http://www.chloraprep.com/en-ml>

Constant Features of the Design

- Glass ampoule for drug containment
- Reticulated polyurethane foam for drug application
- Polymer-based, chemically inert handle which contains ampoule and is attached to foam application surface



Glass Ampoule,

source:
<http://stores.ebay.com/Element-Sales>



Foam,

Source:
<http://www.superior.ie/cleanroomwipers.htm>

Design Alternatives

- Based on our client's requirements, we came up with several design alternatives
- These designs all varied by means of drug release mechanism
- These design alternatives are:
 - Torsion-Activated Mechanism
 - Spring-Loaded Mechanism
 - Syringe Mechanism
 - Notched Mechanism

Design Alternatives: Torque-Activated Design

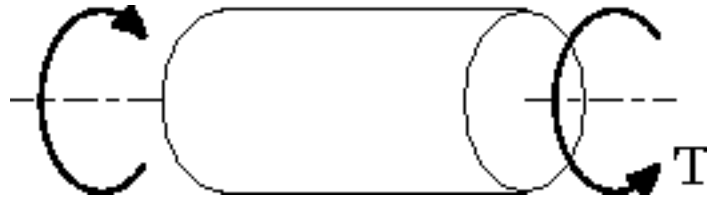
- Design is similar to current devices
- Glass ampoule is housed in a semi-rigid polymer-based cylinder, and glued at either end
- Cylinder is attached to foam applicator
- Device is activated by applying a torque to handle, fracturing ampoule

- Pros

- Simple

- Cons

- Inefficient and uncontrolled drug delivery
- Operation requires two hands



Source:
http://en.wikibooks.org/wiki/Strength_of_Materials/Torsion

Design Alternatives: Spring-Loaded Mechanism

- Drug solution is housed in glass ampoule
- Spring-loaded mechanism, upon activation, propels ampoule towards pin, releasing drug
- Pros:
 - Unique mechanism for drug delivery
 - Could possibly be more efficient than current designs
- Cons:
 - Still no control of drug release
 - Could prove overly complex to manufacture

Design

Alternative: Syringe Mechanism

- Premise: release the drug solution using a hand-held piston
- Pros
 - Good control of drug solution release
 - Simple, ergonomic design
- Cons
 - Continuous flow may make it difficult to apply discrete, incremental aliquots

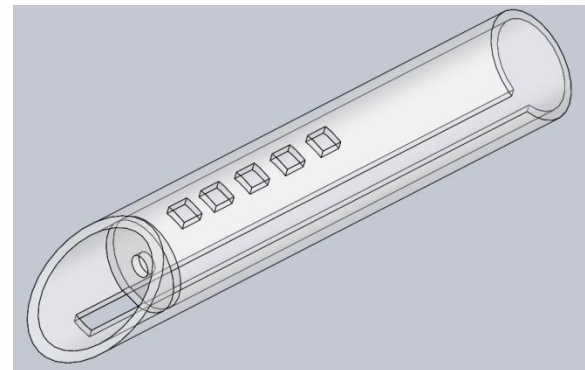


Source:

http://www.growforce.co.uk/product_images/1061/thumbs/1/10-cc-plastic-syringe.jpg

Design Alternatives: Notched Mechanism

- Design is similar to the syringe mechanism
- Adds additional feature of notches, allowing greater control of drug release
- Pros
 - Good control of drug release rate
 - One-handed operation
- Cons
 - May prove slightly more difficult to manufacture than syringe mechanism

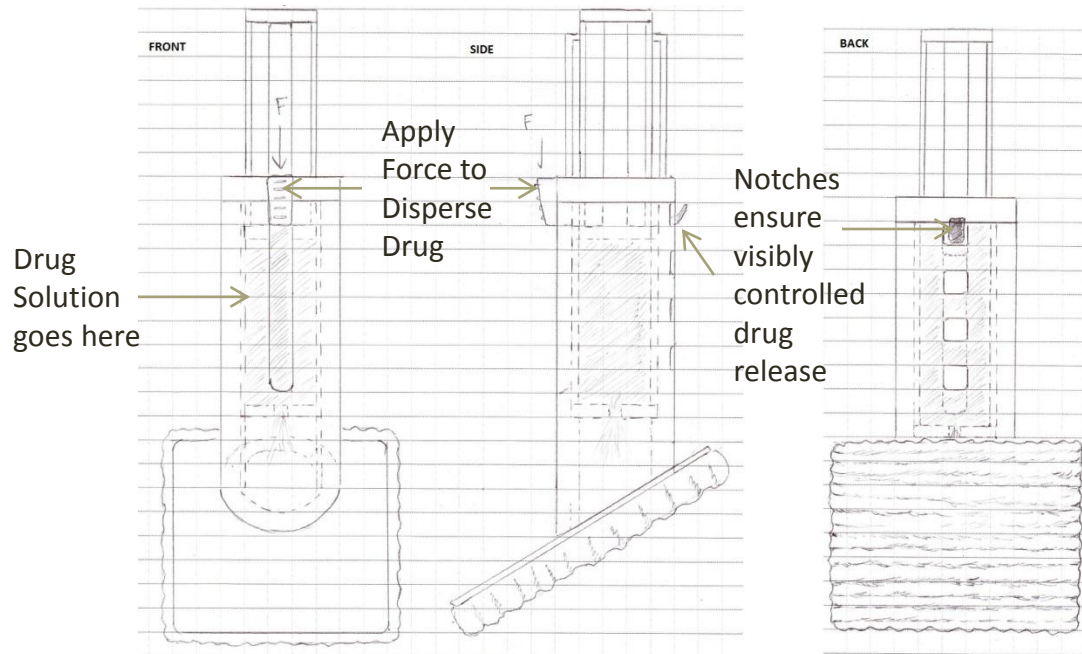


Design Matrix

Design Alternative	Ease of Manufacturing (10)	Ease of use/ Ergonomics (15)	Control of Drug Diffusion Rate (30)	Cost (20)	Efficiency of Drug Delivery (25)	Total (100)
Current Design	10	12	20	12	16	70
Syringe Mechanism	9	13	26	18	21	87
Notched Mechanism	7	12	28	17	25	89
Torsion-Activated Mechanism	8	10	18	19	15	70
Spring-Loaded Mechanism	5	11	20	13	20	69

Final Design

- Based on the design selection criteria we have chose to pursue the notched mechanism
- Some preliminary sketches of what the device will look like:



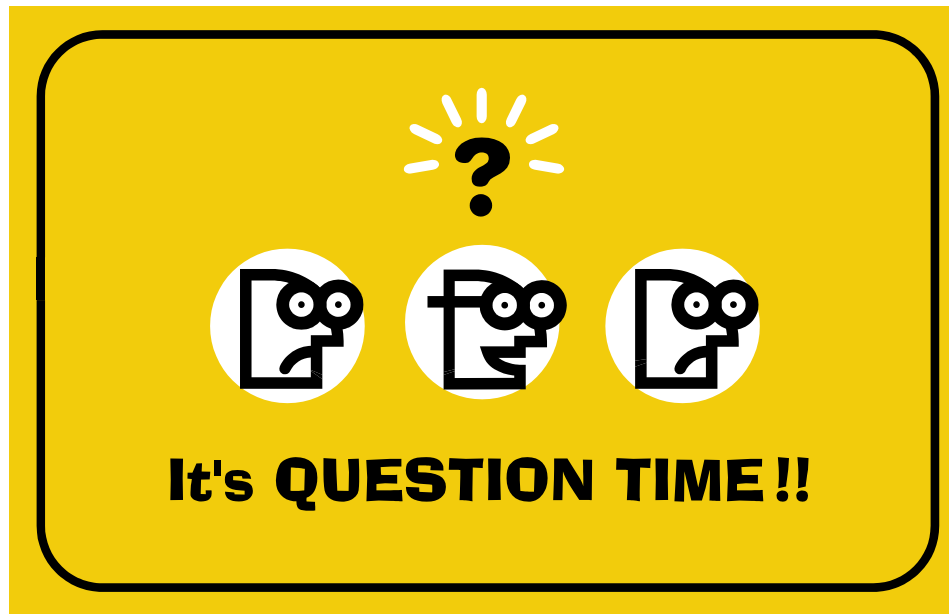
Future Work

- Incorporate a slightly abrasive application surface to remove dead skin cells and promote drug-solution absorption
- Use a colorant in the drug solution to indicate where it is applied on the skin to facilitate administration
- Conduct testing
 - Weighing device pre- and post-application to assess efficiency of drug delivery
 - Qualitative comparison of effectiveness of drug delivery using the proposed device versus the existing method

Acknowledgements

- Dr. Wan-Ju Li
- Dr. Bill Fahl
- Wisconsin Foam Products Inc.

Questions



It's QUESTION TIME!!