

Topical Pharmaceutical Application Device for Scalp

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Abstract

The pharmaceutical company Procortus has developed a drug, ProDermaCel, to help prevent alopecia (hair loss) as a result of chemotherapy drugs and radiation in cancer patients. The company is ready to perform clinical trials with human subjects but needs a new device to apply the drug solution to a patient's scalp. The current device consists of a L'Oreal hair dye comb attached to a MADomizer spray applicator. However, the current device may not pass standards set by the Institutional Review Board (IRB) because it appears unprofessional and the rubber elements could cause allergic reactions. Additionally, each applicator is expensive since the L'Oreal combs cannot be purchased independently of the hair dye kits. Our group designed an application kit containing a hollow, linearly branching comb, a 20 mL MADomizer spray bottle, and 2 mL of 70% ethanol drug solution. This new design appears more professional and evenly dispenses the drug solution, with an average dead space of 0.68 mL and an average flow variation of 0.034 mL between comb teeth.

Background

- Drug developed by client's company, Procortus
 - Prevents alopecia (hair loss) in cancer patients
- Initial animal testing done in McArdle Laboratory
- Clinical trials proposed for human subjects at UW Hospital
 - 12 patients, daily trial for 25 to 35 days
- Get approval from FDA for human use



Figure 1. Mice pre- and post-radiation therapy in pre-clinical trials. There is no hair loss in the area that was treated with the ProDermaCel drug solution [1].



Current Device

- Current device is rudimentary example
- Appears unprofessional
- Excessive dead space
- Difficult to assemble
- Contains rubber elements that can cause allergic reactions
- Combs are expensive
 - Cannot be purchased individually



Figure 2. Current device used to apply the drug solution. It consists of a Wolfe Tory Medical, Inc. MADomizer attached to a comb via a rubber stopper.



Figure 3. Comb from a L'Oreal hair dye kit. Combs must be purchased as part of the hair dye kit, which costs around \$12.

Design Criteria

- Deliver 2.0 mL \pm 5% to 50 cm² area on scalp
- Minimize amount of wasted drug
 - Minimize amount lost on hair
 - Minimize dead space to 1.0 mL
- One-time use/disposable
- Quick application (60 to 90 seconds)
- Comfortable for patient and research assistant
- \$300 to \$400 budget

Final Design

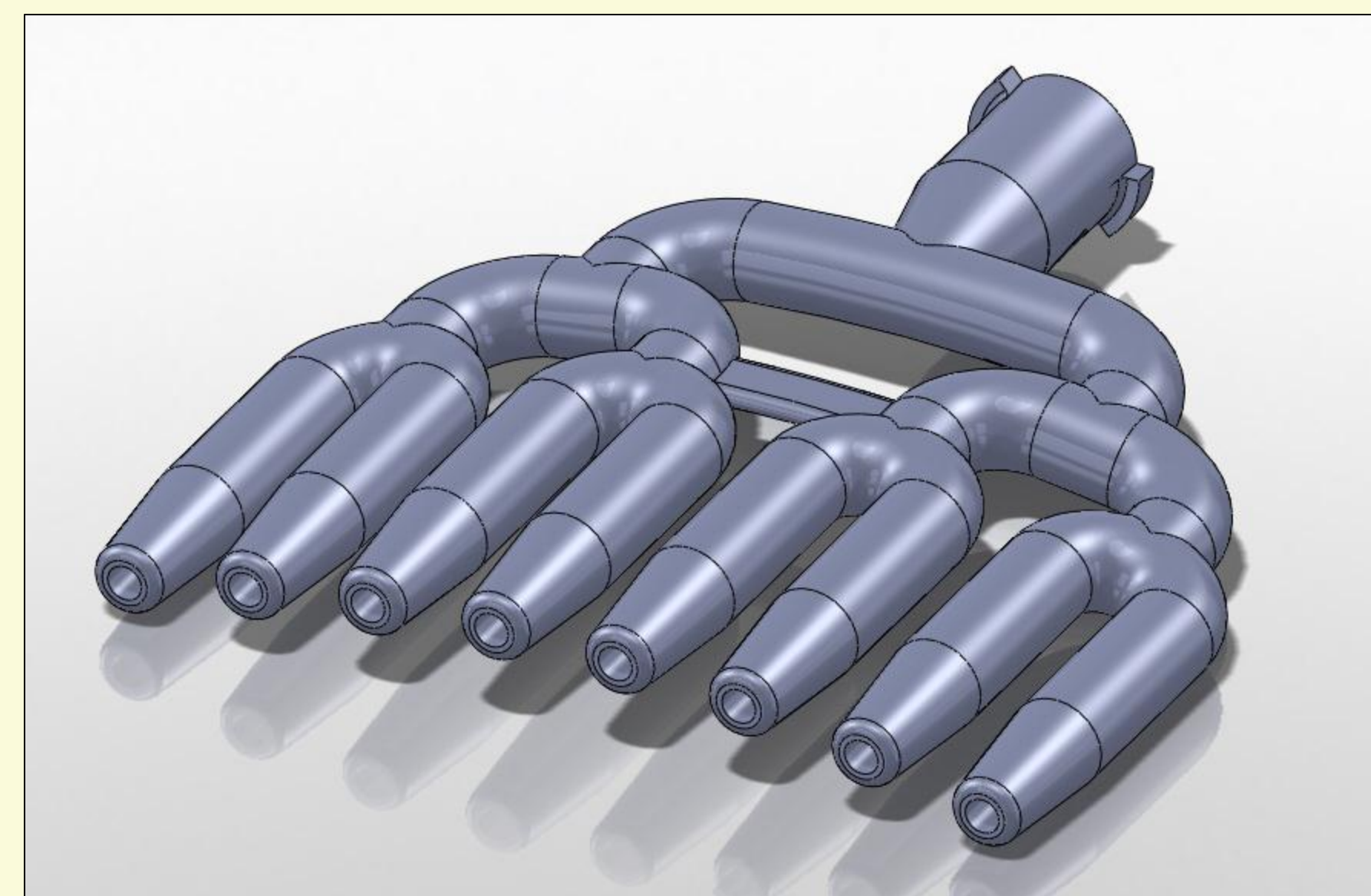


Figure 4. SolidWorks drawing of the final comb tip design. This drawing was used to make a rapid prototype of the part.

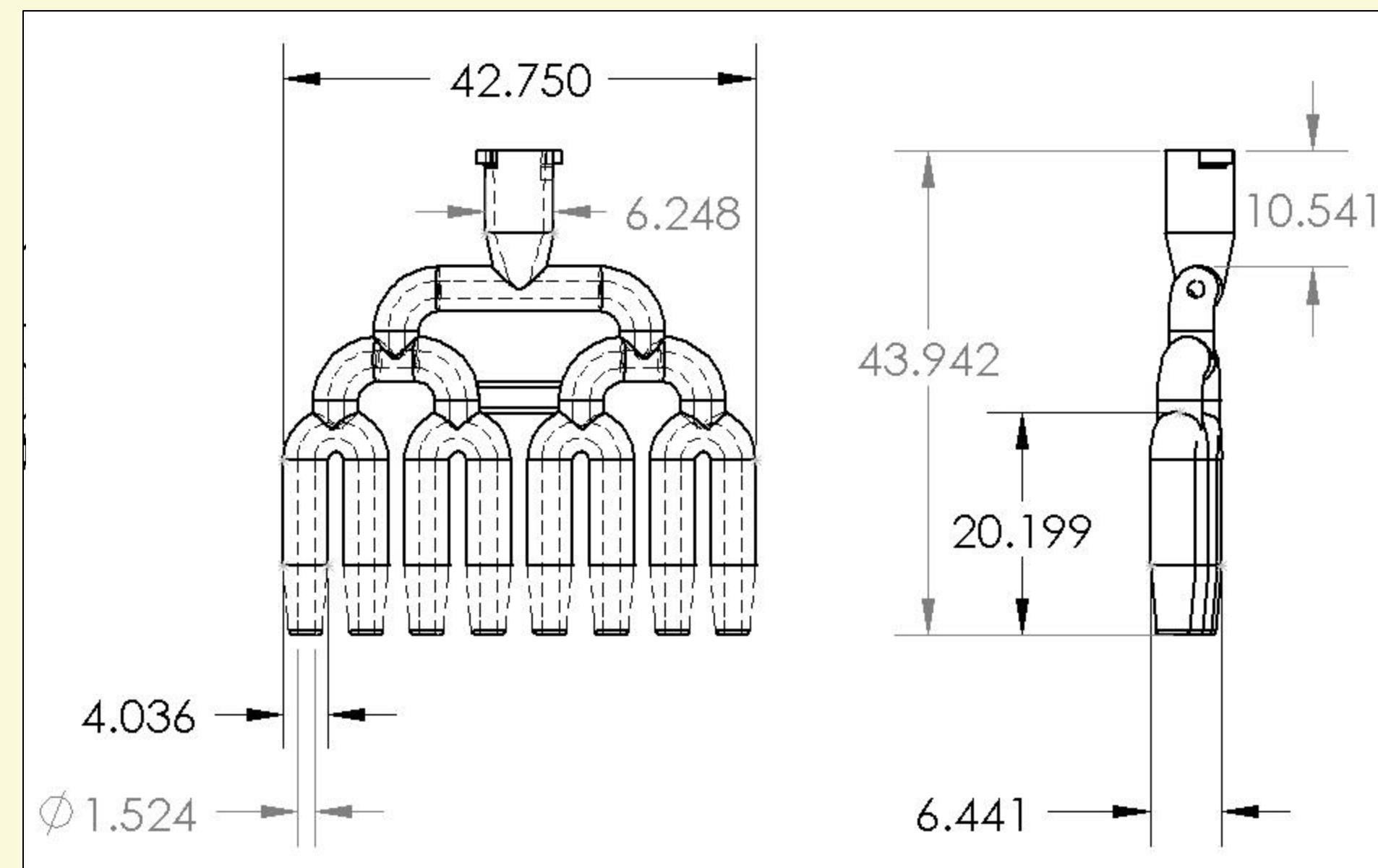


Figure 5. The dimensions of the final design in mm.

Comb Features

- Branched design for even fluid distribution
- Flexed to fit the curvature of the scalp
- Attaches to either Luer-Lok syringe or MADomizer
- Tapered and rounded teeth for greater patient comfort

Kit Contents

- Branched comb tip
- MADomizer spray bottle, filled with drug solution and capped for long-term storage
- MADomizer spray cap attachment

Application Process

- 1) Research Assistant opens kit
- 2) MADomizer inert cap is removed and replaced with spray mechanism
- 3) Comb tip is attached to MADomizer
- 4) Research assistant combs drug solution onto scalp, squeezing 20 times to dispense 2.0 mL
- 5) MADomizer and comb tip are discarded when finished

Future Considerations

Recommendations for Fabrication

Direct Digital Manufacturing

- Fused Deposition Modeling (FDM)
 - 0.005" (0.127 mm) layer thickness [2]
 - ABS-M30 (25-70% stronger than prototypes for testing)
- Cost: \$30 per comb, \$21 per comb for bulk order
- Accuracy of dimensions varies slightly with geometry
 - A single trial should be checked before ordering

Injection Molding

- Must get injection mold machined precisely to form part features
- Part can be made from a variety of plastics
- Our design involves undercutting and two unsymmetrical halves
- Two-cavity family mold can be made by Engineering Industries, Inc. in Verona, WI [4]
- Mold will produce the part in two halves that can be welded together after molding
 - Ultrasonic or hot plate welding
 - Quoted Cost: \$20,000

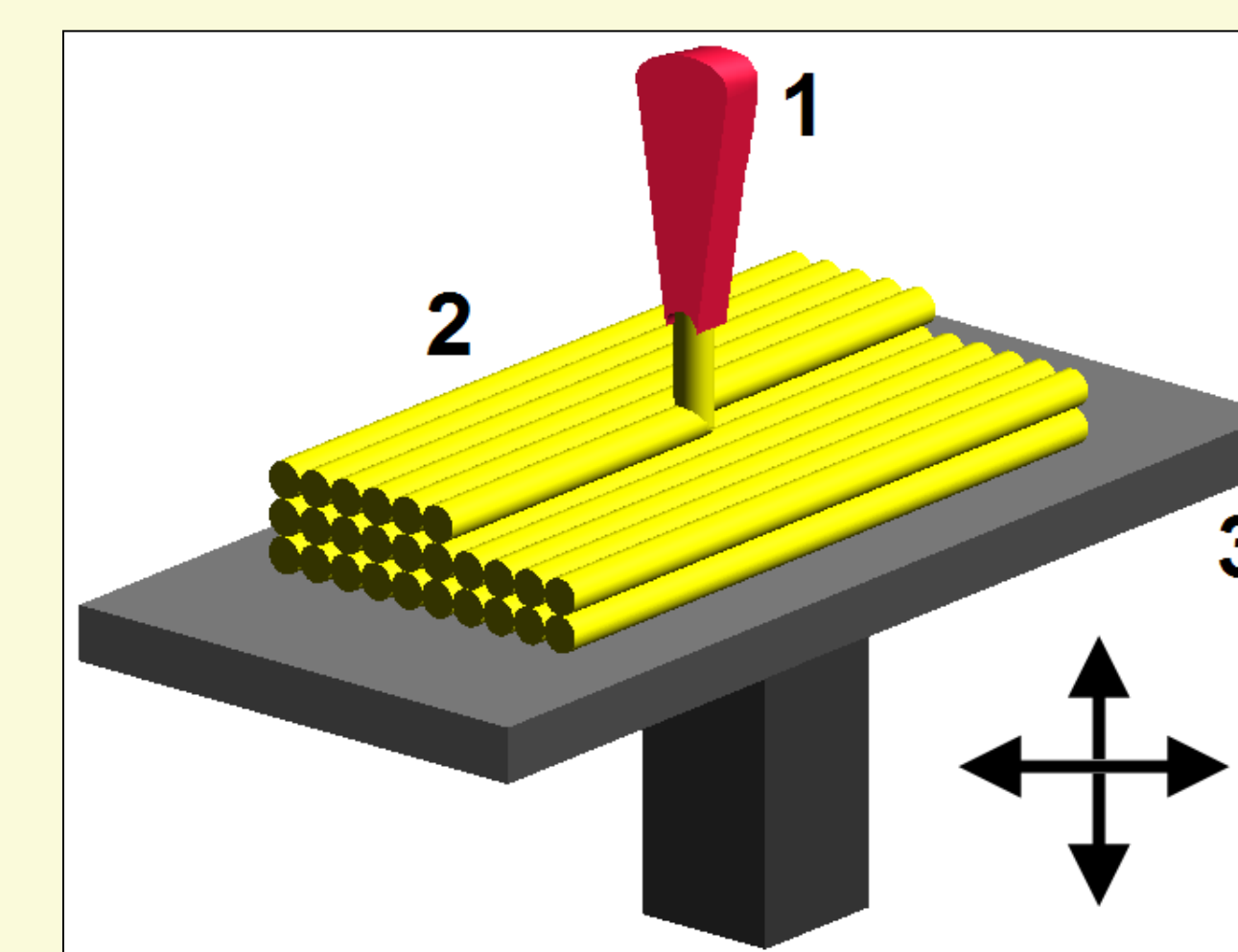


Figure 6. Fused deposition modeling (FDM) method: 1 - nozzle ejecting plastic, 2 - deposited material, 3 - movable table [3].

Testing Results

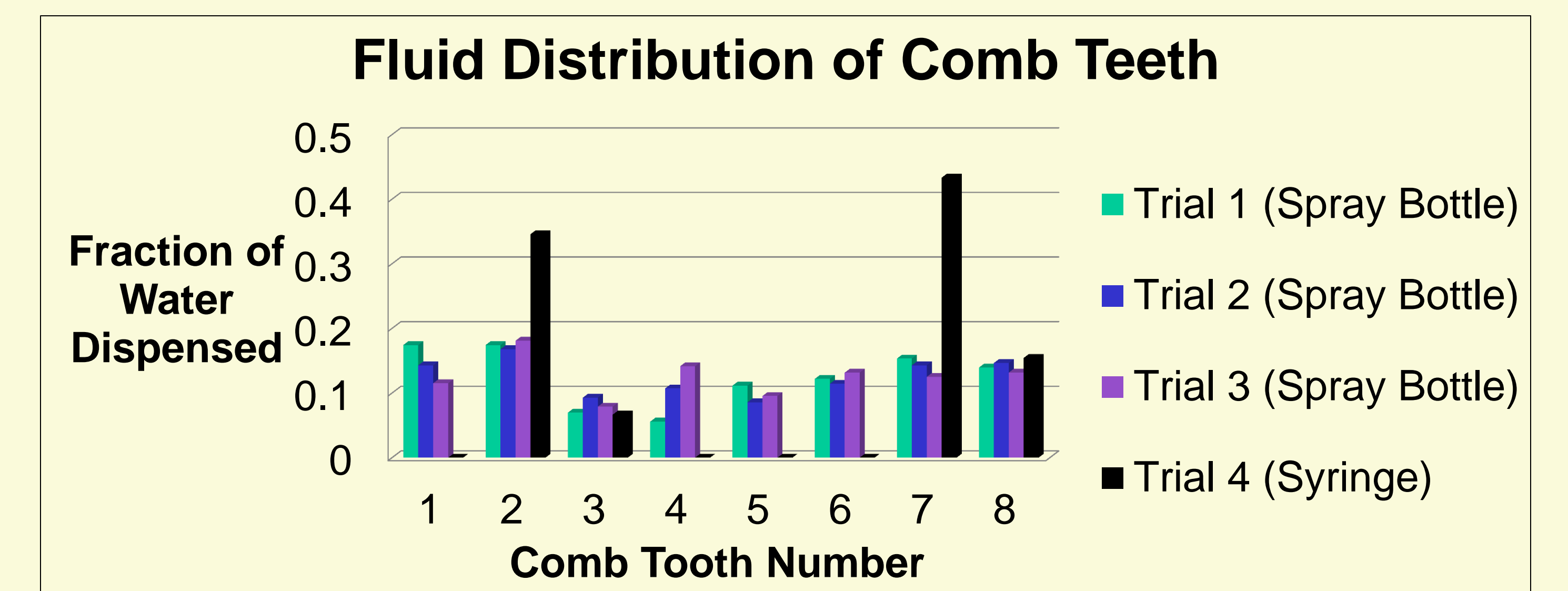


Figure 7. Fluid distribution is much more even between comb teeth when using the spray bottle, as opposed to the syringe.

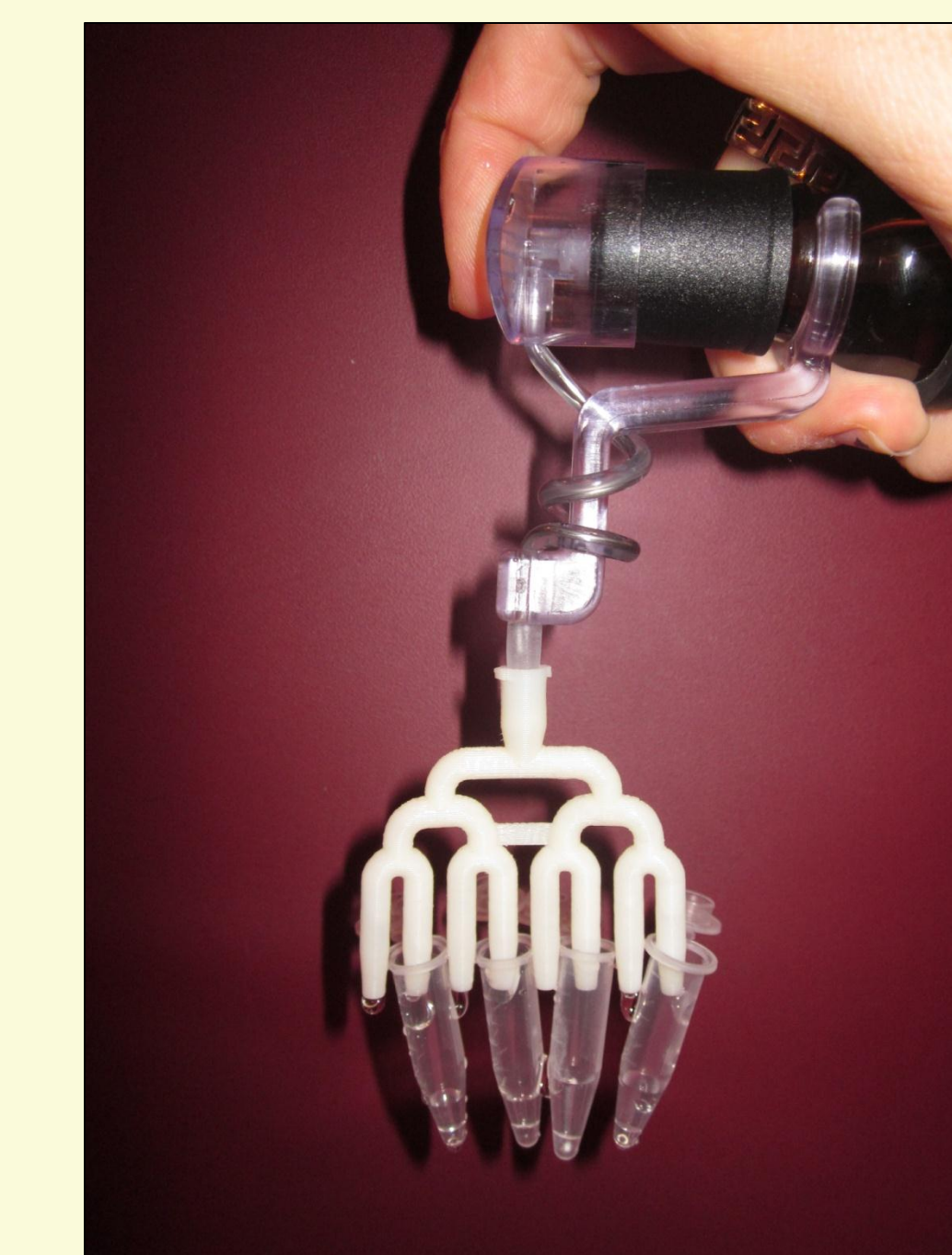


Figure 8. Fluid distribution testing was done with the final comb tip prototype attached to the MADomizer.

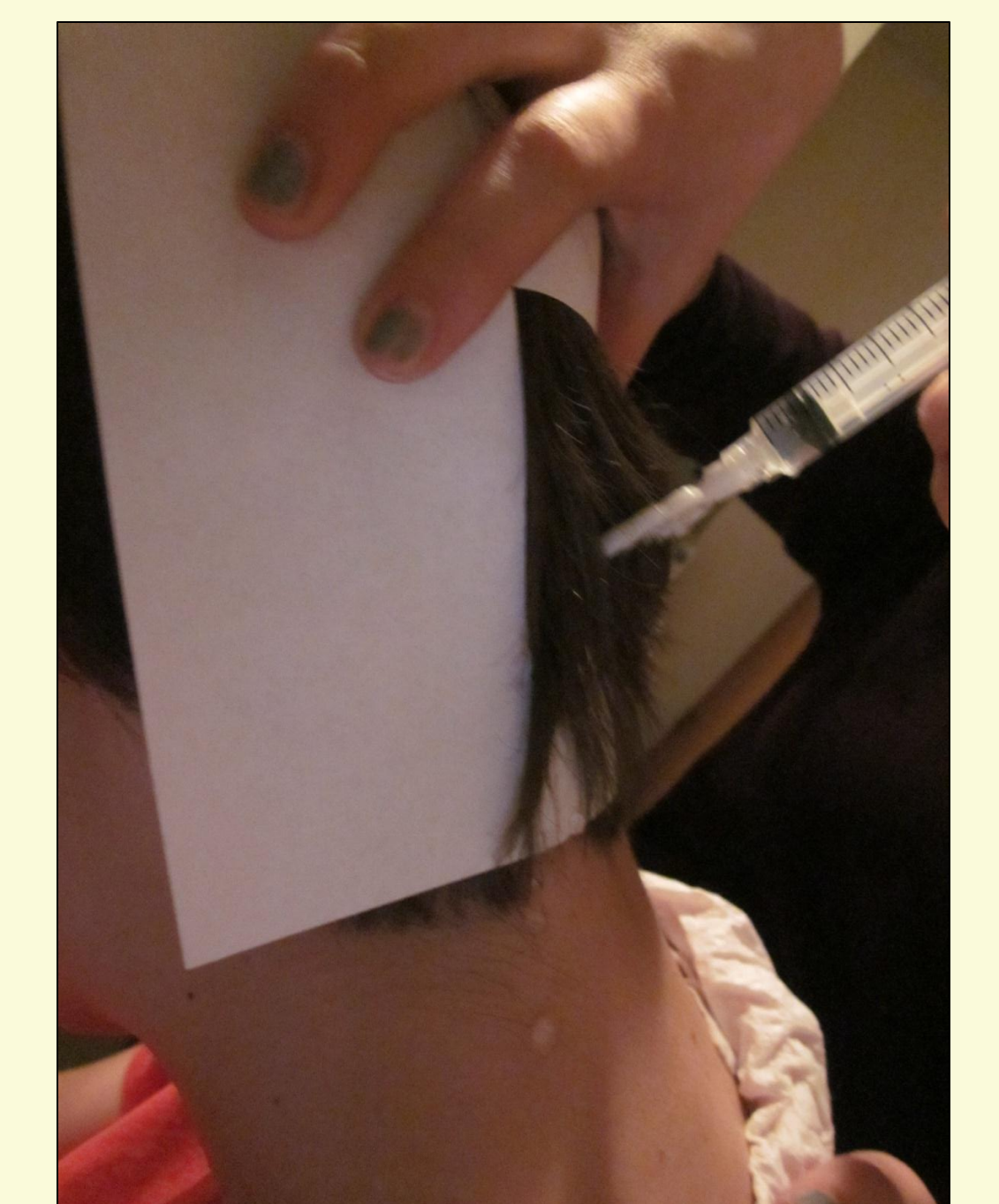


Figure 9. Time trials of application were done by applying 2.0 mL of water to a 50 cm² area on the scalp.

Table 1. Data from dead space and application time testing.

| | Average | Standard Deviation |
|---------------------------|----------|--------------------|
| Dead Space (Spray Bottle) | 0.682 mL | 0.0785 |
| Dead Space (Syringe) | 0.261 mL | 0.147 |
| Application Time | 38 s | 4.077 |

Observed Ergonomics

- Blunt, rounded teeth are comfortable and reduce chance of scratching scalp
- Research Assistant discomfort using MADomizer is minimized because it takes only 20 squeezes to dispense the necessary 2.0 mL

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