BME Design-Spring 2024 - KASIA KLOTZ
Complete Notebook

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Jenna Krause

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Table of Contents

Team contact Information

KASIA KLOTZ - Feb 06, 2024, 9:10 PM CST

Last Name	First Name	Role	E-mail	Phone	Office Room/Building
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Linser	Tevis	BSAC	linser@wisc.edu	651-309-7782	

Project description

Jenna Krause - Feb 28, 2024, 7:52 PM CST

Course Number:

BME 402

Project Name:

Eye Drop Assistant

Short Name:

Eye Drop Assistant

Project description/problem statement:

Administration of eye drops is difficult for patients, especially older adults and those with limiting diseases like arthritis. This results in eye drop waste and tip contamination. The team will design a device to assist patients in squeezing the eye drop bottle, while releasing a consistent amount of solution per drop. This device will improve the administration of eye drops for the patient while minimizing eye drop waste.

About the client:

Beth joined the School of Pharmacy in 1998 and was the Director of the Pharmacotherapy Labs for the entry-level Doctor of Pharmacy degree program from 1998 - 2005, where she implemented OSCEs (Objective Structured Clinical Exams - performance based assessments) into the curriculum. She currently co-coordinates the DPH-1 IPPE courses, the Teaching Certificate Program for Pharmacy Residents, and promotes assessment, teaching and learning initiatives in the school.

Current education initiatives Martin is involved with include developing interprofessional practice and education experiences for health sciences students in communications and promoting older adult health and safety. She is serves on several campus committees focused on teaching and learning technologies, promoting student engagement in the classroom and providing peer feedback on teaching.

Her practice experience is in community and managed care pharmacy and she also served as the Director of Educational Affairs for the Pharmacy Society of Wisconsin before transitioning to the School.

Beth Martin's honors include being a Big Ten Academic Alliance Academic Leadership Program Fellow (2020-21), being named an APhA-APRS Fellow in 2018, the UW-Teaching Academy Distinguished Teaching Award in 2017, AACP Excellence in Assessment Award in 2015, the 2011 Wiederholt Prize for Best Paper in JAPhA, AFPE 2004-05 Fellow, the APhA-APRS ESAS postgraduate officer for 2004-05, receiving the 1998-99 and the 2008-09 Teaching Excellence Awards, AACP Innovative Teaching Award 2001, the 1995 Young Pharmacist of the Year Award, and being a 1994 graduate of the SKB/APhA Community Pharmacy Management Program.

Beth's professional affiliations include: PSW, the American Pharmacists Association, the Academy of Communications in Healthcare, the American Association of Colleges of Pharmacy, and the Professional and Organizational Development Network in Higher Education (POD)

02/01/2024 - Client Meeting 1: Semester Goals and Prototype Update

Jenna Krause - Feb 08, 2024, 1:10 PM CST

Title: Client Meeting 1

Date: 2/1/24

Content by: Eva Coughlin

Present: Jenna, Anabelle, Eva, Kasia, Tevis

Goals: To update the client on our progress with prototypes.

Content:

- Beth and Ryan liked the new prototype with the eyebrow platform
    - They think it makes it easier because we don’t have to deal with anatomical differences
- Discussed progress with patent lawyers
    - Ryan mentioned that he submitted a session at the law school to discuss existing patents
- Ryan’s list of progress over winter break:
    - Talked to FDA, this is a Class 1 medical device
    - Started developing pitch for shark tank, need to create a powerpoint for that
    - Looking into distribution channels (Mekenson??)
- Talked about when we should submit our WARF application
    - Should email WARF about this is what we’re going to do, not an official application
    - Talked about shark tank being public disclosure
    - Amy Arnoldsen in pharmacy school
- Discussed cost per unit 3D printing vs. injection molding and including packaging
- Also going to finalize our material choice
- Talked about the IRB, could do an addendum to the initial IRB for putting eye drops in the actual eyes
- Discussed packaging engineer contacts with Beth

Conclusions/action items: The team met with the client and pharmacy student to discuss progress over winter break on both ends. The pharmacy student will be sharing a presentation with us to work on together for the shark tank. The client really liked the latest prototype, which involves resting the device on the brow bone using a platform. A tentative schedule of client meetings is being created.

02/16/2024 - Client Meeting 2: WARF Updates

EVA COUGHLIN - Feb 16, 2024, 3:28 PM CST

Title: Client Meeting 2

Date: 2/16/24

Content by: Eva Coughlin

Present: Jenna, Anabelle, Eva, Kasia, Tevis, Prof. Puccinelli

Goals: Discuss WARF updates and expectations in terms of team roles.

Content:

- Updated client on WARF meeting and potentially going to D2P if WARF doesn't work out
    - Client mentioned D2P with Aimee Arnoldussen
- Now that we have disclosed to WARF, we are able to talk about the device
- Do we get the breakdown from WARF on what they found in terms of our device?
    - We should request it
- Discussed our plan for the semester and how Ryan fits into the plan
    - Client thinks that Ryan is trying to help speed up the process → wants to give him the opportunity
        - Makes sense to the team in terms of Shark Tank
    - We want to make sure we aren't wasting his time
- Prof. Martin will send the expectations for Shark Tank and send us past presentations
    - Room 1105, February 27th at noon
    - The actual ShaRx Tank is April 11th at 3:30 PM, WID
- Prof. Martin asked us about packaging expectations
    - Still need to finalize design before this → pick between nose bridge and eyebrow platform
- Saline or lubricated eye drops for eye drop administration in the second IRB?
    - Lubricating eye drops
    - We are going to try to broaden the population that our device is serving for this, maybe incorporating the staff who works at the retirement community

Conclusions/action items: The team met with the client and advisor together to discuss future plans and expectations. The client will be sending us a shared google drive with example ShaRx Tank presentations from past years. The team expressed that we are ready to start working on that right away. A couple members of the team will attend the next meeting about ShaRx Tank on February 27th at noon.

03/06/2024 - Client Meeting 3: Preference Testing Preperation

EVA COUGHLIN - Mar 06, 2024, 9:37 PM CST

Title: Client Meeting 3

Date: 3/6/24

Content by: Eva Coughlin

Present: Eva, Kasia

Goals: To prepare for the human subjects preference testing at the retirement community.

Content:

- Dr. Martin put the recruitment flyers all over the building and assigned us a room for testing
- We worked on the document needed for the preference testing tomorrow
    - This document was a combination of our screening, script, and the survey
- Dr. Martin helped us with wording things the simplest way possible so that the residents are able to fully understand our expectations of them
- Dr. Martin recommended that we all wear Wisconsin gear of some sort because they need to be able to identify us as UW students
- Ryan will pick up all the devices and eye drops from Tevis tonight
- Ryan and Dr. Martin will go to the retirement community in the morning for the first session of recruiting and testing
- Then the team will go to the retirement community from 5:30-7 PM for the evening session of testing
- Dr. Martin will print out the documents for us so that we have extra copies of them for the evening session
- Dr. Martin recommended that we have someone specifically help direct people into the survey area and find a seat
- She also mentioned that we may need to redirect the conversation and practice reflective listening and note any quotes that we can use for our ShaRx Tank presentation
- Post testing, I will email Dr. Martin to update her on how it went

Conclusions/action items: In conclusion, testing will occur on Thursday, March 7th from 11:30-1:30 PM and 5:30-7 PM at Oakwood Village University Woods retirement community. Dr. Martin and Ryan will handle the late morning/early afternoon session and the BME design team will handle the evening session. We have prepared our script and all documents necessary for testing. We are looking forward to getting feedback on our device from the residents.

04/05/2024 - Client Meeting 4: ShaRk Tank Presentation and Final Remarks

Jenna Krause - Apr 05, 2024, 1:29 PM CDT

Title: Client Meeting 4

Date: 4/5/24

Content by: Jenna Krause

Present: Jenna Krause, Eva Coughlin, Anabelle Olson, Kasia Klotz, Tevis Linser

Goals: To discuss ShaRx Tank presentation and final preparations.

Content:

- Discuss how the team ran a new drop test with a non biased audience.
- Feedback on ShaRx Tank Slides
    - Put a team photo on the first slide of presentation instead of its own slide
    - Change the color of the frames on the “accommodates everyone” slide so they match the right device.
    - Add the competition names to “the gap” slide
    - Do not say smaller. Keep consistent and discuss reducing waste.
    - Add quotes into the presentation to make more of an impact
    - Option can include a mini video of someone using the device.
    - Keep injection molding slide to show business plan for the rubric
        - Backup slide of injection molding
    - Talk about distributions to target pharmacy
    - Change adolescents to pediatrics on the where to find us slide.
    - Dr. Martin recommends that 3 people present. Have Ryan do the starting slide and then 2 members of the BME team join him
    - Quotes: “Market testing has said this…”, “Investment already lined up…”
    - Recommendation to close the presentation:
        - End with quotes from the market

Conclusions/action items:

The team prepared for the ShaRx Tank presentation by refining slides, incorporating feedback from Dr. Martin. The team needs to include impactful quotes from testing and feedback to include in the ShaRx Tank presentation. Action items are for the team to prepare for ShaX Tank Presentation and determine presenters for it. The team also needs to send in a recording with Ryan to receive additional feedback before the presentation on Thursday.

01/26/2024 - Advisor Meeting 1: WARF and Outreach

THOMAS KRIEWALDT - Apr 30, 2024, 10:03 PM CDT

Title: Advisor Meeting 1

Date: 1/26/24

Content by: Anabelle Olson

Present: Anabelle Olson, Kasia Klotz, Jenna Krause, Tommy Kriewaldt, Tevis Linser, and Eva Coughlin

Goals:

- Ask about dimensions and iterations for the wharf application
- Ask about information and updates for the outreach program

Content:

- 402 differences:
    - Journal article: choose a journal that is appropriate for where you are at, shoot for one you could actually publish in.
        - First draft due close to mid semester, should have a good introduction, materials and methods (testing or design depending on what kind of journal you are submitting to) , and an outline of results.
        - Could submit this, but usually requires contact after graduation
        - Look for author guidelines and download it
        - She will look at our list of journal articles
    - Report can just be copy and pasted
    - Preliminary design presentation, casual, just to the advisor
        - Specific goals of timeline is the bulk
    - Packaging research, we should start soon
        - Packaging information should be a part of the appendix
    - Wharf answers:
        - Can we include both iterations in the application?
            - A: wait to do testing on the new prototype, then analyze results, and proceed with the best prototype
    - Dr. P suggests getting the other IRB in right away
    - Mentorship:
        - Meet on thursdays - Sun Prairie High School
        - Make presentation by Monday to send to Sun Prairie

Conclusions/action items:

The team learned about the expectations for this semester with a meeting with our advisor. The team also learned about initial expectations for the mentorship outreach opportunity.

01/29/2024 - Advisor Meeting 2: Outreach

Jenna Krause - Feb 06, 2024, 2:03 PM CST

Title: Advisor Meeting 2

Date: 1/29/24

Content by: Jenna Krause

Present: Anabelle Olson, Kasia Klotz, Jenna Krause, Tommy Kriewaldt, Tevis Linser, and Eva Coughlin

Goals:

- Discuss details of outreach including resources and scheduling

Content:

- Go through the mentorship outreach curriculum
    - Duration 8-10 weeks
    - Week 1
        - Welcome/ice breakers
        - Create a presentation on Biomedical Engineering
        - Can highlight our own design project
        - Weds: Middle School, Thurs: High School
        - Team Formations
            - Mentors divide students based on interests
        - Team choose design project
    - Week 2
        - Deliverable
            - Student must create powerpoint
            - Present research to mentors
    - Week 7
        - Students visit UW for tours
    - Week 8 Final show case presentations (mentors remote)
    - Week 9 Showcase in person
- School Resources
    - Onshape: CAD program for the students
- Do not share current project for the team due to WARF
- Location Sun Prairie East High School
    - 1st week will be in person
- The team needs to come with a pretend client for the students
- They are recruiting kids to stay after school to keep out of trouble so not a specific STEM program but kids that are interested in science.

Conclusions/action items:

Sun Prairie East High School's outreach spans 8-10 weeks, covering biomedical info, design projects, UW tours, and showcases to engage science-interested students through a unique design project approach with pretend clients. Action items for the team is to come up with a project that engages the

students throughout the 8 weeks.

02/06/2024 - Advisor Meeting 3: WARF, IRB, Outreach

Jenna Krause - Feb 06, 2024, 2:04 PM CST

Title: Advisor Meeting 3

Date: 2/6/2024

Content by: Jenna Krause

Present: Kasia Klotz, Jenna Krause, Tevis Linser, Eva Coughlin, and Tommy Kriewaldt

Goals:

- Discuss WARF and IRB
    - Who to include
- Discuss Outreach
    - In person vs virtual commitment
- Preliminary Presentation

Content:

- Updated on the WARF Progress
    - Discuss feedback for inventors and role of each inventors
        - Prof Puccinelli suggested having a seat down meeting with Dr. Martin
    - Have notebooks available for the WARF meetings
        - Show all the iterations of the designs and testing to the WARF team.
        - Stay positive in the meeting and highlight all the novelties of the design and how it is different from devices on the market.
- Outreach Program
    - Reggie explains that the basketball students will be at the outreach meeting before practice so all the students will be attending.
    - Reggie is the main point of contact for the outreach program along with Prof Puccinelli
    - The team plans to meet in person for the outreach this week for another round of introductions to the students. The following 2 weeks the students will be conducting research for the project so the team decides to go remote for the outreach program.
- Preliminary Presentation Feedback:
    - More details on the goals of the research and testing
    - Outreach details do not need to be included in the future plans slide
    - Preliminary Presentation will be on Zoom for Friday
    - Tommy will record his portion of the presentation.

Conclusions/action items:

The team needs to look more into including more details in the preliminary presentation with a clear outline of goals. Action items for the team are conducting the final preliminary presentation with Prof Puccinelli. Tevis and Jenna are meeting with a chief engineer to discuss possibilities of injection molding the prototype.

02/16/2024 - Advisor Meeting 4: General Updates and Preliminary Presentation

EVA COUGHLIN - Feb 16, 2024, 3:34 PM CST

Title: Advisor Meeting 4

Date: 2/16/2024

Content by: Eva Coughlin

Present: Kasia Klotz, Jenna Krause, Tevis Linser, Eva Coughlin, and Anabelle Olson

Goals:

- Discuss preliminary presentation grade and what the team has been focusing on this week

Content:

- Discussed updates with outreach this week and some miscommunication
- Tevis met with Paula for injection molding discussion
    - Big question is do we try injection molding or stay with 3D printing?
    - Journal that is more mechanical engineering focused → networking with also doing journal article at same time?
- Updated Prof. Puccinelli on WARF meeting
    - She discussed resources on campus other than WARF
    - Discussed D2P → should we set up a meeting? yes
- Discussed upcoming meeting with client and what we are going to discuss in terms of roles
    - ShaRx Tank
    - Intellectual Property
- Discussed requesting access to journals through UW-Madison libraries

Conclusions/action items: The team updated the client on outreach, injection molding, and the IRB. The team also asked some questions about the journal article in terms of expectations. Prof. Puccinelli encouraged the team to set up a D2P meeting with Aimee Arnoldussen before we hear back from WARF. Eva will schedule that meeting, and the team will continue working on our current tasks.

02/21/2024 - Advisor Meeting 5: Preliminary Deliverables

Jenna Krause - Feb 26, 2024, 9:36 PM CST

Title: Advisor Meeting 5

Date: 2/21/2024

Content by: Jenna Krause

Present: Jenna Krause, Eva Coughlin, Anabelle Olson, and Tommy Kriewaldt

Goals:

- Discuss preliminary deliverables and journal article requirements

Content:

- Journal Article Feedback
    - Only a draft of the journal article
    - Preliminary testing only 2 sentences at the end of the introduction
    - Relevant testing can be included in the actual testing and methods.
    - Outline of results and discussion section
    - Appendix will include the final report from last semester + raw data
    - Survey style journal
        - Article popular in the education arena.
        - More work to do this with the coding
        - Free software Nvivo
- IRB Update
    - Explain how the team submitted first round of edits which immediately followed up with a second round of edits
    - Had a meeting with the IRB contact to discuss the language
    - All the edits are completed just waiting on training from Ryan.
    - The IRB contact said once all the training is complete, the team will receive IRB certificate within a few days
    - The team will continue to move forward with Dr. Martin to schedule testing at the community center.
- Notebook Submission
    - Expect ongoing research this semester.
    - Need to understand the market a little bit better
    - Work for the executive summary
- Outreach
    - Send a team update at the start of the week to let the school know what the expectations are for the week.

Conclusions/action items:

The team got feedback for the preliminary journal article which discusses how only relevant testing from the previous semester needs to be included. The team needs to start sending weekly updates to Sun Prairie before the Thursday meeting. Action items for the team is to conduct the human preference testing now that the IRB is completed. Also, need to finish the preliminary journal article by next Wednesday.

03/08/2024 - Advisor Meeting 6: Preference Testing and Outreach

KASIA KLOTZ - Mar 11, 2024, 4:16 PM CDT

Title: Advisor Meeting 6

Date: 3/8/2024
Content by: Anabelle Olson
Present: Anabelle Olson, Kasia Klotz, Jenna Krause, Tevis Linser, Eva Coughlin
Goals:

- Talk about how the preference testing went
- Talk about outreach

Content:

- We updated Prof. P. about possibly making an addendum to the IRB to perform another testing day
    - We might change the colors of the devices so they are the same color and this does not factor into their opinion of which device to use
    - Advisor says we could add a question for the next testing section, however don't change any questions we had.
        - Make it a little more obvious about how to use the platform and the nose bridge rest
- Update Prof. P. about the second IRB in process
    - Lady recommended we submit IRB consultation form
        - We should ask during the meeting what kind of timeline we are looking at
    - Not addendum, full new application
- How are we going to unsure that a consumer will know how to use the device without us being there and explaining it
    - We are going to utlize the box packaging to show a picture of someone using the device
- Talked about maybe having caregivers try out our device on a dummy or mannequin
- Do we have any data about the market prepared?
- It was mentioned that using our single drop data as qualitative data in the journal article is bias data
    - If we get our friends or classmates to perform this testing, we need to expand our market population in the writing of the journal article

Conclusions/action items:

The team learned about the expectations for this semester with a meeting with our advisor. The team also learned about initial expectations for the mentorship outreach opportunity.

03/15/2024 - Advisor Meeting 7: Testing Updates

Jenna Krause - Apr 05, 2024, 1:29 PM CDT

Title: Advisor Meeting 7

Date: 3/15/2024

Content by: Eva Coughlin

Present: Anabelle, Eva, Tevis, Jenna

Goals:

- To update Prof. Puccinelli on our testing and IRB meeting
- Decide on what to do for future testing

Content:

- The IRB meeting went well and we discussed the potential of doing the additional IRB for participants to administer the eye drops into their eyes with the device rather than on to a cloth
    - Is it worth it? We were told that there is no guarantee that we will be able to get it done in time for poster presentations end of April
        - Prof. Puccinelli recommended that we reach out to our client and see if she would have time to do it because this would speed up the process
- Testing went well and we got 25 more participants!
    - Mixed reviews on the different versions of the prototype. Should we try to keep both?
        - Prof. Puccinelli thinks that we can keep both as options
- Single drop test doesn't need an IRB approval
    - Should we use the BME 201 students? Yes
- Mold for injection molding would be way too expensive, so we're going to create a 3D printed mold for the presentation
- Getting quote from packaging contact too
    - Prof. Puccinell recommended that we could print labels
- Meeting with Harrow Health is on Monday, so going to do some research beforehand

Conclusions/action items: We discussed testing and future plans with packaging today. Eva will reach out to the client to see if she'd be willing to take on the IRB. We also need to confirm that the single drop test doesn't require an IRB and then we will complete that as soon as next week with the BME 201 students. We will also analyzing the survey data from the preference testing and make some conclusions.

04/12/2024 - Advisor Meeting 8: Final Poster Information

EVA COUGHLIN - Apr 29, 2024, 12:04 PM CDT

Title: Advisor Meeting 8

Date: 4/12/24

Content by: Eva Coughlin

Present: Eva Coughlin, Anabelle Olson, Jenna Krause, Kasia Klotz, Tevis Linser

Goals:

- To update on our ShaRx Tank experience!
- To discuss next steps for final poster presentations

Content:

- Updated Prof. Puccinelli on ShaRx Tank win and our connection with Azita from Abbvie
    - Going to send her our executive summary and see if she can help with patenting
- Another option for patenting is L&E clinic (Law & Entrepreneurship)
- Showed the packaging options and suggested having instructions on the back
- Discussed idea for MyDropper logo to be printed on packaging
- People complimented us on the crossdisciplinary team!
- Discussed wanting to do FDA-regulated IRB study with administration of eye drops into patient's eyes
- Discussed increasing size of the poster to fit business model
    - Don't need to include both sizes of bottles
    - "Business Model" as the name of the section for the poster
    - Make sure to include all dimensions
    - Shrink down future work - only need to include future human subjects testing and new iteration of prototype that Tommy is working on
- Don't mention ShaRx Tank award on final poster for BME design
- Label prototypes for table and place them in order
- Have blank survey from preference testing and maybe we can include quotes from participants
- Still mention something about earlier testing
    - Still include CAD simulation of MTS testing
- She liked the marketing graphic showing the 1.18 million people
    - Change color of poster to fit theme
- Discussed the molds we would need to fit our different versions

Conclusions/action items: We are so happy to have won the ShaRx Tank competition and plan to send our executive summary to Azita once we have it finalized. We will also look into other options for patenting through L&E. We will continue working on the packaging and instructions, so that we're ready for poster presentations. Finally, we hope to make considerable progress on the poster this upcoming week.

04/18/2024 - Advisor Meeting 9: Final Poster Feedback

ANABELLE OLSON (amolson27@wisc.edu) - May 01, 2024, 1:34 PM CDT

Title: Advisor Meeting 9

Date: 4/18/24

Content by: Anabelle Olson

Present: Anabelle Olson, Jenna Krause, Kasia Klotz, Tevis Linser, Eva Coughlin

Goals:

- To get initial feedback on our final poster draft

Content:

- Testing Sections
    - Force testing - simulation: bottle isnt device so not very accurate representation of the force required to squeeze
        - Feedback: should still show something about analyzing the force because it was one of our top design criterias
        - Keep mts testing
    - Single drop test:
        - Do all trials in one graph to keep it simpler
        - Send email with box plot
            - Leaning towards box plot because there is not a significant difference in the means
            - Just one box plots for large bottle and one box plots for small bottle
    - Preference test:
        - Don't need the limitations theme, it sounds negative as if we should have done that testing
- Need labels on images
    - Such as “device goes here”
    - solidworks drawing of prototype
        - Only need length, width and diameter for measurements of the device
        - Also try to change the color of the background to make it white or a different color
    - Label on the circle photos: nose piece, platform rest
- Design criteria: try to keep it to one line per bullet
- Discussion: also try to keep it to one line per bullet, try to get rid of any of the conversational words
- Add a picture of a universal prototype to the future work
- Duration of poster presentation:
    - 10 mins for presenting to advisor
    - 5 mins for presenting to the Tong judges
- Decision matrix is in the competing designs - we can keep this here

Conclusions/action items:

The team will use this feedback to make more adjustments and tweaks to the poster. Additionally, we will continue to finish the testing data and charts to our advisor.

01/24/2024 - Team Meeting 1: Recap of Last Semester

KASIA KLOTZ - Jan 31, 2024, 11:29 AM CST

Title: Team Meeting 1

Date: 1/24/2024

Content by: Thomas Kriewaldt

Present: Thomas Kriewaldt, Kasia Klotz, Tevis Linser, Jenna Krause

Goals:

- Discuss SolidWorks actions for this semester
- Discuss team roles and semester meeting times
- Discuss changes to the progress report

Sources:

[1] “Thin Wall Injection Molding | Materials and Design Tips.” Accessed: Jan. 24, 2024. [Online]. Available: https://www.protolabs.com/resources/blog/thin-wall-injection-molding/

[2] nwmcadmin, “The Cost of Injection Molding Materials,” Rex Plastics. Accessed: Jan. 24, 2024. [Online]. Available: https://rexplastics.com/plastic-injection-molding/the-cost-of-injection-molding-materials

Content:

- Currently making the injection molded prototype
    - **The simulated outcome →**
    - Air traps exists on the mold but with air venting techniques this can be eliminated
    - Weld lines exist at multiple locations but not too concerning devices use because the stress lines will not have pressure on it.
    - Total Displacement was mainly isolated to the handles which is ideal since the bottle portion of the prototype barely displaces
    - Tevis and Jenna will consult with Prof. Lih-Sheng Turng about these results.
- Need to choose a new material
    - Not ABS, maybe PP polypropylene??
    - Consult Tom Turng → Tevis
- Need to consider packaging this semester
    - Package like a toothbrush
    - Cardboard back with heated plastic to form to the shape?
- Will our design be able to withstand shipping and packaging
    - Look up relevant standards to determine forces / other conditions
    - Will we need extra foam or cushioned material?
    - Should we make thin-walled injection molded parts?
- **We are thinking PP, polypropylene.**
    - Thin-walled materials and considerations show PP as one of the best [1].
    - Cost considerations are detailed in source [2].
- Need to find something that is similar to our device so we can compare and build off of it.
- Could zip-tie the device to packaging to ensure it does not move
- Could consider Clamshell package
    - Lower in cost, custom shaped to fit the products.
        - High pressure plastic injection
        - More robust than toothbrush packing
- Discuss packaging more as a collective team

Type of Thermoplastic Material	Unique Features	Common Applications	Price per pound
ABS	durable, lightweight	electronics, keyboards, phone hardware, LEGO bricks, drainpipe systems, kitchen appliances	$1.30
polyethylene	flexible, impact-resistant, leech resistant, moisture resistant, recyclable	food packaging, milk jugs, toys	$1.20
polypropylene	leech resistant, flexible	Tupperware, kiddie pools, toys, utensils, car batteries	$0.90
polystyrene	warp, shrink and impact resistant	compact disc cases, packaging applications, household appliances	$1.00
nylon / (POM)	heat-resistant, durable	high-ware parts, quick-release buckles, gears, hand cranks	$2.20
polycarbonate	impact resistant, optical clarity, vulnerable to chemicals	automobile headlights, bulletproof glass, eyeglasses, greenhouses, DVDs, mobile phones	$2.30

- Potential Changes (wait until Tevis and Jenna talk to Tom):
    - Create more rounded handle supports (so it distributes equally!!)
        - Curve it to flow plastic equally
    - Create a more solidified truss wall (again, so it distributes equally!!)
- For the design matrix – focus on packaging?
    - It is not required, but it would be good to have.

Conclusions/action items:

The full team will meet on Friday an initial advisor meeting to discuss goals and expectations for the upcoming semester. The team will schedule a client meeting to discuss new prototype iterations, as well as continue working on WARF and IRB applications. Lastly, the team should complete all BME first day activities by Friday afternoon.

01/29/2024 - Team Meeting 2: Semester Goals

Jenna Krause - Feb 09, 2024, 3:20 PM CST

Title: Team Meeting 2

Date: 1/29/2024

Content by: Kasia Klotz

Present: Thomas Kriewaldt, Kasia Klotz, Tevis Linser, Jenna Krause, Eva Coughlin, Anabelle Olson

Goals:

Discuss the following:

-
- Outreach
    - Boundaries
    - Expectations for each other
    - Project selection
    - Client profile
- Semester deadlines and expectations
- Team roles
- Goals for the semester
- Training completion pending IRB approval
    - Everyone should have received an email about what needs to be done

Content:

-
- Outreach
    - We will come up with the project and present that, suggest deliverables
    - Need to know what resources they have
        - CAD
        - Tools
    - Do not want to have a to have a ton of out of class work
    - 8-10 week program
    - Sun Prairie East High School
    - Project idea:
        - TBD
- Everyone needs to complete training for IRB as soon as possible
- New progress report template
    - Ask if recording the hours are fully necessary
- Goals for the semester
    - Get initial IRB approved
    - Complete initial testing
    - Submit second IRB
    - WARF application
        - Ask Beth which iteration she prefers so we know which design to move forward with
    - Need to begin thinking about preliminary presentations

Conclusions/action items:

The team will finish creating the introduction presentation for outreach on Thursday. Any questions about outreach can be asked at the meeting at 5:30pm. Team members must complete any necessary training for human testing as soon as possible in order to receive IRB approval. A client meeting is scheduled for Friday where the team will update the client on design progress, including

presenting the most recent iteration of the design. Feedback from the client will determine which design is used in the application for WARF.

02/05/2024 - Team Meeting 3: Preliminary Presentation and IRB

Jenna Krause - Feb 09, 2024, 3:19 PM CST

Title: Team Meeting 3

Date: 2/5/2024

Content by: Kasia Klotz

Present: Kasia Klotz, Tevis Linser, Jenna Krause, Eva Coughlin, Anabelle Olson

Goals:

Discuss the following:

- Preliminary presentation
    - timeline
- Initial IRB application
- Future IRB application
- WARF application

Content:

- Preliminary presentation
    - Creating draft to present to advisor tomorrow
    - Create an updated timeline to include all testing and future applications
- Initial IRB application
    - Make changes suggested
    - Everyone needs to compete required testing
- Future IRB application
    - For accuracy test on human
    - Addendum to initial IRB (hopefully)
    - Goal is to do this when client is back from Florida
- WARF application
    - Ideally would submit this on Tuesday after deciding who needs to be included as inventors

Conclusions/action items:

The WARF application was submitted at this team meeting. The team will prepare an initial draft of the preliminary design presentation for advisor meeting on Tuesday. During today's meeting, the team created a detailed time line for the rest of the semester. The team plans to assist in creating the presentation for Shark Tank at the School of Pharmacy.

02/12/2024 - Team Meeting 4: Warf Meeting and Lots of Logistics

EVA COUGHLIN - May 01, 2024, 9:59 AM CDT

Title: Team Meeting 4

Date: 2/12/2024

Content by: Eva Coughlin

Present: Kasia Klotz, Tevis Linser, Jenna Krause, Eva Coughlin, Anabelle Olson

Goals: To discuss team goals for the week and the journal article for BME 402.

Content:

- We are confused on the journal article requirements so we are reading it over
    - Due on 2/28
    - Goal is to choose a journal this week and to start the article in the shared drive
        - Journal of Pharmaceutical Technology, Manufacturing, and Devices (MDPI)
        - Journal of Medical Devices
        - Decided on *Journal of Assistive Technology*
- Ryan emailed us about lawyers and we need to respond and prepare for meeting on Friday
    - He sent us email about meeting with the law school on March 5th (9:30-10 AM)
    - Ryan mentioned D2P with Aimee Arnoldussen, we can schedule an appointment with her
    - Ryan said he will share Shark Tank slides with us
- Tevis got more eye drop bottles
- Eva needs help with finishing screening document for IRB
- Discussed meeting with WARF last Friday
- Need to remodel prototype and coordinate with Tommy
    - Remodeling needs to be done before mold for injection molding can be completed
    - Does the Makerspace have polypropylene?
        - Yes, need to print prototypes in this material
        - We need the material choice finalized before fatigue testing
- We can start making an addendum to IRB as soon as possible

Conclusions/action items: We decided on the journal we are going to use and created goals for the week in terms of making progress on that. Eva, Kasia, and Anabelle are going to focus on finishing the screening document for the first IRB edits as well as starting the IRB addendum for the second human subjects testing. Jenna and Tevis are going to focus on injection molding. Tommy and Tevis will do some redesigning of the prototype in order to make it easier to injection mold and they will reprint in polypropylene.

02/19/2024 - Team Meeting 5: Journal Article

KASIA KLOTZ - Feb 19, 2024, 3:17 PM CST

Title: Team Meeting 5

Date: 2/19/2024

Content by: Kasia Klotz

Present: Kasia Klotz, Tevis Linser, Jenna Krause, Eva Coughlin, Anabelle Olson, Tommy Kriewaldt

Goals:

- Discuss journal article
- Updates on IRB
- Research topics

Content:

- Decided on a journal article to follow
    - Going with a comparison to show the difference between the use of the device vs just using the eye drop bottle
    - Unsure of how to approach each of the individual test
        - All methods should be together and then all results should be together
        - Single drop test and preference test are most important
    - Emailing advisor to verify the outline we want to use for the journal
- Eva is addressing the IRB feedback
- Research will be focused on the marketing side of the device. This will help prepare the team for Shark Tank

Conclusions/action items:

The team will spend the next few days adding research entries to lab archives. The team will also work on completing the journal article. The IRB will be re-submitted as soon as Eva finishes the changes based on the given feedback. The team hopes to hear from Ryan soon about the Shark Tank template so the draft can be completed by the end of February.

03/04/2024 - Team Meeting 6: Outreach Planning

KASIA KLOTZ - Mar 04, 2024, 9:00 PM CST

Title: Team Meeting 6

Date: 3/04/2024

Content by: Kasia Klotz

Present: Kasia Klotz, Tevis Linser, Jenna Krause, Eva Coughlin, Anabelle Olson, Tommy Kriewaldt

Goals:

- Discuss upcoming meetings
- Discuss testing plan
- Create a list of what we need for outreach

Content:

- Schedule for the week
    - Monday
        - team meeting
        - each member needs to fill out doc for Eva's update email
    - Thursday
        - Outreach at 3:45pm
        - Retirement community for human testing at 5:30pm - 7:00pm
            - Tevis will print seven of each the brow bone and the nose bridge support prototypes, both for the larger bottle size
- Review content from Dr. P's email
    - Eva sends update email on Mondays
- Eva and Kasia will meet with George on Friday and then with Mark from Harrow Ophthalmics on
    - Need to improve shark tank presentation
    - Need to get a quote for single unit price for injection molding

Conclusions/action items:

The team has a very busy week ahead. Tevis is printing prototypes preparing for the preference testing that will happen Thursday evening. Recruiting began today via flyers that were printed and distributed by the client. The team plans to schedule a meeting to discuss how to make the addendum to the initial IRB application in order to complete precision and accuracy testing on humans.

03/11/2024 - Team Meeting 7: Packaging and Meeting with George

KASIA KLOTZ - Mar 11, 2024, 4:11 PM CDT

Title: Team Meeting 7

Date: 3/11/2024

Content by: Kasia Klotz

Present: Kasia Klotz, Tevis Linser, Jenna Krause, Eva Coughlin, Anabelle Olson

Goals:

- Go over schedule for this week
- Discuss content of meeting with George
- Make a testing/IRB plan
    - Accuracy testing
    - Single drop test
    - List of questions for IRB meeting today
    - Make addendum to current script
- Discuss packaging plan
    - Half of the team on IRB, half on packaging?

Content:

- Addendum to current IRB script
    - Have another question
        - Based on your experience today, would you prefer to dispense your eye drops with the device or without the device?
    - What do we need to do to have another testing session?
- New IRB
    - Do we need IRB approval for the single drop test?
- Schedule
    - Monday: team meeting, IRB meeting at 1:00pm
    - Thursday: outreach
    - Friday: tong lecture, preference testing at Oakwood
        - Need to decide on time for testing, possibly canceling advisor meeting
- Meeting with George
    - Talk to Kip about the predicted market and sales values
    - Want to be able to quote him in ShaRx Tank and final poster presentation
    - Find an estimated cost for injection molding of a certain number of units
- Packaging
    - Need a price estimate per unit
    - Might want an example for final presentation

Conclusions/action items:

Kasia, Eva, and Anabelle will meet with the IRB consultant to discuss what is needed for current and future testing. Then, they will begin working on the next application. Tevis and Jenna are doing more research on injection molding and packaging. Specifically, they are trying to find a price estimate so the team can create a more accurate business model.

03/18/2024 - Team Meeting 8: Testing Plans

KASIA KLOTZ - Mar 19, 2024, 9:27 AM CDT

Title: Team Meeting 8

Date: 3/18/2024

Content by: Kasia Klotz

Present: Kasia Klotz, Tevis Linser, Jenna Krause, Eva Coughlin, Anabelle Olson

Goals:

- Review Prof. P's feedback for notebook
- Discuss new plan for testing
    - Plan to analyze preference testing results
    - Plan to conduct single drop test
        - No IRB approval needed
- Discuss plan for finishing out the semester
    - Need to add appendix to journal article
- Prepare for awards
    - ShaRx Tank
        - Keep working on slides
    - Tong
        - Look into requirements and start preparing executive summary

Content:

- Lab Archives
    - Add more descriptive titles to lab archives entries
    - Copy and paste important documents
- Testing
    - Not doing the last round of human testing
        - Not enough time to create testing protocol, client says that it is a new territory for her
    - Single Drop
        - Week following spring break, using 201 kids
        - Population does not really matter because it is quantitative
        - Tuesday or Wednesday at 2:25pm - 5:25pm
    - Analyzing data
        - Single drop
            - Show individual results
        - Preference test
            - Utilize chat GPT for suggested methods
            - Create an excel spreadsheet with combination of results
- Plan for rest of semester
    - Eva and Kasia will meet with Mark today from Harrow Ophthalmics
    - Will try to get quotes/professional opinions that can be used in upcoming presentations
    - Tong requirements
    - ShaRx Tank
    - Packaging
        - Print labels
            - Tommy create image for label?
            - Order small cardboard box?
- Meet with client April 5th
- Hearing back from WARF on the 22nd

Conclusions/action items:

The team will review testing protocol for single drop test and conduct testing after spring break. The team will also work on creating the package “prototype”. Pictures need to be taken of the prototype to be placed on the label. Eva and Kasia will meet with Mark and find out what information will be most important for SharkRx. Eva is sending an email to set up the final meeting for outreach.

04/01/2024 - Team Meeting 9: Single Drop Test and ShaRx Tank

ANABELLE OLSON (amolson27@wisc.edu) - Apr 08, 2024, 11:10 AM CDT

Title: Team Meeting 9

Date: 04/01/2024

Content by: Anabelle Olson & Kasia Klotz

Present: Team

Goals:

- Discuss testing plan for single drop test
- Finalize ShaRx Tank presentation/discuss plan
- Figure out what is happening with outreach
- Executive summary

Content:

- Single drop test:
  - Date: Tuesday 4/1 - 5:30 pm
  - Hoping to get 8-10 subjects
  - Can reevaluate after Tuesday to see if we need another testing day
- ShaRk Tank:
  - Finish slides by Tomorrow (4/2) 4:30 pm
  - Ask Ryan about the ShaRx presentation tomorrow
  - 15 min presentation
  - Market plan: make it work with Mark's product and sell it to him
    - Make it theoretical
- Outreach: need to understand the plan for presentations this week - Eva is sending an email
  - This Thursday is last thursday? Presentations and wrapping things up/celebration?
- Executive summary:
  - Draft due Friday (4 / 5)
  - One page only, single space

Conclusions/action items:

The team has a lot going on this week. Tomorrow we are meeting with the board of ShaRx Tank to practice our presentation and get final feedback. Additionally, the draft of the Tong executive summary is due this Friday. We are going to work towards analyzing the testing data this week and next week.

04/08/2024 - Team Meeting 10: Analyze Testing and Finalize Packaging

THOMAS KRIEWALDT - Apr 30, 2024, 10:04 PM CDT

Title: Team Meeting 10

Date: 4/8//2024

Content by: Tevis Linser

Present: Kasia Klotz, Tevis Linser, Jenna Krause, Eva Coughlin, Anabelle Olson

Goals:

- Finalize ShaRx Tank Slides
- Executive Summary should be turned in
- Analyzing testing results
- Design Notebook Check-in
- Begin Discussing Final Poster

Content:

- Analyze both testing
    - Single drop: Eva and Anabelle
    - Thematic analysis for preference testing: Tevis and Anabelle
- Info/ instructions pamphlet for the device?
    - Jenna can make something for this - Tong
    - Use images (maybe duncan and anabelle)
    - Write steps and have drawing
- Packaging should be coming in soon
    - Jenna got email from Debbie Green
- Forwarded ShaRx tank feedback to Ryan
- Put responses spreadsheet in IRB folder in LabArchives
- Kasia to come up with cost savings for ShaRx tank
- Ask Beth to go first for ShaRx so Dr. P can see it?
- Same stats on this round of single drop test
    - F-Test (variability) and T-Test (averages)
- Jenna to start making the Poster - try to start working on it ASAP (after sharx tank)
    - Will have more room with less testing
    - Reduce background info
- Look for source for 91%... fact so Ryan can vocalize it during pitch
    - Journal of glaucoma study
- Ask Kip about gross profit vs revenue for business model

Conclusions/action items:

We can start gearing up for our poster after ShaRx tank.

Action: Analyze all testing, finalize and practice ShaRx Tank pitch, begin working on Poster, being finishing up packaging/labeling/pamphlet

04/15/2024 - Team Meeting 11: Final Poster Discussion

Jenna Krause - Apr 30, 2024, 7:34 PM CDT

Title: Team Meeting 11 - Final Poster Discussion

Date: 4/15/2024

Content by: Jenna Krause

Present: Kasia Klotz, Tevis Linser, Jenna Krause, Eva Coughlin, Anabelle Olson

Goals:

- To work on the final poster presentation

Content:

- Executive summary
    - Send to Azita to get feedback from Abbvie
    - Wait for feedback from Prof. Puccinelli before sending it to her
- Work on the marketing images for the poster presentation
- Discuss final poster presentation
    - Get rid of precision testing in final poster
    - Add in preference testing to the testing section
    - Look into alternatives for box plot to save room on poster
    - Keeping single drop test data in the
    - Future work will be squeezed down into 3 bullet points
    - “Business Model” will be placed between the discussion and future work
- Anabelle is finishing images for instructions manual
- Jenna and Eva will work on features for the packaging items
- Tommy is working on logo for the final packaging box
- Email Dr. Martin for recording of ShaRx Tank and pictures from the events
- Email Thank Yous to George Zorich for organizing ShaRx Tank

Conclusions/action items:

The team made edits to the final poster based on feedback from the advisor meeting. The team discussed feedback from the ShaRx Tank presentation and thoughts on how to improve on it in the final poster. Future work for the team needs to send thank you emails to the organizers of ShaRx Tank as well as send executive summary to Azita (COO of Abbvie).

04/29/2024 - Team Meeting 12: Semester Wrap-Up

EVA COUGHLIN - May 01, 2024, 9:58 AM CDT

Title: Team Meeting 12

Date: 4/29/2024

Content by: Eva Coughlin

Present: Kasia Klotz, Tevis Linser, Jenna Krause, Eva Coughlin, Anabelle Olson, Thomas Kriewaldt

Goals:

- To discuss plans for final deliverables and wrap up the semester

Content:

- Wednesday - presenting to medical professionals in Senegal? Does anyone have time?
    - No - classes, finals, and work
- Added comments to final journal article, so we need to edit it based on those
- Need to add appendix and add testing to journal article
    - Anabelle and Tevis will add thematic analysis
    - Eva will add single drop testing
        - Redid this testing, should we add box plots to appendix or to the body?
    - Add protocols, survey, raw data, and PDS to appendix
    - Need to add to conclusion
- Add everything to LabArchives!
- Feedback fruits initial feedback is due on Wednesday and reflection is due on Sunday night
- Dinner at Tommy’s house on Friday night to celebrate!

Conclusions/action items: This is our final meeting of the semester and we discussed what we still need to complete. The main priority is updating the journal article and editing it based on prior feedback. We have a couple questions on where new information should be included for the article, so we are going to clarify that with Prof. Puccinelli. We will also update LabArchives and complete Feedback Fruits by Wednesday night.

02/06/2024 - Expert Meeting: Injection Molding at UW

Jenna Krause - Feb 22, 2024, 9:39 AM CST

Title: Expert Meeting 1 - Injection Molding

Date: 2/6/2024

Content by: Jenna Krause & Tevis Linser

Present: Jenna Krause & Tevis Linser

Goals: To learn more about injection molding possibilities for prototype

Content:

- Tevis and Jenna meet with mechanical engineers within UW-Madison who expertise are in Injection Molding
- Design Feedback:
    - Jetting issues with gate location of the part at the top
    - Suggested 3D printing the mold
        - WID injection molding mold base
    - SolidWorks add on to make a mold
        - Injection molding cavity
    - Make triangle one part
    - Modular with different heights (or complex mold)
        - One mold for larger U handle, One for smaller parts (use pins)
- Materials:
    - PE(3) (more engineering option uses this) or PPE(2), polypropylene (PP) mid weight 100-150
    - HDPE (too flexible), PA6 Nylon test in humidity chamber
        - Test Nylon a few days later once it reaches equilibrium
    - PET(1) - control crystallinity
        - Also can control compliance & thickness, One of the most used plastics
    - PP (polypropylene) is one of the more ideal materials for eye drop bottles due to its cheap price as well as the stiffness in material.
    - Look into bottle materials
        - Most bottle materials have a resin number on them. Triangle with a number inside of it. “Type 5” is an example
- Testing:
    - Ideal testing is 3-point bending
        - Compression testing is an option but very difficult to test.
        - Tensile testing not ideal
    - Displacement of bottle, not handles
    - Make the press piece wider variety
    - Point force can be distributed across an area so it is okay to have the force at one singular point location.
    - Use a rope to stabilize one side and then pull the other. Measure it on a Newton Meter Machine.
    - Look into FEA interface on Moldex3D

    - Export the mesh from Moldex3D then you can simulate testing online on this finish injected digital print
    - Take mesh into Digimat
    - Gives structural analysis
- Mention an open conference on March 8th at Monona Terrace.

Conclusions/action items:

By collaborating with UW-Madison engineers, the team received feedback on Injection Molding, focusing on material choices like PE(3), testing methodologies such as 3-point bending, and exploring Moldex3D for structural analysis.Action items for the team is to redesign the part in CAD to incorporate the multi pieces that will correspond to the 3D printed mold. In addition, run a simulation through the FEA interface to see how successful the design is with each material option.

02/09/2024 - Expert Meeting 2: Initial WARF Meeting

KASIA KLOTZ - Mar 18, 2024, 10:11 AM CDT

Title: Expert Meeting 2 - WARF

Date: 2/9/2024

Content by: Jenna Krause

Present: Jenna Krause, Kasia Klotz, Eva Coughlin, Anabelle Olson, Tevis Linser

Goals: To learn more about the WARF process and next steps

Content:

- WARF General INFO
    - Brain Frushour and Michael Carey
    - 30/40 disclosures sent into them each month
    - March 21st is a meeting where all the staff and lawyers get together to discuss possible disclosures to accept
    - In this staff meeting about 30-50% disclosures are accepted
    - If we get accepted, the next meeting will be with a patent attorney
    - There is a year wait to hear anything, then 3-5 years to licenses anything
    - All the inventors would agree to sign ownership to WARF
    - If there is an profit then 20% to inventors, 15% would go to the department
- Project Background
    - The team went through the background of the project with the WARF team and what is the motivation and need for our device.
    - Explain how are device ensures proper location and squeezes one drop
    - Explain how the team’s device captures a larger market not just elder patient
    - Eye drops currently on the market, Just normal squeeze bottles
    - Asked about overdosing is an issue for the patients
        - Talk about the team’s research in drop size.
    - Discuss improvements we made to the device. Explain how the prototypes have two different stability attachments but the rest of the device is the exact same with the mechanical advantage features.
    - Asked the team how do we determine if less force is used to squeeze the bottle.
        - Talk about user preference tests.
        - Discuss the mechanical advantage of using whole hand vs using only your fingers
        - Discuss using the wider handles

        - Asked about utilizing a stopping mechanism for certain bottles.
            - Discuss how the force slightly changes with the bottle
    - Asked about adjustment with the stability mechanism
        - Nose Piece would need to be an adjustable material while the platform would be the same for each device.
    - Discuss current competitors on the market and the patents on the market.
        - Talk about the 2 amazon items and the drawbacks
        - 2 patents of Bandolier Cartilage and the lower eyelid ones.
        - Discuss how the claims are broader than the actual device to make sure it encompasses everything as well as future refinement.
- Future Work
    - Brian is going to do his own patent research to see if anything pops up.
    - Michael will do market research and see if there is a need to be met there.
    - These smaller devices are sometimes harder to license because it is very inexpensive so the profit margins are tighter so the royalties are expensive to pay back then.
    - First to market and brand recognition is more important than patents sometimes.

Conclusions/action items:

The team met with Brain Frushour and Michael Carey who work with WARF. They discussed the disclosure process. The team highlights their eye drop device market appeal, design enhancements, and competitor analysis. Brian and Michael outline plans for future research and market exploration. Action items for the team is to wait to hear back from the WARF team from their March meeting.

02/20/2024 - Expert Meeting 3: IRB Consalt

EVA COUGHLIN - Feb 20, 2024, 8:19 PM CST

Title: Expert Meeting 3 - IRB Meeting

Date: 2/29/2024

Content by: Eva Coughlin

Present: Eva Coughlin, Laura Conger

Goals: To learn more about the last few necessary edits to the IRB that require further discussion and learn about next steps following IRB approval.

Content:

- Laura and I met over Zoom because I had a couple questions on the last few edits of the IRB
- I should keep the exclusion criteria as “Unable to communicate feedback on device or answer survey questions due to language barrier or impaired mental capacity.”
- Question on survey to address language barrier, “Do you feel comfortable communicating in English with the study team? Do you feel comfortable reading and comprehending a survey written in English?”
    - If the potential subject answers no then they would not be eligible to participate in the study
- Question on survey to address impaired mental capacity:
    - Options were to include mini mental exam as part of screening or a teach back method
        - Decided to include teach back method as part of screening
            - Question on screening would be: “Did subject clearly have mental capacity to consent?”
        - In section 10.2 on IRB protocol, include that mental capacity is going to be assessed using teach back method - potential subject will verbally give a brief description of the study team’s expectation of them in order for us to determine if they understand what they’re supposed to do
- Ryan is going to complete the trainings tomorrow, so I will be able to update the edits and resubmit the IRB Thursday
- Going to email for additional questions but these are the biggest edits I was struggling with
- Once the IRB is submitted, Laura will approve it within a day or so, and then we will receive a certification of IRB approval and be able to start the study when we choose

I was thinking of deleting the "due to language barrier or impaired mental capacity" in the exclusion criteria and editing it to "Unable to communicate feedback on device or answer survey questions." Then for the screening questions, I would replace number 4 with "Do you feel comfortable communicating in English with the study team? Do you feel comfortable reading and comprehending a survey written in English?"

Right now, we have written, "Survey feedback will be anonymously filled out and stored securely by lead investigators." I know we have to be more specific about this. Would this be acceptable: "Survey feedback will be anonymously filled out. These feedback documents will be filed and stored securely by the lead investigator Beth Martin at her office at UW Pharmacy School."

-

Conclusions/action items: I met with Laura on Zoom this afternoon to clarify the last round of edits on the IRB that I was struggling with. She was able to explain to me what she means by specifying language barrier and impaired mental capacity in the IRB exclusion criteria. She gave me advice on how to address these issues, and I may double check them again with her before submitting the IRB officially. We should have the IRB submitted and approved by the end of the week.

02/23/2024 - Expert Meeting 4: Cardinal Health

Jenna Krause - Feb 23, 2024, 3:12 PM CST

Title: Pharmacy Operations - Cardinal Health Meeting

Date: 2/23/2024

Content by: Jenna Krause

Present: Jenna Krause, Kasia Klotz, Anabelle Olson, Tevis Linser, Beth Martin

Goals: Discuss industry aspect and opportunities

Content:

- Debra Fluno
    - Got her doctrine from Minnesota
    - Practice clinical pharmacy on the hospital side
    - Works at Cardinal Health
        - 2 Division Pharm division/Medical division
- Updated Debra on the team's design and motivation and get feedback
    - Discuss Market areas to sell
        - Retail is a main target, hospitals might be questionable and could be a harder market to target with nurses.
        - Pharmacies could be another market
        - Parents that have kids with eye infections is another market
    - Market Perspective: a lot of the antibiotics are another expensive area
    - How would you price it?
        - Look at current products on the market and price it based on that
        - Also, need to think of production cost
        - Might not buy it right away, but the overall net price for
    - Look at the packaging of the competitors products to see where they might be doing their manufacturing (could be on the label).
        - Abbvie, medline, uline
            - Look into their products line to see if these companies are
    - Packaging
        - How stable/durable is the team's design.
        - Box structure might be more stable than being free by itself
        - Box would be cheaper option compared to a clamshell option
        - Want packaging to illustrate a photo of the device so the buyer can understand its use and function.
    - Look into data for amount of eye drop bottles used in a year
    - Look into competitors with how long they have been in the field and how much they make in a year.
        - What is the market share of these specific competitors?
        - Make a table breakdown to visual compare to the competitors
    - Updated on WARF process and other engineering opportunities like design 2 product.

Conclusions/action items:

While talking about the team's design and motivation, importance was placed on potential markets, with retail being a main target. Pricing considerations involve analyzing competitors, production costs, and choosing packaging. Action items for the team is more research into market analysis. This would include packaging research and competitor research analysis.

02/26/2024 - Expert Meeting 5: D2P

Jenna Krause - Feb 26, 2024, 11:52 AM CST

Title: Discovery to Product (D2P) Meeting

Date: 2/26/2024

Content by: Jenna Krause

Present: Jenna Krause, Kasia Klotz, Anabelle Olson, Tevis Linser, Eva Coughlin, Thomas Kriewaldt

Goals: To meet with a Discovery to Product (D2P) employee and get advice on next steps

Content:

- Discuss the team's prototype and motivation for the project. Get feedback from Aimee.
    - Try to get as much feedback from WARF as possible so if the team goes to pitch the device they can discuss that they talk to experts in the field.
    - Laying out on a slide the team's market competition
        - No device only using fingers, Gentle Drop, etc
        - Aware of the competition and know where the team's product differs
            - "Similar to our prototype, however it is lacking ___, so it misses a large part of the market.."
        - Spatial chart, one is credibility and another axis is function
            - Check boxes is an option
            - Need to show the benefits, "successfully administer drops, yes or no"
    - Make sure to set up the problem well in the beginning of the presentation
        - "Our typical user is ….."
        - Set up for a narrow customer market
    - On the pitch, spend more time on where the device is going and the team's strategy for the market.
    - "How are you going to transition to manufacturing"
        - Look into talking to a few companies
            - Calculation of volume is going to be a factor
        - Discuss the price per unit to see if it is worth to do
        - Try to talk to companies that do injection molding to get a quote
            - Setting up the mold is the biggest expense
            - Outside the university quote is the best estimate of cost.
    - If a patent does go through it would be a design patent
    - The team would not need a patent for the start up, the goal would be bought out by a company but would need a client base for this to happen.
    - Go to PitchBook is another website to use
        - Go ot wisc.edu, type pitchbook, copy and paste the url, create a free account
        - Gentle drop = BeDo solutions LLC
            - LLC do not get external funding
    - The team can reach out to competitors or experts in the field to see if they would acquire it.

        - Risk of this is they could take the design for themselves.

    - For shark tank propose the team is doing a startup with a longer goal in mind

Conclusions/action items:

The team met with Aimee Arnoldussen, an expert within D2P, on advice for Shark Tank presentation. Also, the team got feedback on future pathways for the prototype. Action items for the team is to finalize the shark tank presentation draft to review with the pharmacy board. Attend WARF meeting in March to see if a patent was approved for the team

02/27/2024 - Expert Meeting 6: ShaRx Tank Meeting

EVA COUGHLIN - Feb 28, 2024, 6:36 PM CST

Title: ShaRx Tank Meeting

Date: 02/27/2024

Content by: Eva Coughlin

Present: Eva Coughlin, Ryan Smith

Goals: To present the draft of our ShaRx Tank pitch slides and get feedback.

Content:

- Ryan and I presented the rough draft of the team's ShaRx Tank slides (attached below)
  - this was intended to be a very rough draft, so that the event coordinators of ShaRx Tank are able to give us direction and talk through our product as well as our delivery of the information
- Loved the MyDropper graphic that Tommy created for our product!
- Device prototype slide was very busy and potentially distracting
  - once we decide on eyebrow platform vs. nose bridge we will be able to eliminate half of this slide
- Loved the competitive landscape chart, but we need to add prices to the devices
- Explain that device can be used in an expanded market
  - caregivers, parents administering kids eye drops, in addition to the elderly
- Include proper eye drop technique discussion before discussing how device ensures proper eye drop placement
- Mentioned possibility of including a video of administration in the presentation
  - will have prototypes in-person for judges too
- Need to introduce ourselves as BME students and Ryan as a pharmacy student
  - gives us more credibility and expertise
- Beyond just estimating product cost, we should try to estimate how much we think we could sell in the first year being available
  - this estimation should be based on prevalence of eye disease, number of prescription drops dispensed, insurance rejection claims data on eye drops, etc.
  - provides a more compelling business model
- Instead of having references at end of presentation, put them at the bottom of the slides they're used in with small font
- Less words on slides in general
- George Zorich (CEO of ZedPharma) is the creator of ShaRx Tank at the Pharmacy School
  - called our product prime time for market!
  - recommended potentially connecting with Harrow Health to pitch our product to them
    - he will reach out to his connection, Mark Baum (CEO of Harrow Health) for us (https://www.harrow.com/index.html)

Conclusions/action items: The practice pitch for ShaRx Tank went well, and we received very helpful feedback. The team will begin making these changes progressively throughout the semester, so we don't have to make all of these changes the week of the presentation. The biggest thing we need to focus on is our business model and making sure the slides are not academic. Finally, we have already been in contact with George Zorich regarding Harrow Health and will stay updated on this connection.

EVA COUGHLIN - Feb 28, 2024, 5:08 PM CST

Download

ShaRx_Tank_Presentation.pdf (1.54 MB)

03/08/2024 - Expert Meeting 7: George Zorich

KASIA KLOTZ - Mar 11, 2024, 9:57 AM CDT

Title: Meeting with George Zorich

Date: 03/08/2024

Content by: Kasia Klotz

Present: Kasia Klotz and Eva Coughlin

Goals: prep for meeting with CEO of Harrow Opthalmics, Mark L. Baum

Content:

- Presented current shark tank slides
  - should select 3 slides that summarize our talk and send them to Mark in advance before the meeting'
    - competitive landscape slide
    - MyDropper slide
    - Market size slide
- Regarding predicting the market size
  - look into current market for assistive devices
  - emphasize stats showing how many people currently use eye drops
  - touch on the variety of market (elderly, adolescent, caregivers)
- Discuss initial feedback from preference testing
  - may be useful to have direct quotes from users
- Really important to ask HIM questions, and also pitch why selling our device would benefit hi,
- Remember, we are claiming to reduce the amount of drops being dispense from the eye drop bottle which could be a low point for him since he sells eye drops
  - emphasize that with current methods, people become frustrated and oftentimes miss doses or just stop using drops all together
  - our device will encourage users to follow their treatment plan and therefore continue using eye drops
  - device could be sold with each bottle

Conclusions/action items:

This meeting with Mark will be a great networking opportunity for the team. Even if it does not directly lead to the product being sold through Harrow, the team can reference the conversation as validation for points that will be made in ShaRx Tank. Being able to reference a professional in the field increases the team's credibility on the matter. This will also be useful during final poster presentations.

03/11/2024 - Expert Meeting 8: IRB Consultation

KASIA KLOTZ - Mar 11, 2024, 4:11 PM CDT

Title: IRB Consultation Meeting

Date: 03/11/2024

Content by: Eva Coughlin and Kasia Klotz

Present: Eva Coughlin, Kasia Klotz, Anabelle Olson, Stephanie Metzgar

Goals: ask questions regarding current IRB applications and future applications

Content:

- Would not require a change of protocol for the user preference testing as long as we don't have repeats of the same participants!
    - Would be possible to change survey questions if we submit it today or tomorrow to make it for Friday
    - Current have this scheduled for this Friday at 10-11:30
- Single drop test - do we need an IRB?
    - We clarify that we would not be collecting any data on participants for this test
    - Might not require IRB approval → she is going to look into it for us and check with Jake Rome
        - She doesn't think it requires approval but wants to know
    - Explained different definitions of human subjects for research which makes things more complicated
- Asked if FDA needs to be involved and why
- New IRB for administering eye drops in eyes will be another protocol-based application
    - She says it will still be classified as minimal risk
    - Is this feasible in time for the rest of the semester?
        - Because it's FDA regulated we don't have expedited review like our first one did so it makes it more complicated → probably not because the process is going to take very long
- Sending me templates and other documents that are on the website
- With it being a retirement community and elderly population, cognitive capacity to consent is main concern
    - Talked about how this came up in last protocol and she said it was good that we used the teach back method
        - Use question examples from Alzheimer's studies, she will send them
- Need to describe our population in detail so IRB will understand we will not have issues with capacity to consent due to it being a retirement community, not a nursing home
    - Also administering their own eye drops already
    - Mention it would be a lot of the same people probably
- Why does this need to be FDA-regulated?
    - Testing the safety or efficacy of a medical device!
    - DO NOT need FDA approval for this device
    - This is investigational
    - Need to include why our device is not a significant risk medical device
        - She will send a link to the checklist
- She said we have put more thought into this than some of the MD/PhD students do

Conclusions/action items:
A request has been submitted to change the survey being used in the preference testing. There does not need to be a change to the IRB in order to complete another test on Friday, as none of the participants are participating more than once, and our application specified one round of testing per participant. We are waiting to hear back about whether or not we will need IRB approval to complete the single drop test. We need to submit the application for the next round of human testing involving the administration of

eye drops directly into the eye as soon as possible so there is enough time to review. This application may take longer to review than the last one because the study will be FDA regulated.

03/18/2024 - Expert Meeting 9 - Mark Baum from Harrow Health

EVA COUGHLIN - Mar 18, 2024, 8:47 PM CDT

Title: Meeting with Mark Baum from Harrow Health

Date: 03/18/2024

Content by: Kasia Klotz and Eva Coughlin

Present: Kasia Klotz, Eva Coughlin, Mark Baum

Goals: To get a third party opinion on our device from an ophthalmic professional.

Content:

- Introduce us
- Tasked with creating an eye drop assistive device that eases the administration of eye drops, especially for the elderly and those with dexterity issues, and therefore leads to more patient adherence to their prescriptions
- Questions
    - We've done some research on your company and were wondering if you could give us a brief overview of your company and your mission statement first hand?
    - With a company that prides itself on providing value to eye care providers and patients and providing access to innovative and affordable medicines in service, would a device like this that reduces drop size and makes patients prescriptions last longer further emphasize your company's values?
    - Do you see a need for a device like this in the field?
    - Have you seen other eye drop dispensers on the market and what do you like/dislike about them?
    - How would you describe the market for a device like this?
    - What strengths do you see in this device, and what advice do you have on pitching this device?
- Tons of assistive devices on the market that he has seen
- Talked about the new eye drops that they just launched Vevye (water free)
    - Surface tension is different which makes it difficult because you don't need to squeeze the bottle for drops to come out
        - He said if we could build a device that was geared towards one of his products specifically, he'd buy all of them
- Biggest weakness with our product is the lack of adaptability for different faces with the nose piece and not universally fitting all bottles
- Focus our energy on consumer preference! (we shared that we already did preference testing at the retirement community and he thought that was great)
- If you make this design "bulletproof", you can charge much more than your competitors
- Many patients don't use assistive devices (probably around 5% he thinks)
- Acknowledges a huge problem with eye drop administration and that if we can make our device more universal, there is a huge area of opportunity
- He mentioned that he has talked to Nanodropper company in the past
    - Liked how our device doesn't cause any contamination risk (by not touching the bottle tip or the eye directly), unlike the Nanodropper
- Create a unified experience! A foolproof method of getting the eye drop in the patient's eye. Consistency!

- Expand our market for ShaRx Tank presentation - anyone who puts in eye drops

Conclusions/action items: We had a great time talking with Mark Baum, getting to know him and getting his feedback on our product. He admired the product, pointing out both strengths and weaknesses. He also discussed the possibility of sending us eye drop bottles that Harrow creates to see if they are compatible with our design. We are going to follow up with him over email and thank him for his time today.

2024/04/15 - Retractable Prototype: SolidWorks Model and Dimensions

THOMAS KRIEWALDT - Apr 15, 2024, 9:43 PM CDT

Title: Retractable Prototype: Solidworks Model and Dimensions

Date: 3/31/2024, 4/13/2024

Content by: Thomas Kriewaldt

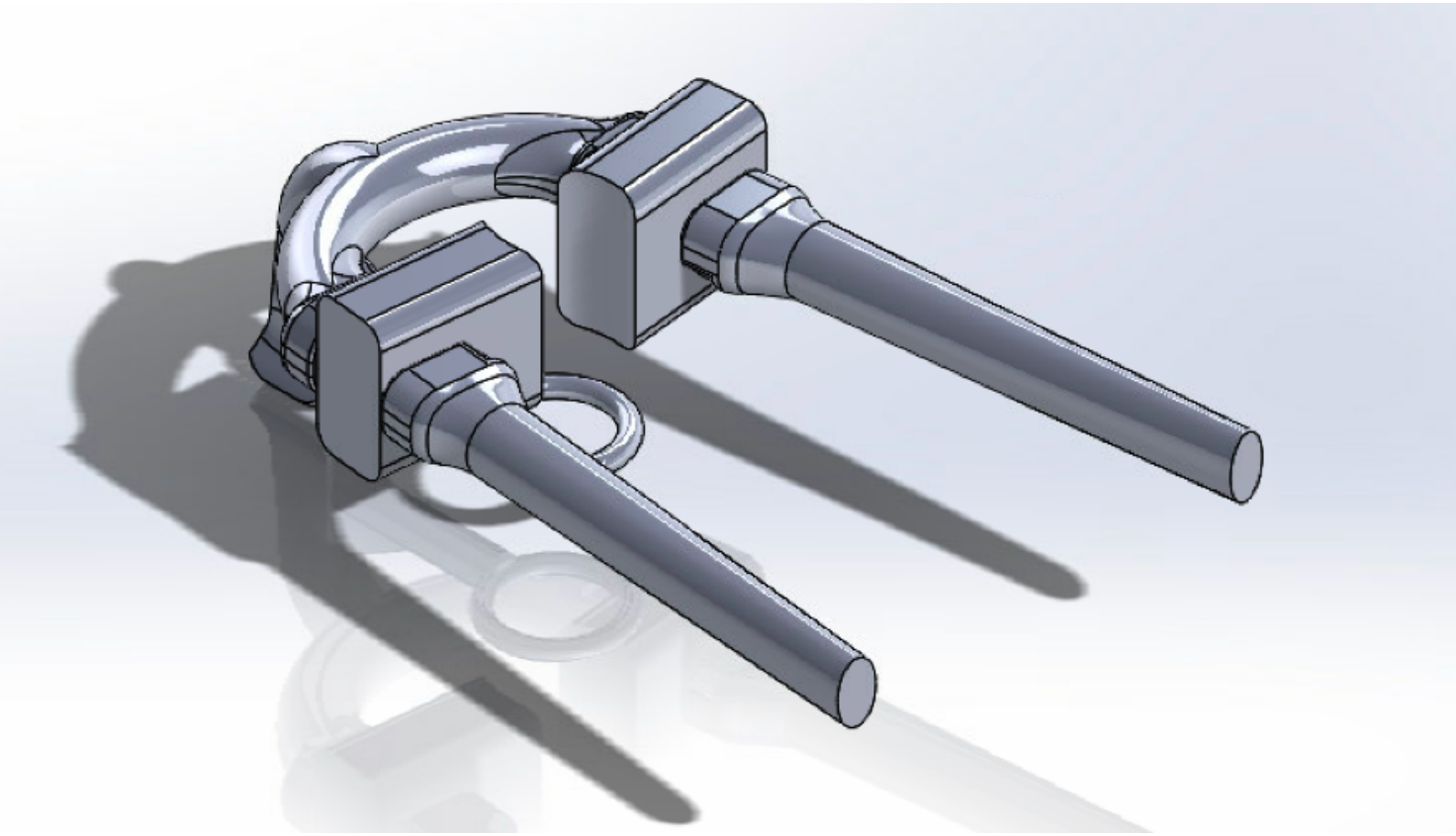
Present: N/A

Goals: To create a SolidWorks model and sketches of the retractable design prototype.

Content:

-

Retractable Prototype:



This model was made from the current prototype the team is using -- with some changes.

- Stem and Holding Ring:
  - Adjusted vertical dimension to be even with both bottle sizes
    - 8 mm cut from large stem; 5 mm addition from small stem
  - Made universal for both bottle sizes
  - Adjusted trusses accordingly
    - Maintained 30 deg angle with the holding ring extension
  - Added new cross section to hold the pegs of the **squeezer**.
    - Five 2.5 mm (diameter) holes for pegs to fit into
    - Gave ample room to move the pegs around (for adjustability)
    - Used various sized fillets to smooth edges of this component
  - No changes made to the holding ring
- Squeezer:
  - Made cut through the handles 15 mm wide to accommodate new part
  - Expanded contact area to 23 mm vertically to encompass all bottle sizes
  - Included pegs for the component to rest on the other two parts of the device
    - 2.5 mm in diameter, 5.5 mm long with fillet
- Handle:

- Cut off through to accommodate the new **squeezer**.
- Extruded 75 mm from cutoff point
  - Slightly smaller than the original prototype (by ~2 mm)
- Added new cross section to hold the pegs of the **squeezer**.
  - Five 2.5 mm holes for pegs to fit into
  - Gave ample room to move the pegs around (for adjustability)
  - Used various sized fillets to smooth edges of this component
- Maintained same ovular lofted shape
- Still allows for mechanical advantage

-

Other Notes:

Retractable stem component idea was scrapped.

Still need to determine the locking mechanism for this new retractable prototype

- Otherwise the device might be able to slip horizontally in either direction (most likely away from bottle) when in use
- Also should ensure that the connection between these three parts is stable enough for use.

4/15 - Sketches for each part are included in the attachments

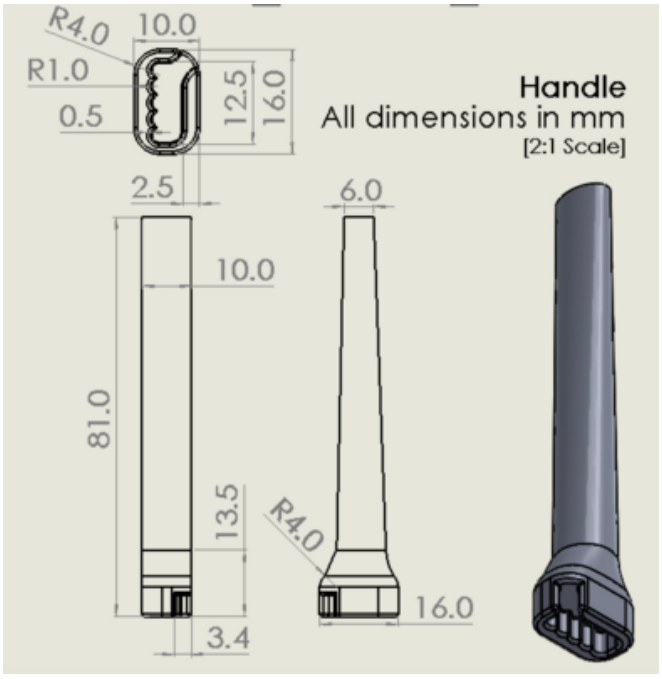
4/15 - Part models and attachments (to this entry and the drive) were updated. Previous links were saved as an invalid format and were not able to be opened.

-

Conclusions/action items:

- Include sketches of the assembly in this entry with dimensions - **DONE 4/15**
- 3D print these five parts and assemble the prototype
  - Make observations on the 3D printed prototype / parts (connection, stability, strength to elicit a drop, complexity etc.)
- Alter the retractable prototype model according to observations
- Alter the retractable prototype model to include a new locking mechanism that stabilizes the device when squeezing an eye drop bottle.

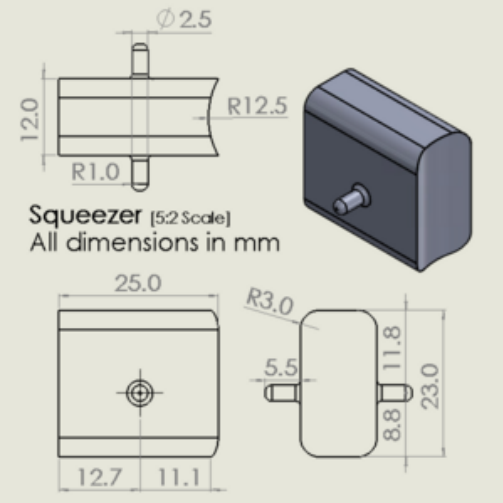
THOMAS KRIEWALDT - Apr 15, 2024, 9:38 PM CDT



Download

Handle_Drawing.png (140 kB)

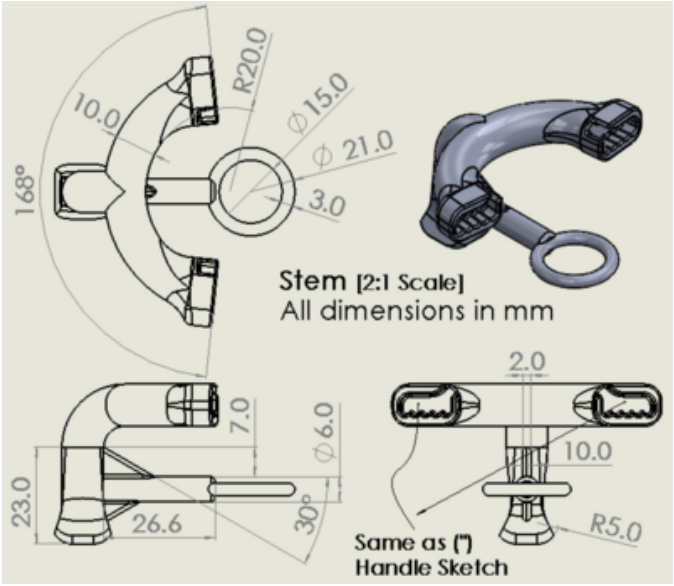
THOMAS KRIEWALDT - Apr 15, 2024, 9:38 PM CDT



Download

Squeezer_Drawing.png (118 kB)

THOMAS KRIEWALDT - Apr 15, 2024, 9:38 PM CDT



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Stem_Drawing.png (180 kB)

THOMAS KRIEWALDT - Apr 15, 2024, 9:38 PM CDT

Download

Stem_Assembly.SLDPRT (0 B)

THOMAS KRIEWALDT - Apr 15, 2024, 9:38 PM CDT

Download

Handle.SLDPRT (0 B)

THOMAS KRIEWALDT - Apr 15, 2024, 9:38 PM CDT

Download

Squeezer.SLDPRT (0 B)

2024/04/26 - Retractable Prototype: 3D Print Observations

THOMAS KRIEWALDT - Apr 30, 2024, 10:01 PM CDT

Title: Retractable Prototype: 3D Print Observations

Date: 4/26/2024

Content by: Thomas Kriewaldt, Tevis Linser

Present: N/A

Goals: To make observations on the retractable prototype model

Content:

Photos of the 3D Printed Prototype

Unfortunately, these 3 pieces do not connect at all with each other due to the design of the print.

-

Notable Observations:

- The holes on the handle and stem portions did not print well
  - Too small, do not allow the extruded portion of the squeezing mechanism to fit snuggly
    - Slips, not locked in place at all, can move horizontally AND vertically super easily..
- The extruded portion of the squeezing mechanism is too long
  - There is space between the parts when it should be a snug fit.
- Not secured at ALL, just falls apart
  - Need to print the handle and stem as one component or redesign so these can be secured in place.
    - Like something on the bottom and top of the squeezing mechanism to disallow detachment

Also, we need to create a horizontal locking mechanism so the device does not move from the desired position.

The retractable stem was not built into this prototype, but should be used in future prints.

- Positive feedback about the idea at the final poster presentation.

Conclusions/action items

- This print was not very functional
- Do a complete redesign if some members of the team decide to continue with this project next semester.
- Create an idea for vertical and horizontal locking mechanisms
    - Make sure it is easy to use and understand for our target audience.

4/30/2024 - Expenses Master Sheet Final

Title: Expenses Master Sheet

Date: 4/30/2024

Content by: Tevis Linser

Present: N/A

Goals: To record and track the expenses associated with the project

Content:

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Existing Devices								
Droppy Eye Drop Dispenser	Competing Design	Droppy, Amazon	DR001	9/25	1	9.99	9.99	Link
GentleDrop Eye Drop Guide	Competing Design	GentleDrop, Amazon	ASIN: B0BQBHRKV1	9/25	1	17.99	17.99	Link
Prototyping								
Silicone Eyelash Curler	Prototype Materials (Handle Grips)	PETUNIA SKINCARE, Amazon	ASIN: B00UVLNDVQ	10/25	1	7.49	7.49	Link
MakerSpace Print	Prototype v1	UW Makerspace Ultimaker 3D Print	N/A	10/31	1	4.96	4.96	N/A
MakerSpace Print	Prototype v2	UW Makerspace Ultimaker 3D Print	N/A	11/10	1	5.07	5.07	N/A
MakerSpace Print	Prototype v3	UW Makerspace Bambu Labs 3D Print	N/A	11/13	1	4.5	4.5	N/A
MakerSpace Print	Prototype v3	UW Makerspace Bambu Labs 3D Print	N/A	11/14	1	4.96	4.96	N/A
MakerSpace Print	Prototype v3	UW Makerspace Ultimaker 3D Print	N/A	11/15	1	8.16	8.16	N/A
MakerSpace Print	Prototype v4	UW Makerspace Ultimaker 3D Print	N/A	11/17	1	10.08	10.08	N/A
MakerSpace Print	Test Fixture	UW Makerspace Ultimaker 3D Print	N/A	11/29	1	13.78	13.76	N/A
MakerSpace Print	Final Prototype	UW Makerspace Ultimaker 3D Print	N/A	12/1	1	7.36	7.36	N/A

MakerSpace Print	Multiple Final Prototypes	UW Makerspace Ultimaker 3D Print	N/A	12/8	1	11.6	11.6	N/A
MakerSpace Print	Multiple Final Prototypes	UW Makerspace Ultimaker 3D Print	N/A	2/6	1	7.84	7.84	N/A
MakerSpace Print	Prototype Adjusted For IM	UW Makerspace Ultimaker 3D Print	N/A	2/23	1	2.15	2.15	N/A
MakerSpace Print	Parts for Connection Mechanism	UW Makerspace Ultimaker 3D Print	N/A	2/26	1	2.8	2.8	N/A
MakerSpace Print	Prototypes for Testing	UW Makerspace Ultimaker 3D Print	N/A	3/4	1	8.2	8.2	N/A
MakerSpace Print	Prototypes for Testing	UW Makerspace Ultimaker 3D Print	N/A	3/4	1	8.75	8.75	N/A
Packaging Label	Various Printed Stickers for Packaging	Student Print	N/A	4/24	1	40.39	40.39	N/A

Total: $176.07

Conclusions/action items:

As the budget was $500, the team has budget to work with as we further develop the product.

04/03/2024 - Single Drop Test Protocol

Title: Single Drop Test Protocol

Date: 04/03/2024

Content by: Kasia Klotz

Present: Kasia Klotz, Jenna Krause, Anabelle Olson, Tevis Linser

Goals: Evaluate the ability of the device to reduce eye drop waste

Content:

Single Drop Testing Protocol

Date of testing: 4/2/2024 and 4/3/2024

- Scope
  - To perform testing to quantify the amount of eye drop solution released from the bottle for each squeeze of the handles.
- Purpose
  - To understand the effectiveness of the eye drop assistant device in minimizing eye drop waste per use and delivering a consistent dosage of medication.
- Test Samples
  - Multiple subjects will perform trials, so that the data collected is more representative of a variety of users, such as male and female.
- Materials and Equipment
  - Eye drop assistant devices
  - Scale
  - Weight Boats
  - 15 mL eye drop bottle
  - 2.5 mL eye drop bottle
- Methods
  - 13 total subjects will participate in the testing
  - Each subject will perform two tests with 10 trials each:
    i. 15mL without the device
    ii. 15mL with the device
  - or :
    i. 2.5mL without the device
    ii. 2.5mL with the device
  - For each trial the weight boat will be set on top of the scale and the scale will be zeroed out. After the scale reads zero, the user will handle the bottle either with or without the device and hold it above the weight boat. Next the user will dispense a single drop into the weigh boat. If using the device, the subject will squeeze the handles of the eye drop assistant device together to administer one drop. Once there is a visual indication that a drop has dropped, the user will set the device down away from the scale. Then the scale measurement will be recorded. Ten trials are performed, so there are ten measured drops for the use of the eye drop assistant device. Each test participant will complete these ten trials.
- Data Analysis and Documentation Requirements
  - The weight of eye drop solution dispensed per trial will be recorded for each of the four tests. For each individual subject, the average and standard deviation of the ten trials will be calculated for each of the two tests they completed. These will be used to create box plots of each individual subject's data to visually compare use of the device with not using the device for both of the bottle sizes. Then, the averages and standard deviations will be combined to calculate the overall average and overall standard deviation across subjects for each of the four tests. These overall averages and standard deviations will be used for a statistical test.
  - A t-test will be run to compare the overall average eye drop size when using the device compared to not using the device for both the 15 mL bottle size and the 2.5 mL bottle size.

        i. The goal is for the average drop size when using the device to be statistically significantly lower than without using the device. This result will indicate that our device effectively minimizes eye drop waste compared to regular eye drop bottles.
    - A f-test will be run to compare the overall variance in eye drop size when using the device compared to not using the device for both the 15 mL bottle size and the 2.5 mL bottle size.
        i. The goal is for the variance in drop size when using the device to be statistically significantly lower than without using the device. This result will indicate that our device delivers a more consistent dose of eye drop medication compared to regular eye drop bottles.

Conclusions/action items:

The subjects of this test include 13 sophomores from the Biomedical Engineering Department. This test was previously completed by team members, however it was reconducted to remove biased. Once the data is collected, team members will analyze the data. The team hypothesizes that the results will be the same as last time, and therefore that the device will produce a more consistent drop size and decrease the size of the drop on average.

04/09/2024 - Single Drop Test Results & Analysis

Title: Single Drop Test Results & Analysis

Date: 04/09/2024

Content by: Eva Coughlin

Goals: To run statistical tests to analyze the data from the single drop test.

Content:

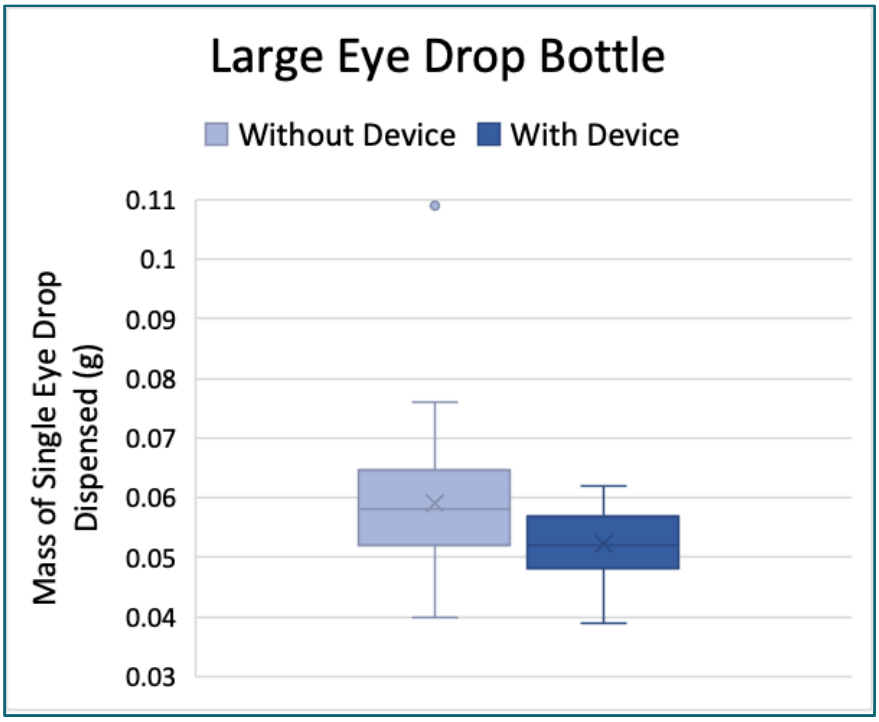
- the single drop test was repeated with BME 201 students to ensure that results are unbiased
- total of thirteen subjects, some subjects used the device for smaller sized bottles and some used the device for larger sized bottles, so that we are covering both
  - ten trials per subject
  - measured the drop size (on a scale) dispensed with the eye drop bottle alone compared to using the device
- **f-test:** the purpose of this test is to determine if there is a statistically significant difference in the variability of drop size when not using the device compared to using the device
  - combined data from subjects for each bottle size, calculated standard deviation of drop size for both bottle sizes (with and without the device)
  - total of sixty trials for 15 mL bottle size and total of seventy trials for 2.5 mL bottle size
    - for 15 mL bottle:
      - standard deviation without device = 0.01035423437
      - standard deviation with device = 0.005080676809
      - F = 4.1533
      - p-value = < 0.001
    - for 2.5 mL bottle:
      - standard deviation without device = 0.004031347149
      - standard deviation with device = 0.002850338689
      - F = 2.0004
      - p-value = 0.004
    - both of the p-values are well under the significance level of 0.05, so these results are statistically significant
    - **we can conclude that the eye drop assistant device dispenses a more consistent amount of eye drop solution**
- **t-test:** the purpose of this test is to determine if there is a statistically significant difference in the average drop size when not using the device compared to using the device
  - because the drop size dispensed is highly dependent on the force each individual person is applying to squeeze the device, we did a t-test on each individual's ten trials
  - p-values for the t-tests for each subject:
    - Subject 1 < 0.0001
    - Subject 2 = 0.136655
    - Subject 3 = 0.0361
    - Subject 4 = 0.3325875
    - Subject 5 = 0.0613095
    - Subject 6 = 0.4218615
    - Subject 7 = 0.0001615
    - Subject 8 = 0.007326
    - Subject 9 = 0.045982
    - Subject 10 = 0.001863
    - Subject 11 = 0.105001
    - Subject 12 = 0.037486
    - Subject 13 = 0.0027155
  - the p-values of eight out of the thirteen participants were under the significance level of 0.05, which is statistically significant
  - therefore, using the device reduced the drop size of solution dispensed for eight out of the thirteen participants
  - we did expect the p-values to be significant for all thirteen participants because one drop of eye drop solution is so small that we expected the masses to be fairly similar with and without the device

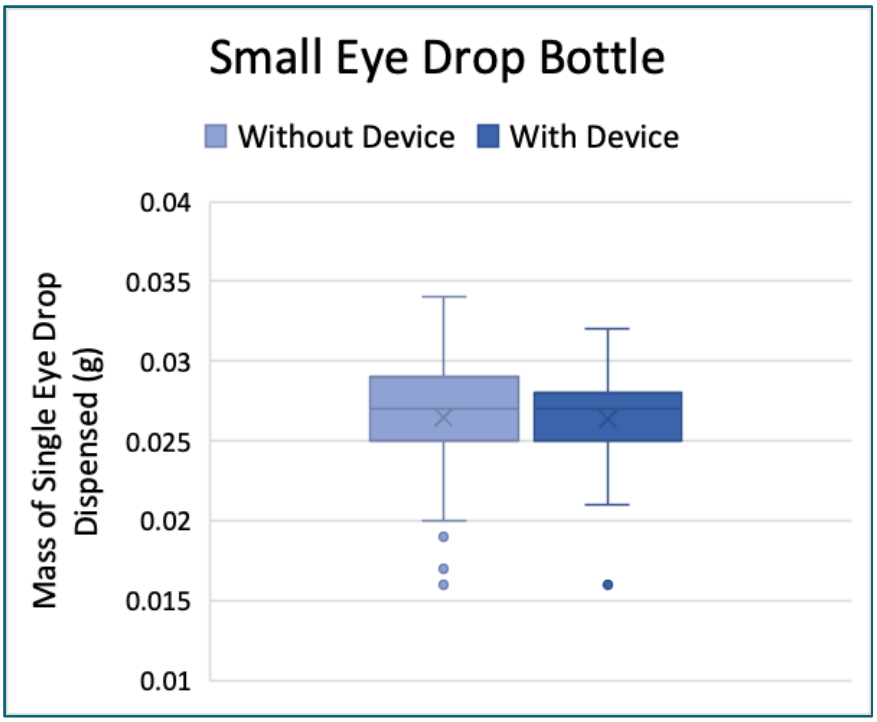
Raw Data:

Subject	Subect 1		Subject 2		Subject 3		Subject 4	
Bottle Size	15 mL	15mL	2.5 mL	2.5mL	15 mL	15mL	2.5 mL	2.5mL
Device	no	yes	no	yes	no	yes	no	yes
Unit	grams	grams	grams	grams	grams	grams	grams	grams
Trial 1	0.058	0.047	0.031	0.028	0.047	0.046	0.025	0.024
Trial 2	0.066	0.048	0.032	0.028	0.047	0.048	0.026	0.025
Trial 3	0.059	0.052	0.027	0.027	0.056	0.039	0.029	0.026
Trial 4	0.066	0.05	0.029	0.026	0.047	0.05	0.027	0.026
Trial 5	0.059	0.045	0.029	0.028	0.053	0.045	0.028	0.025
Trial 6	0.064	0.045	0.03	0.029	0.052	0.044	0.027	0.028
Trial 7	0.057	0.05	0.029	0.028	0.061	0.053	0.028	0.027
Trial 8	0.069	0.049	0.02	0.028	0.049	0.052	0.026	0.027
Trial 9	0.065	0.05	0.031	0.027	0.049	0.048	0.027	0.03
Trial 10	0.071	0.046	0.032	0.028	0.057	0.053	0.026	0.028

Subject 5		Subject 6		Subject 7		Subject 8		Subject 9	
15mL	15mL	2.5mL	2.5mL	15mL	15mL	2.5mL	2.5mL	15mL	15mL
no	yes	no	yes	no	yes	no	yes	no	yes
grams	grams	grams	grams	grams	grams	grams	grams	grams	grams
0.109	0.046	0.021	0.025	0.063	0.052	0.016	0.023	0.052	0.048
0.05	0.044	0.023	0.027	0.071	0.051	0.017	0.021	0.046	0.051
0.049	0.052	0.025	0.025	0.065	0.058	0.019	0.025	0.052	0.054
0.05	0.051	0.025	0.029	0.074	0.058	0.022	0.021	0.054	0.057
0.053	0.058	0.025	0.028	0.067	0.058	0.021	0.022	0.063	0.059
0.058	0.058	0.027	0.031	0.063	0.06	0.019	0.021	0.069	0.054
0.06	0.05	0.025	0.016	0.066	0.058	0.021	0.026	0.064	0.048
0.061	0.051	0.02	0	0.063	0.06	0.022	0.022	0.068	0.06
0.063	0.054	0.025	0.027	0.062	0.059	0.022	0.021	0.073	0.062
0.06	0.056	0.027	0.029	0.057	0.057	0.02	0.021	0.076	0.06

Subject 10		Subject 11		Subject 12		Subject 13	
2.5mL	2.5mL	15mL	15mL	2.5mL	2.5mL	2.5mL	2.5mL
no	yes	no	yes	no	yes	no	yes
grams	grams	grams	grams	grams	grams	grams	grams
0.032	0.027	0.053	0.049	0.021	0.026	0.027	0.022
0.033	0.028	0.054	0.051	0.028	0.026	0.027	0.024
0.033	0.025	0.048	0.052	0.024	0.028	0.029	0.026
0.03	0.028	0.055	0.055	0.026	0.028	0.03	0.026
0.031	0.029	0.051	0.053	0.028	0.028	0.026	0.023
0.034	0.03	0.04	0.055	0.03	0.028	0.026	0.027
0.028	0.026	0.05	0.059	0.027	0.028	0.028	0.025
0.03	0.029	0.053	0.053	0.028	0.028	0.033	0.026
0.03	0.03	0.053	0.055	0.025	0.03	0.026	0.027
0.028	0.029	0.056	0.053	0.025	0.029	0.028	0.026





- Decided that box plots would be the best way to visually represent this testing for the poster
  - one for large bottle and one for small bottle
  - comparing use of the device to not using the device, which shows that there is a greater range of values without the device

Conclusions/action items: The team redid the single drop test because we want to have participants other than ourselves complete the testing in an effort to reduce bias. Thirteen subjects completed the testing and we used an f-test to analyze the variability in drop size when using the device to dispense drops compared to not using it. The f-test was statistically significant, so we are confident in concluding that the device ensures a more consistent administration of eye drops. We decided that we are not going to use the data from the t-test for means because even though it does show that the device reduced the drop size by a significant amount for the majority of participants, we don't want to make any conclusions that would cause concerns about dosage required for therapeutic effect.

04/19/2024 - Preference Testing Statistical Analysis

EVA COUGHLIN - May 01, 2024, 12:15 PM CDT

Title: Preference Testing Statistical Analysis

Date: 05/01/2024

Content by: Eva Coughlin

Goals: To perform a statistical analysis on the ratings of ease in dispensing a single drop using our device compared to the traditional eye drop bottle.

Content:

- Ratings were on a scale of 1-10, with 1 being very difficult and 10 being very easy
- Throughout the testing we observed that many residents gave a "10" to dispensing a single drop without the device even when they dispensing several drops of solution at once
  - we think there was some confusion with the residents when trying to emphasize *"a single drop"*
  - because of this we decided to include a question at the end of the survey asking if they would like to use the assistive device and if it made eye drop administration easier for them because that was the overall objective with this testing

Subject Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37
Dispensing a single drop out of the eye drop bottle without the assistive device	5	8	9	9	8	7	5	10	5	5.5	2	4	5	7	10	7	6	5	6	7	10	10	1	6	10	10	8	2	10	10	10	3	10	5	10	10	9
Dispensing a single drop out of the eye drop bottle with the assistive device	10	8	10	9	10	9	9.5	10	8	8	1	3	10	8	10	9	10	9	9	7	9	10	10	10	10	10	9	8	10	10	10	9	10	10	10	10	8

- 4 out of the 37 participants rated the ease of a dispensing a single drop with the device lower than without the device
- I ran a t-test to compare the mean ratings for these two categories
  - Null hypothesis: The average rating for dispensing a single drop with the device compared to without the device is the same.
  - Alternative hypothesis: The average rating for dispensing a single drop with the device is higher than without the device.
- the t-value is -3.29 and the **p-value is 0.0007765**
- the p-value is less than 0.05 indicating a statistically significant result

Conclusions/action items: The first two questions of the preference testing survey at the local retirement community were asking to rate the ease dispensing a single drop out of the eye drop bottle without the assistive device and with the device on a scale of 1-10. With an appropriate sample size (n > 30), I ran a t-test to compare the average ratings of these two categories. The result from the t-test was statistically significant, indicating that dispensing a single drop out of the eye drop bottle with the device was significantly easier than without the device for the residents. This result is extremely encouraging as the overall goal of our device is to ease the administration of eye drops for those over 65.

02/22/2024 - IRB Submission Process - Ease of Eye Drop Administration with use of the Eye Drop Assistant Dev

Title: IRB Submission Process - Ease of Eye Drop Administration with use of the Eye Drop Assistant Device

Date: 02/22/2024

Content by: Eva Coughlin

Goals: To outline the edits throughout the process of the IRB and attach the final version of the document that was approved by the IRB for our testing.

Content:

Eye Drop Assistant Ergonomics Test
Ease of Eye Drop Administration with use of the Eye Drop Assistant Device

APPLICATION DETAILS

ID: 2024-0116
PI: Beth Martin
Reviewing Board: MRR IRB
Staff Reviewer: Laura Conger
Reviewer Contact: laura.conger@wisc.edu

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THE UNIVERSITY of WISCONSIN MADISON

Ease of Eye Drop Administration with use of the Eye D

Lead Researchers:

Professor Tracy Jane Puccinelli: BME department, tracy.puccinelli@wisc.edu, 608-265-8267

Dr. Beth Martin: School of Pharmacy, beth.martin@wisc.edu, 608-265-2667

Co-Investigators:

Anabelle Olson: BME department, amolson27@wisc.edu, 920-680-7550

Kasia Klotz: BME department, kmklotz@wisc.edu, 920-493-5051

Jenna Krause: BME department, jlkrause4@wisc.edu, 847-404-6627

Eva Coughlin: BME department, emcoughlin@wisc.edu, 262-751-0089

Thomas Kriewaldt: BME department, tkriewaldt@wisc.edu, 608-807-6650

Tevis Linser: BME department, linser@wisc.edu, 651-309-7782

Ryan Smith: School of Pharmacy, rrsmith7@wisc.edu

Version 1

December 1, 2023

Table of Contents

1. **Statement of Compliance**

I confirm that I have read this protocol. I will comply with the IRB-approved protocol, and applicable regulations, guidelines, laws, and institutional policies.

I agree to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above commitment.

Name Signature Date

_____ _____ _____

Principal investigator

2. **List of Abbreviations**

AE	Adverse Event
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
PHI	Protected Health Information
PI	Principal Investigator

3. **Study Summary**

1. Synopsis

Full Title	**Ease of Eye Drop Administration with use of the**
Short Title	Eye Drop Assistant Ergonomi

Number of Site(s)	There will be one study site. Enrolled subjects for this study will be from the Oakwood Village U
Main Inclusion Criteria	• Adults with ophthalmic conditions treated by eye drops. • Experience difficulties when using the conventional eye drop bottle. • Ability to hold and manipulate a hand held device. • English-speaking (able to provide consent and complete questionnaires).
Main Exclusion Criteria	• Do not use eye drop bottles.
Objective(s)	Primary Objective • To evaluate the effectiveness of the device in making the administration of eye drops easier compared to the traditional eye drop bottle. • To determine if the device should be commercially distributed and available to consumers. Secondary Objectives • To assess the efficiency of the device in administering a consistent dose of medication each use.
Endpoints	Primary Endpoint • Ease of use scale score for the device after the duration of the test. Secondary Endpoints • Device consistently administers a single drop of solution in each of the device's use.
Study Design	This is an observational study because the sample population being studied is surveyed as it is. The team will observe the subjects using the eye drop assistant, and the v
FDA Regulatory Overview	As low risk devices not being evaluated for safety/effectiveness the protocol is not subject to IDE requirements.
Study Device	The eye drop assistant device aims to make it easier to dispense an eye drop. The device has two handles to allow for a large grasp area for the user. The device contains component of the device is the nose bridge rest which allows the device to be positioned in the favorable position to correctly administer the eye drop into the bottom ey
Total Number of Subjects	At least thirty subjects will participate in the study.
Study Population	Males and females aged 65 years or older that use eye drops and who are residents at the Oakwood Village University Woods Retirement Community. Study aims to hav
Statistical Methodology	A t-test will be performed to determine if there is a statistical difference in the mean scores of difficulty for using the traditional eye drop bottle and using the eye drop a
Estimated Subject Duration	The duration of the study for each subject is approximately 45 minutes.
Estimated Enrollment Period & Study Duration	Study enrollment will be completed on the same day as the study protocol. The total duration will be one day.

2. Schematic of Study Design

4. **Key Roles**

The following is a list of all key personnel and roles:

Principal Investigator	Tracy Jane Puccinelli Professor/PhD University of Wisconsin-Madis BME Department 608-265-8267 tracy.puccinelli@wisc.edu
Co - investigators	**BME Department:** Anabelle Olson: amolson27@wisc.edu, 9 Kasia Klotz: kmklotz@wisc.edu, 920- Jenna Krause: jlkrause4@wisc.edu, 847 Eva Coughlin: emcoughlin@wisc.edu, 2 Thomas Kriewaldt: tkriewaldt@wisc.edu, Tevis Linser: linser@wisc.edu, 651-3 **Pharmacy Student:** Ryan Smith: rrsmith7@wisc.e
Participating Site(s)	University of Wisconsin-Madis Oakwood Village University Woods Retirement Commu
Local Laboratory Services	UW - Makerspace 215 N Randall Ave, Madison Wi 5
Study Monitoring Contact	Beth Martin PhD University of Wisconsin-Madis 608-265-2667 beth.martin@wisc.edu
Funding Sponsor	Beth Martin PhD University of Wisconsin-Madis 608-265-2667 beth.martin@wisc.edu

5. **Introduction**

1. Relevant Disease

Most ophthalmic diseases are treated by medicated eye drops. This treatment presents issues for patients with limited dexterity, as the eye drop bottle is often found hard to squeeze. Resultantly, patients a prescription eye drops. It is dangerous for patients to run out of their eye drops too quickly because they rely on the medication to prevent their vision loss from worsening.

2. Current Standard of Care

For the proper technique of administering eye drops, the patient must first tilt their head back and look up. With one hand, the patient should pull their lower eyelid down and away from their eyeball. Wit prescribed number of eye drops into the conjunctival sac, which is the eyelid pocket. For at least one minute, the patient should close their eye and press their finger lightly on their tear duct to prevent the

3. Name and Description of the Study Activity

The approach used in this study is a hand held medical device. The device contains four components to make the dispensing of an eye drop easier. The first component of the device is the handles, which support for the device and allows the user to position the device over their eye, such that the proper eye drop technique is used. The next component is the spring stopper mechanism, which has a spring c

separate. This ultimately ensures that only one drop of eye drop medication is dispensed, and the user does not willingly dispense too much. In the case that the medication dose requires two drops, the us bottle sizes, allowing this device to be more universal and reach a larger audience. Together, these components of the Eye Lash Dropper design allow for ease and accuracy of eye drop administration.

4. Rationale

This study will be conducted to understand the effectiveness of the device in making the administration of eye drops easier for the user. If the study results suggest that this device makes the administratio adherence to their treatment program.

6. **Study Objectives and Endpoints**

Objectives

Primary
To assess the effectiveness of the device in making the administration of eye drops easier compared to the traditional eye drop bottle
Secondary
To evaluate the effectiveness of the device in administering a consistent dosage of eye drop solution.

7. **Study Design**

1. General Design

This Phase 1 single site, observational trial will compare the safety and efficacy of the eye drop assistant device versus the conventional eye drop bottle in administering a single eye drc

The study population will consist of at least 30 adults, adults above the age of 65 who currently use eye drops.

Subject accrual will occur over 1 month at 1 site. Subjects will complete 1 study visit over the course of approximately 1 day. Each subject will contribute 1 survey result.

2. End of Study Definition

The end of the study is defined as the date of completion of data collection described in the protocol.

8. **Subject Selection**

1. Inclusion & Exclusion Criteria

Eligibility will be determined by inclusion and exclusion criteria below

Inclusion Criteria

1. Ability to understand an informed consent document.
2. Willing to comply with all study procedures and be available for the durati
3. Individuals at least 65 years of age.
4. Adults with ophthalmic conditions treated by eye drops.
5. Experience difficulties when using the conventional eye drop bottle.
6. Ability to hold and manipulate a hand held device with one hand.
7. English-speaking (able to provide consent and complete questionnaires).
8. Has the mental capacity to give informed consent.

Exclusion Criteria

1. Unable to use hands for the required tasks.
2. Unable to communicate feedback on device or answer survey questions due to language

2. Vulnerable Populations

This study aims to enroll senior citizens specifically subjects who are above the age of 65 years old. This demographic is chosen because the eye drop assistant device under investigati that the device will not be utilized on or near the eye area. To further minimize risks for senior citizens, investigators will be present during the study to assist study participants in prope

3. Subject Identification

1. **Identification in Retirement Community**

There will be a recruitment flyer for the study posted at the retirement community stating the room, date, and time that the study will take place. The study team will ask interested s be identified at Oakwood Village University Woods Retirement Community. The study team member will screen the subjects using the screening document submitted with the IRB

4. Subject Recruitment

About 30 subjects will be recruited from Oakwood Village University Woods Retirement Community site in Madison, Wisconsin. Individuals from populations who are underrepresente individuals, federally recognized nations and tribes) will be enrolled with a goal of ensuring that all eligible patients are given the opportunity to participate in research and that research

A recruitment strategy will be employed at the Oakwood Village University Woods Retirement Community site in Madison, Wisconsin. The specific recruitment strategy is the followin

1. **Recruitment through Retirement Community Facility**

If the potential subject is agreeable and meets the requirements, they will be verbally asked to participate in study. No contact information will be collected for the study.

5. Early Termination and Withdrawal

Subjects are free to withdraw from participation in the study at any time upon request.

The Principal Investigator (PI) may discontinue or withdraw a subject from the study for the following reasons at his/her discretion:

- Subject non-compliance with study requirements
- If any clinical adverse event (AE) or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the s

9. **STUDY AGENT (STUDY DRUG, DEVICE, BIOLOGIC, VACCINE, ETC.)**

1. Materials and Administration

The study agent is the eye drop assistant device provided with lubricating eye drop solution bottles that are also provided by the research team. The control products are the various participant of the study will be shown a demonstration by a co-investigators on how to use the device. Once the participant receives this demonstration, the device will be handed to solution provided by the research team. It should be noted that the participant should not administer eye drops into their own eyes, rather they should hold the device above a cloth a assistive device. Finally, the participant will be instructed to complete a survey about the difference in difficulty in the two methods.

2. Method for Assigning to Treatment Groups

No treatment groups in this study so no randomization or blinding procedures will occur.

3. Study Compliance

The lead researcher will be present with the subject for the whole duration of their trial. The lead researcher will monitor the trial to make sure the subject is adhering to the study steps.

10. **Study Visits and Procedures**

1. Study Calendar

The procedures performed at each study visit are listed in the table below.

Procedure	Screening Visit	End of Stu
Visit Window	Day 1	Day 1 Remote
Informed Consent	X	
Administer Study Demonstration	X	
Survey		X
Data Analysis		X

2. Screening and Enrollment

1. **Informed Consent**

Preliminarily eligible subjects will be identified at Oakwood Village University Woods retirement community for informed consent and brief screening. The informed consent proce obtained prior to conducting any study-related activities.

The informed consent process will be performed as follows:

- Co-investigators will review the informed consent form and discuss the study in detail with the potential research subject.
- Co-investigators will explain the study, its risks and benefits, what would be required of the research subject, and alternatives to participation.
- The subject will have the opportunity to ask questions and have all questions answered by the co-investigators and/or lead researchers.
- Co-investigator will confirm participant's capacity to consent through the teach-back method.

2. **Screening Visit**

The screening will be performed on the same day as the study visit. The screening is done for research purposes only to ensure that all potential study participants meet the inclusion crit

Ability to understand an informed consent document.

Willing to comply with all study procedures and be available for the durati

Individuals at least 65 years of age.

Adults with ophthalmic conditions treated by eye drops.

Experience difficulties when using the conventional eye drop bottl

Ability to hold and manipulate a hand held device.

English-speaking (able to provide consent and complete questionr

Has the mental capacity to give informed consent.

The study team will ask potential participants the following questions. If the participant answers yes to all of these questions and is willing to partici

1. Do you currently use eye drops?

   Yes ☑ No ☑

   If yes, do you administer eye drops on your own?

   Yes ☑ No ☑
2. Are you over the age of 65?

   Yes ☑ No ☑
3. Are you comfortable with researchers asking you questions about what you experience throughout the experiment?

   Yes ☑ No ☑
4. Do you feel comfortable communicating in English with the study team and reading a survey written in English?

   Yes ☑ No ☑
5. Did the potential subject clearly have the mental capacity to consent?

   Yes ☑ No ☑

Thank you for your time!

Summary of study: The study will ask participants to administer eye drops on a paper towel using the traditional bottle and then using the experience and preferences concerning the application of eye drops with and without the device.

3. **Enrollment**

A research subject will be defined as "enrolled" in the study when they meet the following criteria:

- The subject has been consented by study staff.

- The subject and study staff have completed the screening.
- The PI has verified that the subject meets all of the inclusion criteria.
- The PI has verified that the subject meets none of the exclusion criteria.

3. Study Activities

    1. **Visit to Oakwood Village University Woods Retirement Community**

- Co-investigators will provide demonstration on eye drop assistant device use to study participants (~10 minutes)
- Study participants will experiment with using the eye drop assistant device and dispensing the drops onto a cloth (~10 minutes)
- Study participants will dispense eye drops from the conventional eye drop bottle onto a cloth (~10 minutes)
- Study participants will complete the survey to evaluate the device usability (~15 minutes)

4. Unscheduled Visits

No unscheduled visits will occur in this study.

11. **Data Handling and Record Keeping**

    1. Data Collection

        1. **Data Collection Forms**

The survey listed below is the only data collection form in this study.

Survey:

On a scale from 1-10, with 1 being extremely difficult and 10 being extremely easy, rank the following:

Dispensing a singular drop out of the eye drop bottle **without** the assistive device: _____

Dispensing a singular drop out of the eye drop bottle **with** the assistive device: _____

Ease of handling and holding the assistive device: _____

How easy was it to understand how to use the device?: _____

If you had a choice between the two versions of the prototype shown, which would you prefer?: _____

What changes, if any, would make the assistive device easier to use? Consider how it would feel to use this device while dispensing eye drops into your lower eyelid pocket.

---

2. Confidentiality and Privacy

Subject confidentiality and privacy are strictly held in trust by the participating investigators. The study protocol, data, and all other information generated will be held in strict confiden

All research activities will be conducted in as private a setting as possible.

All study staff engaged in the conduct of this project have completed training on the protection of human subjects.

Information about study subjects will be kept confidential according to campus policy. Subjects will not sign any informed consent or HIPAA authorization form. Instead, subjects will b anonymously filled out and stored securely by lead investigators. filed, and stored securely by the lead investigator Beth Martin at her office at UW Pharmacy School.

3. Records Retention

Not applicable

4. Retention for Future Research: [Optional or Mandatory] Data, Image, Audio- or Video-Recording & Biospecimen Banking

Not applicable

5. Protocol Deviations

It is the responsibility of the Principal Investigator to use continuous vigilance to identify and report deviations. In the event that the study at Oakwood Village University Woods ret deviation constitutes noncompliance as defined by the reviewing IRB. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.Zsagz

12. **Study Analysis**

1. Statistical Hypotheses

- Primary Efficacy Endpoint(s): To determine if the eye drop assistant device makes it easier to dispense eye drops compared to using the conventional eye drop bottle alone.
  - Null Hypothesis: The survey rating for dispensing an eye drop from the eye drop assistant device is not higher than the survey rating for dispensing an eye drop from the conve
  - Alternative Hypothesis: The survey rating for dispensing an eye drop from the eye drop assistant device is higher than the survey rating for dispensing an eye drop from the co

2. Sample Size Justification

As many subjects as possible from Oakwood Village University Woods retirement community will be recruited and screened for the study. At least thirty subjects will be enrolled in

3. Subject Population(s) for Analysis

The sample for this study is representative of the population over 65 years of age.

4. Statistical Methods

A t-test will be performed to determine whether the null hypothesis should be accepted or rejected. This is a simple statistical method, which will analyze whether or not the average sur rating for dispensing an eye drop from the conventional eye drop bottle. The statistical analysis will be performed after the study team has received all surveys from the enrolled study p drop administration. If the survey rating with the use of the device is not significantly higher than the survey rating without the device, the study team will discuss how the device must b brainstorming design revisions.

5. Planned Interim Analysis

An interim analysis will not be performed.

13. **Risk/Benefit Assessment**

1. Known Potential Benefits to the Subjects

There are no expected benefits to research subjects.

2. Known Potential Risks

1. **Known Study Risks**

There aren't any known study risks associated with the use of the eye drop assistant in this study. It should be mentioned again that the device will not be used to dispense eye dı onto a cloth located on a countertop.

2. **Other Known Study Risks**

There is potential for physical risk associated with using the device, as one could potentially injure themselves due to muscle strain while squeezing either the bottle alone or the regularly uses their hands to squeeze the eye drop bottle.

3. Risk/Benefit Analysis

There is little risk involved in this study, therefore the benefits that society and future eye drop users could gain from the study outweigh the risk.

14. **Study Feasibility**

1. Economic Burden to Subjects

The subjects do not have to endure any cost to participate in this study.

2. Facilities and Locations

Subjects will be recruited and screened at Oakwood Village University Woods retirement community, and the study will also be performed there. This retirement community is located a

3. Feasibility of Recruiting the Required Number of Subjects

The study team will have access to about one hundred residents at Oakwood Village University Woods retirement community. The study team needs at least 30% of the residents to enrc

4. Principal Investigator Considerations

1. **Time Devoted to Conducting the Research**

This study is part of a BME 400 senior design course, so there are bimonthly scheduled meetings with the principal investigator to ensure there is sufficient time to conduct and com

2. **Process for Informing Study Teams**

The principal investigator guides the team through their individual roles at the meetings to ensure that everyone understands the protocol and all individual responsibilities are accou

5. Availability of Medical or Psychological Resources

Medical or psychological resources for subjects is not applicable to this study

Conclusions/action items: The IRB has been a work in progress since first semester of the project. After the IRB was submitted initially, it involved a few rounds of edits, re-submissions, mandator client is available to do some recruiting for the testing on March 7th, and then the team will organize a weekend date after March 7th to conduct testing. The team must begin working on an addendu

02/23/2024 - IRB Approval Certificate

EVA COUGHLIN - Mar 18, 2024, 11:07 AM CDT

Title: IRB Approval Certificate

Date: 02/23/2024

Content:

Submission ID number:

2024-0116

Title:

Ease of Eye Drop Administration with use of the Eye Drop Assistant Device

Principal Investigator:

Beth Martin

Point-of-contact:

Eva Mary Coughlin
IRB Staff Reviewer: Laura Conger

Minimal Risk Research IRB 2/23/2024

A designated MRR IRB member conducted an expedited review of the above-referenced initial application. The study was approved on 2/23/2024 by the IRB member. The study qualified for expedited review pursuant to 45 CFR 46.110 and, if applicable, 21 CFR 56.110 and 38 CFR 16.110 in that the study presents no more than minimal risk involves:

(7)(b) Social science methods

As part of its review, the IRB determined this study does not require continuing review either under federal regulations or institutional policy, or both. Please note, however, that although this study is not required to undergo continuing review, you must still submit the following to the IRB:

1. Changes of protocol prior to their implementation (unless the change is necessary to eliminate an apparent immediate hazard to subjects)
2. Addition of new study personnel
3. Funding updates
4. Reportable events (unanticipated problems, noncompliance, new information) in

   accordance with institutional policy
5. Closure report

In addition, please be aware that the type of funding that supports a study or whether the study falls under FDA regulations can affect whether continuing review may be required in future.

To access the materials approved by the IRB, including any stamped consent forms, recruitment materials and the approved protocol, if applicable, please log in to your ARROW account and view the documents tab in the submission's workspace.

If the IRB required informed consent, please use only copies of the approved consent forms or information sheets to obtain informed consent; give all participants a copy of the consent document.

You have identified the following financial sources to support the research activities in this IRB application:

Faculty salary credit funds, BME Design (Beth Martin)

If this information is incorrect, please submit a change to modify your application as appropriate.

Prior to starting research activities, please review the Principal Investigator and Study Team Responsibilities Investigator Manual, which includes a description of IRB requirements for submitting personnel changes, changes of protocol and reportable events.

If you have general questions, please contact the Minimal Risk Research IRB at 608-263- 2362. For questions related to this submission, contact the assigned staff reviewer.

02/20/2024 - Screening Document

EVA COUGHLIN - Mar 18, 2024, 11:08 AM CDT

Title: Screening Document

Date: 02/20/2024

Content by: Eva Coughlin, Anabelle Olson, Kasia Klotz

Content:

The study team will ask potential participants the following questions. If the participant answers yes to all of these questions and is willing to participate, they will be enrolled in the study:

1. Do you currently use eye drops? Yes No

   If yes, do you administer eye drops on your own? Yes No

2. Are you over the age of 65? Yes No

3. Are you comfortable with researchers asking you questions about what you experience throughout the experiment?

   Yes No

4. Do you feel comfortable communicating in English with the study team

   and reading a survey written in English? Yes No

5. Did the potential subject clearly have the mental capacity to consent? Yes No

Thank you for your time!

Summary of study: The study will ask participants to administer eye drops on a paper towel using the traditional bottle and then using the device. Following this, the participants will be asked to fill out a survey regarding their experience and preferences concerning the application of eye drops with and without the device.

02/16/2024 - Informed Consent

Title: Informed Consent

Date: 02/16/2024

Content by: Eva Coughlin

Content:

University of Wisconsin-Madison

Consent to Participate in Research

Study Title: Ease of Eye Drop Administration with Use of the Eye Drop Assistant Device

Lead Researchers: Beth Martin, PhD, RPh (608 265-4667)
Eva Coughlin (262-751-0089)

Institution: University of Wisconsin-Madison

Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

The purpose of this research study is to evaluate the usability of this eye drop assistant device for administering eye drops. This research is being done because eye drop bottles are small and difficult to use, especially for those with reduced dexterity. Because eye drop bottles are difficult to squeeze, doses of medication are skipped or too much medication is administered, leading to waste. The team designed and fabricated an eye drop assistant device to ease the administration of eye drops. We would like to survey the Oakwood Village University Woods retirement community to evaluate the effectiveness of this device at performing its intended function.

We invite you to take part in this research study because you are an older adult that has used eye drops before. Participation is voluntary.

What will I need to do in this study?

The research team will ask you to watch a demonstration by the lead researcher on how to use the device. Then, the device will be handed to you, and you will have 5-10 minutes to handle the device. You can hold the device above a cloth and administer eye drop solution provided by the research team onto the cloth, rather than administering the eye drops in your eyes. After using the device, you will be asked to administer the eye drops onto the cloth using the eye drop bottle alone. You will be asked to complete a survey about the difference in difficulty between the two methods.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you are:	**You may NOT want to be in this study if you:**
• Comfortable having researchers ask questions about your experience using the device • Experience difficulties when using the conventional eye drop bottle • Willing to participate in the study for about an hour • Interested in contributing to scientific knowledge even though you may not benefit directly from the study	• Have never used eye drops before

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect any services you receive from your health department. There will be no penalty to you. You will not lose any legal rights. You can ask all the questions you want before you decide.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to Beth Martin at 608-265-4667 or another lead researcher listed at the top of this form.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

If I take part in the study, what will I do?

The research team will ask you to:

- Observe a demonstration on how to use the eye drop assistant device.
- Try using the eye drop assistant device for about 5-10 minutes and ask the research team any questions. You will dispense the eye drops onto a cloth on a table. You should not administer any eye drops into your eyes.
- Set the device down and dispense the eye drops from the conventional eye drop bottle without the device. You will dispense the eye drops onto a cloth on a table. You should not administer any eye drops into your eyes.
- Complete a survey about the difference between the ease of dispensing eye drops from the eye drop assistant device compared to dispensing eye drops from the conventional eye drop bottle.
- The survey will have you rank the difficulty on several different categories and ask you to share any ideas for how you would want to change the device.

Overall, you will spend about forty-five minutes on this study in one day. This includes the device demonstration (~10 minutes), use of the eye drop assistant device (~10 minutes), use of the conventional eye drop bottle (~10 minutes), and complete the survey (~15 minutes).

How will the data that is collected be stored, who will have access, and how is confidentiality protected?

The screening document used for this study will not ask for your name or any other information that can be used to identify you. The data that is collected will be stored by the lead investigator, Beth Martin. Only the study team will have access to this data. Because the data is anonymous, your confidentiality is naturally protected.

What happens if I say yes, but I change my mind later?

You can leave the research study at any time. If you choose to leave the study, your choice will not affect any services you receive from your health department. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose any legal rights.

Will being in this study help me in any way?

There is no direct benefit from participating in this study. Your evaluation will help us in improving the eye drop assistant device, so that an improved prototype can be designed.

What are the study risks?

There is a small risk that you could injure yourself when using the eye drop assistant device because it involves squeezing with your hands. However, this is not likely to occur because all participants in this study regularly use their hands to squeeze eye drop bottles as part of their regular daily activities.

What else do I need to know?

How many people will be in this study?

We expect about 30-100 people will be in this research study.

Who is funding this study?

This research is being funded by UW School of Pharmacy as a part of a biomedical engineering senior design project.

02/13/2024 - Recruitment Flyer

EVA COUGHLIN - Mar 18, 2024, 11:10 AM CDT

Title: Recruitment Flyer

Date: 02/13/2024

Content by: Eva Coughlin

Content:

Do you use eye drops?

Would you be willing to try our

eye drop assistant device

and provide us with your feedback?

Please drop in to review the device and provide your valuable feedback using a brief survey tool. Estimated time: 10-15 minutes.

Date: Friday, March 15th

Room: Nakoma/Westmorland

Times: 10 – 11:30 AM

UW BME Design

This device is designed by six senior biomedical engineering students at UW-Madison as part of their capstone project, in collaboration with Ryan Smith (DPH-2) & Dr. Beth Martin at the School of Pharmacy

04/01/2024 - Preference Testing Survey Results Spreadsheet

Title: Preference Testing Survery Spreadsheet

Date: 04/01/2024

Content by: Anabelle Olson

Goals: To keep track of the preference testing survery results and keep them all in one area to use for future analysis.

Content:

Subject	Start of second iteration of survey	
Dispensing a single drop out of the eye drop bottle without the assistive device	5	8
Dispensing a single drop out of the eye drop bottle with the assistive device	10	8
How would you rate the ease of handling and holding the assistive device	6	8
How easy was it to understand how to use the device	10	10
If you had a choice between two versions of the prototype shown, which would you prefer?	Nose piece	Nose Piece "looks easier"
Would you prefer to dispense your eye drops with our without the assistive device?	Prefer to use device so that drops don't drip down face	Just bottle
What changes if any would make the assistive device easier to use?	"The systane drops fall out all over my face", takes getting used to handles . Nose bridge would keep drops in same place	No changes

Conclusions/action items:

The team will use these answers to the survey questions to preform a thematical anaylsis and make conclusions regarding the feelings towards the prototype and the preference between the tw

04/16/2024 Thematic Analysis

Title: Thematic Analysis Results

Date: 4/16/24

Content by: Anabelle Olson & Tevis Linser

Goals:

To analyze the responses to the preference test survey and come up with common thoughts and preferences regarding the prototype.

Content:

Steps of a thematic analysis:

1. Become familiar with the data
2. Generate Initial Codes
    a. The codes we came up with include

Issues with using the current bottles ease of use
Issue with releasing single drop from current bottle
Suggested improvements to handle
Suggested improvements to nose bridge
suggested improvements to platform
Cannot comment without using device to administer eye drops
Noticed increased Control with device
Increased Accuracy with the use of the device
No Changes to the device
Positive Feedback - Platform
Positive Feedback regarding Nosebridge component
Noticed increased Stability with device
Negative Feedback regarding the device
Interest in purchasing device
Positive Feedback regarding the Device
Struggle with ease of Use
Interest in using their own eye drops

    b. Next, we counted the number of occurrences of each code

2
1
5
2

1
6
4
2
6
5
2
2
6
1
1
3
2

c.

4. Search for Themes

a. Based on these codes and the number of occurrences of each code, we came up with five themes to encapsulate the responses of the subjects

i. Increased ergonomics while using device as compared to the bottle

1. Increased Accuracy with the use of the device
2. Noticed increased Control with device
3. Noticed increased Stability with device

ii. Issues with the eye drop administration with just bottle

1. Issues with current bottle ease of use
2. Issue with releasing single drop from current bottle

iii. Interest in using the device

1. Interest in purchasing the device
2. Positive Feedback regarding the Device
3. Positive Feedback - Platform
4. Positive Feedback - Nosebridge

iv. Suggestions regarding device components

1. Suggested improvements to handle
2. Suggested improvements to Nose bridge
3. Suggested Improvements to platform

v. User Experience and adaptation challenges/ limitations resulting from testing conditions

1. Struggle with ease of Use
2. Cannot comment without using device to administer eye drops

5. Define Themes

1. Increased Ergonomics While Using the Device as Compared to the Bottle This theme involves the attitude towards enhanced user experience during eye drop

administration from our device, compared to just using the eye drop bottle alone. Subjects expressed a sense of enhanced accuracy, control, and stability while using the device. Codes such as “increased accuracy with the use of the device”, “user noticed increased control with the device”, and “user noticed increased stability with the device” were identified and grouped under this theme.

2. ***Issues with Eye drop Administration with just the bottle*** This theme highlights that current eye drop users struggle with administering eye drops from the bottle by itself. Subjects reported various difficulties and frustrations associated with the use of the traditional eye drop bottle. Two key codes that were identified to fall under this theme are “issues with the use of the current bottle” and “issues with releasing a single drop from the current bottle.” These codes reflect subjects’ struggles with the usability and functionality of the current eye drop bottles.
3. ***Interest in Using the Device*** This theme involves the subjects’ feelings towards using the eye drop assistive device. Many subjects reported strong interest in acquiring one of the devices for themselves and expressed interest in the components of the device. The four codes that defined this theme include: “interest in purchasing the device”, “overall positive feedback surrounding the device”, and “positive feedback on the stabilization mechanisms of the device”.
4. ***Suggestions Regarding Device Components*** This theme covers feedback and suggested changes regarding the handle, the nose bridge, and the platform design aspects. Codes such as “Suggested improvements to handle”, “Suggested improvements to Nose bridge”, and “Suggested Improvements to platform” were included in this theme.
5. ***User Experience and Adaptation Challenges/Limitations Resulting from Testing*** This theme incorporates instances where participants expressed general troubles of using the device without ideas for changes to improve the design. This theme also highlights the notion that the participants felt as if they were not able to provide feedback based on the testing procedure. Codes such as “Struggle with ease of Use”

and “Cannot comment without using the device to administer eye drops” were included in this theme.

Conclusions/action items:

While conducting this thematic analysis several themes have emerged, highlighting the study subjects’ attitudes, experiences, and suggestions regarding the eye drop assistive device. Collectively, these themes provide valuable insights that will inform the implementation of the device to enhance user satisfaction and adherence to eye drop treatments. Themes 1 and 3 highlight the potential benefits of the eye drop assistive device in improving the patient experience while administering eye drops, potentially leading to increased adherence to eye drop treatments. Theme 2 emphasizes the need for an eye drop assistive device. Lastly, themes 4 and 5 will be the basis for future research and modifications to the device design, such that future testing procedures will allow the subject to administer eye drops into their own eyes. This provided feedback will guide future research into potential design changes.

04/11/2024 - UW Madison School of Pharmacy ShaRx Tank

KASIA KLOTZ - May 01, 2024, 12:36 PM CDT

Title: UW-Madison School of Pharmacy ShaRx Tank

Date: 4/11/2024

Content by: Kasia Klotz

Present: N/A

Goals: Include slides used in ShaRx Tank

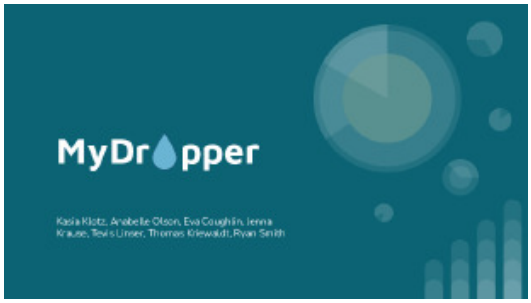
Content:

Included below are the slides that were presented in the ShaRx Tank competition.

Conclusions/action items:

The team won 1st place in the competition. There was a strong emphasis on the marketing side of the device. This information was then implemented into poster presentations and assisted the team in winning the Tong Award.

KASIA KLOTZ - May 01, 2024, 12:33 PM CDT



Download

ShaRx_Tank_Presentation.pdf (2.91 MB)

04/19/2024 - Branding Ideas

THOMAS KRIEWALDT - Apr 21, 2024, 11:24 PM CDT

Title: Branding Ideas

Date: 04/19/24

Content by: Thomas Kriewaldt

Present: N/A

Goals: Create sketches of logo ideas to use for future marketing

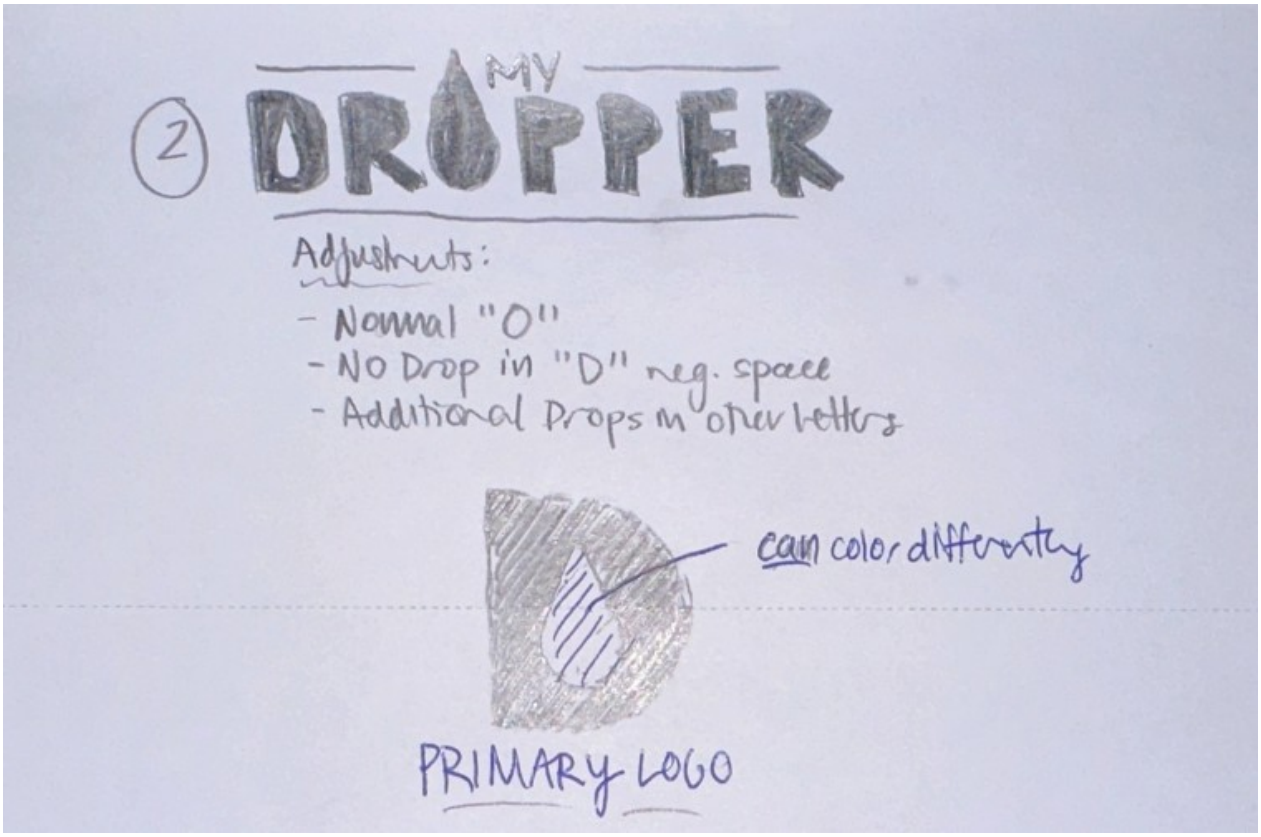
Content:

Idea 1: Keep a similar identity as we have now.

- Only adjustment to this design may be a different font or arrangement of text.

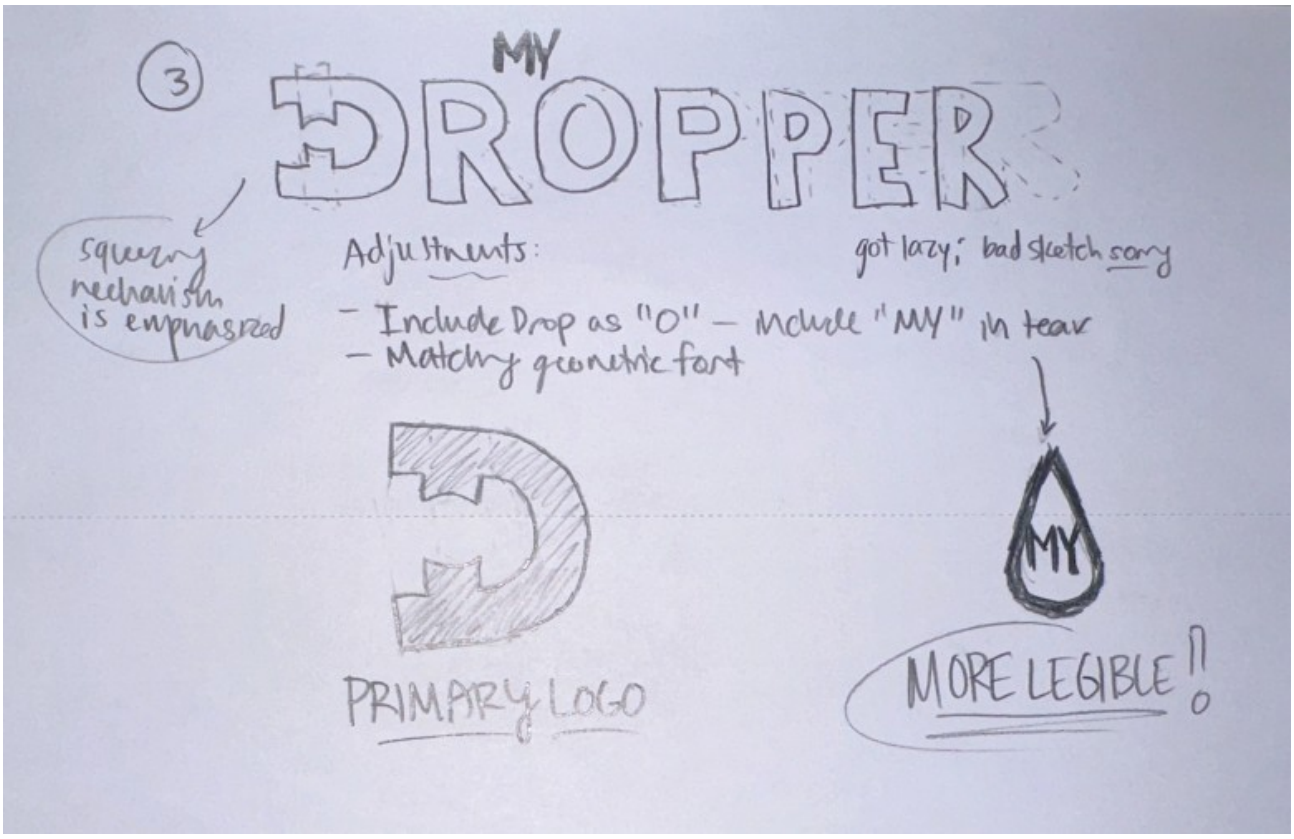
Idea 2: Keep the eye drop in the logo, but with the negative space of the "D"

- More subtle
- Might not be enough to stick out from competition down the line
    - Could also make adjustments as noted on the sketch..



Idea 3: "D" of the logo represents the device

- Might be a bit confusing or hard to read
- Including the crucial squeezing mechanism of our device gives more brand recognition
    - Could also make adjustments as noted on the sketch..



Conclusions/action items:

Decide which logo option the team wants to move forward with.

04/21/2024 - Market Analysis

KASIA KLOTZ - Apr 21, 2024, 9:48 PM CDT

Title: Market Analysis

Date: 04/21/2024

Content by: Kasia Klotz

Present: N/A

Goals: Conduct a market analysis of main competitors in the space, and create a visual to compare them directly to our product

Content:

	 MyDropper	 Gentle Drop	 Droppy
Prevents Contamination	✓	✓	X
Provides Stability	✓	✓	✓
Reduces Eye Drop Waste	✓	✓	X
Accommodates Dexterity Issues	✓	X	✓
Allows for Proper Eye Drop Placement	✓	X	X

- Gentle Drop
  - Main competitor in the space
  - created by eye doctors
  - patented device
  - prevents contamination, provides stability, and claim to reduce eye drop waste
  - does not accommodate dexterity issues or allow for proper eye drop placement into the lower eyelid pocket
- Droppy
  - provides stability as well as a mechanical advantage
  - does not prevent contamination (in direct contact with area around eye), reduce eye drop waste, or allow for proper eye drop placement
- My Dropper
  - prevents contamination by keeping the bottle and device out of contact with the eye or the area around it
  - provides stability via either the nose piece or platform
  - reduces eye drop waste by producing a more consistent drop size (and smaller)

- accommodates dexterity issues by providing a mechanical advantage (user can utilize their entire hand rather than just fingers)
- allows for proper eye drop placement by properly aligning the bottle tip with the lower eye lid pocket

Conclusions/action items:

It is important to conduct a market analysis to become familiar with the competitors in the space. After receiving feedback from WARF, we are confident that we are not infringing upon any existing intellectual property. These two competitors were chosen based on popularity as well as comparability. The visual provides an easy way for an audience to compare the three directly. We will need to emphasize this in future market pitches.

04/21/2024 - Logos and Branding

Title: Logos and Branding

Date: 04/21/2024

Content by: Thomas Kriewaldt

Present: N/A

Goals: To develop a logo that can be used for this project marketing and labeling

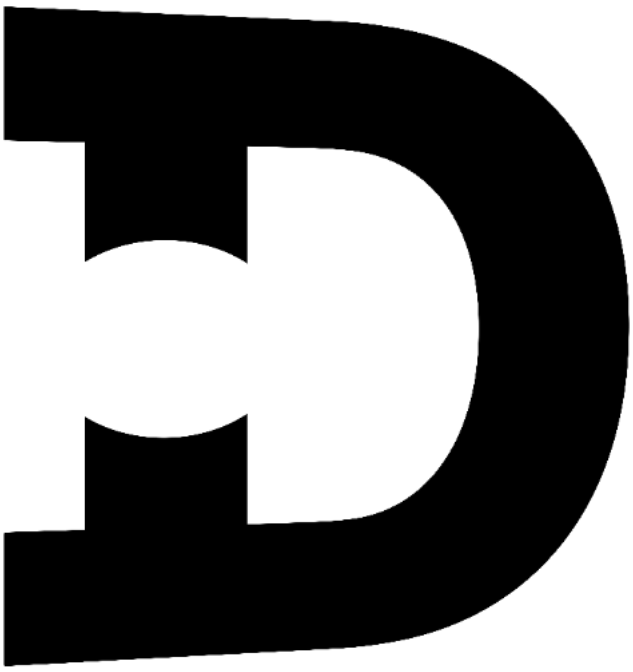
Content:

The team decided to the best option is a hybrid mixture of design ideas 2 and 3.

- Eye drop used as the "O" of the logo as in idea #2
- "D" is the devices' squeezing mechanism as in idea #3

The all-black, color-blocking of the logo is shown below:

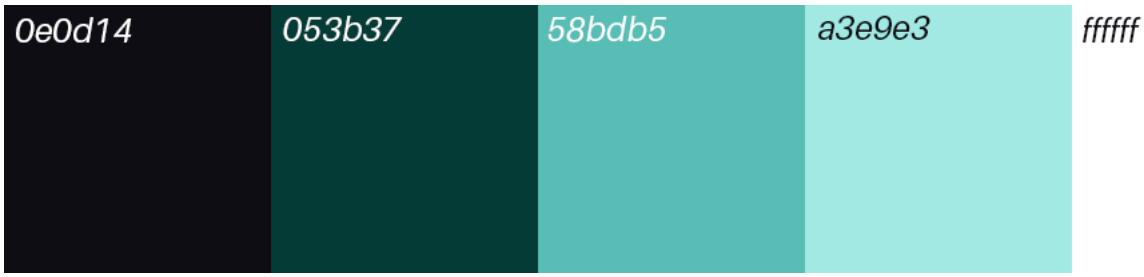
An alternate, smaller "D" only logo can be used as well.



The team decided to stick with similar colors to what we used in the ShaRx tank slides.

- A base of blue-green with lighter and darker hues as needed by the branding.

The colors, with hex codes, are shown below:



The team chose a clean, sans serif font - **Aileron**

- Structure of the font promotes strength and stability
- Easiest to read -- especially important given our target audience
- 16 different line styles for us to use in the future
    - **Also, this font family is free to use commercially**

-

The overall branding really represents our device well.

- Shows the device as a key component of the logo.
- Simple but structured geometric font.
- Includes colors of eye drops in its palette.

I have included a logo, the front branding, and the back branding to be used on the plastic packaging, below.

Conclusions/action items:

Use these logos on our poster and in future marketing work!

THOMAS KRIEWALDT - Apr 22, 2024, 12:01 AM CDT

Download

MyDropper-Final-Logo-Black.png (379 kB)

THOMAS KRIEWALDT - Apr 22, 2024, 12:01 AM CDT

Download

MyDropper-Large-Clip.png (88.2 kB)

THOMAS KRIEWALDT - Apr 22, 2024, 12:01 AM CDT

Download

MyDropper-Front-Branding.png (228 kB)

04/26/24 - Instruction Manuals

ANABELLE OLSON (amolson27@wisc.edu) - May 01, 2024, 12:53 PM CDT

Title: Instructions for Use of Device

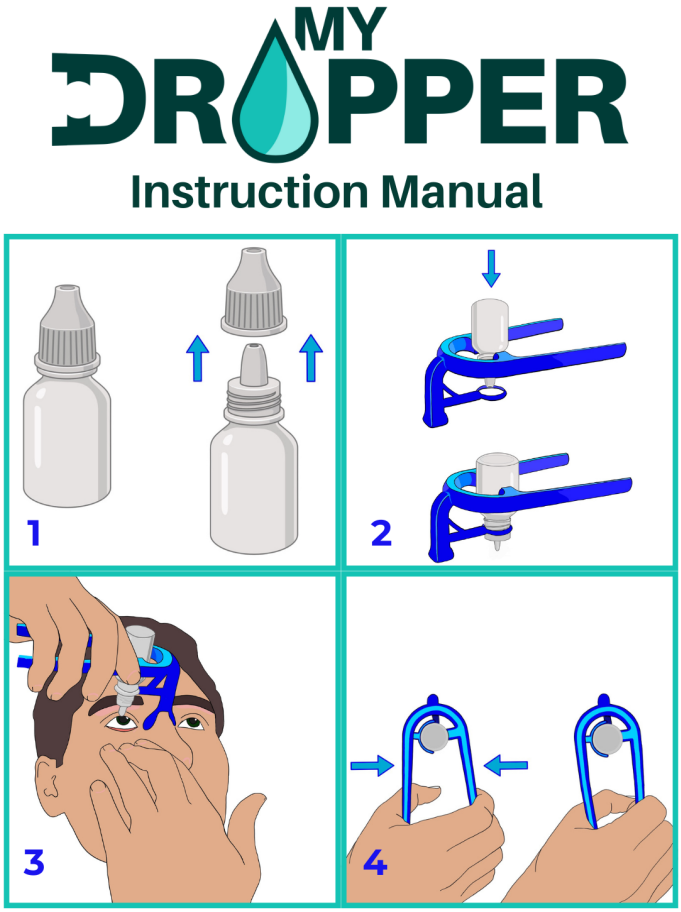
Date: 04/26/24

Content by: Anabelle Olson

Goals: To include easy to follow instructions for use of the device with the packaging.

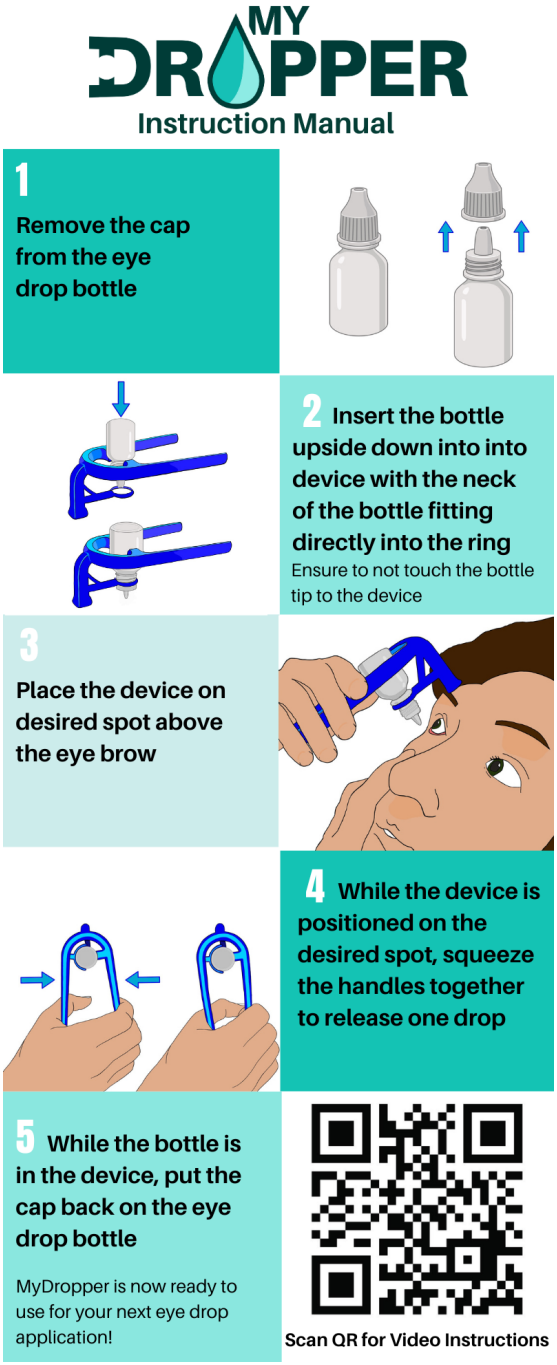
Content:

Nose bridge rest instruction manual:



1. Remove the cap from the eye drop bottle
2. Insert the bottle upside down into the device with the neck of the bottle fitting directly into the ring
3. Place the device onto the nose bridge
4. While the device is positioned on the nose bridge, squeeze the handles together to release one drop into the eye
5. After the release of one drop, remove the device from the nose bridge, leave the bottle in the device and put the cap back on the eye drop bottle

Eye Brow Rest Instruction Manual



Conclusions/action items:

These instruction manuals will be included in the packaging of the device and will be on display at the poster presentation.

04/30/2024 - Eye Drop User Market

Jenna Krause - May 01, 2024, 12:20 PM CDT

Title: Eye Drop User Market

Date: 04/30/2024

Content by: Jenna Krause

Present: N/A

Goals: To learn about the population of eye drop users in the United States

Citation:

Statista Research Department and F. 5, “U.S.: Usage of eye drops and eye wash 2011-2024,” Statista, https://www.statista.com/statistics/285907/usage-of-eye-drops-and-eye-wash-in-the-us-trend/

Content:

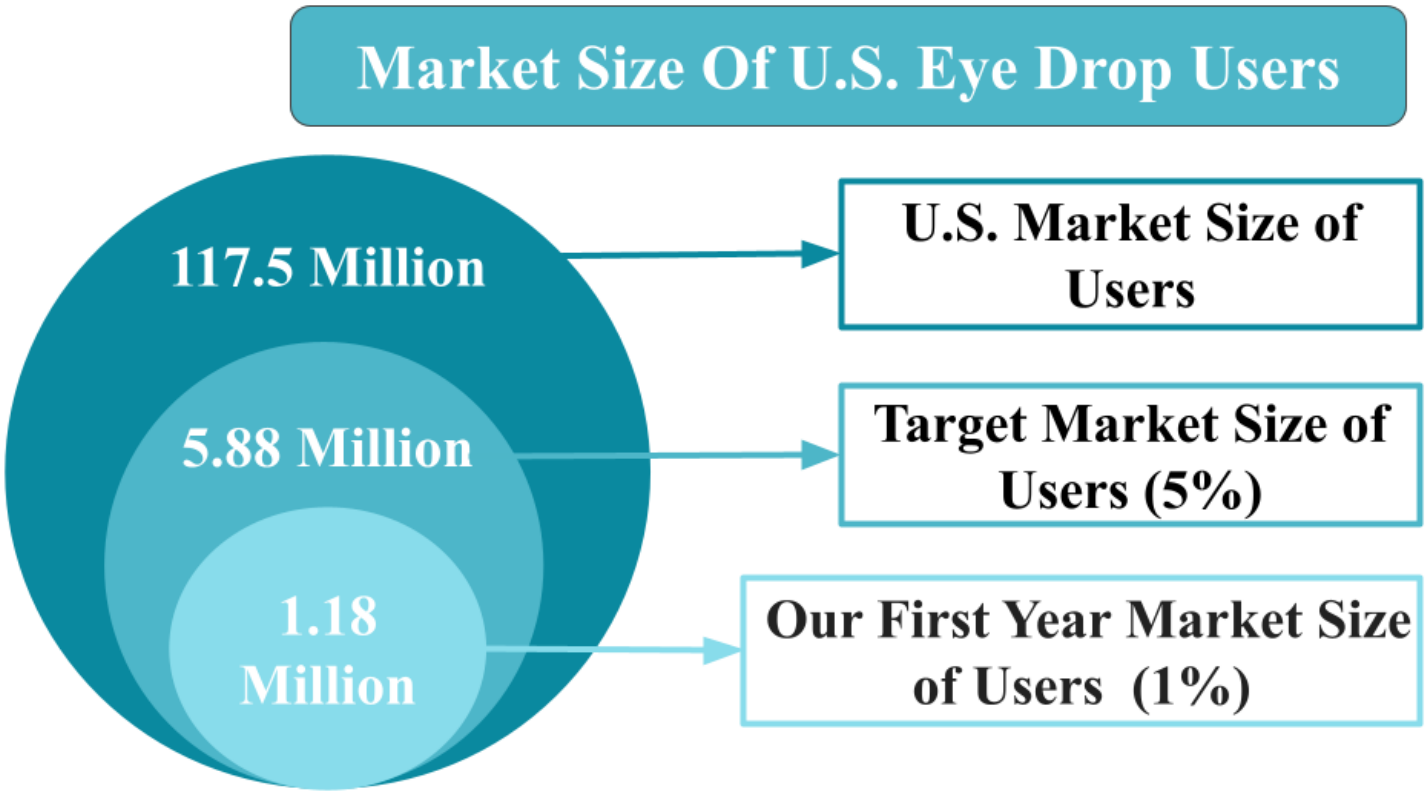
- The data has been calculated by Statista based on the U.S. Census data and Simmons National Consumer Survey (NHCS).

- According to this statistic, 117.45 million Americans used eye drops and eye wash in 2020

- This figure is projected to increase to 123.35 million in 2024.

- Mark Baum CEO of Harrow, an ophthalmic pharmaceutical company, suggested 5% of total eye drop users will be out total market for the team's device.

- From this the team took 1% of the market size for the first year projection



Conclusions/action items:

This resource is important for projecting the device's potential market. By finding the total number of eye drop users in the United States the team can work backwards to finding the project's serviceable obtainable market. This number was found with the advise and expertise from Mark Baum. The graphic above was then made to be included in ShaRx Tank presentation and BME final poster.

05/01/2024 - Device Packaging

Jenna Krause - May 01, 2024, 5:07 PM CDT

Title: MyDropper Device Packaging

Date: 05/01/2024

Content by: Jenna Krause

Present: N/A

Goals: To find and assemble packing for the MyDropper Device.

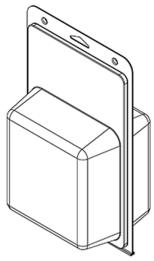
Citation:

“Clear plastic clamshell packaging,” VisiPak - CLAMSHELL PACKAGING, https://store.visipak.com/clamshell-packaging/ (accessed May 1, 2024).

Content:

- The following samples were obtain from Steve Kent (Regional Account Manage from VisiPak). The team was sent 4 stock clamshell packages to look at and determine which was best for the team's prototype.

584TF:



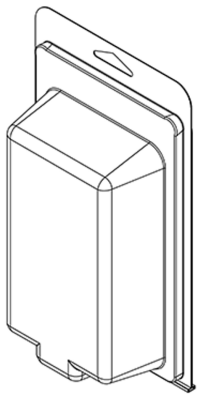
$1.18 per package = 200 Per Order = $236.34

Overall Outside Dimensions:

Length A = 10.938" / Width B = 6.875"

Cavity Dimensions:

Length C = 5.531" / Width D = 5.063" / Depth E = 4.563"



410TF (S):

$.81 per package = 300 per order = $242.31

Overall Outside Dimensions:

Length A = 8.250" / Width B = 4.938"

Cavity Dimensions:

Length C = 5.563" / Width D = 3.188" / Depth E = 2.250"

494TFM:

$.61 per package = 200 per order = $122.72

Overall Outside Dimensions:

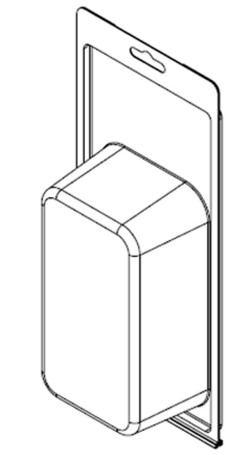
Length A = 10.150" Width B = 4.563"

Cavity Dimensions:

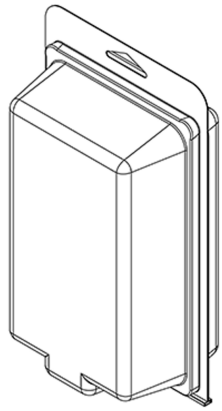
Length C = 5.805" Width D = 3.080" Depth E = 2.220"

Insert Card Dimensions:

Length F = 9.000" Width H = 4.125"



406TF:



$.81 per package = 300 per order = $242.31

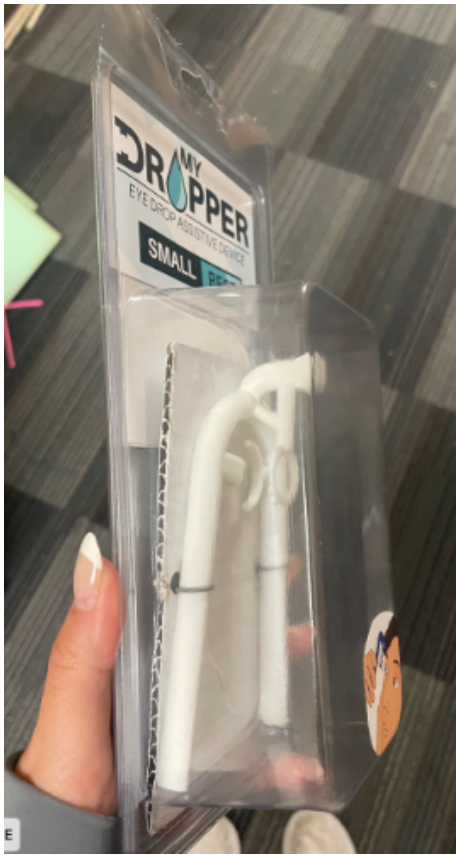
Overall Outside Dimensions:

Length A = 8.250" / Width B = 4.938"

Cavity Dimensions:

Length C = 6.250" / Width D = 3.563" / Depth E = 2.925"

Final assembly of the packaging is below:



Conclusions/action items:

I reached out to some possible clamshell vendors to see if I could be sent any samples. Steve from VisiPak responded saying their stock clamshell packaging have free samples that the team could try out. I requested 4 different samples based on the dimensions of our MyDropper device. From these the team determined to continue with the 494TFM as the final packaging option. I printed Tommy's logos and feature list he created at student print in a sticker format to give it a more professional look. Assembled the rest of the packaging at the maker space using hole puncher and wire ties. Future work for packaging is creating a more custom design package to fit the MyDropper device better.

03/21/2024: Response from WARF

KASIA KLOTZ - Apr 21, 2024, 9:54 PM CDT

Title: Response from WARF

Date: 03/21/2024

Content by: Kasia Klotz

Present: Whole Team

Goals: Document important communication with WARF discussing intellectual property

Content:

Email received from WARF in response to initial meeting:

Re: EYE DROP ASSISTANT DEVICE, Beth Martin, Jenna Krause, Eva Coughlin, Kasia Klotz, Tevis Linser, Anabelle Olson, Thomas Kriewaldt, P240235

Dear Inventors,

The patent and licensing staff here at WARF has reviewed the referenced disclosure and WARF has chosen not to pursue patent protection on your invention. Although a number of patent and licensing criteria were considered in our decision, the committee was primarily concerned about whether companies in this space would be willing to license a patent for a device such as this. Please appreciate that WARF's decision is primarily a business judgment and is not intended to reflect upon the scientific or technical merit of your technology.

In closing, I would like to thank you for bringing this invention to us and ask you to help us review our invention evaluation process. If you would, please take a moment to complete WARF's Disclosure Survey. Your input is appreciated and will help WARF evaluate the quality of the service we provide to inventors.

If we can be of further service to you in regard to this or any other matter, please do not hesitate to contact us.

Sincerely,

Brian

Brian Frushour
Intellectual Property Manager
Wisconsin Alumni Research Foundation (WARF)
614 Walnut Street, 13th Floor
Madison, WI 53726

Conclusions/action items:

This email was interpreted as follows: WARF has turned down pursuing our product. This was a business based decision, and therefore had nothing to do with infringing upon existing intellectual property. The committee was most concerned with finding a company to license the device. The team will pursue other avenues for patent opportunities.

04/18/2024 - Equity Review

Title: Equity Review

Date: 04/18/2024

Content by: Kasia Klotz

Present: Kasia Klotz, Anabelle Olson, Eva Coughlin, Tevis Linser, Jenna Krause, Thomas Kriewaldt

Goals: Determine obligations of invention rights

Content:

RE: Invention # 109798 / P240235
Title: EYE DROP ASSISTANT DEVICE

Dear Inventors,

The attached confidential letter details the findings of the equity review conducted by the University of Wisconsin-Madison Office of the Vice Chancellor for Research, for your above-referenced invention. It has been determined that no federal research funding administered by the University of Wisconsin-Madison was involved in the invention, and that no UW-Madison third party agreement contains provisions which obligate rights in this invention.

The equity review includes:

- a review of the intellectual property language in all relevant UW-Madison federal and non-federal agreements (industrial, association, foundation, consortia, material transfer, etc.) to determine what obligations may be attached to inventions; and
- a review of UW-Madison funding sources, including UW-Madison inventor payroll and active grants during the inventive work period.

The Office of the Vice Chancellor for Research has responsibility for providing notice of the inventive work to the federal government (if applicable) and/or notification to other parties when mandated by agreement in which UW-Madison is a party. Regardless of whether or not WARF has decided to pursue intellectual property protection for your invention, the Office of the Vice Chancellor for Research must still conduct an equity review to assure the UW-Madison's ability to comply with its obligations arising under federal law or in extramural sponsor agreements.

Sincerely,

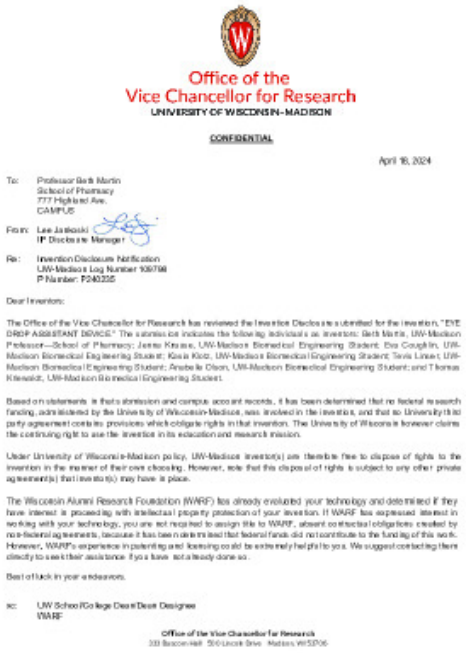
Lee Jankoski
Intellectual Property Disclosure Manager
Office of the Vice Chancellor for Research
University of Wisconsin-Madison
(608) 890-1867
lee.jankoski@wisc.edu

Conclusions/action items:

The team interpreted this information as follows:

The team owns all rights to this invention, and therefore can move forward as we see fit. Since there was no government funding involved, there is not concern for a government body owning the rights to this invention. Therefore, there are no obligations attached to this invention.

KASIA KLOTZ - Apr 21, 2024, 9:57 PM CDT



Office of the
Vice Chancellor for Research
UNIVERSITY OF WISCONSIN-MADISON

CONFIDENTIAL

April 18, 2024

To: Professor Beth Martin
School of Pharmacy
777 Highland Ave.
CAMPUS

From: Lee Jankowski
IP Disclosure Manager

Re: Invention Disclosure Notification
UW-Madison Log Number 109798
P Number: P240235

Dear Inventors:

The Office of the Vice Chancellor for Research has reviewed the Invention Disclosure submitted for the invention, "EYE DROP ASSISTANT DEVICE." The submission indicates the following individuals as inventors: Beth Martin, UW-Madison Professor—School of Pharmacy; Jenna Krause, UW-Madison Biomedical Engineering Student; Eva Coughlin, UW-Madison Biomedical Engineering Student; Kasia Klotz, UW-Madison Biomedical Engineering Student; Tevis Linser, UW-Madison Biomedical Engineering Student; Anabelle Olson, UW-Madison Biomedical Engineering Student; and Thomas Kriewaldt, UW-Madison Biomedical Engineering Student.

Based on statements in this submission and campus account records, it has been determined that no federal research funding, administered by the University of Wisconsin-Madison, was involved in the invention, and that no University third party agreement contains provisions which obligate rights in that invention. The University of Wisconsin however claims the continuing right to use the invention in its education and research mission.

Under University of Wisconsin-Madison policy, UW-Madison inventor(s) are therefore free to dispose of rights to the invention in the manner of their own choosing. However, note that this disposal of rights is subject to any other private agreement(s) that inventor(s) may have in place.

The Wisconsin Alumni Research Foundation (WARF) has already evaluated your technology and determined if they have interest in proceeding with intellectual property protection of your invention. If WARF has expressed interest in working with your technology, you are not required to assign title to WARF, absent contractual obligations created by non-federal agreements, because it has been determined that federal funds did not contribute to the funding of this work. However, WARF's experience in patenting and licensing could be extremely helpful to you. We suggest contacting them directly to seek their assistance if you have not already done so.

Best of luck in your endeavors.

cc: UW School/College Dean/Dean Designee
WARF

Office of the Vice Chancellor for Research
333 Bascom Hall 500 Lincoln Drive Madison WI 53706

Download

Equity_Review_109798_P240235.pdf (359 kB)

05/01/2024 - Communication with AbbVie Following ShaRx Tank

Title: Communication with AbbVie Following ShaRx Tank

Date: 05/01/2024

Content by: Eva Coughlin

Present: Eva Coughlin, Kasia Klotz, Jenna Krause, Tommy Kriewaldt, Tevis Linser, Anabelle Olson

Goals: To follow up on our connection with Azita (judge from ShaRx Tank).

Content:

EC

Eva Mary Coughlin
To: azita.gerhardt@abbvie.com
Sun 4/21/2024 4:35 PM
Cc: KASIA MARIE KLOTZ; ANABELLE M OLSON; TEVIS JON LINSER; **+3 others**

402-Tong-4-eye_guide-Execu... 46 KB
MyDropper_ShaRx Tank Pres... 18 MB

2 attachments (18 MB) Save all to OneDrive - UW-Madison Download all

Hi Azita,

We hope you are doing well! I am the communicator for the team that worked in creating the My Dropper device for easing the administration of eye drops. First, we want to say thank you so much for your encouragement and feedback on our product at the ShaRx Tank. We enjoyed the competition and talking with you after. We discussed sending you a summary of our project, so you and your team can decide if you're interested in pursuing our product. I attached the executive summary of our project to this email as well as our slide deck from ShaRx Tank. Please let me know if there is any other information that would be helpful for me to send. We're looking forward to hearing back from you and hope you're having a great weekend!

Thank you,

Eva Coughlin
B.S. Biomedical Engineering 2024
University of Wisconsin-Madison
emcoughlin@wisc.edu

SA

Saleki-Gerhardt, Azita <azita.gerhardt@abbvie.com>
To: Eva Mary Coughlin
Mon 4/22/2024 9:16 AM
Cc: KASIA MARIE KLOTZ; ANABELLE M OLSON; TEVIS JON LINSER; **+3 others**

Thank you Eva for sharing your proposal, congratulations again to all of you for winning this year's ShaRx Tank competition.
I am circulating your proposal with our commercial team, will let you know what we hear back and level of interest,
Best
Azita

AZITA SALEKI-GERHARDT, PH.D.
EVP, Chief Operations Officer
Chair, Executive Crisis Management Team

abbvie

AbbVie
Operations
1 North Waukegan Road
North Chicago, IL 60064
OFFICE +1 847-938-2059
FAX 8479371820
EMAIL azita.gerhardt@abbvie.com

abbvie.com

EC

Eva Mary Coughlin

To: Saleki-Gerhardt, Azita <azita.gerhardt@abbvie.com>

Wed 5/1/2024 11:21 AM

Cc: KASIA MARIE KLOTZ; ANABELLE M OLSON; TEVIS JON LINSER; **+3 others**

Hi Azita,

Thank you for sharing our proposal with the commercial team. I wanted to update you on some exciting news with our project. Last Friday we had our final biomedical engineering poster presentations. We won the Tong Biomedical Design Award! This is awarded to innovative solutions and outstanding prototypes for projects that have performed an in-depth analysis of their commercial and intellectual property potential. It is presented by industry judges. https://bmedesign.engr.wisc.edu/awards#winners
We are looking forward to hearing back from you regarding thoughts from your team and appreciate the time you've invested into helping us continue this project.

Thank you,
Eva

Conclusions/action items: The team met Azita Saleki-Gerhardt, COO of AbbVie, at the Pharmacy School ShaRx Tank. Azita expressed that she loved our product and wants to help us with getting this patented. I reached out to Azita to follow up on this opportunity, and she responded saying that she is circulating our proposal through her commercial team. I am going to continue making an effort to keep up on this communication.

02/19/2024 - Peermax

Title: Peermax and Owen Mumford

Date: 02/19/2024

Content by: Kasia Klotz

Present: N/A

Goals: evaluate competing company design

Links:

https://peermaxcare.com/

https://www.owenmumford.com/us/intellectual-property

Citations:

[1] Peermax, https://peermaxcare.com/ (accessed Feb. 19, 2024).

[2] “Intellectual property,” Owen Mumford, https://www.owenmumford.com/us/intellectual-property (accessed Feb. 19, 2024).

Content:

- Company with a variety of assistive device for eye drops

$5.00 Off

Peermax

Peermax Drop Direct Eye Drop Dispenser

$14.99

Peermax

Peermax Drop Right 2 in 1

$13.99

Peermax

Peermax Drop Smart Eye Drop Guide

$13.99

00 Off

Owen Mumford

AutoSqueeze Bottle Aid

$13.99

EZ Drops

EZ Drops Reflective Eye Drop Application Strips

$9.99

Owen Mumford

AutoDrop Eye Drop Guide

$13.99

- These products are similar to many other products on the market
  - could not find any patents under this companies name
- Owen Mumford is another company featured on the pictured products
  - medical device company with a variety of products
  - many of their products are patented, however, it does not look like their eye drop assistive devices are patent
    - does target people with arthritis and dexterity issues
    - provides mechanical advantage but does not allow user to look in a mirror
    - claims that the drop hits the correct location, completely covers eye

Conclusions/action items:

The products listed on the Peermax website show the variety of competing devices that are on the market. There do not seem to be many patents in this space, as many companies have similar devices. There may be an advantage to patenting devices in this space, as it would knock out many competitors.

02/20/2024 - Gentle Drop

Title: Gentle Drop

Date: 2/20/2024

Content by: Kasia Klotz

Present: N/A

Goals: complete a market analysis of gentle drop

Links:

https://www.dropbetter.com/

https://www.sciencedirect.com/science/article/pii/S2589419621000119?via%3Dihub

Citations:

"GentleDrop: A Revolutionary new way to use your Eye Drops," GentleDrop. Accessed: Feb. 25, 2024. [Online]. Available: https://www.dropbetter.com

F. G. Sanchez *et al.*, "Novel Eye Drop Delivery Aid Improves Outcomes and Satisfaction," *Ophthalmology Glaucoma*, vol. 4, no. 5, pp. 440–446, Sep. 2021, doi: 10.1016/j.ogla.2021.01.001.

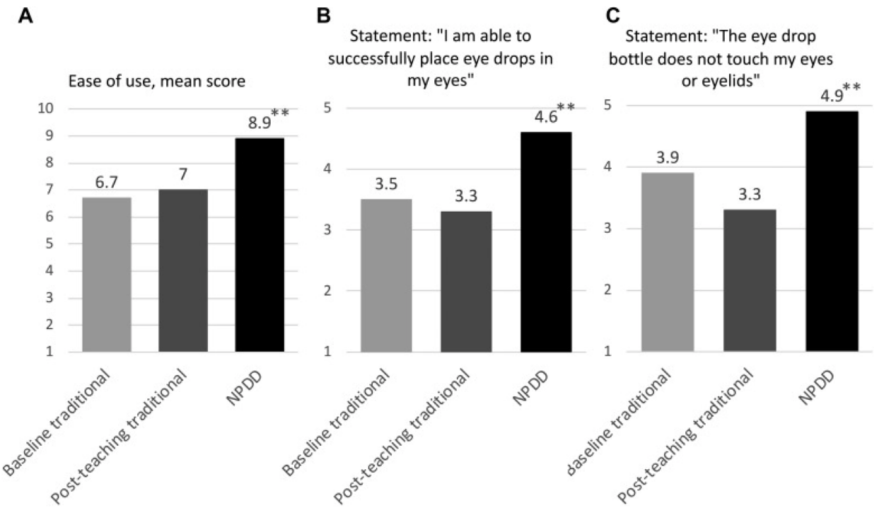
Content:

- The product is currently being sold for $15
- They conducted a study with 50 glaucoma patients
  - 47 patients preferred using the bottle with the device rather than without
  - 49 were comfortable using the device
- GentleDrop reduces the average number of drops used from 2.2 to 1.7 per eye
- GentleDrop reduced chances of the bottle touching the eyes or eyelid by 46%
- One thing that stood out to me about this study was their inclusion/exclusion factors

  - Inclusion and Exclusion Criteria

    Inclusion criteria were: (1) existing diagnosis of perimetric or preperimetric glaucoma or ocular hypertension; (2) bilateral self-administration of 1 or more type of intraocular pressure-lowering eye drops with at least 6 months of prior usage; and (3) any self-perceived difficulty instilling eye drops. Exclusion criteria were: (1) cognitive or physical limitations interfering with eye drop administration; (2) current use of an eye drop delivery aid; or (3) allergy to preserved artificial tears.

  - This implies that this device might not be useful for those with dexterity issue, which may make our device stand out among competitors



- The chart above shows the success in the use of their device. I believe these results would have been drastically different if they had included subjects with any sort of arthritis or dexterity issues.

- Unfortunately, I was not able to find anything regarding the amount of sales this company has done for their product. I plan to continue looking into this.

Conclusions/action items:

Gentle Drop is likely the team's biggest competitor currently on the market. They not only claim to be an eye drop aid, but they also have clinical evidence showing a reduction in the amount of solution dispense from an eye drop bottle while using their product. Their biggest downfall is that they do not consider patients with reduced dexterity. The was apparent in their exclusion criteria for their clinical trial. Although they used patients with glaucoma, they did not allow patients who could had physical limitations that interfered with eye drop administration.

Novel Eye Drop Delivery Aid Improves Outcomes and Satisfaction

Facundo G. Sanchez, MD,[1,2] Steven L. Mansberger, MD, MPH,[1,2] Fangtai Kang, MD,[1] Stuart K. Gardiner, PhD,[2] Claude F. Burgoyne, MD,[1] Emmett T. Cunningham, Jr., MD, PhD,[1,3,4] Jack P. Rice, B.A.,[1] Emily P. Jones, MD,[1] Robert M. Kwasi, MD[1,2]

Purpose: To compare a nose-pivoted drop delivery device (NPDD) with traditional eye drop delivery in glaucoma subjects.

Design: Repeated-measures case series.

Participants: Fifty glaucoma subjects (100 eyes) who reported difficulty self-administering eye drops.

Methods: We compared eye drop delivery using a NPDD against traditional delivery techniques at baseline (baseline traditional) and after standardized teaching (post-teaching traditional). Subjects used a 1-to-10 scale (10 being easiest) to rate the ease of delivery with each technique and completed a satisfaction survey. Two graders used digital video to independently review eye drop delivery and recorded: (1) accurate placement: the eye drop reached the ocular surface; (2) no contact: no bottle tip contact against the ocular or periocular surface; and (3) number of eye drops dispensed. We defined primary success as accurate placement and no contact; secondary success as primary success with only 1 drop dispensed.

Main Outcome Measures: We used logistic-transformed generalized estimating equation (GEE) regression to compare technique satisfaction, accuracy, no contact, and primary and secondary success. Number of drops dispensed was compared using a Cox model.

Results: Forty-seven of 50 subjects (94%) preferred the NPDD over traditional eye drop delivery. The mean score for ease of use was higher for the NPDD (9.9 ± 1.1) than baseline traditional (6.7 ± 2.1; $P < 0.001$) and post-teaching traditional (7.5 ± 2.2; $P < 0.05$). Forty-nine of 50 (98%) subjects thought the NPDD was comfortable to use and would recommend the device. The eye drop reached the ocular surface in a similar percentage of subjects (~80%) with each method. The bottle tip contacted fewer eyes with the NPDD (10 eyes) than baseline traditional (50 eyes; $P < 0.001$) and post-teaching traditional (25 eyes; $P = 0.026$). The number of drops dispensed was lower with the NPDD (1.7 ± 1.2) than baseline traditional (2.2 ± 1.6; $P = 0.017$) and post-teaching traditional (2.4 ± 1.8; $P = 0.036$). The NPDD increased primary and secondary success of eye drop delivery (86% and 54%, respectively) compared to baseline traditional (66% [$P = 0.001$] and 28% [$P < 0.001$]) and post-teaching traditional (70%, $P = 0.005$ and 40% [$P = 0.018$]).

Conclusions: Eye drop users preferred the NPDD over traditional eye drop delivery. The NPDD improved eye drop delivery success, reduced bottle tip contact, and decreased the number of eye drops wasted. *Ophthalmology Glaucoma 2021;4:440-448* © 2021 by the American Academy of Ophthalmology. *This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).*

Glaucoma affects more than 60 million people worldwide.[1] Eye drop medications are the most common method of treating glaucoma. Poor adherence to prescribed eye drop medications can result in glaucomatous vision loss.[2–4] Eye drop adherence for all ocular diseases has 2 components: (1) possession and regular use of the medication as prescribed and (2) successful delivery of the medication to the eye. Most glaucoma patients struggle at self-administering eye drops.[5–7] Patients who struggle with eye drop self-administration could benefit from delivery aids.[8,9]

Prior studies indicate that up to 90% of glaucoma subjects instill their eye drops incorrectly, with 7% to 30% of patients missing the eye with the drop and 29% to 80% contacting the eye or eyelids with the bottle tip.[5,7,10,11] Poor eye drop instillation also wastes valuable medication, which can worsen adherence further if a bottle empties prematurely.[12,13] Self-administering eye drops can be challenging for patients, who may fear bottle tip contact against the eye, missed medication, or vision loss resulting from poor delivery.[14] Although useful, existing delivery aids have not been adopted widely, possibly because they are not user friendly.[15]

We aimed to test whether a novel eye drop delivery aid would improve eye drop instillation success in patients with self-reported difficulty placing eye drops and whether they preferred such an aid over their traditional, unassisted technique. One of the authors (CFB) developed a nose-pivoted drop delivery device (NPDD; GentleDrop [Bodo Solutions LLC]). The NPDD rests on the bridge of the nose

https://doi.org/10.1016/j.ogla.2021.01.008
ISSN 2589-4196

Download

GentleDrop.pdf (1.16 MB)

2/28/2024 - Product Comparison

KASIA KLOTZ - Feb 28, 2024, 11:46 AM CST

Title: Product Comparison

Date: 2/28/2024

Content by: Kasia Klotz

Present: N/A

Goals: Create a visual showing why our product is better than the existing ones on the market

Content:

	 MyDropper	 Gentle Drop	 Droppy Drop
Prevents Contamination	✓	✓	
Provides Stability	✓	✓	✓
Reduces Eye Drop Waste	✓	✓	
Accommodates Dexterity Issue	✓		✓
Allows for Proper Eye Drop Placement	✓		

- updated image of device can be seen above

Conclusions/action items: The criteria included in the visual addresses contamination, stability, eye drop waste, dexterity, and eye drop placement. These are all important criteria to consider when using an assistive device to dispense eye drops. This graphic will be useful in both the shark tank presentation as well as the final poster presentation.

2/28/2024 - Harrow Opthalmics

Title: Harrow Opthalmics

Date: 2/28/2024

Content by: Kasia Klotz

Present: N/A

Goals: Learn more about Harrow Opthalmics as a company

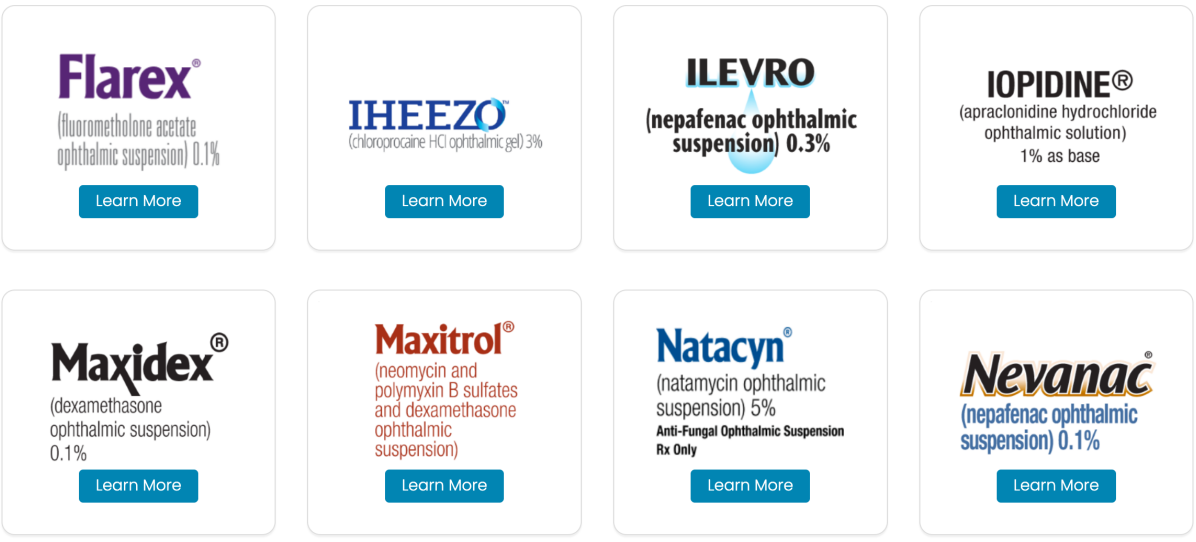
Source: https://www.harrow.com/about.html

Citation:

[1] M. L. Baum, "Our Company," in About Harrow. Harrow Inc., 2023. [Online]. Available: https://www.harrow.com/about.html. [Accessed: Feb. 27, 2024].

Content:

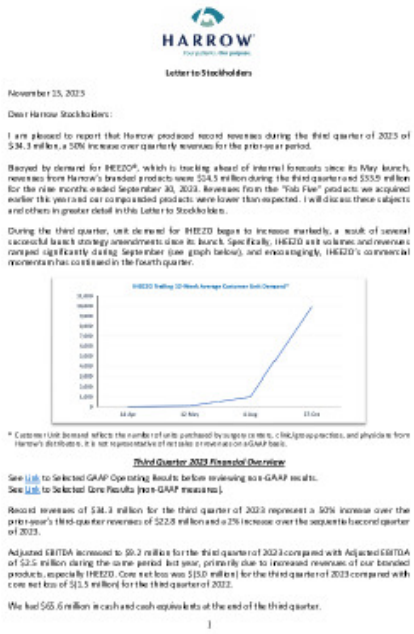
- Eva networked during the intial board meeting for sharktank and recieved contact information for Mark Baum, CEO of Harrow Opthamics
  - Could be a good opportunity for partnership with our product
- "Reimagining eye care, we built a simple and transparent platform to help ophthalmologists and optometrists better serve patients."
- Make pharmaceutical products for
  - over 8 million annual ophthalmic surgeries in the U.S.
  - make medications prescribed to treat:
    - patients managing chronic and acute eye conditions:
      - dry eye disease, glaucoma, allergies, infections, and other ophthalmic inflammatory conditions
- Supported by an integrated national sales and customer service organization, as well as an efficient, scalable, and tech-enabled national production and distribution platform licensed to do business in all 50 U.S. states
- Produces and distributes a variety of eye drops



- Detailed information about each of these eye drops can be found on the company website
- This company is very successful and has been growing consistently. The attached PDF shows stock information for Harrow Opthalmics

Conclusions/action items: Partnering with a company like Harrow Opthalmics may be a great way to go to market with the device. Shark tank has already turned out to be an incredible marketing opportunity, and the team is looking forward to keep networking. Networking will be the most important aspect of this semester, as many of us have very little experience in business. It will be beneficial to gain help from people who are already in this field.

KASIA KLOTZ - Feb 28, 2024, 8:42 PM CST


HARROW

Letter to Stockholders

November 15, 2023

Dear Harrow Stockholders:

I am pleased to report that Harrow produced record revenues during the third quarter of 2023 of $34.3 million, a 50% increase over quarterly revenues for the prior-year period.

Buoyed by demand for RHEZO®, which is tracking ahead of internal forecasts since its May launch, revenues from Harrow's branded products were $14.5 million during the third quarter and $35.5 million for the nine months ended September 30, 2023. Revenues from the "Fab Five" products we acquired earlier this year and our compounded products were lower than expected. I will discuss these subjects and others in greater detail in this Letter to Stockholders.

During the third quarter, unit demand for RHEZO began to increase markedly, a result of several successful launch strategy amendments since its launch. Specifically, RHEZO unit volumes and revenues ramped significantly during September (see graph below), and encouragingly, RHEZO's commercial momentum has continued in the fourth quarter.

RHEZO Trailing 12-Week Average Customer Unit Demand*

* Customer Unit Demand reflects the number of units purchased by surgeon centers, clinic/group practices, and physicians from Harrow's distributors. It is not representative of net sales or revenue on a GAAP basis.

Third Quarter 2023 Financial Overview

See Link to Selected GAAP Operating Results before reviewing non-GAAP results.
See Link to Selected Core Results (non-GAAP measures).

Record revenues of $34.3 million for the third quarter of 2023 represent a 50% increase over the prior-year's third-quarter revenues of $22.8 million and a 2% increase over the sequential second quarter of 2023.

Adjusted EBITDA increased to $0.2 million for the third quarter of 2023 compared with Adjusted EBITDA of $2.5 million during the same period last year, primarily due to increased revenues of our branded products, especially RHEZO. Core net loss was $15.0 million for the third quarter of 2023 compared with core net loss of $11.5 million for the third quarter of 2022.

We had $65.6 million in cash and cash equivalents at the end of the third quarter.

1

Download

HarrowInvestors.pdf (858 kB)

Red Permit

KASIA KLOTZ - Feb 21, 2022, 9:51 PM CST

Title: Red Permit

Date: 2/21/22

Content by: Kasia Klotz

Present: Kasia Klotz

Goals: complete red permit

Content:

See pdf of proof of red permit completion below.

Conclusions/action items:

Complete green permit.

KASIA KLOTZ - Feb 21, 2022, 9:52 PM CST

Download

Red_Permit.pdf (207 kB)

Green Permit

KASIA KLOTZ - Mar 08, 2022, 9:07 PM CST

Title: Green Permit

Date: 03/08/2022

Content by: Kasia Klotz

Present: N/A

Goals: learn how to use a lathe and mill

Content:

proof of completion below

Conclusions/action items:

KASIA KLOTZ - Mar 08, 2022, 9:06 PM CST

Download

Green_Permit.png (254 kB)

Chemical and Biological Safety Training

KASIA KLOTZ - Mar 28, 2022, 10:59 PM CDT

Title: Chemical and Biological Safety Training

Date: 03/08/2022

Content by: Kasia Klotz

Present: N/A

Goals:

Content:

Proof of completion shown below

Conclusions/action items:

KASIA KLOTZ - Mar 08, 2022, 9:04 PM CST

Download

Screen_Shot_2022-03-08_at_8.57.15_PM.pdf (141 kB)

02/27/2024 - Eye drop technique and patient-reported problems

Jenna Krause - Feb 28, 2024, 1:29 PM CST

Title: Eye drop technique and patient-reported problems in a real-world population of eye drop users

Date: 2/27/2024

Content by: Jenna Krause

Goals: To learn more common problems with eye drops for a target market

Citation:

Mehuys, E., Delaey, C., Christiaens, T., Van Bortel, L., Van Tongelen, I., Remon, J.-P., & Boussery, K. (2019). Eye drop technique and patient-reported problems in a real-world population of Eye Drop Users. *Eye*, *34*(8), 1392–1398. https://doi.org/10.1038/s41433-019-0665-y

Content:

- The study contain Participants (n = 678) had a mean age of 68.9 ± 12.4 years.
- Previous studies have shown that patients perform relatively poor when instilling eye drops.
- These studies were done in glaucoma patients recruited from eye clinics or private ophthalmology practices, mostly in the United States.
    - However, data from a broad patient population in primary care are currently lacking. T
- Results:
    - During the demonstration, almost everyone (98.0%) successfully instilled at least one drop in the eye, although 14% required multiple attempts to achieve this.
    - Only 3% of the sample exhibited perfect drop technique, meaning that they performed correctly all the steps.
    - Most common deviations were touching the bottle to the eye or eyelid (40.7% of patients), and failing to close the eye (67.8%).
    - Forty percent of patients reported ≥ 1 problem with eye drop instillation.
    - Most common problems were difficulties with getting a drop in the eye (18.3% of patients), too many drops coming out of the bottle (14.6%), and difficulty squeezing the bottle (12.2%).
    - Below are examples of problems with the eye drops.
    - Self-reported problems with eye drop instillationa

Patients with at least one problem	269 (39.7)
Difficult to get drop in eye	124 (18.3)
Too many drops come out	99 (14.6)
Hard to squeeze the bottle	83 (12.2)
Not sure drop actually gets in eye	44 (6.5)
Hard to open bottle	33 (4.9)
Too much blinking	30 (4.4)
Hard to hold bottle over eye	27 (4.0)
Hard to tilt back the head	17 (2.5)
Shaky hands	15 (2.2)
Other	27 (4.0)

    - Only 9.1 % know there are eye drop dispensing aids and only .7 % of the study uses them.

Conclusions/action items:

The findings underscore the prevalent challenges individuals face in correctly administering eye drops, with a notable lack of awareness and utilization of eye drop dispensing aids. These results emphasize the importance of developing effective assistive devices, aligning with the team's goal of addressing poor eye drop technique in real-world scenarios. Action items for the team are to take these statistics for market analysis.

02/07/2024 - Injection Molding Materials

Jenna Krause - Feb 27, 2024, 7:46 PM CST

Title: Injection Molded Materials

Date: 2/7/2024

Content by: Jenna Krause

Goals: To learn more about injection molded materials and pricing options

Citation:

Nwmcadmin, “The cost of injection molding materials,” Rex Plastics, https://rexplastics.com/plastic-injection-molding/the-cost-of-injection-molding-materials (accessed Feb. 7, 2024).

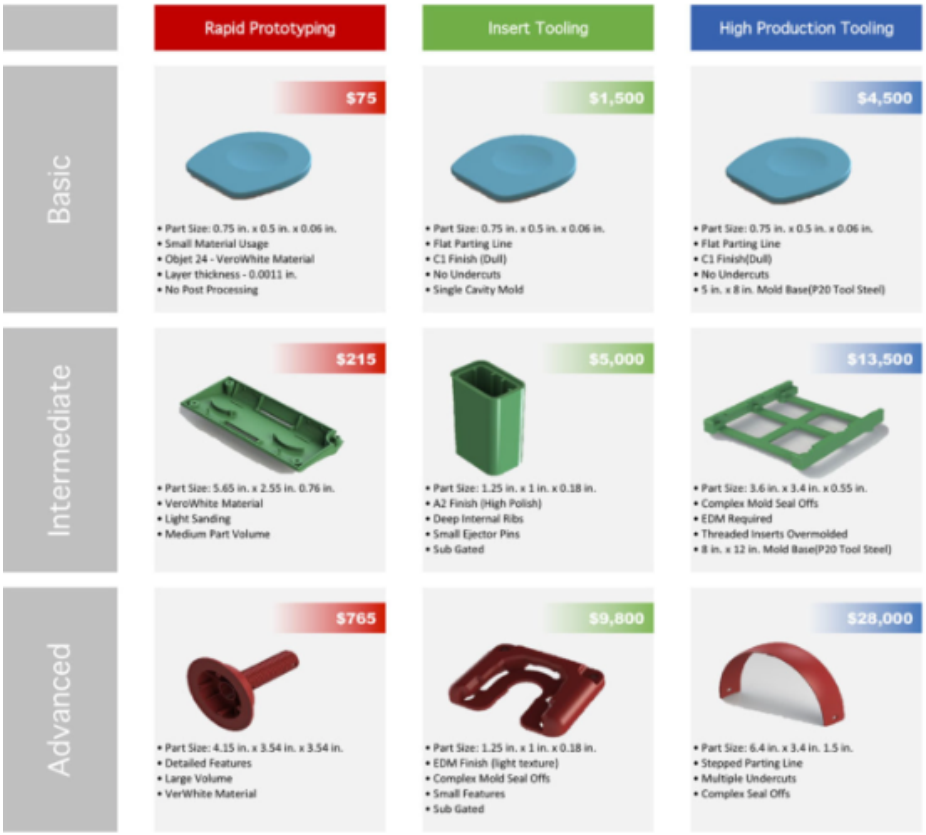
Content:

- Injection molding cost can range anywhere from $100 to $100,000+ depending on the scope and intricacy of the project.
  - A small and simple single-cavity plastic injection mold usually costs between $1,000 and $5,000.
  - Very large or complex molds may cost as much as $80,000 or more.
  - On average, a typical mold that produces a relatively simple part small enough to hold in your hand costs around $12,000.
- If you’re looking at price per unit, plastic injection molding is one of the cheapest, most cost-efficient forms of manufacturing.
  - With injection molding, the more units you create with your mold, the cheaper the price per unit becomes.
- 3 Methods for Making Molds or Toolings
  - Computer numerical control (CNC) machine:
    - CNC machines, ideal for diverse production needs, utilize materials like tool steel, metals, plastics, foam, glass, and wood, providing precision down to a fraction of a millimeter for various projects.
  - Electric discharge machine (EDM):
    - EDM machines excel in intricate mold designs, utilizing a dielectric fluid to facilitate precise shaping of the workpiece electrode through recurring current discharges between the workpiece and tool electrode.
  - 3D printing:
    - 3D printing offers a cost-effective and efficient approach for rapid injection mold production, requiring minimal equipment and professional labor, enabling design testing and material trials before committing to mass production tooling.
- Materials used in injection molding are plastics, specifically thermoplastics.
  - most common thermoplastics used in injection molding are:
    - Polypropylene = $.90
    - Polyethylene = $1.20
    - Acrylonitrile Butadiene Styrene (ABS) = $1.30

Type of Thermoplastic Material	Unique Features	Common Applications	Price per pound
ABS	durable, lightweight	electronics, keyboards, phone hardware, LEGO bricks, drainpipe systems, kitchen appliances	$1.30
polyethylene	flexible, impact-resistant, leech resistant, moisture resistant, recyclable	food packaging, milk jugs, toys	$1.20
polypropylene	leech resistant, flexible	Tupperware, kiddie pools, toys, utensils, car batteries	$0.90
polystyrene	warp, shrink and impact resistant	compact disc cases, packaging applications, household appliances	$1.00
nylon / (POM)	heat-resistant, durable	high-ware parts, quick-release buckles, gears, hand cranks	$2.20
polycarbonate	impact resistant, optical clarity, vulnerable to chemicals	automobile headlights, bulletproof glass, eyeglasses, greenhouses, DVDs, mobile phones	$2.30

-

- The last thing to consider when pricing out your injection molding cost is the cost of service or professional labor you will need
  - The injection molding cost examples are categorized by type (Rapid Prototyping, Insert Tooling, High-Production Tooling), and degree of difficulty (Basic, Intermediate, Advanced).



Conclusions/action items:

Injection molding costs vary based on project complexity, ranging from $1,000 to $80,000 or more for molds. With an average of around $12,000 for small, simple parts. Plastic injection molding, especially in higher quantities, becomes cost-efficient, with materials like Polypropylene and Polyethylene commonly used. Connecting to the team's eye drop prototype, future considerations of injection molding with PP material and a 3D printed mold align with cost-effective manufacturing methods for precision and efficiency.

02/08/2024 - Clamshell Packaging Vendor

Jenna Krause - Feb 27, 2024, 8:08 PM CST

Title: Clamshell Packaging Vendor

Date: 2/8/2024

Content by: Jenna Krause

Goals: To learn more about Clamshell packaging vendor option

Citation:

“Custom clamshellhdx filters,” VisiPak, https://www.visipak.com/hdx-refrigerator-filters-case-study.html (accessed Feb. 8, 2024).

Content:

- VisiPak offers unique solutions to meet the needs of virtually every application and budget.
- Plastic clamshell packaging is most commonly made with PVC and PET with wall thicknesses ranging from .010" to .060" to accommodate a wide variety of applications.
    - PET is a plastic resin that is commonly used in the food and pharmaceutical industries when an FDA approved package is required.
    - PVC is a synthetic plastic polymer. It is the most common and most economical material used.
- All materials exhibit high clarity and are extremely durable.
- Plastic clamshells are great for protecting your product and, at the same time, displaying its most precise details.
- Stock Product Lines
    - With over 200 stock clamshell packages, VisiPak leads the industry for quick, cost-effective clear clamshell packaging solutions. These lines require no tooling charges, no design fees and samples are readily available for testing
- Semi-Custom Solutions
    - Semi-Custom clamshells feature reduced tooling charges, reduced design fees and reduced time to market. They are made utilizing standard mold bases with custom cavity inserts designed to your exact specifications.
    - Creating a semi-custom clamshell is as simple as 1 - 2 - 3! We have a list mold bases that accommodate customized inserts and graphics like the one you see here.
        - 1) Pick a stock base
        - 2) Create a custom cavity
        - 3) Complete with your own graphics
- Custom Solutions
    - With extensive design experience and comprehensive rapid prototyping capabilities, our packaging design team can create a custom solution tailored to your exact needs.
    - All custom clamshells are manufactured with quality and efficiency in the company's ISO 9001:2015 Certified facility in St. Louis, Missouri.

Conclusions/action items:

VisiPak provides a wide range of clear clamshell packaging solutions, utilizing materials like PVC and PET with high clarity and durability, offering stock, semi-custom, and custom options. Considering the team's eye drop prototype, exploring VisiPak for manufacturing estimates could be beneficial, given their expertise in clear clamshell packaging and customizable solutions.

02/28/2024 - Ophthalmic Eye Dropper Market Size

Jenna Krause - Feb 28, 2024, 2:11 PM CST

Title: Ophthalmic Eye Dropper Market Size and Share Will Reach USD 22.93 Billion By 2032, Growing at a CAGR of 6.2%: Polaris Market Research

Date: 2/28/2024

Content by: Jenna Krause

Goals: To learn more about the eye drop market

Citation:

[1] Polaris Market Research & Consulting LLP, "Ophthalmic Eye dropper market size and share will reach USD 22.93 billion by 2032, growing at a CAGR of 6.2%: Polaris Market Research," GlobeNewswire News Room, https://www.globenewswire.com/en/news-release/2024/02/16/2830774/0/en/Ophthalmic-Eye-Dropper-Market-Size-and-Share-Will-Reach-USD-22-93-Billion-By-2032-Growing-at-a-CAGR-of-6-2-Polaris-Market-Research.html#:~:text=The%20global%20Ophthalmic%20Eye%20Dropper,study%20by%20Polaris%20Market%20Research. (accessed Feb. 28, 2024).

Content:

- The global eye dropper market size and share are currently valued at USD 13.44 billion in 2023.
- It is anticipated to generate an estimated revenue of USD 22.93 billion by 2032.
- Market Definition
    - There are several eye drops obtainable, spanning from over-the-counter eye drops to eye drops, that will be handed out with appropriate recommendations only.
    - The ophthalmic eye dropper market growth can be attributed to escalated eye cure research and development funding, causing the advancement of more productive and effortlessly adjustable customized to manifold eye-connected situations

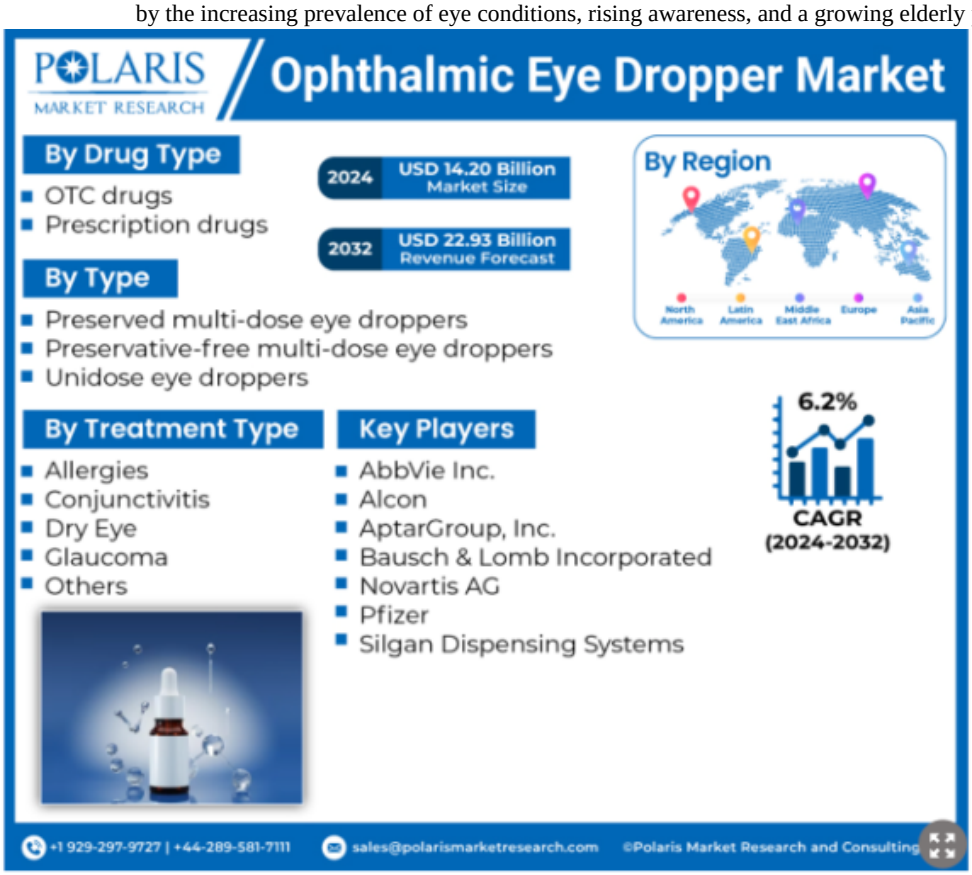
- Ophthalmic Eye Dropper Market Key Companies

    - AbbVie Inc.
    - Alcon
    - AptarGroup, Inc.
    - Bausch & Lomb Incorporated
    - Novartis AG
    - Pfizer
    - Silgan Dispensing Systems

- Market Developments

    - Growth Drivers:
        - Eye illnesses:
            - pervasiveness of eye conditions involving customary proceedings such as glaucoma, withered eyes, and allergies is surging globally.
            - The ophthalmic eye dropper market size is expanding as more persons are encountering these eye-associated health problems, and there is an escalating demand for productive solutions to handle and relieve indications.
        - Digital progression
            - The ophthalmic eye dropper market sales are soaring as the extended screen subjection has caused surging eye illnesses and infections.
            - The environmental alterations linked with climate change also cause a surge in eye infections and diseases.
            - The growing usage of smartphones, laptops, PCs, and tablets for academic, enjoyable, and work intention causes a surge of eye illnesses where the eye becomes withered, exasperated, red, and overlooks flexibility.
    - Industry Trends
        - Maintenance of eye hygiene
            - The pervasiveness of eye infections is expected to surge worldwide due to exposure to contemporary pathogens
        - Awareness of eye check-ups:
            - The escalating identification of perpetuating eye health and consistent eye assessment has caused an upswing in the demand for ophthalmic eye drops

- Regional Insights
  - North America:
    - North America dominates the ophthalmic eye dropper market, attributed to significant healthcare expenditure, facilitating widespread access to advanced eye care products. The region's market growth is further propelled by the increasing prevalence of eye conditions, rising awareness, and a growing elderly population.



Conclusions/action items:

The global ophthalmic eye dropper market, currently valued at USD 13.44 billion in 2023, is projected to reach USD 22.93 billion by 2032. Market growth is fueled by the increasing prevalence of eye conditions globally, emphasizing the need for innovative solutions like the team's eye drop assistant prototype to address challenges in administering eye drops effectively.

27FEB2024 - Thematic Analysis

Title: Thematic Analysis

Date: Feb 27 2024

Content by: Tevis Linser

Present: N/A

Goals: To find out what is needed to complete a thorough thematic analysis of quantitative data

Sources:

[ ] "How to Do Thematic Analysis," Delve. Accessed: Feb. 27, 2024. [Online]. Available: https://delvetool.com/blog/thematicanalysis

[ ] J. Caulfield, "How to Do Thematic Analysis | Step-by-Step Guide & Examples," Scribbr. Accessed: Feb. 27, 2024. [Online]. Available: https://www.scribbr.com/methodology/thematic-analysis/

Content:

What is thematic analysis?

- Thematic analysis is a qualitative data analysis method that involves reading through a data set (such as transcripts from in depth interviews or focus groups), and identifying patterns in meaning across the data to derive themes.

1. Familiarize yourself with the data

- actively observe meanings and patterns that appear across your data set.

2. Create your initial codes

- create a set of initial codes that represent the meanings and patterns you saw in the data. Create a codebook to keep track of the codes

Code	Description	Examples
Behaviors	Type of behaviors observed during research analysis	Re-reading transcript, keeping track of good quotes, looking for patterns
Collaborating	When groups of researchers collaborate on the same project	Working together as a team, co-analysis with clients
Motivations	Motivations behind why people decide to use an analysis tool	Saving time, staying organized, increasing transparency

3. Collate codes with supporting data

- Now, group together all the excerpts associated with a particular code.

4. Group codes into themes
    - Now that you have a set of initial codes, sort the codes into potential themes. Themes in qualitative research are a powerful way to see trends and patterns in your data.

5. Review and revise themes
    - sider merging together themes that are similar, and removing themes that don't have enough data to back them up.

6. Write your narrative
    - Writing the narrative is the final step to tell the story of your data. You should have fully thought out themes, and now it's your chance to communicate to your readers about the validity or your analysis.

Conclusions/action items:

This method is very important to ensure the proper analysis of our qualitative data. This method will be implemented to tell the story about our initial survey data.

Action: Apply this when we get data from the survey.

27FEB2024 - 3D Printing in Mass Production Application

Title: 3D printing Exploration

Date: Feb 27 2024

Content by: Tevis Linser

Present: N/A

Goals: To find out what the ideal Manufacturing method is for large scale production

Sources:

[1] “When to use 3D printing for mass production,” TCT Magazine. Accessed: Feb. 27, 2024. [Online]. Available: https://www.tctmagazine.com/api/content/c64935b4-d141-11ec-80e1-12274efc5439/

[1] “3 Reasons to Use 3D Printing For Mass Production,” Formlabs. Accessed: Feb. 27, 2024. [Online]. Available: https://formlabs.com/blog/three-reasons-3d-printing-mass-production/

Content:

Low-volume production run

Executing low-volume production runs with a manufacturing method like injection molding results in a high cost-per-part, a lower profit margin, and long lead times. 3D printing can help you bring a product to market faster, and you can produce parts cost-effectively no matter the size of your production run. When 3D printing, you won’t need to create hundreds or thousands of parts to achieve a reasonable cost-per-part, so you can start turning a profit with fewer parts.

Comparing Injection Molding vs. 3D Printing

Injection molding is ideal for high-volume production and for projects with longer turnaround times. Although it can be used with parts of various sizes, injection molding offers less design freedom. 3D is better for low-volume production runs, designs with frequent changes, and projects with quick turnaround times.

Companies that Lead in 3D Printing:

1. Stratasys, Ltd. (SSYS)

2. 3D Systems Corp. (DDD)

3. Proto Labs Inc. (PRLB)

4. Materialize NV (MTLS)

5. Desktop Metal Inc. (DM)

Conclusions/action items:

I think it will be a smart plan to continue investigating an initial low production run in 3D printing as a start. Injection molding is still the front runner for long term mass production of our product.

Action: continue with injection mold research.

27FEB2024 - IM Unit Price

Title: Price Per Unit Exploration

Date: Feb 27 2024

Content by: Tevis Linser

Present: N/A

Goals: To find out how much one unit will cost with injection molding (not including packaging)

Sources:

Protolabs Quote

Content:

Part price including mold (4 cavities) fixed cost:

Based on percent decrease from 15k-20k units, the estimated cost of 50k units was extrapolated assuming constant decrease rate every 5k units.

(including the mold cost)

5,000: 5.98
10,000: 3.84
15,000: 3.08
20,000: 2.57
25,000: 2.14
30,000: 1.78
35,000: 1.48
40,000: 1.23
45,000: 1.02
50,000: 0.85

Projected assuming constant percent decrease every 5,000 units produced (about 16%)
50,000: $0.85

Conclusions/action items:

The COG for injection molding one unit is around 85 cents. This is extremely low and will likely be lower at our projected first year market rate.

Action: use this figure in ShaRx tank and Tong presentations.

27FEB2024 - Design Review

TEVIS LINSER - Apr 30, 2024, 7:20 PM CDT

Title: Design Review

Date: Feb 27 2024

Content by: Tevis Linser

Present: N/A

Goals: To evaluate the IM feasibility of the current design

Sources:

Protolabs

Content:

See attached PDF

Things to Account for:

Undercut Regions

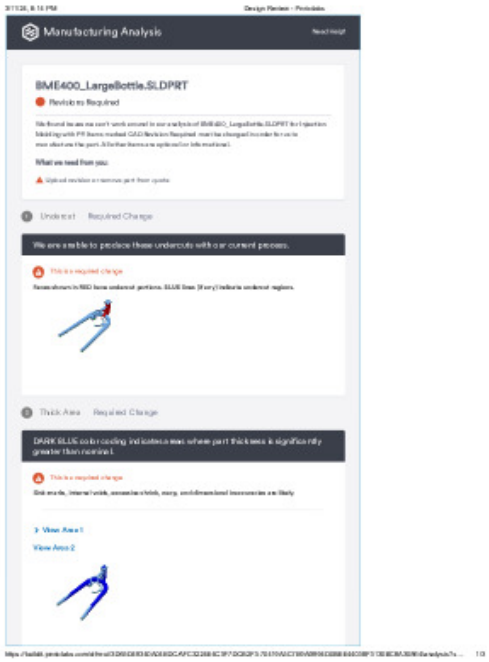
Sink marks, internal voids, excessive shrink, warp, and dimensional inaccuracies are likely

Conclusions/action items:

The undercut regions will be taken care of by modular design. Two part mold with manual manufacturing post processing will be needed.

Action: Use this info as we move toward large scale manufacturing and designing to scale the project.

TEVIS LINSER - Apr 30, 2024, 7:17 PM CDT



Download

Design_Review_-_Protolabs_1_.pdf (363 kB)

27FEB2024 - Modular Connection Mechanism

Title: Modular Connection Mechanism

Date: Feb 27 2024

Content by: Tevis Linser

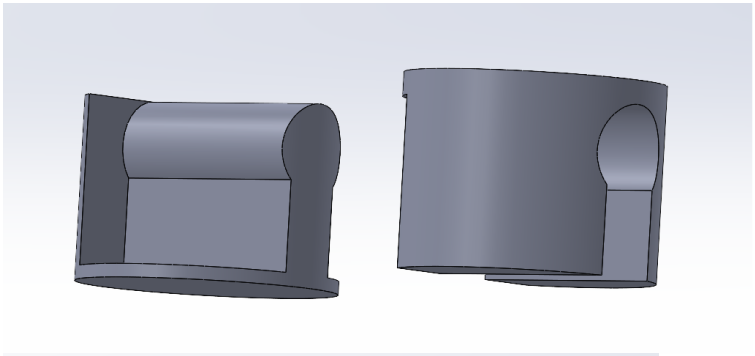
Present: N/A

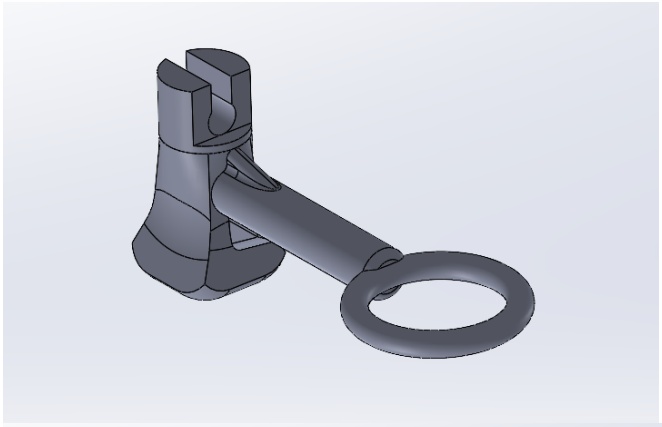
Goals: To design a connection point between the modular pieces

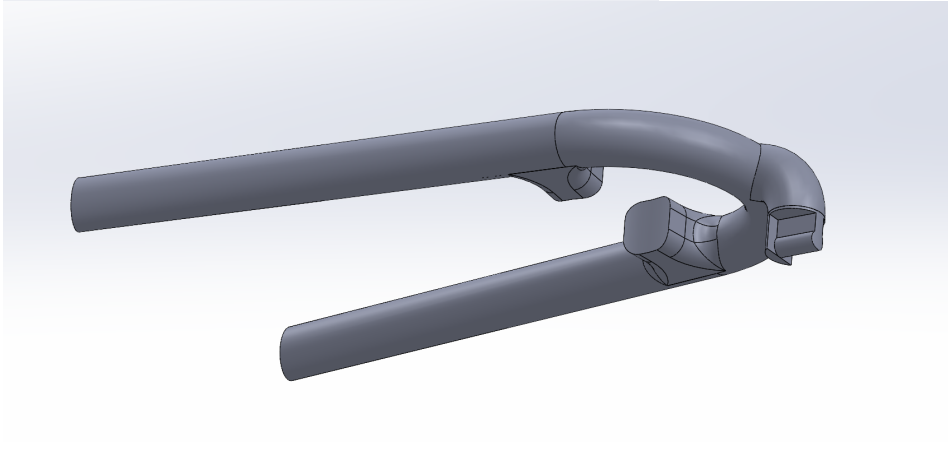
Sources:

N/A

Content:







Splitting the device into modular units requires a mech that will connect them. The first idea I came up with is a simple slide mechanism. It would feature a small magnet to lock in place.

Conclusions/action items:

Print this in 3DP to see if it works, continue to design if not. Collaborate with Tommy to adjust the handle design.

4/30/2024 Safety Training

TEVIS LINSER - Apr 30, 2024, 7:29 PM CDT

Title: Safety Training

Date: 4/30/2024

Content by: Tevis

Present: N/A

Goals: Document Safety Training

Content:

Training Information Lookup Tool **University of Wisconsin-Madison**

WISCONSIN
UNIVERSITY OF WISCONSIN–MADISON

This certifies that Tevis Linser has completed training for the following course(s):

Course	Assignment	Completion	Expiration
Biosafety Required Training	Biosafety Required Training Quiz 2022	3/10/2022	
Chemical Safety: The OSHA Lab Standard	Final Quiz	3/10/2022	

Data Last Imported: 03/10/2022 12:21 PM

Conclusions/action items:

N/A

4/30/2024 GreenPass

TEVIS LINSER - Apr 30, 2024, 7:29 PM CDT

Title: Green Pass

Date: 4/30/24

Content by: Tevis

Present: N/A

Goals: Document Green Pass

Content: see attached

Conclusions/action items:

N/A

TEVIS LINSER - Mar 30, 2022, 12:45 AM CDT

Download

IMG_0068_1_.jpg (3.48 MB)

02/26/2024 - Statistics for Shark Tank Pitch

EVA COUGHLIN - Feb 28, 2024, 4:26 PM CST

Title: Statistics for Shark Tank Pitch

Date: 02/26/2024

Content by: Eva Coughlin

Goals: To learn more about the overlap between ophthalmic diseases like glaucoma and arthritis for the shark tank pitch about the market.

Source:

[1] A. M. Eaton *et al.*, "A novel eye drop application monitor to assess patient compliance with a prescribed regimen: a pilot study," *Eye*, vol. 29, no. 10, pp. 1383–1391, Sep. 2015, doi: https://doi.org/10.1038/eye.2015.155.

[2] W. Jin *et al.*, "Do eye diseases increase the risk of arthritis in the elderly population?," *Aging*, Jun. 2021, doi: https://doi.org/10.18632/aging.203122.

[3] "Arthritis and Your Eyes," *American Academy of Ophthalmology*, Nov. 13, 2019. https://www.aao.org/eye-health/tips-prevention/arthritis-eyes-inflammation-steroids#:~:text=Some%20people%20with%20arthritis%20may%20develop%20glaucoma.

[4] "Incidence and probability of progression to blindness due to open-angle glaucoma decreases dramatically - Mayo Clinic," *www.mayoclinic.org*. https://www.mayoclinic.org/medical-professionals/ophthalmology/news/incidence-and-probability-of-progression-to-blindness-due-to-open-angle-glaucoma-decreases-dramatically/mac-20430155#:~:text=Glaucoma%20is%20a%20leading%20cause

[5] CDC, "Arthritis," *Centers for Disease Control and Prevention*, Oct. 05, 2023.
https://www.cdc.gov/chronicdisease/resources/publications/factsheets/arthritis.htm#:~:text=In%20the%20United%20States%2C%2021.2

Content:

- doctors have tried implementing electronic monitoring and ask patients direct questions regarding eye drop regimen compliance, and drug delivery failure is still an issue
- out of subjects claiming not to miss the eye when applying drops, 1/3 actually missed and 1/3 could not get a drop onto the eye at all
- **recent study found that only 9% of patients who use eye drops are able to properly self-administer them [1]**
- some patients waste copious amount of eye drop solution trying to get the medication into their eyes
- combines data from longitudinal studies which assess whether eye diseases are a risk for arthritis and how this occurs, for a total of 8,423 individuals
- the study showed that **cataracts, glaucoma, and other eye diseases increase the likelihood of arthritis after two years by 131.8% [2]**
    - cataracts being the most significant
- some people with arthritis may develop glaucoma
    - happens when inflammation affects the part of the eye that helps drain fluid
    - glaucoma can also develop as a side effect of corticosteroid use for arthritis treatment [3]
    - if fluid can't drain properly, eye pressure can increase and damage the optic nerve, causing vision loss (glaucoma)
        - needs to be treated via eye drop medication
- using steroids to treat arthritis can also increase risk of developing cataracts
- glaucoma affects more than 2.7 million people age 40 or older in the U.S.
    - About 2% of the total population [4]
- arthritis affects 21.2% of adults in the U.S. [5]

Conclusions/action items: I wanted to do some more research on compelling statistics to capture the attention of the sharks on why an effective eye drop assistant is necessary. I also wanted to present brief statistics on glaucoma and arthritis because this information is important when explaining the scale of our market. It was also interesting to learn that many patients with glaucoma and other ophthalmic diseases, which use eye drops for treatment, are more susceptible to arthritis and dexterity issues. This makes the mechanical leverage component of our device a huge selling point, which we should highlight during our pitch.

02/28/2024 - Remedic Eye Drop Aid

EVA COUGHLIN - Feb 28, 2024, 5:30 PM CST

Title: Remedic Eye Drop Aid

Date: 02/28/2024

Content by: Eva Coughlin

Goals: To record some information about another eye drop aid that is adversed as "arthritis-friendly".

Source: "Remedic Eye Drop Guide Aid - Easy and secure application," *Remedic*. https://remedic.co/product/remedic-eye-drop-guide-arthritis-friendly-dispenser/

Content:

- Remedic is a brand that has been developing "innovative caregiving and healthcare products for over 25 years working for major senior care brands and retailers"
  - Create user-friendly products for the elderly and disabled
- Remedic Eye Drop Aid is sold on their website and on Amazon
- helps to ensure eye drops go directly into eye to eliminate frustration with trying to self-administer drops
- "arthritis-friendly" dispenser
- soft rubber that holds the eyelid open, allowing for accurate drop placement with one hand
- fits standard round and oval eye drop bottles
- "helps reduce the risk of injury and infection by keeping the bottle tip clear of the eye"
- reusable, washable, and made of nontoxic material
  - clean the funnel before each use
  - clean the guide by placing it in boiling water for a few minutes
- precise targeting to ensure eye drop lands in eye
- "this innovative device takes the hassle out of applying eye drops, especially for those with arthritis or dexterity challenges"

Conclusions/action items: The Remedic Eye Drop Aid is an eye drop assistant device that our team has not discussed yet and would be highly competitive with our device (MyDropper). This device is geared towards those with arthritis and dexterity issues, which has been a huge selling point for our device too. It is also washable, which is an advantage that our team has not discussed with regards to our device. The major drawback to this competing device is that it holds the eyelid open manually, whereas our device avoids contact with the patient's eyes.

02/22/2024 - Eye Drop Dispenser Market Analysis

EVA COUGHLIN - Feb 28, 2024, 6:49 PM CST

Title: Eye Drop Dispenser Market Analysis

Date: 02/22/2024

Content by: Eva Coughlin

Goals: To analyze the market for eye drop dispensers and the projected growth.

Source:

[1] “Fact.MR – Eye Drop Dispenser Market Forecast, Trend Analysis & Competition Tracking - Global Market Insights 2018 to 2028,” *www.factmr.com*. https://www.factmr.com/report/3421/eye-drop-dispenser-market

[2] vik singh, “Ophthalmic Squeeze Dispenser Market Insight: Market Trends, Growth, Forecasted from 2023 TO 2030,” *Medium*, Dec. 02, 2023. https://medium.com/@viksingh034/ophthalmic-squeeze-dispenser-market-insight-market-trends-growth-forecasted-from-2023-to-2030-ce80f6472847.

Content:

- eye drop dispenser devices are helping to instill drops in the eyes properly
  - help patients with arthritis, Parkinson's, and weak hands [1]
  - allow more accurate eye drop placement
  - make eye drop administration easier to control dosage
- in May 2016, Aptar Pharma launched new multi-dose ophthalmic squeeze dispenser focused on merging activities for the development of new products to meet patient needs
- Eye Drop Dispenser Market is currently valued at $329.54 million
- Eye Drop Dispenser Market has high growth potential
  - increasing number of eye disorders
  - especially, increasing prevalence of glauma expected to boost demand
    - according to Glaucoma Organization, estimated 3 million Americans have glaucoma
  - increasing aging population
  - precise application of eye drops
- global eye drop dispenser market players:
  - Cameron Graham Limited
  - Owen Mumford
    - focused on user-friendly design
    - produces AutoDrop and AutoSqueeze
  - Aptar Pharma
    - known for advanced technology and precise dose delivery
  - Silgan Holdings:
    - specialized in packaging solutions [2]
  - Jotteq Inc.
  - Gulden Ophthalmics
  - Novartis AG (Alcon)
  - Maddak Inc.
- segmented into hospital, ophthalmic clinics, and home care
  - home care is expected to experience the most growth due to simpler designs and new technology
- North America is expected to contribute a major revenue share in the global eye drop dispenser market
- emerging trends in the Eye Drop Dispenser market:
  - demand for products that offer precise and controlled eye medication dosage [2]
    - ex: development of dispensers with smaller nozzle sizes and metered dose capabilities
  - preference for eco-friendly packaging solutions
    - recyclable and biodegradable
  - improving patient convenience through portability
- two areas of focus are single dose vs. multi-dose
  - trend is pushing toward multi-dose

Conclusions/action items: I tried requesting the full market research report from both sources, so I think that would be helpful in getting more in depth information. The market for eye drop dispensers/aids is definitely growing, but also very competitive due to the saturation in the market. Many companies are focused on helping elderly patients and those with dexterity issues. It may be more advantageous for us to hit a different market opportunity such as pediatrics, so that we are more unique.

02/28/2024 - Packaging

EVA COUGHLIN - Feb 28, 2024, 7:17 PM CST

Title: Packaging

Date: 02/28/2024

Content by: Eva Coughlin

Goals: To learn more about considerations for packaging medical devices and explore injection molded packaging.

Source:

[1] “The Basics of Medical Device Packaging | TechTip,” *STERIS AST*. https://www.steris-ast.com/techtip/the-basics-of-medical-device-packaging/.

[2] “Injection Molded Packaging | Plastics Injection Molding | Natech Plastics,” *natechplastics.com*, Jun. 03, 2021. https://natechplastics.com/injection-molded-packaging.

[3] “Custom Plastic Injection Molding Service,” *www.xometry.com*. https://www.xometry.com/capabilities/injection-molding-service/#:~:text=The%20injection%20molding%20process%20involves

Content:

- Package Integrity Testing [1]:
  - important in determining the sterility and the shelf life of a medical device
  - ASTM F1886/F1886M Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- Package Strength Testing [1]:
  - force required to separate the two components of the sterile barrier system
  - seal strength allows manufacturer to confirm reproducibility of sealing process
  - ASTM F88/F88M Standard Test Method for Seal Strength of Flexible Barrier Material
- Natech Plastics is a company that specializes in custom injection molded packaging
  - package medical devices including microfluidic devices and pharmaceutical drug delivery applications [2]
  - injection molding design process: initial product design, prototyping, design for manufacturing, tool building, manufacturing
- custom injection molding [3]:
  - most cost-effective way to make a plastic part at scale
  - injecting molten plastic into a mold tool and ejecting solidified part
  - process repeats numerous times causing the cost per unit to be very low
  - offers consistent quality across every part
  - highest variety of materials, colors, polishes, and surface textures

Conclusions/action items: I did some very brief research on packaging and discovered there are many standards for medical device packaging. There are several companies that focus on injection molded packaging such as Natech Plastics. The greatest downside of custom injection molding is the expense. I need to learn more about packaging in general and what would be the most cost-effective option while hopefully still being sustainable.

03/17/2024 - Harrow Research for Meeting

EVA COUGHLIN - Mar 18, 2024, 11:46 AM CDT

Title: Harrow Research for Meeting

Date: 3/17/2024

Content by: Eva Coughlin

Goals: To learn more about Harrow before the meeting with Mark on Monday.

Content:

- Harrow makes pharmaceutical products for over 8 million annual ophthalmic surgeries in the U.S. and medications to treat dry eye, glaucoma, allergies, and other ophthalmic inflammatory conditions
- Harrow serves over 10000 doctors, hospitals, and ambulatory service centers
- Mark Baum is the CEO of Harrow and founded the company in December 2011
    - "100% no-excuses commitment to serving patients"
    - dedicated to making medications more accessible and affordable
    - "we started with no customers and no products"
- a culture of innovation, curiosity, and communication - constantly asking doctors what they need to take better care of their patients
    - these conversations lead to product development opportunities
        - Many were patentable! some serve small numbers of patients and others had broad appeal
- in 2021, first U.S. ophthalmic pharmaceutical company to provide high quality compounded formulations and branded FDA approved products
- in October 2015, Turing Pharmaceuticals increased the price of Daraprim to $750 per tablet and Harrow made sure patients had access to this medication by making an alternative that was as low as $0.99 per pill
- **Mission**: To help patients manage the preservation of their sight by providing access to innovative and affordable medicines and services
- **Vision**: To deliver novel eyecare solutions to physicians and patients today at accessible prices
- **Values**:
    - **integrity**: matching behaviors to words
    - **innovation**: constantly renew the portfolio to explore options to meet the realities of the new healthcare economy with the aim to increase value for all stakeholders
    - **evidence-based development**: listen to what the market wants and provide effective solutions
    - **great products**: consistently high quality and safe
    - **people**: "can-do" attitude and foster a collaborative and supportive environment
- FDA-approved eye drops that are available from Harrow: Flarex, Ilevro, Iodipine, Maxidex, Maxitrol, etc.

Conclusions/action items: Harrow is an ophthalmic pharmaceutical company that is customer and patient focused. Harrow sells several FDA-approved eye drops at affordable prices. Harrow places emphasis on innovation and product development opportunities. I think Mark will have a great perspective on the eye drop dispenser market and am going to write down some questions for him before the meeting.

2024/02/07 - Packaging Design Research

Title: Competing Packaging Designs

Date: 02/07/2024

Content by: Thomas Kriewaldt

Present: N/A

Goals: To get some ideas about packaging design from similar designs

Sources:

[1] S. Venna, “P&G adopts sustainable packaging for toothbrush,” Packaging Gateway. Accessed: Feb. 07, 2024. [Online]. Available: https://www.packaging-gateway.com/news/pg-adopts-sustainable-packaging-for-toothbrush/

[2] “Amazon.com: Owen Mumford OP 6100 Autosqueeze : Health & Household.” Accessed: Feb. 07, 2024. [Online]. Available: https://www.amazon.com/Owen-Mumford-OP-6100-Autosqueeze/dp/B002M3TBSU

[3] “AUTOSQUEEZE Eye Drop Bottle Assister Squeezer Arthritis Medical Disability Aid,” eBay. Accessed: Feb. 07, 2024. [Online]. Available: https://www.ebay.com/itm/183829859867

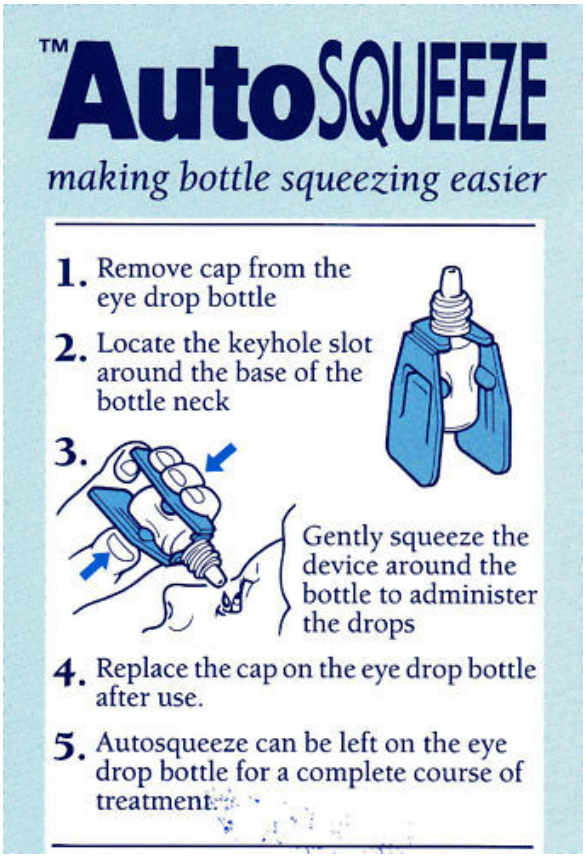
Content:

The first design looked at was of this set of Oral-B toothbrushes [1].

- This design has sustainable packaging, using recycled plastic materials instead of injection molding.
- No PVC or PE materials used, instead using DPET or Direct Polyester Plastic.
    - Would be more environmentally friendly for users
    - Would increase the cost of production
    - Would have to outsource purchasing instead of creation
        - Might stick with injection molding for now due to the small scale we are building, as we won't have a lasting impact on the environment
        - If we decide to take this to market, this might be an important consideration though!
- Overall, this shape of custom-shaped individual packaging is a solid idea for the team to consider.
    - Injection molding process would work for this packaging
    - Could use recycled paper backing to reduce environmental impact
    - Minimizes the space the device would take up in mass packaging and shipping
    - No room for instructions to be included in the packaging.
- Probably tough to scale up given the size and odd of our device.

Another option that we could use would be similar to the Owen Mumford OP 6100 Autosqueeze [2, 3].

- This kind of packaging leaves room for critical user instructions like shown below.
  - Will likely need to have extensive user instructions to make all functions of our device clear to the target audience.
  - Might even have to include some safety hazards, like poking or breaking of the device.
- Likely to be more environmentally friendly.
  - Use almost exclusively recyclable materials and no plastics.
- Cost of production not definitely known, but we should definitely look into comparing plastic and thin cardboard.
- Injection molding process does not need to be used at all.
  - No clear packaging to see the product.
  - Would have to do a good job with the outside of the packaging to make the product clear and advertisable.
  - Likely easier and less convoluted design and fabrication processes.
- We would likely have to outsource all of the materials.
  - Probably not a cost burden, but honestly not as cool as making our own PE or plastic for prototypes.
- Packaging would have to be large to fit the abnormal shape of our device.
  - Increase in cost for more outer and inner "stuffing" packaging materials.
  - Does leave more room for labeling on the outside.
  - Could sell these in packs of two for the different device sizes!
    - Could also do this for the first option, but would be tougher to produce the shape of the combined devices and fit them into the package.



Conclusions/action items:

These two packaging ideas seem the most common when looking at competing designs. There are likely additional methods the team could go about packaging our device, but given the custom shape, ease of fabrication, and cost, these two seem the most practical. Still, further research should be conducted to determine the best choice.

We could try to pursue both of these packaging designs and then do some user testing to see which one is more practical for our device(s) specifically.

- Do additional research on packaging methods or the packaging of competing designs.
- Do research on labeling requirements and marketing on our packaging.
- Create initial design sketches of our product in these (and additional) packaging styles.

2024/02/07 - ASTM Packaging Standards

Title: ASTM Packaging Standards

Date: 02/07/2023

Content by: Tommy Kriewaldt

Present: N/A

Goals: To find standards that might help guide our design of packaging for our device.

Sources:

[1] “Standard Practice for Packaging/Packing of Plastics.” ASTM, Jul. 10, 2020.

[2] “Standard Practice for Commercial Packaging.” ASTM, Oct. 04, 2023.

[3] “Standard Guide for Transport Packaging Design.” ASTM, Apr. 05, 2018.

[4] "Standard Specification for Plastic Films Made from Low-Density Polyethylene and Linear Low-Density Polyethylene for General Use and Packaging Applications.” ASTM, Dec. 27, 2016.

Content:

Took notes on several standards that may relate to our project. The summary of these standards and their relation to our project are written below. Each standard was researched through ASTM Compass through UW-Libraries.

D3892-15 [1]:

- Covers packaging and packing of thermoset and thermoplastic resins.
  - No known ISO equivalent standard.
- Need to pre-examine plastics, packaging, packing, count, weight, and markers prior to delivery according to Table 1.
- Package needs to be designed to ensure no damage during shipment, handling, and storage.
  - Odd shapes need to be protected against physical and mechanical damage in transit.
- All ordering instructions in Section 6 should be followed.
  - Name of standard, title, number, material, color, form, uniformity, level of packing, and marking requirements.

D3951-18 [2]:

- Establishes minimum requirements for packaging of supplies and equipment relevant to our project.
- There are numerous other standards referenced in the 2. *Referenced Documents* section.
  - Many of these are not relevant to our project, but it would still be good to look some of them over.
- Items should be preserved, free of dirt, preserved to prevent corrosion / degradation, and cushioned according to the design of the product.
- Each package should have a "unit package" with only one device each.
- Table 1 discusses the weight and size limits of shipping containers
  - Should follow the container standard: D5118/D5118M as the weight of shipped boxes will be less than 120 lb due to the lightweight nature of our design.
- Each package should have markings (requirements repeated from D3892-15), shipping container markings (consignee, consignee address, part and/or UPC barcode number, manufacturing markings, and shelf-life, storage, and precautionary markings as applicable), and unitization markings among other optional requirements outside of the scope of our project.
- Practice D4169 should be followed when determining performance of shipping packaging
  - **Need to research this further!**

D6198-18 [3]:

- Covers approach to designing packaging for survival through distribution (handling, storage, and transportation).
  - More or less guidelines to how we can alter our prototype to be effective in later stages.
- There are numerous other standards referenced in the 2. *Referenced Documents* section.
  - Many of these are not relevant to our project, but it would still be good to look some of them over.
- Package design includes marketing and distribution, including graphics, identification, and compliance labeling.
  - Compliance labeling: bar codes, hazards etc. but depends on the country.
  - Distribution requirements: number of units, shelf life, package disposal, handling / storage requirements, total volume, transport modes, domestic / international regulations on transport, freight classification, environmental hazards are some listed here.
  - Also need to research if there are any environmental hazard.

        - ***At the very minimum, we should have designated areas on our packaging design for these things!***
- Consider trade-offs using trade-off comparison analyses
    - Package performance, total cost, environmental impacts etc.
        - "Reduce, Reuse, Recycle, Energy Recovery, and Safe Disposal."
- Comparing designs as a benchmark for overall effectiveness to your packages is an effective strategy.
- Each component of the package should be tested for strength and other properties.
- Test Methods to look at to verify our package design will be sufficient:
    - D642, D880, D999, D4003, D4728, D5276, D5487, D6055, D6179, D6344, D6653/D6653M, D7030, D7387, and D7660.
- Checking actual in-transit results is important, but probably not relevant to the scope of this semester.
    - Leads to redesigns potentially too in the future.

D4635-16 [4]:

- "This specification covers unpigmented, unsupported, low-density polyethylene and linear low-density polyethylene films"
    - Standard Low-Density-PE Density: 0.91-0.925 g/cm^3
    - Could be SUPER relevant if we decide to go through with the "toothbrush" route.
- Also covers dimensional routes dimensions, classifications, quality requirements, and test methods.
- Film should be made of an ethylene homopolymers, copolymers, or blends of these to meet the density requirement above.
- **Physical Requirements** for Classification:
    - Type: Table 1 (T1), Surface: T2, Class: T3, Finish: T4, Tensile Properties: T5, Heat Sealability: T6, and an Odor < 3.5 rating.
    - Need to determine the film thickness, coefficient of friction, wetting tension, haze %, tensile properties, and time of heat seal to classify the film.
        - Did not want to include vast amounts of specific information, reference as needed.
- **Dimensions** are classified by Size, Thickness Tolerance, Width Tolerance, Yield Tolerance, Flatness -- included in Tables 7-9 -- and are based on physical requirements.
- Standard also goes into detail about Workmanship, Finish, and Appearance
    - More along the lines of the manufacturing process, might buy our own film for this semester. Reference if needed, or if there is an issue with recieved film.
- **Test Methods (bolded in potential project scope)**:
    - Conditioning: 23 +/- 2°C (73.4 6 3.6°F) and 50 +/-10 % relative humidity for not less than 40 h prior"
        - ASTM D618 Procedure A for full outline.
    - **Test Conditions**: 23 +/- 2°C (73.4 +/- 3.6°F) and 50 +/- 10 % relative humidity.
    - **Width**: measure width with a ruler capable of an accuracy of +/- 1.59 mm.
    - **Thickness**: use ASTM D6988.
    - **Yield**: use ASTM D4321.
    - **Density**: measured in accordance to ASTM D1505 or D792.
    - Coefficent of Friction: use D1894 for static and kinetic COF measurements.
    - Optical Properties: Clarity, Gloss, and Haze use D2457 and D1003.
    - **Wetting Tension**: use D2578.
    - **Impact Resistance**: use D1709.
    - **Heat Sealability**: use F88 Test Method B Dynamic Load Testing.
    - Odor: use E1870.
    - **Tear Resistance**: use D1922 or D1938.
- Film should be packaged and labeled while shipping.
    - Manufacturer's Name, Type, Surface, Class, Finish, Spec No. (if applicable).

I could not open ISO Standards but referenced a few that could be helpful if we get access:

ISO 780:2015 - Packaging: Distribution packaging: Graphical symbols for handling and storage of packages

ISO/IEC Guide 41:2018 - Packaging: Recommendations for addressing consumer needs

ISO 17480:2015 - Packaging: Accessible design: Ease of opening

ISO 18602:2013 - Packaging and the environment: Optimization of the packaging system

Conclusions/action items:

Most of this information relates to future work other than this semester, however, it is a good idea to plan ahead so that our packaging design is accounting for all these factors in shipping and manufacturing if we decide to take this design to market.

- Research Test Methods for packaging and PE sealing (if we decide to use it)
- Look into additional competing packaging designs
- Begin drafting initial packaging ideas

2024/02/07 - ASTM Packaging Testing Procedures

Title: ASTM Test Procedures

Date: 02/07/2024, 02/27/2024

Content by: Tommy Kriewaldt

Present: N/A

Goals: To outline some procedures that may prove to be relevant to testing our packaging this semester

Sources:

[1] “Standard Guide for Packaging Test Method Validation.” ASTM, Mar. 14, 2018.

[2] “Standard Practice for Conditioning and Testing Flexible Barrier Packaging.” ASTM, Jul. 22, 2020.

[3] “Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection.” ASTM, Dec. 27, 2016.

Content:

F3263-17: Standard Guice for Packaging Test Method Validation [1].

- Guidance from ISO 11607-1 and 11607-2
  - ISO 16775 does not relate here, as we do not have a sterile packaged device,
  - Provides information to show us how to validate test methods on our future packaging design.
- Capability studies on our packaging should be used to determine that our packaging process is sufficient to any specification.
  - Spec. Tolerance / (6 * Total Variation) >= 2.0
- A gage R&R study can be used as well where:
  - % SV (Study Variation) = Test Method Variation / Total Variation <= 30%
  - **Simplifying the math with a z-score of 5.15, indicating the central 99% of the data points** (AIAG standard): a precision to tolerance ratio (or %P/T) of 5.18% or less!
    - %P/T "..measures the percent of the tolerance attributable to the test method variation."
- A lot of this document (Section 4.2) is more about the process setup of inspections and validation of part specifications prior to packaging. This will come into play later on in the product lifecycle if we do take it to market.
  - It is important to consider taking samples of our own parts and packaging to validate that we are able to produce it on a small scale though!
  - A lot of the statistics mentioned above and in the ATMV studies could be relevant, but might be too advanced for us to consistently employ on such a small scale.
- Repeatability and reproducibility (R&R) is an important factor to consider though.
  - Need to have at least 30 total parts for this process
  - We actually do this in my role in my co-op for FAI and first pass yield.
    - I plan to reach out to see how to properly conduct these studies to ensure that our early packaging prototypes meet R&R standards!
- Gage R&R for measuring variability in test methods and inspection equipment tolerance ranges.
  - Helps us estimate both variances for repeatability and reproducibility.
  - **Three** test samples or batches at a minimum
  - **Two** people measuring the same part or reference distance at a minimum

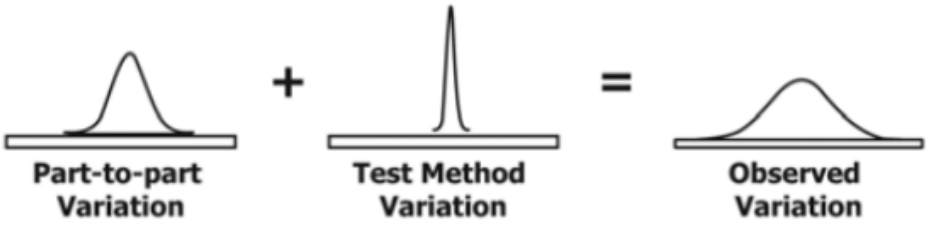


FIG. 1 Observed Variation

- Test Method Variation = sqrt(Repeatability Variation ^ 2 + Reproducibility Variation ^ 2)
- Following these steps and statistical tests will help generate a report that will prove that the test methods used to inspect and test certain aspects of a device are sufficient to this standard and ISO 11607-1 / 2
  - Again, not sure how relevant this document will be to our semester unfortunately.

E171/E171M-11(2020): Standard Practice for Conditioning and Testing Flexible Barrier Packaging [2].

- If we choose to use injection molded or custom fit plastics to package our device, this standard will be super relevant
  - This decision has yet to be made, however, we will decide in the next few weeks.
- Other relevant standards: ASTM D4332, F17, and F2825
  - Practice for Conditioning Packaging Components for Testing, Terminology, Climatic Stressing of Systems
    - These other documents may be useful to look at to see if our device is able to withstand certain atmospheric conditions (rain, wind, temperature) or extreme forces felt during shipping and delivery phases of the device.
- Conditioning used to lower the standard deviation of future testing results that stem from a variety of atmospheric factors being different over time.
- Temperature, humidity, light, pressure and other factors should be considered.
  - Research on PLA (or other final material) should be conducted to see what the shelf life properties are.
  - Testing should be carried out to ensure the shape, size, and other unique aspects of our device do not differ from this future research.
- ***Temperature***: 23 +/- 2°C (73 +/- 4°F)
- ***Humidity***: 50 +/- 5 % Real Humidity
- *Other specifications vary depending on the device and packaging apparatus.*
- We should be able to conduct basic testing at this level and at the extremes outlined in F2825
  - Need to review that standard as well.

F1886/F1886M-16: Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection [3].

- This standard will be in our scope this semester if we choose to use plastic packaging that requires glue or another type of sealed connection to alternate material (such as cardboard).
- Test method is for visual inspections of unopened seals that could affect our device if unintentionally unopened. This test procedure is pass/fail.
- The seal should be tight to a width of 75 um or 0.003 in with 60-100% certainty.
- Inspect the seal using magnification devices or imaging technology for uniformity.
  - Note any position on the seal where channels are visible.
  - Note the total number of visible channeling instances per seal.
- Use Section 8 and Tables 1-4 to conduct statistical analysis on the binomial pass/fail data.
  - Use Section 8.1 to classify the different packaging types.
- We should first ensure this testing method is within our scope then reach out to Dr. P about possible tools at our disposal to ensure our packaging seals will meet this visual inspection standard.
- Appendix X1: Possible causes of seals which "Fail"
  - *Unsealed areas*: from improper heat seals, rupture damage, foreign matter contamination etc.
  - *Nonhomogenous / Undersealed areas:* too little heat on heat sealer, incorrect process parameters, uneven pressure, seal material thickness defects etc.
  - *Oversealed areas:* too much heat on heat sealer (evidenced by brittle, cracking, material fusion).
  - *Narrow Seals:* seal creep from environmental stress, misalignment, sterilization etc.
  - *Wrinkles/Foldovers/Cracks*: material folding in heat sealer, improper handling
  - Tears, Pinholes, Channeling also are discussed in this section.

Conclusions/action items:

- Reach out to co-workers at GE to see if they can help with setting up a capability study of our packaging design later on in the semester.
- Research and review ASTM D4332 and **F2825** to see if these standards and methods could be relevant to our project.
- Research PLA (or other final material choice) for shelf-life properties for temperature, humidity, and other relevant conditions.
  - Carry out simple material testing to ensure PLA (or other material) meets the values found in literature.
- See if the inspection method outlined in F1886 is possible to conduct using resources available to the team on campus.

2024/02/27 - Final Prototype Design Ideas

Title: Prototype Design Ideas

Date: 02/27/2024

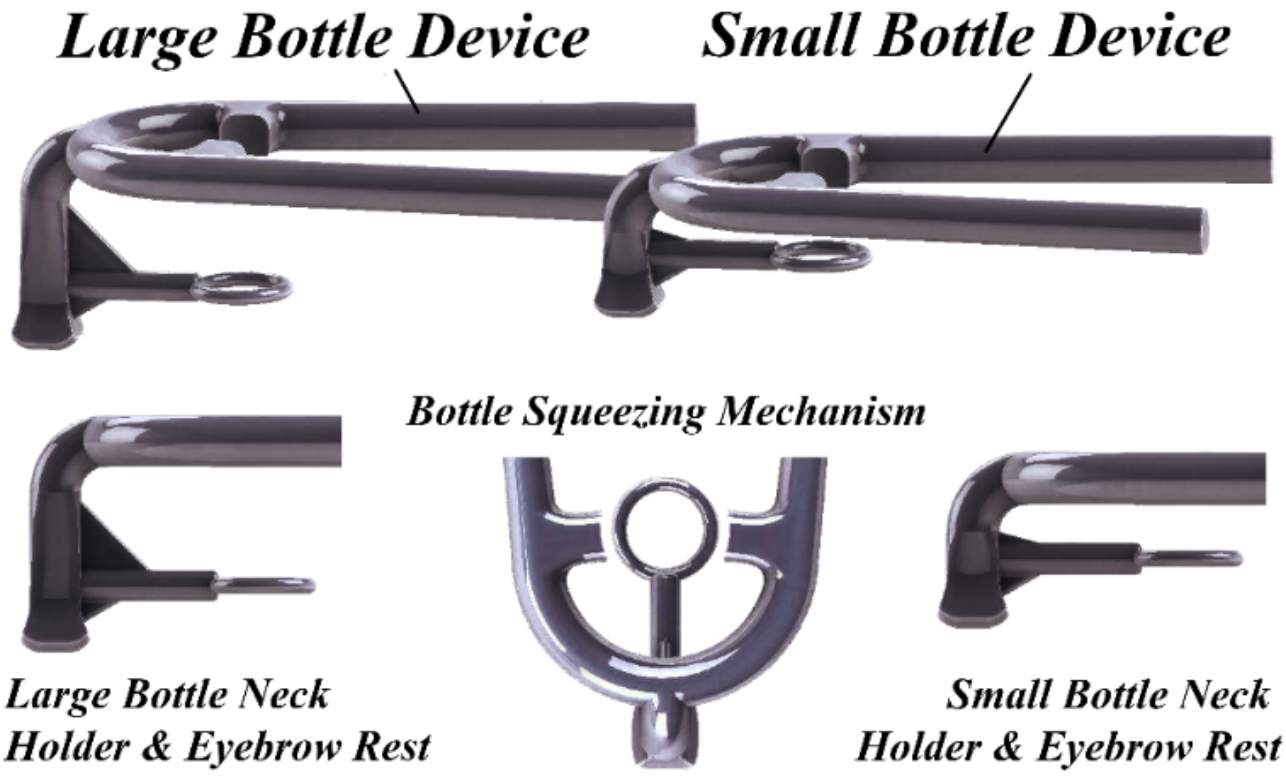
Content by: Thomas Kriewaldt

Present: N/A

Goals: To evaluate our current prototypes, seek areas that need improvement, and offer potential solutions to any current issues.

Content:

Current Design (as of Feb. 27th, 2024):



Aspects of the Current Design:

Bottle Squeezing Mechanism:

- **PROS**:
  - One piece to injection mold
    - Easier to mass produce and assemble components
  - Adjustments to the rounded edges make the part easier to injection mold
  - Allows eye drops to be released from large bottles with ease
- **CONS**:
  - Squeezing arm dimensions to the specifications for the large bottle only
  - Does NOT allow eye drops to be elicited from small bottles without excessive force that extends well beyond the capabilities of our target audience

Eyebrow Rest:

- **PROS:**
  - Distance from the eye drop bottle allows the device to rest comfortably on any subject's forehead
  - The curved structure allows for different patients to rest the device differently on their face
    - Factors in personal preferences for device orientation and patient-to-patient anatomical variabilities
- **CONS:**

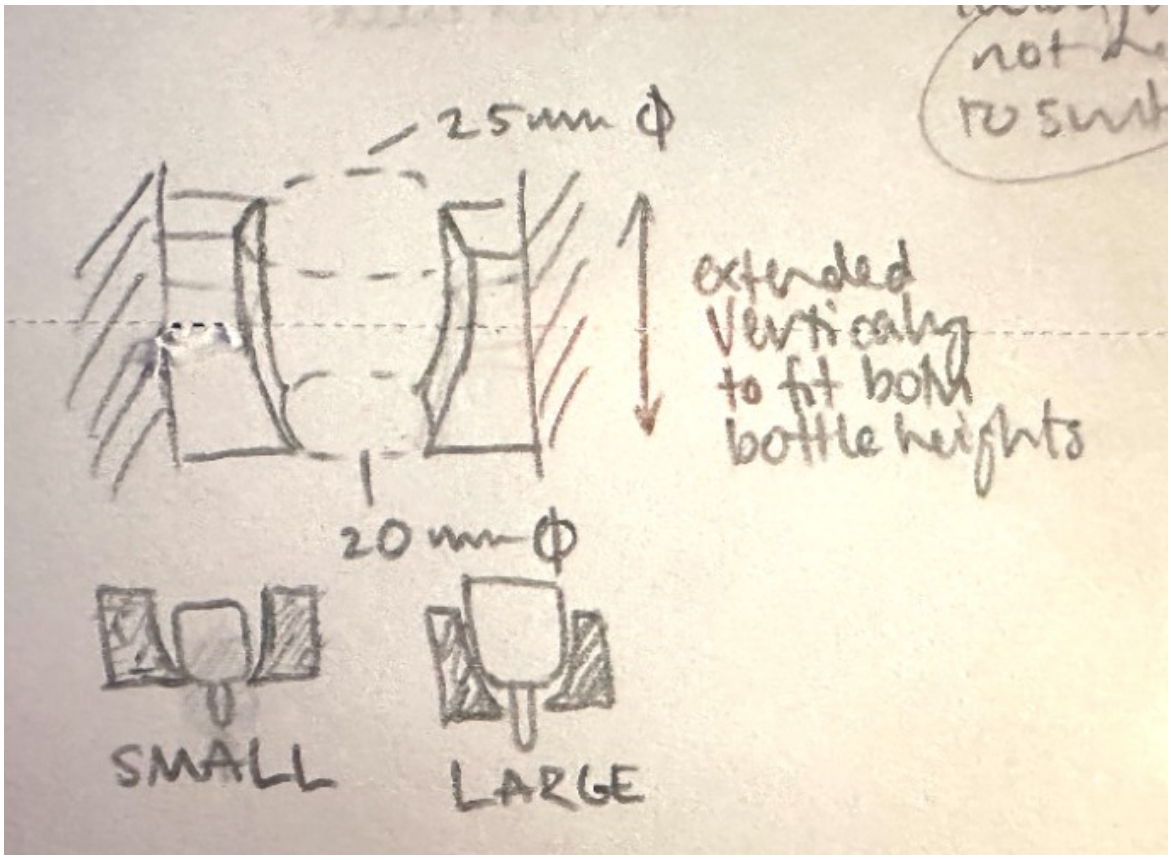
    - Two different bottle sizes mean two different parts to injection mold
        - Harder to mass produce and assemble components.
        - Locking mechanism is needed to move between different sized bottles.

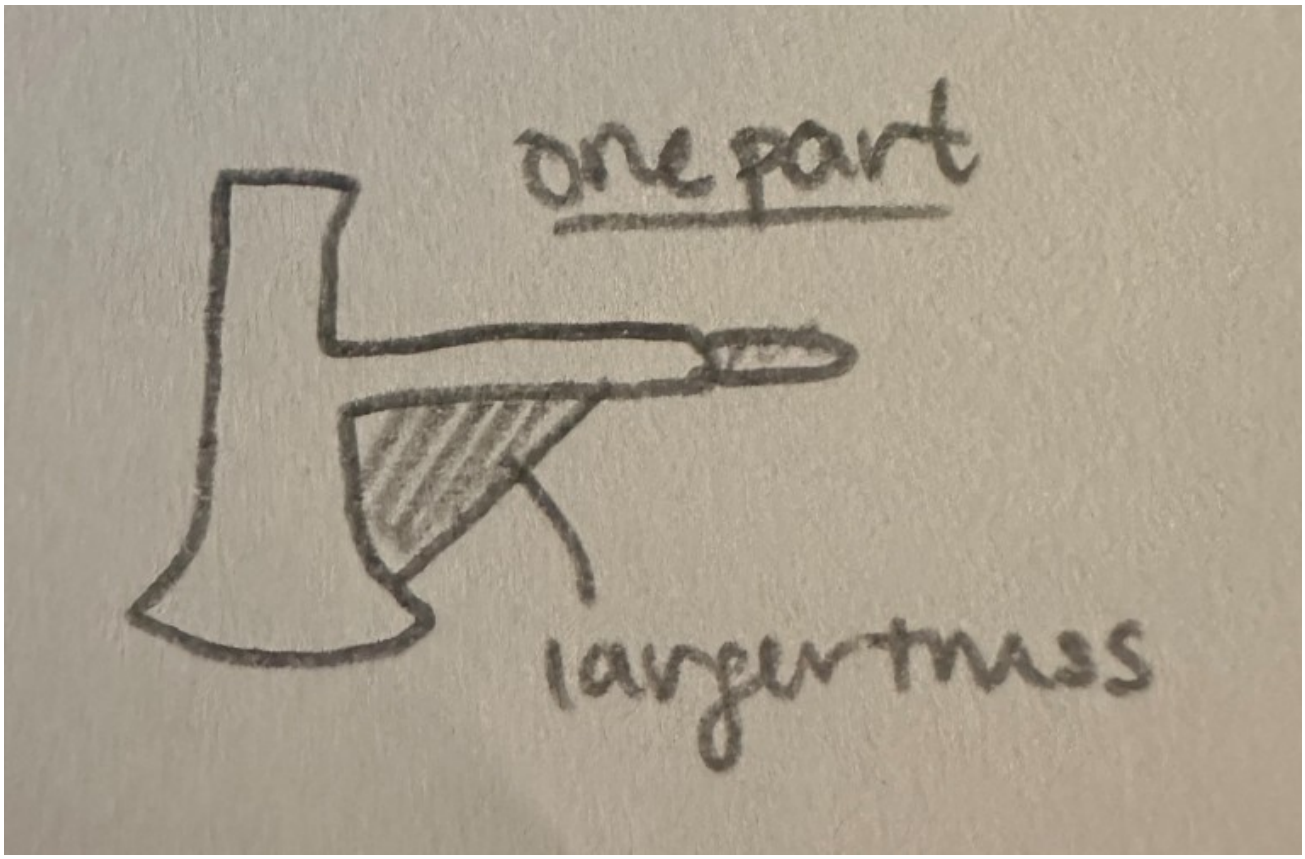
Bottle Neck Holder:

- **PROS:**
    - Holds and stabilizes both bottle sizes consistently
    - Allows the cap to be screwed on with the bottle still attached to the device
        - Makes the device simpler to use, as patients can simply release eye drops without additional steps (compared to just using the bottle).
            - (Unscrew cap > squeeze device / squeeze bottle > recap device)
- **CONS:**
    - At different locations for different bottle sizes
    - Two different bottle sizes mean two different parts to injection mold
        - Harder to mass produce and assemble components.
        - Locking mechanism is needed to move between different sized bottles.
    - Revised support trusses are very poor quality using 3D printing
    - Revised support trusses do not offer real structural support or stability to the device

Potential Solution:

Sketches:





Changes:

- **Make the two Support [Eyebrow Rest and Bottle Neck Holder portion] parts into one single part**
  - Easier for injection molding procedures
  - Allows the device to hold both bottles a consistent distance from the eye
    - The drop nozzles are the same height as each other
  - Allows patient to switch between bottles with ease
    - Patient can simply insert any desired bottle size into one device, without manually switching parts
- **Add a larger truss to the Bottle Neck Holder**
  - More support, likely will resist more force than the previous prototype
  - Does not affect the 3D print quality; May need to still redesign the truss geometry.
- **Alter the shape - add a curve - to the Squeezing Arms; 20 mm diameter (for the small bottle) at the bottom, 25 mm diameter (for the large bottle) at the top.**
  - Allows both devices to fit into the Squeezing Mechanism
  - Allows the small bottle to actually be able to release eyedrops without excessive forces
  - Locking mechanism to switch between devices is not necessary (besides manufacturing maybe)
  - Might be more difficult to injection mold or 3D print
- **Extend the Squeezing Arms further vertically**
  - Allows both bottle sizes to fit in the device
  - Allows both bottle sizes to be squeezed without excessive force
  - Might have to adjust the handles of the device to accommodate this design change
  - Might be more difficult to injection mold or 3D print

Conclusions/action items:

- Determine all dimensions of each bottle size that are relevant to these design changes
  - Height from holding position to end of the nozzle
  - Height from holding position to maximum bottle diameter
  - Height from holding position to beginning of curve to maximum bottle diamerte
  - Maximum bottle diameter
  - Height that the maximum bottle diameter extends
- Make an accurate SolidWorks model of each bottle size
- Create sketches of curves that could meet the specifications of each device found above
- **Make CAD Model that can fit and squeeze each bottle size**

2024/03/18 - Bottle Measurements, Design Considerations, and Future Ideas

THOMAS KRIEWALDT - Apr 09, 2024, 10:05 PM CDT

Title: Bottle Measurements, Design Considerations, and Future Design Ideas

Date: 3/18/2024

Content by: Thomas Kriewaldt

Present: N/A

Goals: To discuss issues with the previous design idea, as well as positives to focus on moving forward.

Content:

After obtaining measurements of the two bottle sizes, it has become clear that the previous "all bottle size" design is not feasible.

Measurements

- For the large bottle:
  - Two bottles measured, only Systane lubricating eyedrop bottle is shown in this entry.
    - Figure 1. Distance from cap base to bottle Base: ~50.4 mm (48.7, 52.11 mm)
    - Figure 2. Max width of the bottle: ~24.5 mm (24.54, 24.66 mm)
    - Figure 3. Distance from cap base to the start of bottle curve: ~6.34 mm (4.99, 7.68 mm)

Figure 1: ~48.7 mm from cap base to bottle base for Systane bottle.

Figure 2: ~24.65 mm is the maximum width of the Systane bottle

Figure 3: ~4.99 mm from cap base to the start of bottle curve for the Systane bottle

- For the small bottle:
  - One bottle measured, Glaucoma unbranded eyedrop bottle is shown in this entry.
    - Figure 4. Distance from cap base to bottle base: ~23.51 mm
    - Figure 5. Max width of the bottle: ~19.39 mm

- ***(NOT PICTURED)*** Distance from cap Base to start of bottle curve: ~3.32 mm

Figure 4: ~23.51 mm from cap base to bottle base for glaucoma bottle.

Figure 5: ~19.39 mm is the maximum width of the glaucoma bottle

Given these measurements, the squeezing mechanism needs to be expanded in both directions vertically

- 5 mm downwards to accommodate the small bottle
- 8 mm upwards to accomodate the large bottle

The curve described in the previous entry is not possible given these specifications.

- This curve would have to expand 5 mm in width over about a 25 mm
- Given the distance between the cap base and start of the bottle curve for each type of bottle, this curve would have to cut into the large bottle.
    - It would be far too steep to create the curved squeezing mechanism and still have both bottles be able to be held in place by the holding ring of the device.
    - Two seperate devices would have to be created, which is not the goal of future designs.
        - **The team wishes to simplify the device into one model to optimize future injection molding procedures**

Also, the curved nature of the squeezing mechanism design is flawed.

- There are no mechanical stops in the vertical (z-) direction.
    - When any bottle is inserted and the handles are squeezed, the bottle will likely pop upwards and out of the device.
    - A cap to hold the bottle in place vertically (or similar feature) will be needed.
        - This could prove hard to design.

Because of these issues, a serious redesign is needed.

-

There are a couple of bright spots here though:

- The expansion of the squeezing mechanism is a good idea.
    - Expand by 5 downwards (reaches small bottle), and expand by 8 upwards (reaches large bottle)
    - Try a SolidWorks model with flat, uncurved surface towards the bottle.

- Keeping the design able to encapsulate multiple bottle sizes is also a good idea.
    - Having one design makes it easier to injection mold in the future.
    - Keep future prototype iterations as a single device!

-

Some ideas for future designs:

- An adjustable, slider design could work to capture multiple bottle sizes.
    - Vertically and/or horizontal adjustments? - Need to determine.
    - This would include some sort of locking mechanism to keep a **desired diameter constant**
    - **Maybe even have a design where the squeezing mechanism changes radius? -** Need to determine if this is possible.
- Continue to pursue seperate device sizes for different bottle sizes.
    - Easier for patients to use a device without excessive motions.
    - Wouldn't need to make large design changes detailed above.

Conclusions/action items:

- Create a SolidWorks model with flat, uncurved surface towards the bottle.
- Pursue an adjustable design that moves to fit a wide range of bottle sizes.
    - Determine locking mechanism to keep desired bottle size in place indefinitely.
- Seriously alter the squeezing mechanism to be all encompassing of any potential bottle size used in tandem with our device.

2024/03/23 - Retracable Prototype Design Idea

THOMAS KRIEWALDT - Apr 09, 2024, 11:20 PM CDT

Title: Adjustable Prototype Design

Date: 3/23/2024

Content by: Thomas Kriewaldt

Present: N/A

Goals: To describe a retractable prototype design idea that is able to fit most eye drop bottle sizes.

Content:

This design idea is outlined by the super rough sketch in Figure 1, below.

General Principles + Design Changes:

- New squeezing mechanism design
  - Expanded 13 mm vertically (5 mm down, 8 mm up)
  - Flat, cylindrical cut (no curve) that lines up with the shape of the bottle.
  - Exists as a separate part than the rest of the device
  - Moves horizontally, inward & outward, toward the eye drop bottle
    - Is not adjustable in the vertical direction.
- No major changes to the nose piece/eyebrow rest or the handles
  - Only a slight alteration at the connection points to the new squeezing mechanism

The rough sketch is pictured below. If this is confusing, please refer to the explanation of each part below.

Please ignore the dimensions mentioned here -- I am planning out these values to create a future SolidWorks model.

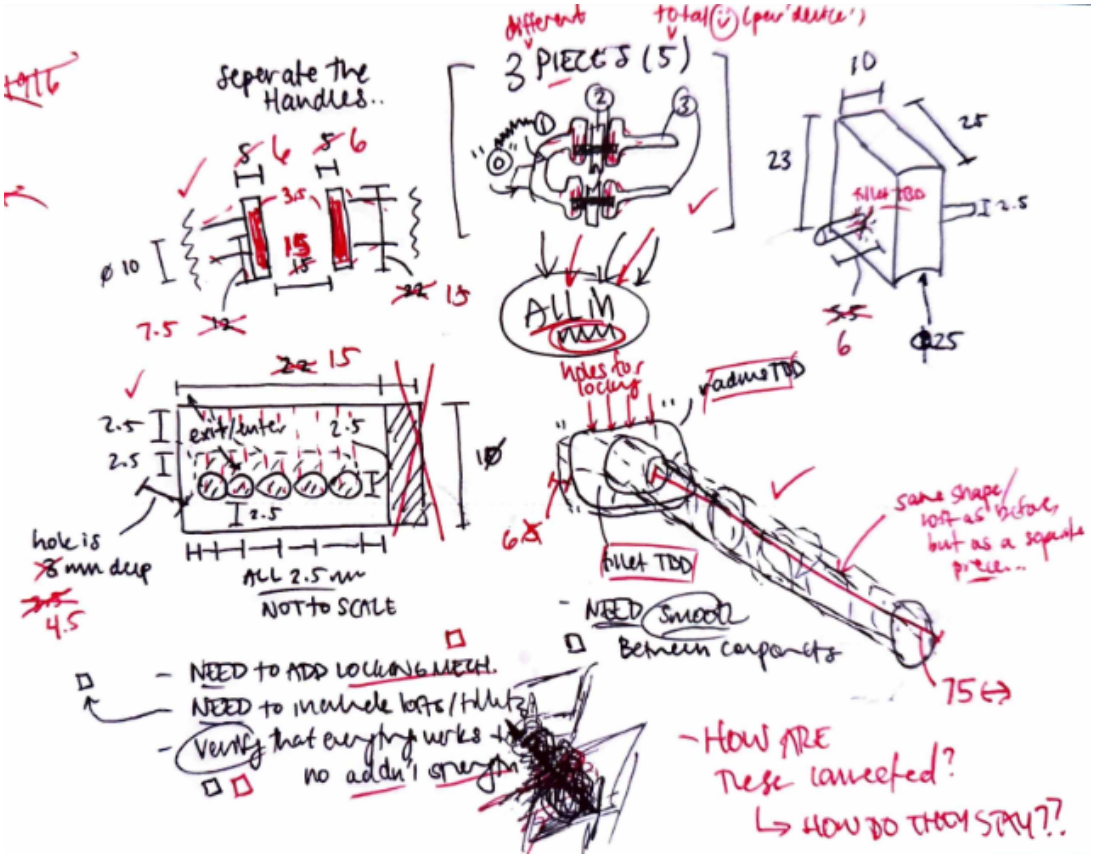


Figure 1: Rough sketch of the Retractable Prototype Design

Fillets are not accounted for in these sketches, but are planned to be added in any future 3D models.

- Everything should be smooth enough to ensure no harm can be induced from use of our device.

-

Components:

There are three distinct parts used in this prototype, which are outlined below

Stem: 1 part per device

- Same concept as in previous prototypes
  - Users have the option between either the nose clip or the eyebrow rest
- Slightly cut off to accommodate new squeezing mechanism part
- Cut out a small volume of the component to hold the squeezing mechanism pegs
  - Shown in the bottom left of Figure 1
  - Connects these two components together
  - Five pegs in total allow for the position of the squeezing mechanism to be adjusted

Squeezing Mechanism: 2 parts per device

- Rectangular box, similar to previous squeezing mechanism design
  - Shown in the top right of Figure 1
- Expanded 13 mm vertically to accommodate most bottle sizes
- Curve of the mechanism has been adjusted
  - Unspecified diameter - Need to determine
  - Still will act to squeeze the bottle, and hold it in place while not in use
- Features pegs on both sides of the part
  - Fits into the cutout sections of the stem and handle parts, respectively
  - Allows for the position of the part to be adjusted horizontally

Handles: 2 parts per device

- Same concept as in previous prototypes
  - Shown in the bottom right of Figure 1
- Slightly cut off to accommodate new squeezing mechanism part
- Cut out a small volume of the component to hold the squeezing mechanism pegs
  - Same cutout as in the Stem, but mirrored
  - Connects these two components together
  - Five pegs in total allow for the position of the squeezing mechanism to be adjusted

The overview of how these parts join together can be seen at the top of Figure 1

- In short, two squeezing mechanism parts are sandwiched in between the stem and the two handles on both sides of the device
  - Replaces the previous idea, where the mechanism was built into the handles.
    - Could switch this to build into only one side -- less adjustable, but easier to produce.

-

Conclusions/action items:

- Figure out the locking mechanism between parts
  - Create a push-down lever or other type of mechanical stop part
    - Will prevent backward movement when the device is in use
- Figure out the connection mechanism between components
  - No real support besides the connection between the pegs (of the squeezing mech.) and cutouts (of the stem and handles)
  - Could fail to maintain structural integrity when 3D printed
- Decide on the set diameter of the squeezing mechanism
  - Or figure out a way to make this diameter adjustable, and correlated with the part's horizontal position
- Create the SolidWorks model of this prototype design
- Make the end piece of the stem removable so that the nose piece and eyebrow rest can be interchanged easily

2024/2/12 Journal Research

ANABELLE OLSON (amolson27@wisc.edu) - Feb 18, 2024, 10:20 PM CST

Title: Journal Research

Date: 2/12/24

Content by: Anabelle Olson

Goals: To find a journal that would make sense for us to publish our prototype and testing to for our preliminary report.

Content:

Journal: Assistive Technology, the Official Journal of RESNA

- Aims and Scope: "assistive technology is an applied, scientific publication in the multi-disciplinary field of technology for people with disabilities. The journal's purpose is to foster communication among individuals working in all aspects of the assistive technology arena including researchers, developers, clinicians, educators and consumers. The journal will consider papers from all assistive technology applications. Technical notes describing preliminary techniques, procedures, or findings of original scientific research may also be submitted."
- Examples of articles that include some elements similar to our project, or present the research in a way that we could do:
    - https://doi-org.ezproxy.library.wisc.edu/10.1080/10400435.2018.1467513
        - I think that this could work for our device because we could talk about how we designed the device and then the preliminary evaluation would involve all the testing we did last semester and maybe the preference testing as well
    - https://doi.org/10.1080/10400435.2018.1475431
        - I think a comparative study could work for our project because we could compare the use of the device to the use of just the eye drop bottle, as we did with multiple of the testing preformed last semester.
    - https://doi.org/10.1080/10400435.2018.1453888
        - for this, we could talk about the effect our device would have on promoting the use of eye drops in individuals with reduced dexterity or something like that

Conclusions/action items :I think that this would be a pretty cool journal to be able to submit our work to, promoting that need for eye drop assistance to those with reduced dexterity and issues administering eye drops. The next steps from here will be to have the rest of the team review these three articles, or any other from this journal, and choose which direction we want to go for our journal preliminary report.

2024/01/28 Packaging Research

ANABELLE OLSON (amolson27@wisc.edu) - Feb 28, 2024, 10:44 AM CST

Title: Packaging Research

Date: 1/28/24 - ongoing

Content by: Anabelle Olson

Goals: To learn more about packaging options for commercialization of our device. This will be an ongoing research doc as our prototype might change over the semester (into more than one piece).

Content:

Materials:

- rigid plastics
    - PETG, PETE, ABS, HDPE
    - thermoplastics
    - can be vacuum formed into clamshells, trays, and components used for protective packaging

Logistics:

- if use a rectangle, cardboard box, the device needs a way to be secure in the box, so that everytime the box is moved or picked up, the device doesn't move around in the box.

Pulp Wine Shippers

    - maybe something like this to keep the device in place?
- If we go with clamshell packaging, the device will be able to be seen visibly through the plastic clamshell, however if we go with a cardboard box, the box needs to have a descriptive picture on the outside of the package showing the device to prevent consumers from opening the box and trying to see what it looks like at a store.
- The clamshell packaging maybe be hard to open for the target audience we are trying to sell to here. Being that this clamshell packaging typically needs to be cut open, and even with scissors it is hard to open
- Another option could be the packaging that uses a cardboard back and then a plastic clamshell on the front. And usually the plastic part is just clued around the cardboard so it is easy to pull apart for consumers. Additionally, this packaging would show if a person tried to open it because you cant put the packaging back together once opened.

Conclusions/action items:

Depending on the final prototype, different packaging routes of actions may be pursued. As we continue to modify the current porotype, I will add more packaging research. Additionally, when considering environmental conscious packaging, I would prefer to stay away from the plastic packaging, however that will be something that has to be taken into consideration with our funds.

2024/2/21 Market Research

ANABELLE OLSON (amolson27@wisc.edu) - Feb 28, 2024, 10:46 AM CST

Title: Market Research for our product

Date: 2/21/24

Content by: Anabelle Olson

Goals: to understand the current market available for an eye drop assistant device and ultimately decide if this product could be sold at market.

Content:

- according to a study, the global eye dropper dispenser market was valued at 300.5 million in 2022 and is projected to increased to 627.8 million by 2029 with a CAGR of 11.1(percent) during review period.
    -
        - “Market research Reports and Industry Analysis Reports - Market Reports World,” *www.marketreportsworld.com*. https://www.marketreportsworld.com/enquiry/pre-order-enquiry/23602110?trk=article-ssr-frontend-pulse_little-text-block (accessed Feb. 21, 2024).
- Global eye drop dispenser key players include Aptar Pharma, Opticare, Owen Mumford, Silgan Holdings, Alcon.
    - Global top 3 manufacturers hold a share over 50%
    - Europe is the largest market, with a share over 40%, followed by North America and Asia-Pacific, both have a share about 45%
    - multiple dose dispensers is the largest segment?
    - Application: the largest application is pharmacy company followed by home care
- EziDrops is one of the leading manufacturers of eye drop aids
- Owen Mumford
    - AutoDrop
    - AutoSqueeze
        - In a study, more than 60% of patients reported these two devices helpful
        - Zhu CQ, Sadlak N, Fiorello MG, Lee D, Desai M. A Comparison of Patient Acceptance of 3 Eye Drop Instillation Aids. J Glaucoma. 2021 Aug 1;30(8):725-731. doi: 10.1097/IJG.0000000000001891. PMID: 34049349; PMCID: PMC8366596.
- Precision Dropper
    - https://precisiondropper.com/
    - This is an interesting competing product, looks like there would be some tip contamination

Conclusions/action items:

Based on the market research I conducted, it seems like there is very much space to operate as this seems to be a growing market. Additionally, with the aging population, ophthalmic diseases will continue to rise in numbers, therefore presenting more potential consumers of our device. From here, additional research will have to be done to assess our compeititors market and sales history.

2024/2/24 Competing Companies on Market

ANABELLE OLSON (amolson27@wisc.edu) - Feb 28, 2024, 3:00 PM CST

Title: Competing Companies on Market Research

Date: 2/24/2024

Content by: Anabelle Olson

Goals: Researching to understand more about the competitive landscape for an eye drop aid that would enter the market.

Content:

Auto Squeeze Eye Drop Bottle Squeezer

- $7.39 on Amazon
- Manufacturer: Owen Mumford
    - They advertise to combine auto squeeze and auto drop together to "make squeezing the bottle easier"
- Date first available: August 19, 2009
- "Helpful devices provides additional leverage to help users with weak or arthritic fingers"
- Reviews: Overall users like this device.
    - Pros: Many buyers say that the device helped squeeze the bottle for users with weak fingers. A buyer said "enables precise control of drop size and drop placement.
    - Cons: a buyer mentioned that the device initially worked when the bottle was full, but then it stopped working
- Summary: I could not find much information regarding the number of sales of this product.

Droppy Eye Drop Dispenser

- $13.99 on Amazon
- Brand: Droppy
- Manufacturer: AK Technology
- Date first available: May 8, 2019
- Reviews:
    - Pros:
        - The wings make it easy to squeeze even the hardest bottles
        - the eye part helps keep the eye open
    - Cons:
        - the price was good, but the product came in several pieces that needed to be assembled for each use
            - Hard to snap together and unsnap
        - a few reviewers sad that it does not work properly, drops go everywhere
        - doesn't work with eye drop vials, only bottles
        - "the major problem of not being able to see a tiny bottle of eyedrops when you are farsighted, is that you cannot actually see the drop end of the bottle when it is close enough to your eye to squeeze the bottle and get the drops to hit your eye. This product does not help reduce this problem at all"
            - this is an interesting problem that I did not think of prior to reading this review
        - "It seems that if you don't have dexterity with your fingers the tool is not helpful. It works but limited to your ability to control your fingers."

Conclusions/action items:

While I did find more information of high eye drop assistant competitors, I didn't find much on the market size regarding to either of these product sales. So, I will need to do more intensive research to hopefully find this information about these products.

ANABELLE OLSON (amolson27@wisc.edu) - Feb 28, 2024, 1:16 PM CST

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squeeze-leaflet.pdf (422 kB)

2024/04/14 - Graphic Visuals for Marketing, Packaging, and Instructions

ANABELLE OLSON (amolson27@wisc.edu) - May 01, 2024, 2:27 PM CDT

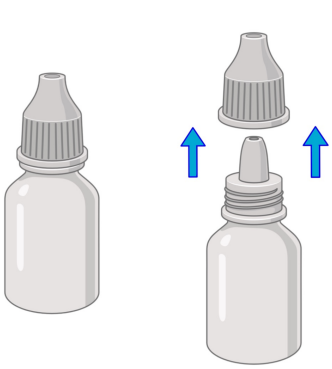
Title: Graphic Visuals for Marketing, Packaging, and Instructions

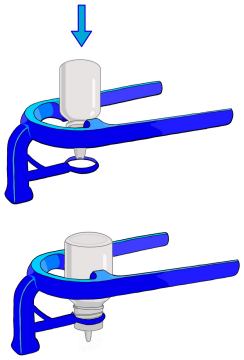
Date: 04/14/2024

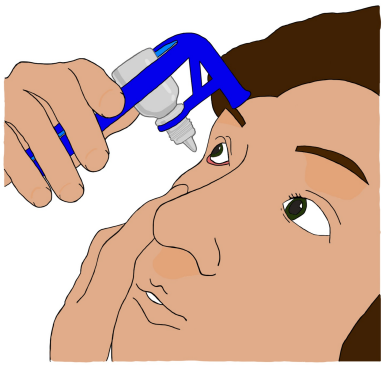
Content by: Anabelle Olson

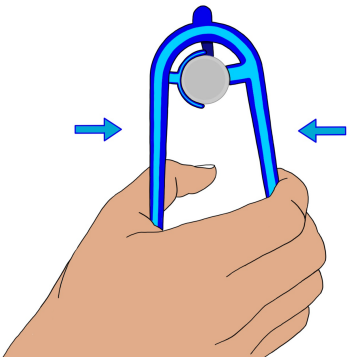
Goals: To create drawings that visually depict how to use our device in a simple manner

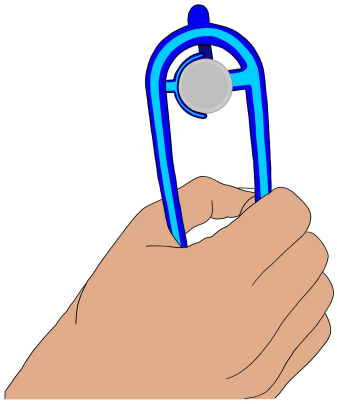
Content:











Conclusions/action items:

These drawings will be used to make instructions for use manuals along with potential marketing flyers and packaging.

2024/1/27 Good Clinical Practice for Drug/Device Researchers

ANABELLE OLSON (amolson27@wisc.edu) - Feb 27, 2024, 5:47 PM CST

Title: Good Clinical Practice for Drug/Device Researchers

Date Completed: 1/27/2024

Content by: Anabelle Olson

Goals: To learn about practice standards for clinical trials of drugs, biologics, and devices. In our case, learn more about device clinical trials for use with our IRB protocol.

Content:

See attachment for Completion Certificate.

Conclusions/action items: Through this training I learned about good practice with human subjects such as how to recruit subjects without coaxing them into participating and how to properly gather informed consent from subjects. Additionally, how to manage and control adverse events that could/may occur during a clinical trial. These lessons will help me as we go through our human subject feasibility testing.

ANABELLE OLSON (amolson27@wisc.edu) - Feb 27, 2024, 5:38 PM CST

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	27-Jan-2024	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID: 1384)	27-Jan-2024	9/9 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1386)	27-Jan-2024	4/4 (100%)
Overview of New Drug Development (ID: 1351)	27-Jan-2024	8/8 (100%)
Overview of ICH GCP (ID: 1352)	27-Jan-2024	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	27-Jan-2024	5/5 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	27-Jan-2024	3/3 (100%)
Managing Investigational Agents According to GCP Requirements (ID: 1356)	27-Jan-2024	8/8 (100%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1368)	27-Jan-2024	3/3 (100%)
Detecting and Evaluating Adverse Events (ID: 1366)	27-Jan-2024	4/4 (100%)
Reporting Serious Adverse Events (ID: 1361)	27-Jan-2024	4/4 (100%)
Audit and Inspections of Clinical Trials (ID: 1363)	27-Jan-2024	8/8 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID: 1349)	27-Jan-2024	4/5 (80%)
Completing the CITI/GCP Course (ID: 1364)	27-Jan-2024	No Quiz
University of Wisconsin - Madison (ID: 12120)	27-Jan-2024	No Quiz

Collaborative Institutional Training Initiative (CITI Program)

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2024/1/28 Human Subjects Research - UW Human Subjects Protection Course

ANABELLE OLSON (amolson27@wisc.edu) - Feb 27, 2024, 6:00 PM CST

Title: UW Human Subjects Protection Course

Date Completed: 1/28/24

Content by: Anabelle Olson

Goals: To complete UW Human Subjects Research course in preparation for our initial human subjects usability testing.

Content:

See attached file for completion certificate.

Conclusions/action items:

Through this course I learned more about ethical research with human subjects. The knowledge I learned through the modules will help me use an ethical approach to all aspects of our usability study.n

ANABELLE OLSON (amolson27@wisc.edu) - Feb 27, 2024, 5:55 PM CST

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2014/11/03-Entry guidelines

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity. subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03-Template

John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items:

BME Design Fall 2023- Notebook

Jenna Krause - Jan 28, 2024, 10:03 PM CST

BME Design Fall 2023 - KASIA KLOTZ
Complete Notebook

PDF Version generated by
Jenna Krause
on
Dec 13, 2023 @ 12:12 PM CST

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