BME Design-Spring 2024 - Ellie Steger
Complete Notebook

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EMILY WHEAT

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Team contact Information

EMILY WHEAT - Feb 28, 2024, 9:10 PM CST

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Project description

Ellie Steger - Feb 22, 2024, 11:51 AM CST

Course Number: 402

Project Name: Radiologic pathologic correlation in renal cell carcinoma

Short Name: RCC Blade

Project description/problem statement: The goal of this project is to develop a blade for a tumor resection coring device. The blade should be able to effectively resect a tissue sample from an ex-vivo tumor without causing tissue damage to the overall tumor. Currently, the resection device used is too blunt and thick to effectively extract samples without causing surrounding tissues to be damaged and un-imageable on CT. By creating a new blade design, the pathologist can preserve the tumor sample during the coring process. In maintaining the integrity of the tumor tissue, the pathologist will be able to accurately correlate CT image markings with their location in the patient sample.

About the client: Dr. Meghan Lubner works in the University of Wisconsin-Madison Department of Radiology.

2024/02/14 Testing Protocol Meeting

ERIN SCHLEGEL - Feb 14, 2024, 9:37 AM CST

Title: Discussion of Testing Protocols

Date: 02/14/24

Content by: Erin Schlegel

Present: Emily Wheat, Aleks Skutnik, Ellie Steger, Olivia Jaekle, Erin Schlegel

Goals: The goal of this call was to meet with our team to align on testing for the semester.

Content:

- Comparison test for old blade and new blade- durability test repeat the test again now on pig kidneys
  - Do we need to fabricate a new blade?
  - Create a note of it on the poster/presentation that blades have already been used
- Tissue Damage test- for new blade and coring device unit
- Recapping blade test
- Mold test- prove that the CAD model- making sure the models made have the same thickness and same diameter and comparing dimensions
- Cap sealant- needle, possible slit in the cap-
  - How big is the cap (1/2-3/4")
  - taper made it easy
- Need quantitative data- put under MTS machine
  - How to measure internal pressure it can withstand?
- Final ergonomic survey- for unit of the coring device

Conclusions/action items: We will individually research and together decide on which journal we will be presenting too. We will also have Dr.Puccinelli look over our proposed tests and ask any remaining questions about them.

2024/02/21 Preliminary Report Meeting

EMILY WHEAT - Feb 28, 2024, 7:52 PM CST

Title: Preliminary Report Meeting

Date: 2/21/2024

Content by: Emily

Present: Emily, Erin, Aleks, Ellie, Olivia

Goals: To break up the sections for the preliminary report and pick which article to base it off of.

Content:

- the team met on zoom

- the team came up with 6 journal articles to potentially pick from

- each member will fully read one of the articles and take notes on it and pros/cons

- the team will then discuss and chose which article to move forward with

- the team broke up sections for the preliminary report and discuss what needed to be mentioned in each section

Conclusions/action items: Each member will write their assigned sections before the teams determined deadline. The team will meet back up soon to revise the preliminary report and make sure it is formatted similar to the chosen article. The team will meet with our advisor and client in the upcoming days to stay on track with the project.

2024/02/23 Protocol and Manual Meeting

EMILY WHEAT - Feb 28, 2024, 7:57 PM CST

Title: Team meeting for protocols and manuals

Date: 2/23/2024

Content by: Emily

Present: Emily, Aleks, Olivia

Goals: To complete the testing protocols and manuals for the project.

Content:

- the "testing" team members have been slowly working on completing the testing protocols and manuals
- most of the testing protocols can be reused from last semester since the same tests will be run
    - a few changes had to be made for the premade blade and to get rid of the chicken breasts
- completed the user manual
- completed the safety manual
- completed the maintenance instructions

Conclusions/action items: The team finished the necessary manuals and protocols needed for the preliminary report. Each member needs to work on their assigned sections of the report. Moving forward, testing will be starting soon so the team needs to prepare for that.

2024/02/26 Preliminary Report Revision

EMILY WHEAT - Feb 28, 2024, 7:44 PM CST

Title: Preliminary Report Revision Meeting

Date: 2/26/2024

Content by: Emily

Present: Emily, Erin, Ellie, Olivia, Aleks

Goals: To revise the preliminary report and make final corrections before submitting.

Content:

- the team met on facetime

- went over the entire introduction of the report and didn't make many corrections

- decided to add certain topics/ideas to the methods section

- discussed the abstract section and whoever wrote the corresponding section of the report wrote the few sentences for the abstrat

- discussed if we thought it was okay to have such short results and discussion sections

    - decided to ask Dr. Puccinelli during office hours in 2 days

- cleaned up the references

Conclusions/action items: Overall, the preliminary report is almost finished and ready to be submitted. The team will attend Dr. Puccinellis office hours on Wednesday at 3pm to ask our final questions about the outline. If everything looks good, the report will be submitted soon after.

2024/3/02 Prep for Outreach

Olivia Jaekle - May 05, 2024, 11:16 AM CDT

Title: Meeting to prep for outreach

Date: 2024/03/02

Content by: Olivia

Present: Emily, Erin, Aleks, Ellie

Goals: Make sure everything is ready for outreach

Content:

- finalized our presentation

-cut out all of the hands needed for the students

-made kits for the activity

-confirmed with the school that we are still coming March 11.

- mentally prepped to teach 120 kids!

Figure 1: our team working on cutting hands outside of 1410 engineering hall.

Conclusions/action items:

Overall, we are super excited to teach 4th graders about biomechanics. Everything is prepped and ready to go!

2024/3/11 Outreach Day

Olivia Jaekle - May 05, 2024, 11:22 AM CDT

Title: Went to school for outreach

Date: 2024/03/11

Content by: Olivia

Present: Emily, Aleks, Erin, Ellie

Goals: Teach 120 kids about biomechanics

Content:

-taught 4 classes total, 30 kids per class

- all students were able to complete the activity in 50 minutes

- students seemed to like activity

-teachers also enjoyed activity and asked next time we give them more content beforehand to get kids more prepared

-If to do again, like change the type of straws and thickness of paper used for hands

Conclusions/action items:

The outreach day was a huge success! Students and teachers all had a great time and have asked us to come back. We are keeping a look out for the evaluations being sent to us by the teachers at the school. They would love to keep a relationship with us and we are looking forward to continue that bond.

2024/3/15 Testing Tube with Pig Kidney

Olivia Jaekle - May 05, 2024, 11:35 AM CDT

Title: Testing thinner tube on pig kidney

Date: 2024/3/15

Content by: Olivia

Present: Emily, Aleks, Olivia

Goals: Try testing newly printed tubes on pig kidney

Content:

-couldn't get any good data because pig kidney fat was too thick and did not match perinal fat from human kidney

- was able to get a few decent cuts with no fat, but that was not what we were looking for becuase that is not good representation of the human kidney

Figure 1: pig kidney and fat

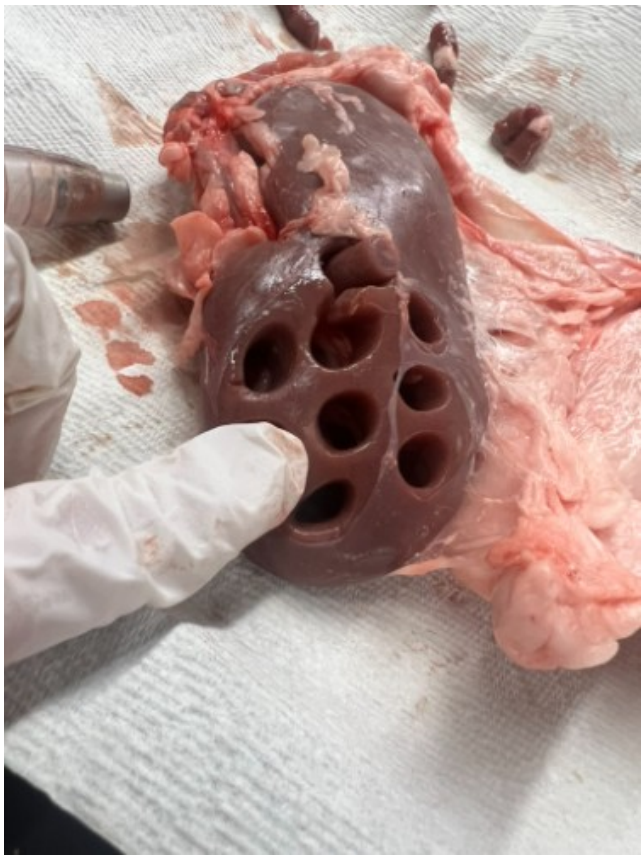

Figure 2: trying to cut through pig kidney with fat

figure 3: shows blade goes into tube with too much force

figure 4: device struggling to get through with fat attached

figure 5: blade stuck in fat

Conclusions/action items:

Overall, we weren't able to get any data points because the blade kept getting stuck in the fat and couldn't cut through it well. We realized the only way we can truly find out if the new tube works is to meet with client and do testing on human kidneys.

2024/04/25 Final Report and Presentation Review

ALEKSANDRA SKUTNIK - Apr 25, 2024, 3:38 PM CDT

Title: Final report and presentation review

Date: 2024/04/25

Content by: Aleks Skutnik

Present: All

Goals: To practice the final presentation and finalize details of the project.

Content:

- The team met to discuss report deadlines and split up portions of the final report
- The team practiced presenting the final presentation in preparation for the BME poster session on 04/26

Conclusions/action items:

The team will work on their designated sections of the final report to submit.

2024/01/26 Initial Client Meeting

ALEKSANDRA SKUTNIK - Jan 26, 2024, 1:39 PM CST

Title: Initial Client Meeting New Semester

Date: 2024/01/26

Content by: Aleksandra Skutnik

Present: All

Goals: To meet with the client at the beginning of the new semester to establish expectations and discuss the next steps of the project.

Content:

- Make functional device
- Figure out how blade and tube will come together
    - Has been a struggle in the past
- Fabrication of blade?
    - Prefabricated?
    - Blade angle can be challenging
    - Try standardizing how the blade is manufactured
    - Maybe better to have just multiple blades
- Really wants to just make a functional device
- Limited design time: how to reasonably put the two together
- Maybe put MRI compatibility on back burner
- Testing phantom
    - Fat and fibrous layers is hard to mimic
    - Can do what we did in the past by using already processed real human kidney specimens when comfortable with prototype
    - Potentially get animal tissues with fat left on the kidneys
    - Primarily make sure that we can successfully get the blade and coring tube to fit together
- Has done journal article like reports in the past
- Can send the liver box article to us for reference and use as a template
    - Willing to work on the journal report with us
    - Use a reference manager (endnote, paperpile, zotero)

Next steps:

- Move forward with blade 1 based on results from testing last semester
- Consider adding a thread
    - Can print a tube with a corresponding thread
- Share designs with Sylvanna to help with printing and logistics

    - Potentially set up a meeting with her to talk through printing issues/best approach to attaching blade to the coring tube

- Shortening the blade to appropriate length
- Look into pre-manufactured blades
    - If it exists, she is open to ordering pre-manufactured blades for future prototypes and designs
    - She is very open to moving forward in any direction

Conclusions:

The team will set up a meeting with the biomedical engineer, Sylvana, on the client's team to work through 3-D printing issues and discuss potential approaches to combining the blade to the 3-D printed coring tube.

2024/02/23- Client Update Meeting

Olivia Jaekle - Feb 28, 2024, 6:53 AM CST

Title: Update Client Meeting Before Preliminary report

Date: 2024/02/23

Content by: Aleks Skutnik, Olivia Jaekle

Present: All

Goals: To update the client on current manufacturing progress and device development.

Content:

- Updates on blade
  - Pre manufactured blade
  - 1 cm diameter
  - With tapered edge
- Ellie and Erin met with Sylvana about 3D printing
  - Reprinting in process
  - Can send over orientation for printing to avoid issues
- Should try out final device when possible
- Will look into testing on old specimens
- Next steps is to ensure that the blade and the corer will fit together
- Still doing lego clips
- Make sure the blade can be taken out just as easily and being put in so that imaging can take place
- See if the blade can be sterilized for reuse
  - Using for research should be fine to be autoclaved between uses
- Stainless steel resistant to rust so exposure to water and sterilization will be fine

Next steps:

- Try testing again on specimens
- Do the surveys again
- Testing within the next couple of weeks
- Dr. Lubner will ask other members on her team to test the blade

Preliminary journal recommendations:

- Dove press currently looking at, but low impact score
- Radiology journals: technical innovations
  - AJR
  - If we used the biopsy device in a specimen, it may be used
  - Abdominal radiology-- interventional medicine special sections

Conclusions/action items:

Dr. Lubner will help look into articles/journals that the team can look into to see where the project best fits into. The team will plan for testing the final biopsy device in the coming weeks with the client and her team. The team will work on finalizing the final design in preparation for testing. The press to fit feature of the blade and coring tube will be evaluated and modified if necessary prior to meeting with the client.

2024/03/01 Testing Round 1

EMILY WHEAT - Mar 01, 2024, 1:13 PM CST

Title: Human Kidney Testing Day 1

Date: 3/1/2024

Content by: Emily

Present: Emily, Aleks, Ellie, Olivia, Erin

Goals: To testing the entire device, blade and coring tube together, on a human kidney specimen

Content:

- the team met at WIMR
- this is the first time the blade will be tested in conjunction with the coring tube
- the coring tube finished printing this morning and it successfully snaps over the blade
- 2 team members went down into the lower part of the hospital to test with Meg
- the ergonomics survey will be given to all those who test using the device
    - this includes our client, Dr. Meghan Lubner
    - Dr. Rong Hu
    - Dr. Daniel Shapiro

PROS:

- blade cut was great
- could tell two different kinds of tissue/fat
- no staircase on the samples

CONS:

- the coring tube width started to cut the specimen
- coring tube started to fall apart
    - could be because of how slimy it became

FUTURE:

- the client would like us to create a push device to push the sample out of the tube
- make sure the tube material is super smooth and polished inside and out

Conclusions/action items: Per the results of the ergonomics survey, the team will make adjustments to the design. The team is planning on completing tissue damage testing in the next 2 weeks on pig kidneys. All of this data will be compiled and made into figures and graphs.

2024/04/19- Testing Round 2

ALEKSANDRA SKUTNIK - Apr 20, 2024, 4:36 PM CDT

Title: Testing with the Client on Human Kidney

Date: 2024/04/19

Content by: Aleks Skutnik

Present: Aleks Skutnik, Emily Wheat, Olivia Jaekle

Goals: To conduct testing on human kidneys with a thinner coring tube prototype.

Content:

- The team met with Dr. Hu Rong and Dr. Daniel Shapiro at WIMR
- The clients used the biopsy device to perform resection tests on a processed human kidney
    - Disclaimer: this kidney was post-processing and ready to be discarded, only the clients handled the kidneys and performed resection tests
- Coring tube did not function as well as the thicker prototype
    - Making the coring tube thinner compromised its ability to stay together when being pushed into the kidney tissue
- The two parts of the thinner coring tube fell apart easily, they did not lock into place as the thicker tube did

Conclusions/action items:

The team should reconsider the thinner tube design. The team may also want to change the locking mechanism of the two parts of the coring tube to create a more secure attachment between the two halves to prevent them from splitting during a biopsy.

ALEKSANDRA SKUTNIK - Apr 25, 2024, 3:31 PM CDT

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2024/02/22 Coring Tube 3D Printing

Ellie Steger - Feb 22, 2024, 2:45 PM CST

Title: 3D Printing Coring Tube

Date: 02/22/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To successfully print the final iteration of our coring biopsy tube.

Content:

- The tube will be printed using biomed clear resin
- The tube will not be cured to prevent bowing caused by the rapid temperature change
- The layer thickness cannot be reduced in the UW Makerspace- it has already been set to the minimum thickness of .05mm
- The tubes were oriented vertically to ensure the integrity of the thin lip of the tube
    - The concaved elements of the tube were positioned to have a 15 deg contact angle with the resin, this is consistent with research on how to best maintain their integrity

Conclusions/action items: With consultation with the makerspace this print was started on the Formlabs 3 printer. The print time is 12 hours and the print cost $11.50.

2024/01/26 Initial Advisor Meeting

ERIN SCHLEGEL - Jan 26, 2024, 1:19 PM CST

Title: Initial Advisor Meeting

Date: 01/26/2024

Content by: Erin Schlegel

Present: Dr. Puccinelli, Ellie Steger, Olivia Jaekle, Emily Wheat, Aleks Skutnik, Erin Schlegel

Goals: The goals of this meeting were to establish goals for this semester and cover any updates to the course.

Content:

- navigate to the course page and look for bme design 402 to see specific requirements
- The preliminary presentation is more focused on planning for the semester and not on design evaluation, somethings not applicable
- need specific goals with a detailed timeline, set up weekly goals by month
- just a project timeline, not outreach
- instead of a report, we will be writing a journal article
- the report will now act as an appendix
- Changed format of the progress report, frontload more important client details
- follow the order given
- Show and tell will be in a larger audience where we will act as an advisor to bme 301/201
- Outreach, we are in contact with Deforest schools, waiting for them to give feedback on our activity
- grades 4-7
- give Dr.Puccinelli contact of the

Conclusions:

There are multiple updates to the forms and templates used in the course that we must include in the semester. We also need to

Action items:

The team will meet with the client to establish and align semester goals. The team will also meet separately to create a timeline for preliminary presentations.

2024/02/09 Preliminary Presentation Feedback

ERIN SCHLEGEL - Feb 09, 2024, 1:14 PM CST

Title: Preliminary Presentation Feedback

Date: 02/09/24

Content by: Erin Schlegel

Present: Dr. Puccinelli, Erin Schlegel, Emily Wheat, Aleks Skutnik,

Goals: To receive feedback and answer questions about our preliminary presentation.

Content:

Is there concern about solvent dissolving PLA?

- — - they use PLA for thumb caps
- — silicone is aligned with what we need in a surgical environment
    - — disposable? one use
    - — How to dispose of cap?
        - — go into a bin to be cleaned

How to ensure safety of putting the cap on?

- — include it in the safety precautions
- — were able to see they have surgical instruments, ask them how they clean them and keep them safe, can ask the client
- — look into OSHA standard for recapping needles- good procedure
- — supposed to recap needle by putting cap on table and place needle into cap on table include in URM and safety
- — silicone can be sticky- make the silicone stiff

Sealant?

- — why not just by silicone? ease of use for future projects
- — See CAD for silicone before printing and let her know the silicone
- — bme copy room 2nd floor

Conclusions/action items: Pick up package from Dr.Puccinelli and follow up with her about CAD design before purchasing Silicone.

2024/02/16 Advisor Meeting #3

ERIN SCHLEGEL - Feb 16, 2024, 8:05 PM CST

Title: Advisor Meeting #2

Date: 2024/02/16

Content by: Erin Schlegel

Present: Dr.Puccinelli, Olivia Jaekle, Emily Wheat, Aleks Skutnik, Ellie Steger, Erin Schlegel

Goals: The goal of this meeting was to check in with our advisor and ask questions regarding testing.

Content:

- testing protocols will use user data- semi quantitative, use the likert scale to get more quantitative data
    - if we wanted to we could use a solidworks simulation for the internal pressure capacity, but not necessary
- User manual- failure tests, life in service tests,
- look into doing durability thickness for new blade,
- show old data for blades as preliminary testing, it is not ok to compare the durability test values though considering they are different mediums and already made blades
- it is not necessary to do just blade testing, more important to test the entire unit together
- for testing protocols think about the entire process start to finish, what's important, it is important to test to coring tube that we designed, does it stays together, does it cause tissue damage
- cap protocol, refer to the old osha standard? or look for standards around corneal tissue device, look for skin biopsy standards
- tests should include: remove blade, reusable blade, tissue preservation, look at top 5 from PDS, look at design matrix,

Conclusions/action items:

Now that the team has decided what aspects are important to test, we can go forward with writing test protocols and performing testing.

2024/02/21- Advisor Meeting Preliminary Report

ALEKSANDRA SKUTNIK - Feb 21, 2024, 4:18 PM CST

Title: Advisor Meeting Preliminary Report

Date: 2024/02/21

Content by: Aleks Skutnik

Present: All

Goals: To go over expectations for the preliminary report.

Content:

- Ellie and Erin met with Sylvana (3D printing Engineer at WIMR)
    - changed dimensions on the coring tube
    - Curing after printing can cause shrinkage which was causing the bowing
- Preliminary report
    - Rubric? Faculty form for the rubric
    - Also covers the appendix
    - Journal article draft + outline of results and discussion
    - Appendix should have PDS, design matrix, basically final report
    - Raw data
    - can refer to old group but anything thats related to our design
    - Journal Article: very open, look at sources used to make design
        - Source examples online
        - Medical Devices, Radiology- if they have an area for design, look at topics and make sure it is applicable
        - impact factor 3, no higher than 6
    - Manuals- at least an outline, in appendix as supplemental information
        - service, maintenance, safety manuals
    - Print PDF and send to Dr.P of journal
    - Upload journal with appendix to canvas by Wednesday 11:59
- Outreach
    - Date set for March 11
    - Working on outreach presentation
    - Have supplies
    - Run through activity guide as practice

Conclusions/action items:

The team should work on the preliminary report and the outreach presentation. The team should also begin testing the final device as soon as possible. The team should start compiling supplies for outreach and cutting out cardboard hands.

2024/03/08 Advisor Meeting

Olivia Jaekle - May 01, 2024, 7:58 AM CDT

Title: Advisor Meeting

Date: 2024/03/08

Content by: Olivia Jaekle

Present: Olivia, Aleks, Emily, Erin, Ellie

Goals: Regroup from the past week

Content:

- **Dr.Puccinelli recommends a long consistent circular tube with potentially a hollow interior**
  - **plunger printed in ABS- it is autoclavable**
  - **check with Dr.Lubner that they have an ABS printer**
- **Take pictures on a microscope for tissue damage?**
  - image J analysis- make sure you are the exact same distance this time
  - can we automate in image J a 10 mm circle
  - This data will be good for a journal article
- Have an explanation of our design in the journal article early on
- Add dr.lubner and dr.puccinelli to author list
- Add a sentence or two on the current procedure not being adeqate and how ours is better, addressing what is wrong with the current method
  - Answer the question: Why is it improtant to use this device at all?

Conclusions/action items:

Going to print tube in ABS and followup with Dr.Lubner about taking pictures for tissue damage.

2024/03/15 Advisor Meeting

ALEKSANDRA SKUTNIK - Mar 15, 2024, 7:23 PM CDT

Title: Advisor Meeting Post Testing and Outreach

Date: 2024/03/15

Content by: Aleks Skutnik

Present: Aleks Skutnik, Emily Wheat, Olivia Jaekle, Ellie Steger

Goals: To discuss the advances in our project.

Content:

- Discussed the outcomes of the outreach activity that the team completed
- The team successfully reprinted a coring tube that better fits the diameter of the blade to minimize surrounding tissue damage
- The team conducted tissue damage testing with the new coring tube
    - Pig kidneys did not successfully encompass the correct anatomy of a resected human kidney
    - Future tissue damage testing will be conducted with the client on human kidneys

Conclusions/action items:

The team should complete the post-outreach reflection essay. The team should also move forward in testing with the client and offer the client multiple coring tube designs to receive feedback on.

2024/04/05 Advisor Meeting

EMILY WHEAT - Apr 05, 2024, 12:52 PM CDT

Title: Weekly advisor meeting

Date: 04/05/2024

Content by: Emily

Present: Emily, Erin, Aleks, Ellie

Goals: To discuss everything that needs to be done within the last 3 weeks of class

Content:

- asked about testing
    - as of right now we are trying to test next Friday
- talked about the executive summary
    - we picked the excellence award
    - the summary asks us to write our poster number (we are number 7)
    - did we thoroughly follow the design process?
        - each step should be highlighted
    - we can put previous data and results in it since we don't have a ton of data now
    - have until Sunday to finish the executive summary

Conclusions/action items: The team will be meeting next week in person for the advisor meeting Friday. If we are testing with our client during the scheduled advisor meeting time, we will have to reschedule the advisor meeting so all team members can attend. The team will finalize the executive summary and submit it by Sunday night.

2024/04/22 Advisor Meeting

EMILY WHEAT - Apr 29, 2024, 9:28 PM CDT

Title: Final Advisor Meeting

Date: 4/22/2024

Content by: Emily

Present: Emily, Aleks, Olivia, Erin, Ellie

Goals: To get feedback on our final poster presentation

Content:

- the team had completed the final poster before the meeting

- Dr. Puccinelli gave feedback on every section of the poster:

- come up with a new name rather than "background"

- get rid of the blade design specs

- add plunger design specs

- add more testing pictures

- add more labels about dimensions of all figures

- add IRB to the final testing section

- make sure all headers are centered

Conclusions/action items: The team will implement all of these corrections following this meeting. In the next few days the team will practice the presentation and submit the final poster to both canvas and the website. Friday the team will show up to ECB for the final poster session!

2024/02/16 3D printing meeting

ERIN SCHLEGEL - Feb 16, 2024, 7:58 PM CST

Title: 3D Printing Meeting

Date: 02/16/24

Content by: Erin Schlegel

Present: Sylvana Garcia (UW Health), Ellie Steger, Erin Schlegel

Goals: The goal of this meeting is to get feedback from UW Health's 3D printing specialist on how to prevent bowing in our 3D printed coring device.

Content:

- plastic bowing can be a result of thermal expansion and the stresses/strains that come from that
- stresses in the material that is counteracting, if one layer is harder than the other, plastics expand to temperature, have that problem when curing
- she doesn't cure her 3D printed parts, curing makes it tougher, so we might want to change the curing parameters (time or temperatures) to get a better result or ask form labs to see what would be best for our design
    - could also try leaving it in the curing device for a long time to ease the temperature out of the printer (not go straight from hot to cold)
    - ask the makerspace to alter the parameters, or tell them not to cure it
- another option is to maybe take down the layer thickness,
- to keep from failing, have the part be slanted so that the laser doesn't have to cover a large area in a single layer,
    - depending on the cross section it can be larger or smaller
    - could also increase the density of the supports, or do a full raft/support,
    - try different orientations so that it is not flat, try to increase the density of the supports or increase the contact area
- the software generates a warning that print might fail if you have "cups", concave surfaces should not face resin pool because it can create surface tension
- One option to keep parts fitting together better is to have the pins and holes add a lip to the tip of the cylinder

Conclusions/action items: Moving forward we will reprint our product by putting in different parameters such as decreasing the layer thickness, orienting the concave surface away from the resin pool, and asking the maker space not to cure it. This will give us a better idea if the bowing is occurring from the design or printing parameters.

2024/2/28 Updated Expense Sheet Spring 24

Olivia Jaekle - Feb 28, 2024, 4:41 PM CST

Title: Updated Expense Sheet

Date: 2024/2/28

Content by: Olivia Jaekle

Present: ALL

Goals: To show how much we spent so far this semester

Content:

Item	Description	Manufacturer	Quantity	Cost
Trephine Blade	AM0570S 100- 10mm d	Miro surgical	1	$92.71
Coring Tube	Biomed clear resin	Makerspace	1	$11.50
Coring Tube	Biomed clear resin	Makerspace	1	$12.75
Coring Tube	Biomed clear resin	Makerspace	1	$.895

Conclusions/action items: In total we spent, $125.91 so far this semester. Our biggest purchase has been the blade. The coring tube had to be reprinted a couple times due to bowing. Overall, we still have at least $300 so we should be able to finish the semester without any issues with cost!

2024/5/1 Final Expense sheet

Olivia Jaekle - May 05, 2024, 11:53 AM CDT

Title: Final Expense Sheet

Date: 2024/51

Content by: Olivia

Present: Erin, Olivia, Emily, Aleks, Ellie

Goals: Final Expense Sheet

Content:

Item	Description	Manufacturer	Quantity	Cost
Trephine Blade	AM0570S 100- 10mm d	Miro surgical	1	$92.71
Coring Tube	Biomed clear resin	Makerspace	1	$11.50
Coring Tube	Biomed clear resin	Makerspace	1	$12.75
Coring Tube	Biomed clear resin	Makerspace	1	$8.95
Coring Tube	Biomed clear resin	Makerspace	1	$11.04
Coring Tube	Biomed clear resin	Makerspace	1	$12.93
Coring Tube	Biomed clear resin	Makerspace	1	$0.22
Coring Tube	Biomed clear resin	Makerspace	1	$3.70
Coring Tube	Biomed clear resin	Makerspace	1	$7.16
Coring Tube	Biomed clear resin	Makerspace	1	$7.32
Total				**$168.28**

Conclusions/action items:

Overall, our final expenses were under our budget, which was $300. Most of the cost came from having multiple iterations of the coring tube. Our most expensive purchase was the blade.

2024/02/26 Final 3D Print Coring Tube

Ellie Steger - Feb 26, 2024, 5:30 PM CST

Title: 3D Printing Coring Tube

Date: 02/26/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To successfully print the final iteration of our coring biopsy tube.

Content:

- The tube will be printed using biomed clear resin
- The tube will not be cured to prevent bowing caused by the rapid temperature change
- The layer thickness had to be doubled t 0.100 mm because this was printed in the formLabs 3 printer instead of the formlabs 3 printer
- The tubes were oriented vertically to ensure the integrity of the thin lip of the tube
    - The concaved elements of the tube were positioned to have a 15 deg contact angle with the resin, this is consistent with research on how to best maintain their integrity

Conclusions/action items: With consultation with the makerspace this print was started on the Formlabs 2 printer. The print time is 2 hours and the print cost $12.75.

2024/02/27 Coring Tube Solidworks adjustments

Ellie Steger - Feb 27, 2024, 9:55 PM CST

Title: Coring Tube Solidworks Adjustments

Date: 02/27/24

Content by: Ellie Steger

Present: Ellie Steger and Erin Schlegel

Goals: To successfully create the solidworks for the final iteration of our coring biopsy tube.

Content:

- The inner diameter of the tube was adjusted from 9mm to 11mm to garner a bigger sample
    - Due to this change the size of the lip was also decreased to reduce drag when taking the sample
- The angle of the chamfer was also increased to decrease the size the edge of the tube and make it more flush with the blade. This will reduce drag on when taking the sample
- The holes and pegs were also centered

Conclusions/action items: We are now confident that we have adjusted the solidworks for the most successful coring device.

2024/02/28 3D Printed Coring Tube

Ellie Steger - Feb 28, 2024, 1:04 PM CST

Title: 3D Printing Coring Tube

Date: 02/28/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To successfully print the final iteration of our coring biopsy tube.

Content:

- The tube will be printed using biomed clear resin
- The tube will not be cured to prevent bowing caused by the rapid temperature change
- The layer thickness was was decreased back to .05mm the formlabs 3 printer
- The tubes were oriented vertically to ensure the integrity of the thin lip of the tube
    - The concaved elements of the tube were positioned to have a 15 deg contact angle with the resin, this is consistent with research on how to best maintain their integrity

Conclusions/action items: With consultation with the makerspace this print was started on the Formlabs 3 printer. The print time is 12 hours and the print cost $8.95.

2024/02/29 Coring Tube Solidworks

Ellie Steger - Apr 30, 2024, 11:38 AM CDT

Title: Coring Tube Solidworks Adjustments

Date: 02/29/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To successfully create the solidworks for the final iteration of our coring biopsy tube.

Content:

- The print was adjusted to make the tip of the device thicker to ensure print reliability.
- It was also adjusted to ensure a press to fit feature of the blade and the device

Conclusions/action items: We are now confident that we have adjusted the solidworks for the most successful coring device.

Ellie Steger - Apr 30, 2024, 11:32 AM CDT

Download

2.29MChamfered_Tube.SLDPRT (133 kB)

2024/02/29 3D Printing Coring Tube

Ellie Steger - Apr 30, 2024, 11:45 AM CDT

Title: 3D Printing Coring Tube

Date: 02/29/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To successfully print the final iteration of our coring biopsy tube.

Content:

- All previous print conditions were followed
- The new solid works with a better blade fit and larger tip was used to print
- The tube was printed at a 60 degree orientation to the print pad to maintain the integrity of the tip of the tube

Conclusions/action items: With consultation with the makerspace this print was started on the Formlabs 3 printer. The print time is 11 hours and the print cost $11.04.

Ellie Steger - Apr 30, 2024, 11:48 AM CDT

Update: This print was successful and will undergo testing with our client. It is tube #7.

2024/03/01 New Tube Based on Client Feedback and Plunger

Ellie Steger - Apr 30, 2024, 1:16 PM CDT

Title: New Tube Based on Client Feedback and Plunger

Date: 03/01/24

Content by: Ellie Steger

Present: Ellie Steger and Erin Schlegel

Goals: To successfully modify our coring tube design based on client feedback.

Content:

- The outer diameter of the tube was adjusted from 15mm to 13mm to create a thinner tube that will not tear the tissue
- The pitch of the chamfer was decreased to have a more transition from the blade to the body of the coring tube.
    - Due to this change the size of the lip was increased to ensure that the blade does not fall into the tube
- Slits were added to the tube so the patient can measure and correlate the slices of samples these slits were placed 0.5 cm apart. These slits go through the entire tube and are 0.25 mm thick
- A plunger was also developed in solidworks to help the client smoothly remove the sample from the coring tube
    - The plunger is 12 cm in length, 8.5 cm in diameter and features a thumb indent for leverage and comfort
    - The plunger will be made from PLA and will be single use and disposible

Conclusions/action items: We will now print this thinner version of our device with slits to perform client testing again. The plunger will also be printed on the Ultimaker Printer in PLA

2024/03/04 Printing Tube and Plunger

Ellie Steger - Apr 30, 2024, 11:33 PM CDT

Title: Printing Tube and Plunger

Date: 03/04/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To successfully print the final iteration of our coring biopsy tube.

Content:

- The plunger will be printed in PLA plastic on the Ultimaker printer

- The coring tube will be printed in biomedclear resin at a 0 degree angle (flat to the build plate) based on autogenerated supports

Conclusions/action items: With consultation with the makerspace this print was started on the Formlabs 3 printer. The print time is 10 hours and the plunger on the ultimaker will take 1 hour. The prints cost $12.93.

2024/03/07 Plunger Reprint

Ellie Steger - Apr 30, 2024, 11:31 PM CDT

Title: Printing Tube and Plunger

Date: 03/07/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To successfully print the plunger.

Content:

- The past plunger failed in the Ultimaker due to a power outage
- After consulting with the makerspace we have decided that printing in ABS in the Bambu printer would be a better
- This is a more cost effective and more time efficent option
- This tube will be more lightweight however the material is very porous so it is not reusable or autoclavable
    - However due to the fast print and cheap material we believe that it would be best to use the plunger as single use device

Conclusions/action items: With consultation with the makerspace this print was started on the Bambu printer in ABS and will take 12 minutes. The print cost $0.22. Do more research on the mechanical properties of ABS

2024/03/11 Thin Coring Tube Reprint

Ellie Steger - Apr 30, 2024, 11:43 PM CDT

Title: Thin Coring Tube Reprint

Date: 03/11/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To successfully print the final iteration of our coring biopsy tube.

Content:

- The coring tube failed three times in a row in a flat print orientation.
    - There was not enough supports so everytime it would be deformed or fall into the resin tank
- I went in to revaluate the supports. We will now move foreward with a more vertical print orientation

Conclusions/action items: With consultation with the makerspace this print was started on the Formlabs 3 printer. The print time is 10 hours.

2024/04/09 Reprint with final design

Ellie Steger - May 05, 2024, 10:53 AM CDT

Title: Thin Coring Tube Reprint

Date: 04/09/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To reprint the device after testing for a clean tube.

Content:

- Printed in Biomed Clear at 60 degrees
- After consultation with the makerspace they recommended printing in clear rather than biomed clear
    - This advice was misguided as biomed clear and clear do not have the same mechanical properties
    - The difference in hardness would affect the closure mechanism we will proceed with biomed clear because it is CT compatible and we have done research proving its properties

Conclusions/action items: With consultation with the makerspace this print was started on the Formlabs 3 printer. The print time is 10 hours.

2024/04/12 Reprint due to UV curing distortion

Ellie Steger - May 05, 2024, 11:23 AM CDT

Title: Reprint due to UV curing distortion

Date: 04/12/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To reprint the device without distortion.

Content:

- UV Curing the device due to manufacturing guidelines causing bowing making the device not fit together properly
- With consultation from the makerspace we created a new plan to UV cure the device
- We have decided for now we will place the device in direct sunlight after printing
    - In the future we will also
- We also discussed different printing angles to reduce the number of print failures
    - We decided at a 30 degree print angle to maintain the thinness of the tip while also have adequate supports

Conclusions/action items: With consultation with the makerspace this print was started on the Formlabs 3 printer. The print time is 3 hours.

2024/04/16 Reprint Due to Makerspace Errors

Ellie Steger - May 05, 2024, 11:30 AM CDT

Title: Reprint Due to Makerspace Errors

Date: 04/16/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To reprint the device without distortion.

Content:

- The makerspace accidentially UV cured the device causing bowing
- The device will be reprinted with the same parameters but make sure to emphasize that the device does not need to be UV cured

Conclusions/action items: With consultation with the makerspace this print was started on the Formlabs 3 printer. The print time is 3 hours.

2024/04/23 Reprint with Different UV Curing Parameters

Ellie Steger - May 05, 2024, 11:35 AM CDT

Title: Reprint with Different UV Curing Parameters

Date: 04/23/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To reprint the device without distortion and with different curing parameters.

Content:

- With some background research we have decided to print the tube with the same parameters
- For the post-process we are going to try UV curing at 45 degree c for 15 minutes twice

Conclusions/action items: With consultation with the makerspace this print was started on the Formlabs 3 printer. The print time is 3 hours. This process still caused a slight bowing we will move forward with leaving the device out in direct sunlight

Tissue Damage Testing Protocol

Olivia Jaekle - Feb 28, 2024, 3:51 PM CST

Title: Tissue Damage Testing Protocol

Content by: Olivia Jaekle, Emily Wheat, Aleks Skutnik

Present: Olivia Jaekle, Emily Wheat, Aleks Skutnik

Goals: Create Protocol for test

Content:

Materials:

- 8 pig kidneys
- Final prototype of the blades
- Ethanol
- Scissors
- Caliper
- Gloves
- A large, square, polystyrene dish
- Paper towels

Procedure:

1. Prepare the area by layering the polystyrene dish with multiple paper towels
2. Put on gloves
3. Using the scissors, cut open the packages of pig kidneys and drain the liquid
4. Place the pig kidneys in the polystyrene dish, making sure no pig kidneys overlap
5. Cut the pig kidneys by holding the blade in your hand with your thumb pointing down and rotating your wrist
    1. You can rotate your wrist multiple times to cut all the way through the chicken breast, but do not take the blade out and put in back in the chicken to make the cut
6. Once the blade is through the entire chicken, lift the blade up and remove the specimen from the inside
7. Using the calipers, measure the amount of tissue damage the cut created and record this distance in millimeters
    1. This is the distance from the edge of the circle of the intended to the furthest sign of tissue trauma, either a tear in the chicken or a larger than 10mm diameter circle
    2. If no visual damage is seen, record this observation
8. Repeat steps 5-7 for a total of 40 cuts
9. Bag all of the pig kidneys, packaging, and paper towels and dispose of in a black trash bag to be placed trash outside of ECB
10. Using ethanol, wipe down the table, polystyrene dish, scissors, and all blades
11. Put back all materials once dry

Conclusions/action items: This protocol will be followed for when we do our tissue damage test. We used this last semester and it went well.

Ergonomics Survey Testing Protocol

Olivia Jaekle - Feb 28, 2024, 3:53 PM CST

Title: Ergonomics Survey Testing Protocol

Content by: Olivia Jaekle, Emily Wheat, Aleks Skutnik

Present: Olivia Jaekle, Emily Wheat, Aleks Skutnik

Goals: Create Protocol for test

Content:

Materials:

- Pencil
- Final prototype of blades
- Scissors
- Caliper
- A large, square, polystyrene dish
- Gloves
- Paper towels
- Ethanol

Procedure:

1. Prepare the area by layering the polystyrene dish with multiple paper towels
2. Put on gloves
3. Using the scissors cut open the packages of pig kidneys and drain any liquid
4. Place the pig kidney in the polystyrene dish
5. Have the client cut into the pig kidney using one blade
6. Once the blade is through the entire pig kidney, lift up the blade and remove the tissue specimen
7. Have the client note the integrity of the tissue specimen and the overall pig kidney
8. Ask the client the questions of the performance survey and write down their answers
9. If there is noticeable tissue damage, use the calipers to measure how much damage there is in millimeters
10. Repeat steps 5-9 with 3 other clients
11. Place all pig kidney waste, paper towels, and gloves in a bag and dispose of in the trash
12. Using the ethanol, wipe down the calipers, scissors, blades, polystyrene dish, and table
13. Put all materials back where they belong

Performance Survey

Name:

Blade #:

1. Cutting the tissue required minimal pressure using the blade.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

2. It took a limited number of attempts to cut the kidney (<2).

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

3. I did not feel any tension in my wrist or hand when using the blade.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

4. The blade quality did not decrease over time.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

5. The blade did not cause any observable tissue damage.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

6. I am satisfied with the cut of the blade.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

7. The coring tube opens and closes easily.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

8. The coring tube stays intact when I need it to.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

9. The tissue sample in the coring tube did not experience any damage.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

10. Removing the blade from the coring tube after a procedure was easy.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

11. I felt safe removing the blade from the coring tube.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

12. If there was any tissue damage, how widespread was the damage from the cut? Please give an answer in mm.

13. Please provide any other feedback on blade design

Conclusions/action items: This protocol will be followed for when we do our ergonomics test. We used this last semester and it went well. We changed some of the questions in the survey to ask about the coring tube.

Previous Semester (Fall 23) Raw Data

Olivia Jaekle - Feb 28, 2024, 1:33 PM CST

Title: Previous Semester (Fall 23) Raw Data

Content by: Olivia Jaekle

Present: All

Goals: Keep track of what has been done in previous semesters

Content:

Chicken Breast Blade Thickness Data:

	Blade #1	Blade #2	Blade #3	Blade #4 [mm]
Initial	0.18	0.16	0.22	0.04
5 cuts	0.18	0.16	0.21	0.04
10 cuts	0.17	0.15	0.21	0.04
15 cuts	0.17	0.15	0.21	0.04
20 cuts	0.17	0.14	0.21	0.04
25 cuts	0.17	0.14	0.21	0.04
30 cuts	0.17	0.14	0.21	0.03
35 cuts	0.16	0.14	0.21	0.03
40 cuts	0.16	0.13	0.21	0.03

	Blade #1	Blade #2	Blade #3	Blade #4
Total Change	0.02	0.03	0.01	0.01

Ergonomic Survey Data:

	Blade 1	Blade 1	Blade 2	Blade 2	Blade 3	Blade 3	Blade 4	Blade 4
Min Pressure	4.00	4.00	4.00	4.00	3.00	2.00	3.00	2.00
Low # Cuts	4.00	4.00	3.00	3.00	4.00	3.00	3.00	2.00
Limited Tension	3.00	3.00	3.00	3.00	3.00	2.00	2.00	2.00
Sharpness Maintained	4.00	3.00	3.00	3.00	4.00	2.00	3.00	2.00

No observable Damage	4.00	4.00	3.00	3.00	4.00	4.00	3.00	1.00
Satisfied with Cut	4.00	4.00	4.00	3.00	4.00	4.00	3.00	3.00

Conclusions/action items: This info will be in our journal so that anyone reading can see what we have done in the past. This info also tells us how the last blade we used varied a lot and why it was important we changed to a manufactured, reproducible blade.

2024/03/01- Performance Survey Results

ALEKSANDRA SKUTNIK - Mar 01, 2024, 4:28 PM CST

Title: Performance Survey Results

Date: 2024/03/01

Content by: All

Present: All

Goals: To allow the client and her team assess the performance of the combined blade and coring tube device.

Content:

Performance Survey

Name:

Blade #:

1. Cutting the tissue required minimal pressure using the blade.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

2. It took a limited number of attempts to cut the kidney (<2).

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

3. I did not feel any tension in my wrist or hand when using the blade.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

4. The blade quality did not decrease over time.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

5. The blade did not cause any observable tissue damage.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

6. I am satisfied with the cut of the blade.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

7. The coring tube opens and closes easily.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

8. The coring tube stays intact when I need it to.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

9. The tissue sample in the coring tube did not experience any damage.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

10. Removing the blade from the coring tube after a procedure was easy.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

11. I felt safe removing the blade from the coring tube.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

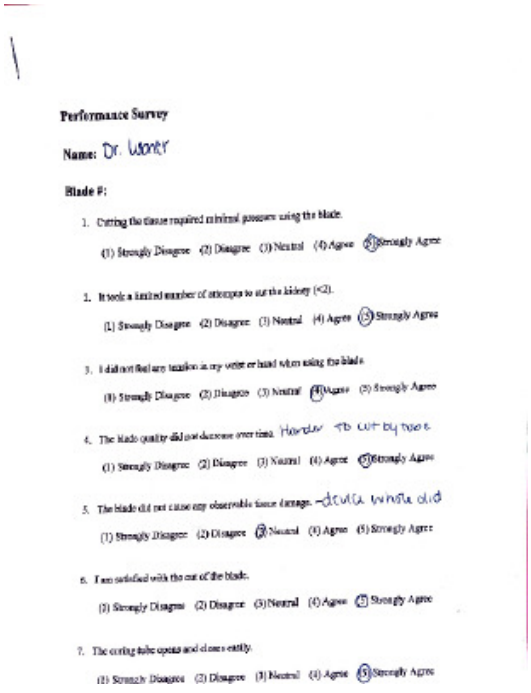
12. If there was any tissue damage, how widespread was the damage from the cut? Please give an answer in mm.

13. Please provide any other feedback on blade design

Conclusions/action items:

The results of the performance survey are attached to this document. The team will work on improving the device based on the feedback received from the clients. The team's main focus will be to modify the coring tube to better match the diameter of the blade to minimize drag and damage to surrounding kidney tissue and repeat testing with the client as necessary. This modification will also include the addition of scoring slits in the coring tube.

ALEKSANDRA SKUTNIK - Mar 01, 2024, 4:28 PM CST



Performance Survey

Name: Dr. Wonky

Blade #:

1. Cutting the tissue required minimal pressure using the blade.
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree
2. It took a limited number of attempts to cut the kidney (<2).
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree
3. I did not feel any tension in my wrist or hand when using the blade.
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree
4. The blade quality did not decrease over time. Harder to cut by twice
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree
5. The blade did not cause any observable tissue damage. - drula wasn't old
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree
6. I am satisfied with the cut of the blade.
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree
7. The cutting tube opens and closes easily.
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

Download

Sp24_Performance_Survey_Results.pdf (3.67 MB)

2024/03/15- Tissue Damage Testing

ALEKSANDRA SKUTNIK - Mar 15, 2024, 7:15 PM CDT

Title: Tissue Damage Testing on Pig Kidneys

Date: 2024/03/15

Content by: Aleks Skutnik

Present: Aleks Skutnik, Olivia Jaekle, Emily Wheat

Goals: To assess any tissue damage inflicted on the pig kidney by the biopsy device.

Content:

- The testing team acquired the pig kidneys and performed test biopsy cuts on them to ensure that the blade and coring tube did not inflict any tissue damage on the pig kidney tissue surrounding the biopsy site or the tissue sample itself
- Pig kidneys acquired from the UW butcher shop had excessive perirenal fat attached to them, making it difficult to pierce the kidneys

Conclusions/action items:

The pig kidneys acquired from UW butcher shop did not accurately depict an accurate tissue disposition of human kidneys in these circumstances. The fat and connective tissue on the pig kidneys appeared to be harder to pierce through than that of human kidneys. However, the tissue samples collected by the team from the pig kidney did not show any noticeable tissue damage and was able to cut through multiple layers of pig kidney tissue while keeping the sample intact.

2024/04/19 Testing Performance Survey

ALEKSANDRA SKUTNIK - Apr 29, 2024, 9:11 PM CDT

Title: Performance Survey Testing

Date: 2024/04/19

Content by: Aleks Skutnik

Present: Aleks Skutnik, Olivia Jaekle, Emily Wheat

Goals: To test the performance of our new coring devices.

Content:

Here is a copy of the questions asked on the performance survey conducted with the client and her team at WIMR. Attached are the results of the survey.

Blade #:

1. Cutting the tissue required minimal pressure using the blade.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

2. It took a limited number of attempts to cut the kidney (<2).

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

3. I did not feel any tension in my wrist or hand when using the blade.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

4. The blade quality did not decrease over time.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

5. The blade did not cause any observable tissue damage.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

6. I am satisfied with the cut of the blade.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

7. The coring tube opens and closes easily.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

8. The coring tube stays intact when I need it to.

1. Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

9. The tissue sample in the coring tube did not experience any damage.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

10. Removing the blade from the coring tube after a procedure was easy.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

11. I felt safe removing the blade from the coring tube.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

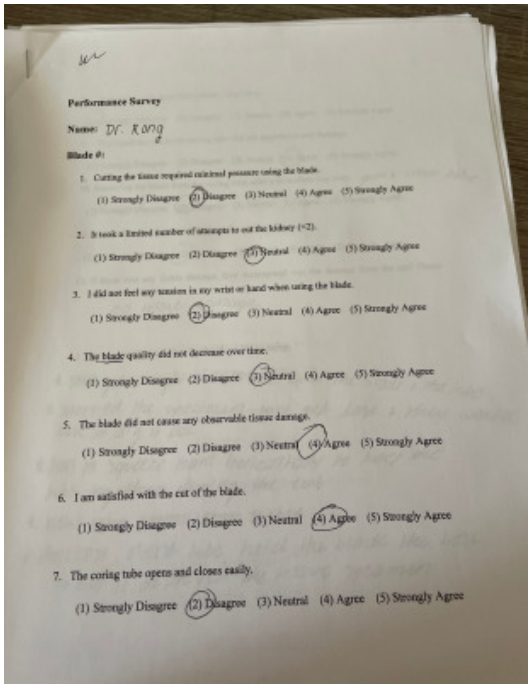
12. If there was any tissue damage, how widespread was the damage from the cut? Please give an answer in mm.

13. Please provide any other feedback on blade design

Conclusions/action items:

After testing our thinner coring tube prototype, it is clear that a thinner tube compromises the device usability. The thinner tube is not as strong and cannot stay in tact during use. The client agreed that the previous tube design, though it was thicker and could cause surrounding tissue damage, worked better and collected far better samples than the thinner prototype.

ALEKSANDRA SKUTNIK - Apr 29, 2024, 9:04 PM CDT



Performance Survey

Name: DV. KONG

Blade #:

1. Cutting the tissue required minimal pressure using the blade.
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

2. It took a limited number of attempts to cut the kidney (<2).
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

3. I did not feel any tension in my wrist or hand when using the blade.
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

4. The blade quality did not decrease over time.
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

5. The blade did not cause any observable tissue damage.
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

6. I am satisfied with the cut of the blade.
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

7. The coring tube opens and closes easily.
   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

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TestingRound2.pdf (14.1 MB)

Maintenance Instructions

Olivia Jaekle - Feb 28, 2024, 3:48 PM CST

Title: Maintenance Instructions

Content by: Olivia Jaekle

Goals: Make maintenance instructions for the blade and coring tube

Content:

GENERAL INSTRUCTIONS FOR CARE, HANDLING AND REPROCESSING OF 3D PRINTED CORING BIOPSY DEVICE

Intended Use: A reusable blade and disposable coring device intended to take coring biopsies of resected kidneys.

How Supplied: Blades are supplied non-sterile and must be cleaned, sterilized, and inspected prior to each use.

Warnings:

- These devices are designed for use by appropriately trained, qualified and competent personnel.
- When reprocessing medical devices always follow local Health & Safety procedures. Always follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.
- Avoid the use of mineral acids and harsh, abrasive agents.
- Some sensitive materials can be damaged by higher alkaline solutions (pH >10).
- The use of the device for tasks other than those for which they are intended may result in failure or damage/breakage.
- Correct cleaning, handling and sterilization will ensure that the device performs as intended and extends its useful life.
- Instruments manufactured from different metals should be processed separately to avoid electrolytic action between the different metals.
- Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated devices.
- Manual cleaning is not advised if an automatic washer/disinfector is available

Care and Handling: The following information is provided to give general guidance on how the circular biopsy blade may be processed to prepare them for use. Equipment, operators, cleaning agents and procedures all have a contribution to the efficacy of the processing and the healthcare facility should ensure that the blade is safe for use at all times.

Pre-Cleaning: Do not allow blood and/or bodily fluids to dry on the instruments. Reprocess as soon as reasonably practicable following use. If they cannot be reprocessed immediately, use an enzymatic cleaner to help prevent any soiling from drying. Remove any gross contaminants with a steady stream of lukewarm water (below 110°F/43°C.) Rinse each instrument thoroughly, do not use saline or chlorinated solutions.

Cleaning: Whenever possible, the automated method should be used as it is a more reproducible process and therefore more reliable.

- Avoid mechanical damage during transportation to the process area.
- Transport to the processing area as soon as possible.
- Do not soak the blade in hot water, alcohol, disinfectants, or antiseptics to avoid coagulation of blood or other body fluids.
- Do not use steel wool, wire brushes, pipe cleaners or other abrasive cleaners.

- Only specifically formulated cleaning agents (detergents). Enzymatic agents with both bacterial and fungicidal properties are preferred for manual cleaning.

Equipment Required:

- Double Sink System (Not used for hand washing) dedicated for blade cleaning.
- Soft Bristle Brush.
- Personal Protective Equipment (PPE) as recommended by the cleaning agent supplier.

Procedure:

- Ensure the water temperature does not exceed 35°C. In the first sink, keeping the blade submerged, using a soft autoclavable brush, apply cleaning solution to all surfaces of the blade until all soiling has been removed.
- In the second sink, rinse instruments thoroughly with soft, high-purity water controlled for bacterial endotoxins.
- Dry the blade.
- Visually inspect all areas of the blade for any remaining soiling and if necessary, repeat the steps above.

Disinfection:

- After cleaning, immerse the biopsy blade in a high-level disinfectant solution recommended for medical instruments.
- Follow the manufacturer's instructions regarding the concentration of the disinfectant solution and the required immersion time.
- Ensure complete submersion of the blade to disinfect all surfaces thoroughly.
- After disinfection, rinse the blade under running water to remove any residual disinfectant solution.

Sterilization:

- Sterilization must follow a washer/disinfector process.
- Ensure proper packaging of the blade before placing it in the autoclave to prevent contamination during sterilization.
- The recommended sterilization parameters are a minimum of three minutes at a minimum temperature of 134°C.
- The three minutes is for exposure, it does not include ramp up times or dry cycle times needed.
  Allow the blade to cool down completely before handling or storing.
- Always follow the instructions of the machine manufacturer.

Note: The final responsibility for validation of sterilization techniques and equipment lies directly with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations

Inspection:

- Visual inspection under good lighting of all parts of the blade should be performed to check for visible soiling, damage or wear.
- Particular attention should be paid to the edge of the blade:
  - Closely inspect for any signs of damage, corrosion, or dullness.
  - If any abnormalities are detected during inspection, do not use the blade and consult with the appropriate personnel for further evaluation or replacement.

Packaging: Blades are to be packed following local protocol in accordance with relevant standards.

Storage:

- The shelf life is dependent on the sterile barrier employed, storage, environmental and handling conditions. A maximum shelf life for sterilized medical devices before use should be defined by the healthcare facility
- Store the biopsy blade in a clean and dry environment to prevent contamination.

- Avoid storing the blade near sources of moisture or heat, as these can promote corrosion or degradation.
- Use designated storage containers or trays to keep the blade organized and protected when not in use.
- Ensure biopsy is stored with its cap properly by adhering to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030)

References:

- BS EN ISO 17664 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- HTM 01-01 Management & decontamination of surgical instruments (medical devices) used in acute care.
- BS EN ISO 15883: Parts 1 & 2: Washer-disinfectors
- OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030)

User Manual

Olivia Jaekle - Feb 28, 2024, 3:48 PM CST

Title: User Manual

Content by: Aleks Skutnik, Olivia Jaekle

Goals: User manual for blade and coring tube

Content:

Instructions for Use

Device Description

This device is a handheld renal cell carcinoma biopsy device which is used to obtain core biopsy samples from soft tissue and tumors of the kidney. This device has a detachable blade head that can be reused between test specimens and a patient specific 3D printed collection tube that is fully disposable after use.

Device Preparation

1. Prior to using the biopsy device, ensure that the reusable blade has been sterilized by autoclave and that its protective packaging has not been damaged to avoid cross contamination. If it does appears that the blade has not been sterilized properly, do not use the device
2. Ensure that the collection tube has been printed correctly and that the outer and inner diameter appear smooth to avoid tissue damage. If the 3D printed collection tube does not meet these standards, do not use the device and request a replacement tube
3. Carefully remove the blade from its protective packaging and push the exposed area into the collection tube
4. Once the blade and the collection tube have pressed to fit, remove the blade cap to expose the working blade
5. Refer to the safety precautions manual for steps on how to handle exposed sharp objects

Performing the Biopsy

1. Identify the target area
2. Prepare the biopsy site as required
3. Place the outer edge of the biopsy blade on the tissue and begin pushing down in circular motions
4. Continue pressing into the tissue until the biopsy device has pierced through the thickness of the tissue
5. Remove the blade from the other side of the resected tissue sample and place into a sterile container to be autoclaved
6. Image the collection tube in the specimen as needed
7. Remove the collection tube from the specimen
8. Carefully open the collection tube from either end to retrieve tissue samples
9. Retrieve tissue samples from the tube for testing
10. Repeat steps 1-9 for any other biopsy sites on the same specimen
11. After collection, dispose of the collection tube to biohazardous waste

Safety Manual

Olivia Jaekle - Feb 28, 2024, 3:48 PM CST

Title: Safety Manual

Content by: Olivia Jaekle

Goals: Safety Manual for blade

Content:

Safety Manual for Reusable Biopsy Blade

Introduction

This safety manual provides guidelines for the safe handling, maintenance, and disposal of reusable biopsy blades in healthcare settings. Adhering to these procedures helps minimize the risk of injuries and ensures compliance with relevant standards and codes.

1. Handling

1.1. Engineering Controls: Employers must provide safety-engineered biopsy devices to minimize the risk of injuries. Use devices with built-in safety features, such as retractable blades or protective caps.

1.2. Personal Protective Equipment (PPE): Wear appropriate PPE, including gloves and eye protection, when handling biopsy blades to protect against cuts and splashes.

1.3. Training: All personnel handling biopsy blades must receive training on safe handling practices, including proper grip techniques and the use of safety features.

2. Maintenance

2.1. Cleaning: Clean biopsy blades promptly after each use following maintenance instructions provided.

2.2. Disinfection: Disinfect blades using a high-level disinfectant approved for medical devices. Follow maintenance instructions provided for concentration and contact time.

2.3. Sterilization: After cleaning and disinfection, sterilize the biopsy blades using autoclaving or another appropriate sterilization method. Ensure proper packaging to maintain sterility, following maintenance instructions

3. Storage

3.1. Sharps Containers: Store biopsy blades in puncture-resistant sharps containers when not in use. Containers must meet OSHA standards for sharps disposal (29 CFR 1910.1030).

3.2. Labeling: Properly label storage containers to indicate the contents and any necessary handling precautions.

4. Disposal

4.1. Sharps Disposal: Dispose of biopsy blades in designated sharps containers once blade is deemed unusable. Do not recap or manipulate blades by hand to avoid needlestick injuries.

4.2. Biohazard Waste: Treat used biopsy blades as biohazardous waste and dispose of them according to local regulations and guidelines (e.g., EPA regulations).

5. Compliance with Standards and Codes

5.1. OSHA Standards: Adhere to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030) for the safe handling of sharps and bloodborne pathogens.

5.2. CDC Guidelines: Follow CDC guidelines for infection control in healthcare settings, including recommendations for the safe use and handling of medical devices.

5.3. Manufacturer's Instructions: Always follow the maintenance and service instructions for the proper use, cleaning, and maintenance of reusable biopsy blades.

Conclusion

By following the guidelines outlined in this safety manual, healthcare facilities can ensure the safe handling, maintenance, and disposal of reusable biopsy blades, reducing the risk of injuries and promoting a safe working environment. Compliance with relevant standards and codes is essential to maintaining workplace safety and protecting healthcare workers and patients from harm.

2024/01/29 Punch Biopsy Blade

ERIN SCHLEGEL - Feb 01, 2024, 11:35 AM CST

Title: Pre-Fabricated Blade Research

Date: 01/29/2024

Content by: Erin Schlegel

Citation:

[1] “Scientific Labwares disposable punch biopsy with protective cap, 6.0mm, sterile, single punch Blade, indivdually packed (box of 10),” Consumables Scientific Labwares Disposable Punch Biopsy with Protective Cap, 6.0mm, Sterile, Single Punch Blade, Indivdually Packed (Box of 10), https://sbtmedicaltt.com/shop/consumables/scientific-labwares-disposable-punch-biopsy-with-protective-cap-6-0mm-sterile-single-punch-blade-indivdually-packed-box-of-10/ (accessed Jan. 29, 2024).

Goals: Our team is looking into the feasibility of buying a professionally manufactured blade to improve the precision of the cut for our client.

Content:

- There are punch biopsy blades available on amazon that are made of Stainless Steel
  - Need to verify exactly what type of Stainless Steel they are because that can change the material properties, ideally 316 stainless steel
  - Will verify with the sales team of the manufacturer to acquire more information
- It looks like we would be able to remove the blade from the handle itself, but this would also require additional fabrication
- Would need to buy the 8mm diameter blade to be aligned with our PDS
- The blade also appears to be long enough to effectively cut through a tumor
- Could be a viable option depending on the material size

Conclusions/action items:

After a response from their sales team verifying the type of stainless steel, we can move forward with deciding if we would like to purchase it or not.
Update: The team verified that the material is 304 Stainless Steel.

2024/01/31 Trephine Blades

ERIN SCHLEGEL - Feb 01, 2024, 11:36 AM CST

Title: Corneal trephines, cutting blocks and artificial anterior chambers

Date: 01/31/24

Content by: Erin Schlegel

Citation:

> [1] T. John, “Corneal trephines, cutting blocks and artificial anterior chambers,” *Corneal Surgery*, pp. 305–312, 2009. doi:10.1016/b978-0-323-04835-4.50041-0

Goals: The goal of reading this article is to understand how trephine or "circular" blades are used in ophthalmology and if they could be used for our purposes.

Content:

- "trephine" is a circular blade that is used for cutting out circular sections of corneal tissue or bone
- some trephines contain suction aspects
- suctionless trephines are sharp and tapered on one end and blunt on the other
    - The surgeon uses their thumb and index finger to rotate the trephine into the cornea, in a similar way to our client
- For donor corneal tissue, the surgeon approaches from the endothelial side using a "guillotine-type" corneal punch as seen below

Conclusions/action items: These blades look promising to purchase, but we should do more research on the available blades.

2024/01/31 Surgical Trephine Blade

ERIN SCHLEGEL - Feb 01, 2024, 5:36 PM CST

Title: Corneal trephine blade long, 16.0mm length, 6.25mm diameter, packaged individually, sterile, disposable, box of 1

Date: 01/31/24

Content by: Erin Schlegel

Citation: [1] “Corneal Trephine Blade, long, 16.0mm length, 6.25mm diameter, packaged individually, sterile, disposable, box of 1,” Ambler Surgical, https://amblersurgical.com/33-0625-corneal-trephine-blade-long-16-0mm-length-6-25mm-diameter-packaged-individually-sterile-disposable-box-of-1?gad_source=1&gclid=CjwKCAiA_OetBhAtEiwAPTeQZ24JYsiO1YsHWHFn6kJ4vmIHQYfOOc83e7MpohmVS3fAraScXvYVUhoCz2AQAvD_BwE#sterilization (accessed Feb. 1, 2024).

Goals: The goal of this webpage was to research possible blades to purchase for our design.

Content:

- Ambler surgical makes a trephine blade with a tapered edge
- However the IFU says that It is not reusable
- The diameter is also a little smaller than ideal at 6.25 mm
- the length is a good dimension at 16mm long
- Will need to verify with the sales team why the blade is not reusable

https://amblersurgical.com/33-0625-corneal-trephine-blade-long-16-0mm-length-6-25mm-diameter-packaged-individually-sterile-disposable-box-of-1?gad_source=1&gclid=CjwKCAiA_OetBhAtEiwAPTeQZ24JYsiO1YsHWHFn6kJ4vmIHQYfOOc83e7MpohmVS3fAraScXvYVUhoCz2AQAvD_BwE#sterilization

Conclusions/action items: We should continue looking for blades that are reusable per the client's request.

2024/02/21 Formlabs Guide to 3D printing

ERIN SCHLEGEL - Feb 21, 2024, 3:45 PM CST

Title: Formlanbs Guide to 3D Printing Tolerances, Accuracy, and Precision

Date: 02/21/24

Content by: Erin Schlegel

Citation:

[1] “Guide to 3D printing tolerances, accuracy, and precision,” Formlabs, https://formlabs.com/blog/understanding-accuracy-precision-tolerance-in-3d-printing/ (accessed Feb. 21, 2024).

Goals: The goal of researching this information was to redesign our 3D printed coring device to 1)fit the measurements of the purchased blade and 2) prevent the bowing that occurs with the current design.

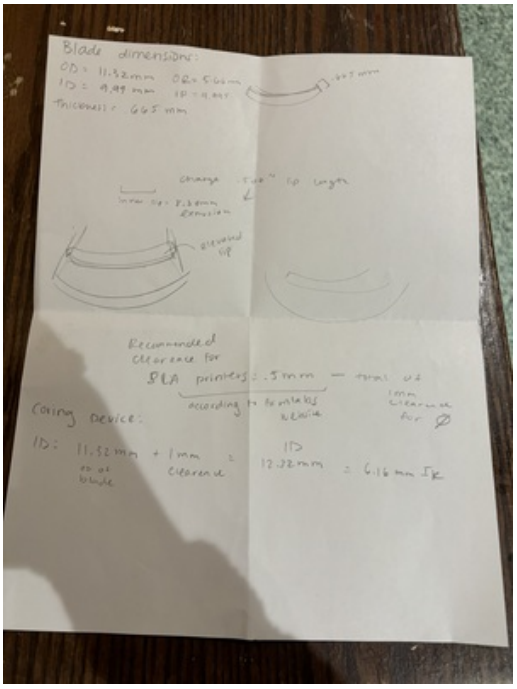
Content:

- SLA printing there is liquid resin exposed to a light source to form thin solid layers that stack up - achieve fine details
- SLA is very precise, and should not encounter warping
- look into doing a solidworks simulation anaylsis of the parts to see where warping could occur?
- SLA post printing
  - Washing, post-curing (optional), removal of support structures (if needed), sanding (optional)
  - the post processing process can affect the dimensions and tolerances of the product
  - post curing causes shrinkage
- Tolerances:
  - will use a transition fit tolerance zone , "push fit"
  - use a .05mm tolerance
- I used this information to redesign our coring device in solidworks to fit our new blade, see attached

Conclusions/action items:

Print the newly dimensioned coring device using the new information gained from research and chatting with Sylvana Garcia to print a new coring device.

ERIN SCHLEGEL - Feb 21, 2024, 3:44 PM CST



Download

IMG_7667.jpeg (4.52 MB)

2024/02/21 What causes bowing in 3D printing?

ERIN SCHLEGEL - Feb 21, 2024, 3:55 PM CST

Title: How to Avoid Out of Spec Flatness due to Part Bowing in 3D Printing

Date: 2024/02/21

Content by: Erin Schlegel

Citation:

[1] T. Xometry, “How to avoid out of spec flatness due to part bowing in 3D printing,” Xometrys RSS, https://www.xometry.com/resources/shop-tips/how-to-avoid-out-of-spec-flatness-due-to-part-bowing-in-3d-printing/#:~:text=parts%20more%20rigidity.-,Layer%20Height,try%20to%20reduce%20part%20bowing. (accessed Feb. 21, 2024).

Goals: The goal of this research is to understand why our 3D printed part has bowing in the center and how to fix it.

Content:

What causes bowing in resin printers?

- The part has insufficient support
- The exposure time is too high or too low (the amount of time that the light source will expose each layer during printing)
  - Underexposed parts will not be strong enough
- Part orientation is not optimal, causing weakness
  - Optimal part orientation will minimize the need for supports
  - it is recommended that you rotate the model 15–20° away from the build plate to reduce the surface area of each layer, thus reducing the resin suction pressure
- The use of low-quality resins with weaker properties
- Wall thickness is too low
  - Wall thicknesses are commonly between 1.5 mm and 2 mm. But increasing wall thickness to at least 2 mm whenever possible will give parts more rigidity
- Layer height is too high for the model
  - too much material to cure means more internal stresses
  - Reduce your layer height from the typical 0.05 mm to somewhere between 0.025 mm and 0.04 mm to try to reduce part bowing.
- Over-curing prints
  - Curing from a liquid to a solid plastic means there can be shrinkage and expansion, adding stress between the layers of the part.
  - To combat this:
    - ensure you have sufficient light, medium, and heavy supports for overhangs or unsupported features, insufficient supports may cause the resin suction pressure to lift layers from each other and deform the part.

Conclusions/action items:

Utilizing these parameters we will reprint the coring device so that we avoid any bowing.

2024/02/26 Possible Reference Article

ERIN SCHLEGEL - Feb 28, 2024, 5:04 PM CST

Title: Noninvasive Point of Care Device for Assessing Cardiac Response to Acute Volume Changes

Date: 02/26/24

Content by: Erin Schlegel

Citation:

[1] H. A. Silber, N. A. Gilotra, and T. Miller, “Noninvasive point of care device for assessing cardiac response to acute volume changes,” *Medical Devices: Evidence and Research*, vol. Volume 16, pp. 219–227, Oct. 2023. doi:10.2147/mder.s416845

Goals: The goal of researching this article is to see if it would be an acceptable article to use as a reference for our BME 402 journal entry.

Content:

- I enjoy how this article combines the materials and methods sections
- instead of abstract it used a "plain language summary" ?
- This article had very clear images of testing that helped convey the protocols
- The testing protocols were also explained very well in a way that was easy to understand for the reader
- The introduction was very easy to understand the problem statement
- I thought the discussion was very dense and could have used more subsections to clarify each point

Conclusions/action items: Overall, I feel this article would be a good reference to use for our BME 402 reference article.

2024/02/28 Biocompatability FDA Terms and Standards

ERIN SCHLEGEL - Feb 28, 2024, 5:00 PM CST

Title: Glossary of Biocompatibility Terms

Date: 02/28/24

Content by: Erin Schlegel

Citation:

> [1]Center for Devices and Radiological Health, “Glossary of biocompatibility terms,” U.S. Food and Drug Administration, https://www.fda.gov/medical-devices/biocompatibility-assessment-resource-center/glossary-biocompatibility-terms#:~:text=The%20FDA%20uses%20the%20same,in%20a%20specific%20situation.%22%20%5B (accessed Feb. 28, 2024).

Goals: The goal of reading this article is to understand what standards would make our 3D printing resin "biocompatible".

Content:

- **Under the ISO standards, Biocompatibility is defined as:**
  "The ability of a device material to perform with an appropriate host response in a specific situation." [SOURCE: ***FDA's Biocompatibility Guidance on Use of ISO 10993-1*****,**
- Furthermore, our device would be considered a direct contact device. **Direct contact**: "A device or device component that comes into physical contact with body tissue."
- **Biological equivalence:** "Situation where two materials or medical devices demonstrate material and contact equivalence." [SOURCE: ISO 10993-18:2020 and Amendment 1 (2022), Annex C.2.]
- Therefore when the Formlabs biomed clear resin claims it is "biocompatible" it is saying that the host response (the resected tissue) will have an appropriate response and will not be affected by our material.

Conclusions/action items: We have verified that our 3D printed resin will not interfere with the tissue specimen.

2024/03/04 Qualification of Manufactured Blade

ERIN SCHLEGEL - May 01, 2024, 7:59 AM CDT

Title: ASTM A269 stainless steel equivalent

Date: 03/04/24

Content by: Erin Schlegel

Citation: “ASTM A269 stainless steel equivalent - knowledge - gnee (tianjin) Multinational Trade Co.,ltd,”English,https://www.stainless-sheets.com/info/astm-a269-stainless-steel-equivalent-56039127.html (accessed Feb. 28, 2024)

Goals: The goal of reading this article is to understand how the ASTM and EIEN standards relate to eachother.

Content:

- The team qualified the new pre-made blade as a sufficient replacement based on three criteria:
  - Material properties
  - Dimensions
  - Reproducibility
- The Microsurgical Technologies blade is made from German standard EN 1.4408 steel, corresponds to the American Society for Testing and Materials (ASTM) A 269 standard 316 Stainless Steel the team used for manual fabrication
- - The materials share 98% of their average alloy composition and display comparable material and mechanical properties.
  - The Microsurgical Technologies blade has a slightly better material composition with up to 4% more chromium content for improved rust resistance.
  - Both materials have similar fatigue strengths of 170 MPA and acceptable elongation % before break, with the manufactured blade surpassing the manual with 34% elongation at break.
  - Manual blade: 6ft long annealed AISI 316 Stainless Steel tubing, 15.875mm Outer Diameter (OD) x 14.859mm Inner Diameter (ID), and .508 mm wall thickness. It also included a 15° taper at the end for easy incision.
  - Manufactured blade: 11.40 mm OD x 10mm ID, with a slightly thicker wall of .7mm.

Conclusions/action items:

Overall, the team evaluated these comparisons and determined that the manufactured blade was extremely comparable in properties and function to the manually created blades.

2024/03/12 How to Make 3D Prints Stronger

ERIN SCHLEGEL - May 01, 2024, 8:09 AM CDT

Title: How to Make 3D Prints Stronger

Date: 03/12/24

Content by: Erin Schlegel

Citation:

Goals: Our 3D print continues to fail, so we must look into ways to reinforce it.

Content:

- Strengthening 3D Printed Parts:

- Manually add supports
  - Utilize stronger materials:
    - PETG, Polycarbonate (PC), and Tough PLA
    - Carbon fibre-filled filaments like Essentium PET-CF and PA-CF
    - Markforged 3D printers with continuous strands of composites like fibreglass and Kevlar
  - Increase infill density:
    - Optimal percentage: 50% to 70%
  - Optimize infill pattern:
    - Hexagonal patterns for best strength-to-weight ratio
    - Triangular patterns for high mechanical strength
  - Add fillets and chamfers to thin parts:
    - Reinforce thin areas and reduce stress during printing
  - Use strongest part orientation:
    - Orient parts to maximize mechanical strength
  - Increase wall thickness:
    - Improve strength and integrate characteristics like overhangs
  - Print with thinner layers:
    - Improve interlayer adhesion and surface finish

Conclusions/action items: Going forward, we will manually add supports as well as perform tests to find the optimal orientation to print at.

2024/02/15 Recapping Standard

EMILY WHEAT - Feb 28, 2024, 8:27 PM CST

Title: OSHA Recapping Standard

Date: 2/15/2024

Content by: Emily

Present: N/A

Goals: To research the proper way to recap needles

Content:

What is the OSHA PPE Standard (osu.edu)

- since there is a sharp blade part of the device, the team needs to determine safety standards for it
- it was suggested we look into OSHA needle recapping standards
- says to not recap needles for disposal
- why is it dangerous to recap:
    - you could miss the cap and stab the hand holding it
    - the needle could pierce the cap
    - poorly fitting cap could slip off a recapped needle and stab the hand
- if recapping is required, tongs must be used
- can use the one-hand scoop method
    - put the cap on the table and only use one hand to slowly scoop the cap onto the needle
- never recap needles by using one hand to hold the cap and the other hand to hold the needle
- dispose of the needle in the sharps container
    - rigid, puncture free
    - typically red in color
- needles used for infectious materials must be disposed of in the biohazard container

Conclusions/action items: This OSHA standard mentions that you should never recap a sharp object by holding the cap. We can apply this to the blade and that cap that goes with it. We will have to take into account these protocols when writing our safety manual.

2024/2/26 Background Research

EMILY WHEAT - Feb 27, 2024, 12:51 PM CST

Title: Further Background Research

Date: 2/26/2024

Content by: Emily

Present: N/A

Goals: To find a few more statistics or information to add to the preliminary report

Content:

https://my.clevelandclinic.org/health/diseases/24906-renal-cell-carcinoma

Current treatment options for RCC:

- treatment depends on cancer stage and overall health of the patient

- treatment for localized RCC is different from treatment for metastatic RCC

Treatment for localized RCC:

- removing the cancer is one form of treatment
    - radical nephrectomy : removes affected kidney and part of surrounding tissue
    - partial nephrectomy : removes only the affected kidney
- if not a candidate for surgery:
    - cryotherapy : freezing the cancer cells to kill them
    - radiofrequency ablation : burning the cancer cells to kill them

Treatment for metastatic RCC:

- could still get surgery to remove the tumors
    - will only help with symptom relief; wont be enough to eliminate the cancer all together
- immunotherapy
- targeted therapy

- There isn't a cure for advanced RCC that has spread beyond the kidney
    - still working to discover better treatment options
    - providers are detecting RCC in earlier stages

Conclusions/action items: The reason I wanted to do further research was to be able to talk about current treatment options for RCC in the preliminary report introduction section. This article has provided many different current treatment options and gave me a cool fact to use in the report: currently there is no cure for RCC that has spread beyond the kidney.

2024/4/18 Anatomy of Human Kidney

EMILY WHEAT - Apr 29, 2024, 9:40 PM CDT

Title: Human Kidney Anatomy Research

Date: 4/18/2024

Content by: Emily

Present: N/A

Goals: To learn the exact human kidney anatomy

Content:

Kidneys: Anatomy, Location, and Function (verywellhealth.com)

- 3 main tubes contribute to the functions of the kidney
    - renal artery: where blood, waste and water enter the kidney
    - renal vein: where filtered blood or excess water leave the kidney
    - ureter: where excess water and waste leave the kidney in the form of urine
- there are many smaller parts within the kidney
- there are a few 'circles' that are repeats of the same organs
- arcuate vein
- arcuate artery
- interlobular artery and vein
- cortex
- medulla
- minor calyxes
- major calyxes
- renal pelvis
- the kidney begins around the 11th or 12th rib space and are sandwiched between the diaphragm and intestines, closer to the back side of the abdomen
- each kidney is roughly the size of a closed fist
- each kidney is about 10-12 cm long and 5-7 cm wide and 3-5 cm thick
- each kidney is covered in thick layer of connective tissue and fat that shapes and protects the organ

Conclusions/action items: Using the above information, I will add a paragraph into the final report about the anatomy of the kidney so the reader has a better idea of what they are reading about. I will most likely add a picture depicting the anatomy of the kidney so they have a better visual as well.

2024/4/18 Human vs pig anatomy

EMILY WHEAT - Apr 29, 2024, 9:47 PM CDT

Title: Human vs. pig anatomy research

Date: 4/18/2024

Content by: Emily

Present: N/A

Goals: To understand the differences between a pig kidney and human kidney

Content:

Human/Pig Comparisons | Fetal Pig Dissection Guide | Goshen College

- all of the major structures foudn in humans are present in the fetal pig

- pigs have all of the same thoracic nad abdominal organs as humans but there are a few small differences in a few organs

- liver: human liver has 4 lobes and fetal pig has 5 lobes

- intestines: there is a significant difference in the structure of the fetal pig colon (it is spiral) compared to the human colon

- stomach, spleen, bile duct system, small intestines, kidneys, bladder: the remainder of the abdominal organs found in the fetal pig are basically the same as found in humans

- adrenal glands: in the fetal pig the adrenal glands are found near the aorta instead of on top of the kidneys as in the case for humans

Conclusions/action items: I didn't gather as much detailed research as I would've hoped from the website. The largest difference I have seen with the kidneys is that while the adrenal glands are located on top of the kidneys in humans, they are actually near the aorta in pigs. I will continue to do further research to see if I can find any other striking differences between the two.

2024/2/26 New Article 2

EMILY WHEAT - Feb 28, 2024, 1:58 PM CST

Title: New Article 2 Journal Research

Date: 2/26/2024

Content by: Emily

Present: N/A

Goals: To read a published journal article and take notes about the format and the content to apply towards our preliminary report journal/

Content:

Title: "A Novel Non-Invasive Device for the Assessment of Central Venous Pressure in Hospital, Office and Home"

- they don't have a typical abstract format, it just has 5 sections: Background, Methods, Results, Discussion and Conclusion, and Key Words
  - each section has 2-5 sentences highlighting the important part of that section

INTRO:

- starts off with what CVP is
- talks about the current ways CVP can be measured
- overall the intro is about 1 page in length
- gives a few specs with percentages and whole numbers
- concludes with "in this paper, we introduce" and talks about the method the paper is about

METHODS:

- has a lot of figures and graphs
- talks about how their info is measured
- talks about the experimental tests conducted

RESULTS:

- very very short section
- 3 paragraphs, 1 for each test conducted
- only focuses on the quantitative data
- no images or graphs within the section itself but refers to figures found on next page

DISCUSSION:

- refers to images and graphs and they are found within the discussion section itself
- very long section
- discusses in length the data in the results section and the reasoning

CONCLUSIONS:

- very short section
- 3 sentence summary of the paper
- highlights the key takeaways

Conclusions/action items: After reading this journal entry, I noticed it is a very similar layout to other journal articles I have read for other classes. It has the standard major headings, all of which we should include in our report as well. This aids in letting us see how long each of our sections should

be and how the paper should flow. I am focusing on the introduction section so I will read a few other journal articles only looking at what the introduction talks about.

2024/2/26 BMC Prostate Sample

EMILY WHEAT - Feb 28, 2024, 2:12 PM CST

Title: BMC Prostate Sample Journal Article

Date: 2/26/2024

Content by: Emily

Present: N/A

Goals: To read the introduction of this journal article and apply the format and key concepts to our own journal article.

Content:

Title: "Quantity and quality of nucleic acids extracted from archival formalin fixed paraffin embedded prostate samples"

INTRODUCTION:

- starts off with a statistical fact about how common the cancer is

- goes into the natural history of the disease

- talks about the current ways information about prostate cancer is gathered

- metions "a strong need" for another solution

    - uses this to lead into the purpose of the journal article

- this journal article is about large population studies and experimental groups

    - our project is based on a medical device so it won't exactly correlate, but the format should be similar

- mentions a study approval number

    - we will not need but good to note that we might need something like this in the future

- overall pretty short in length, less than one page

- final paragraph outlines the trials they completed which leads into the methods section

Conclusions/action items: In conclusion, I personally really like the format of this introduction. I believe I will also be starting the intro off with a statistical fact about RCC since that is how I have done it in the past and now this shows its appropriate to do in a journal. Overall I have noticed the trend that the intro should be about a page, if not a little less, in length.

2024/2/26 Tracheal Intubation

EMILY WHEAT - Feb 28, 2024, 7:38 PM CST

Title: Tracheal Intubation Journal Research

Date: 2/26/2024

Content by: Emily

Present: N/A

Goals: To read the introduction of this journal article and apply the layout and key details to our own journal article.

Content:

Title: "Evaluating the Usability of a 3D-Printed Video Laryngoscope for Tracheal Intubation of a Manikin"

INTRODUCTION:

- starts off with a statistical fact from a specific year
- overall very short, less than 1 page in length
- talks about the benefits of the new method
- goes into the basic design of the method
- used the phrase "attempted to manufacture"
- defined terms via ASTM
- concluded with "the study aimed to"
- doesn't exactly outline what will be read throughout the paper
- mentioned data and what the data suggests
    - is not something I am used finding in introduction sections

Conclusions/action items: This article was pretty similar to the other journal articles I read. However, this article didn't exactly outline what will be found in the rest of the paper, it just gave a lot of definitions. Personally I would've classified this introduction as "background" so I will probably not use it as much to format our journal article.

2024/2/26 BMC Prostate Screening

EMILY WHEAT - Feb 28, 2024, 8:44 PM CST

Title: BMC Prostate Screening Journal Article

Date: 2/26/2024

Content by: Emily

Present: N/A

Goals: To read the intro of the journal article and apply the format and content to my own introduction for the preliminary report

Content:

Title: "Accommodating heterogeneous missing data patterns for prostate cancer risk prediction"

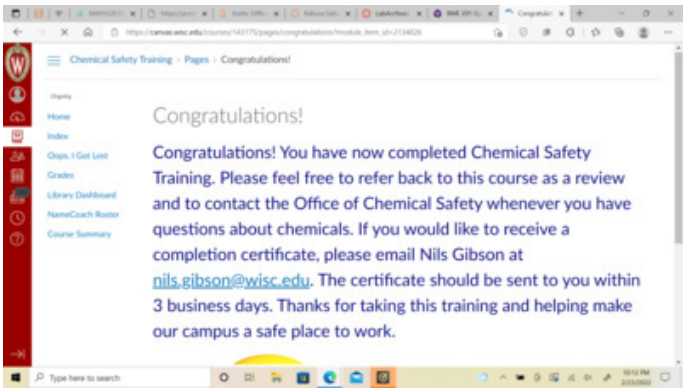
INTRODUCION:

- first journal article I've read that starts with the subheading "background"
- talks about when a certain group was established
- immediately discusses a figure within the second sentence
- includes the figure in the background section
- shows and mentions a second figure as well
- compared clinical data on a small number of variables
- mentions the risk factors
    - I was not planning on mentioning the risk factors of our device in the intro
- "develop and adaptive tool using all the information available"
- ended by talking about the aim of the study
- focused on 4 distinct approaches

Conclusions/action items: I am not as big of a fan about this journal introduction as I have been about the other ones. This journal does not have an introduction, it has a background. Perhaps that is why the content mentioned is a little off-base about what I am planning on writing about. Some of the key phrases seem similar when discussing the aim and scope of the project.

Required Chemical Safety Training (OSHA)

EMILY WHEAT - Feb 23, 2022, 10:15 PM CST



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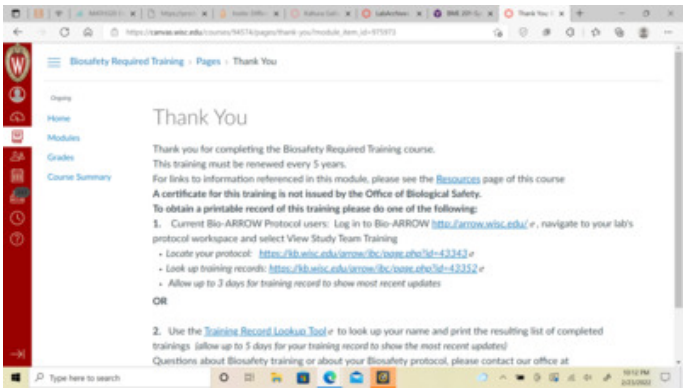
Required Biosafety Training

EMILY WHEAT - Feb 23, 2022, 10:16 PM CST



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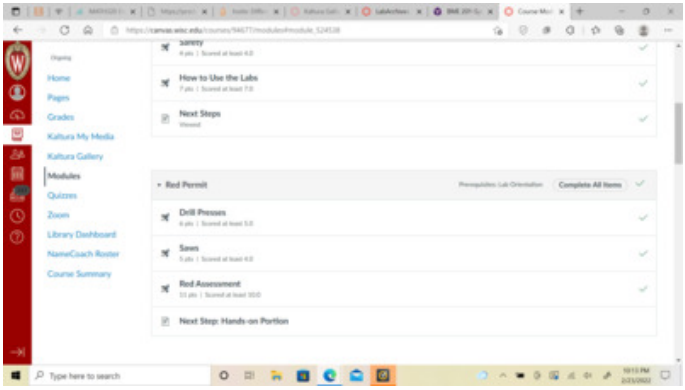
Red Permit

EMILY WHEAT - Feb 23, 2022, 10:16 PM CST



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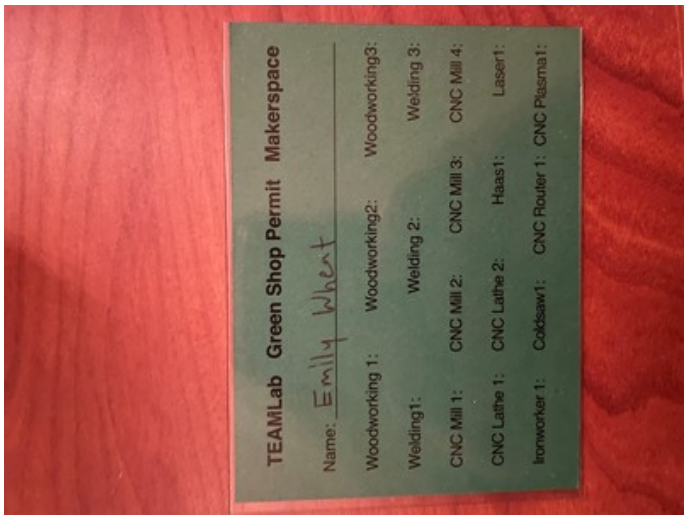
Green Permit

EMILY WHEAT - Mar 31, 2022, 11:35 AM CDT



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GreenPermit.jpg (3.02 MB)

2024/04/20- Human Kidney Anatomy

ALEKSANDRA SKUTNIK - May 05, 2024, 11:36 AM CDT

Title: Human Kidney Anatomy

Date: 2024/04/20

Content by: Aleksandra Skutnik

Links: https://www.niddk.nih.gov/health-information/kidney-disease/kidneys-how-they-work

https://www.news-medical.net/health/Anatomy-of-the-Kidney.aspx

Goals: To identify all of the layers of the human kidney that the biopsy device must puncture through and collect.

Content:

- Kidneys are protected by fat, muscle
  - Perirenal fat protects the kidneys from damage or outside forces
- Gerota's fascia is a fibrous layer outside of the kidney capsule that anchors the kidney to the posterior abdominal wall
- The outer most part of the kidney is the renal capsule
- Next is the cortex, then the inner renal tissue referred to as the medulla
- Inside the medullar spaces are renal pyramids called papilla, which contain loops of Henle of each renal tubule as well as collecting ducts
- The inner most structure is the renal pelvis, which collects urine and passes it down to the ureters

With the above in mind, it is important that the biopsy device is able to effectively penetrate through the multiple tissue layers of the kidney. This aspect is crucial to the device's performance.

Conclusions/action items:

Include this basic human kidney anatomy into the final report when describing the biopsy tests so that it is clear that the blade and coring tube must be able to penetrate multiple layers of tissue. In addition to the common human kidney anatomy, the biopsy device must be able to puncture the tumors in/on the resected kidney.

ALEKSANDRA SKUTNIK - Apr 20, 2024, 4:01 PM CDT

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12642.webp (83.9 kB)

2024/04/20- Pig Kidney Anatomy Comparison

Title: Pig Kidney Anatomy

Date: 2024/04/20

Content by: Aleksandra Skutnik

Present: N/A

Goals: To understand the tissue comparison when using pig kidneys for testing prior to testing on human kidneys.

Link: https://www.sciencedirect.com/science/article/pii/S0085253824000723#:~:text=Pig%20kidneys%20have%20fewer%20total,nephrons%20compared%20with%20human%20kidneys.&text=

Content:

- Pig kidneys have fewer nephrons in total
- May have reduced ability to filtrate urine concentrations in comparison to human kidneys
- Nonetheless, a good animal model for research
- Apart from metabolic function, kidney anatomy is generally the same

Conclusions/action items:

If pig kidney anatomy is similar to human kidney anatomy, then pig kidneys should be a good animal model to use for testing. However, it was found that the perirenal fat on pig kidneys that the
Additionally, the connective fibrotic tissue layer encapsulating the kidney itself was not representative of human kidney tissue.

2024/01/31- Fisher Scientific punch biopsy blade

ALEKSANDRA SKUTNIK - Jan 31, 2024, 1:25 PM CST

Title: Fisher Scientific Punch Biopsy Blade

Date: 2024/01/31

Content by: Aleks Skutnik

Present: n/a

Goals: To find manufactured blades to compare designs and possibly implement into the future steps of the project.

Link: https://www.fishersci.com/shop/products/10mm-biopsy-punch-pk-50/NC9236770

Content:

- Blade by Fisher Scientific used for punch biopsies
- Sizes range from 1-12 mm in diameter

Conclusions/action items:

The team should discuss the future steps toward standardizing manufacturing of the blade. The team should consider purchasing a pre-manufactured blade to make the process easier and the blade more reliable.

ALEKSANDRA SKUTNIK - Jan 31, 2024, 1:25 PM CST

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Screen_Shot_2024-01-31_at_1.25.45_PM.png (217 kB)

2024/02/01- Biopsy Dermal Keys

ALEKSANDRA SKUTNIK - Feb 01, 2024, 11:37 AM CST

Title: Biopsy dermal keys

Date: 2024/02/01

Content by: Aleks Skutnik

Present: n/a

Goals: To find competing blade designs.

Link: https://www.graylinemedical.com/products/miltex-integra-miltex-biopsy-punch-dermal-keyes-4mm-4mm-bite-stainless-steel-rsbl-ea?variant=19329707933753&gad_source=1&gclid=CjwKCAiA_OetBhAtEiwAPTeQZ0Cqz3EyihviIm9c1Svx-s4tGADLGODV2CPhT0-fQPn6wrTvrJygLxoCFO8QAvD_BwE

Content:

- Biopsy punch collection tube with adjustable biospy blade diameters
- Stainless steel
- Reusable and autoclavable

Conclusions/action items:

The team wants to ideally have a reusable blade that can be used for multiple biopsy cycles to reduce waste and costs. The team will consider purchasing a pre-manufactured blade to standardize manufacturing of the device as a whole.

ALEKSANDRA SKUTNIK - Feb 01, 2024, 11:37 AM CST

Download

Screen_Shot_2024-02-01_at_11.37.21_AM.png (258 kB)

2024/02/26- BMC Prostate Screening

ALEKSANDRA SKUTNIK - Feb 28, 2024, 6:26 PM CST

Title: BMC Prostate Screening

Date: 2024/02/26

Content by: Aleks Skutnik

Present: n/a

Goals: To decide what journal/article the team wants to base the preliminary and final report off of.

Content:

Pros:

- Flow of the article makes sense for the project
- Lots of pictures incorporated throughout the length of the article
    - Includes graphs for data analysis
- Length of introduction is appropriate and describes a clear need for risk prediction and the effected groups
- Abstract separated into categories to easily be scanned by the reader

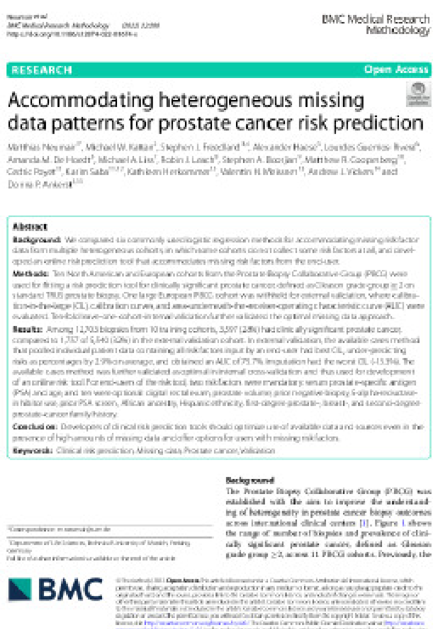
Cons:

- Discussion did not have subcategories
    - Subcategories is likely something that the team will want to include in our own report to cover all areas of the project
    - Ethical discussions may be something the team will look into and error sources

Conclusions/action items:

The team will narrow down an article/journal to follow the formatting for the preliminary report and continue with this format through the rest of the semester.

ALEKSANDRA SKUTNIK - Feb 28, 2024, 8:19 AM CST



BMC Medical Research Methodology

RESEARCH Open Access

Accommodating heterogeneous missing data patterns for prostate cancer risk prediction

[Download](#)

BMC_Prostate_Screening.pdf (2.54 MB)

2024/02/26- RSNA Imaging Cancer

ALEKSANDRA SKUTNIK - Feb 28, 2024, 6:28 PM CST

Title: RSNA Imaging Cancer

Date: 2024/02/26

Content by: Aleks Skutnik

Present: n/a

Goals: To decide what journal/article the team wants to base the preliminary and final report off of.

Content:

Pros:

- Has sectioned abstract that is easy to scan and understand
- Subcategories under each main category like methods and materials
    - Allows for better organization of ideas
- Good incorporation of images throughout the article, including graphs for data analysis

Cons:

- Key words box is randomly in the middle of the introduction, disrupting the flow
    - I do like having a key words box for the reader to refer to when necessary

Conclusions/action items:

The team will narrow down an article/journal to follow the formatting for the preliminary report and continue with this format through the rest of the semester.

ALEKSANDRA SKUTNIK - Feb 28, 2024, 8:45 AM CST

Radiology: Imaging Cancer

Quantitative US Delta Radiomics to Predict Radiation Response in Individuals with Head and Neck Squamous Cell Carcinoma

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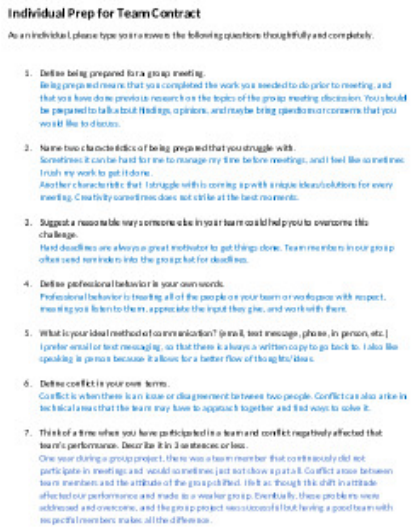
osapoetra-et-al-2024-quantitative-us-delta-radiomics-to-predict-radiation-response-in-individuals-with-head-and-neck.pdf (1.05 MB)

2023/10/11 Individual Prep for Team Contract

ALEKSANDRA SKUTNIK - Oct 11, 2023, 7:37 PM CDT



Individual Prep for Team Contract

As an individual, please type your answers the following questions thoughtfully and completely.

1. Define being prepared for a group meeting.
   Being prepared means that you completed the work you needed to do prior to meeting, and that you have done previous research on the topics of the group meeting discussion. You should be prepared to talk about findings, opinions, and maybe bring questions or concerns that you would like to discuss.
2. Name two characteristics of being prepared that you struggle with.
   Sometimes it can be hard for me to manage my time before meetings, and I feel like sometimes I rush my work to get it done.
   Another characteristic that I struggle with is coming up with unique ideas/solutions for every meeting. Creativity sometimes does not strike at the best moments.
3. Suggest a reasonable way someone else in your team could help you to overcome this challenge.
   Hard deadlines are always a great motivator to get things done. Team members in our group often send reminders into the group chat for deadlines.
4. Define professional behavior in your own words.
   Professional behavior is treating all of the people on your team or workspace with respect, meaning you listen to them, appreciate the input they give, and work with them.
5. What is your ideal method of communication? (email, text message, phone, in person, etc.)
   I prefer email or text messaging, so that there is always a written copy to go back to. I also like speaking in person because it allows for a better flow of thoughts/ideas.
6. Define conflict in your own terms.
   Conflict is when there is an issue or disagreement between two people. Conflict can also arise in technical areas that the team may have to approach together and find ways to solve it.
7. Think of a time when you have participated in a team and conflict negatively affected that team's performance. Describe it in 3 sentences or less.
   One year during a group project, there was a team member that continuously did not participate in meetings and would sometimes just not show up at all. Conflict arose between team members and the attitude of the group shifted. I felt as though this shift in attitude affected our performance and made us a weaker group. Eventually, these problems were addressed and overcome, and the group project was successful but having a good team with respectful members makes all the difference.

Download

Skutnik_Individual_Prep_for_Team_Contract.docx (17.1 kB)

Green Permit

ALEKSANDRA SKUTNIK - Feb 17, 2023, 1:27 PM CST

Title: Green Permit training and certification completed

Date: 2023/01/19

Content by: Aleksandra Skutnik

Content:

- Learned how to use lathe and mill machinery in the Team Lab at UW-Madison.

ALEKSANDRA SKUTNIK - Feb 17, 2023, 1:26 PM CST

Download

Screen_Shot_2023-01-26_at_12.23.11_AM.png (307 kB)

Biosafety and Chemical Safety Training

ALEKSANDRA SKUTNIK - Feb 16, 2023, 9:05 PM CST

Title: Biosafety and Chemical Safety Training Certification

Content by: Aleksandra Skutnik

Goals: To understand the biosafety and chemical safety standards when working in a laboratory setting.

Content:

Biosafety and chemical safety modules and assessments completed.

ALEKSANDRA SKUTNIK - Feb 16, 2023, 9:04 PM CST

Download

TrainingSkutnik_1_.pdf (254 kB)

2024/2/2 OSHA Bloodborne Pathogens Standard

Olivia Jaekle - Feb 28, 2024, 1:47 PM CST

Title: 2024/2/2 OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030)

Date: 2024/2/2

Content by: Olivia Jaekle

Present: Olivia Jaekle

References: [1] “Bloodborne Pathogens - Standards | Occupational Safety and Health Administration.” Accessed: Feb. 28, 2024. [Online]. Available: https://www.osha.gov/bloodborne-pathogens/standards

Link: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030

Goals: Standards and Codes for Maintenance instructions

Content:

OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030)

Aimed at protecting workers from exposure to bloodborne pathogens

Key provisions include:

Exposure Control Plan development and implementation

Universal Precautions: Treat all blood and OPIM as infectious

Engineering Controls: Use sharps disposal containers, self-sheathing needles

Work Practice Controls: Prohibit hand recapping of needles, proper handling and disposal

Personal Protective Equipment (PPE): Provide gloves, face shields, gowns; ensure proper training

Hepatitis B Vaccination: Offer vaccination series at no cost; allow employee declination

Post-Exposure Evaluation and Follow-Up: Provide prompt medical evaluation, testing, counseling, and treatment for exposed employees

Conclusions:

In conclusion, OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030) plays a crucial role in protecting the health and safety of workers who may encounter bloodborne pathogens in the course of their job. By outlining regulations and requirements, this standard ensures that employers take proactive measures to minimize the risk of exposure to potentially harmful pathogens. From the development of exposure control plans to the provision of personal protective equipment and post-exposure follow-up procedures, employers are required to implement a range of measures aimed at protecting employees. This is exactly the type of standard that needs to be in the maintenance instructions

Action items:

Continuing researching for other standards and codes for maintenance instructions

Look at standards and codes for service and safety instructions

2024/2/05 ISO 13485:2016

Olivia Jaekle - Feb 28, 2024, 4:04 PM CST

Title: ISO 13485:2016

Date: 2024/2/05

Content by: Olivia Jaekle

Present: Olivia Jaekle

Goals: Learn about ISO 13485:2016, the requirements for quality for medical devices

Link: https://www.iso.org/standard/59752.html

Cite: [1] 14:00-17:00, “ISO 13485:2016,” ISO. Accessed: Dec. 12, 2023. [Online]. Available: https://www.iso.org/standard/59752.html

Content:

ISO 13485:2016

Medical devices

Quality management systems

Requirements for regulatory purposes

ISO 13485:2016 outlines the criteria for a quality management system when an organization aims to demonstrate its capability in consistently delivering medical devices and related services that meet customer and relevant regulatory requirements. These organizations may be involved in various stages of the life cycle, such as design, development, production, storage, distribution, installation, servicing of medical devices, and the provision of associated activities like technical support. Suppliers or external parties offering product and quality management system-related services to such organizations can also use ISO 13485:2016.

The standard's requirements are applicable to organizations of any size and type, except when explicitly stated otherwise. When specified for medical devices, these requirements equally apply to associated services provided by the organization.

Processes mandated by ISO 13485:2016 that are relevant to the organization but not executed by the organization are its responsibility, and they are incorporated into the quality management system through monitoring, maintenance, and control.

If regulatory requirements permit excluding design and development controls, organizations can justify their exclusion from the quality management system. The responsibility lies with the organization to ensure that claims of conformity to ISO 13485:2016 accurately reflect any exclusions of design and development controls.

If a requirement in Clauses 6, 7, or 8 of ISO 13485:2016 is deemed inapplicable due to the organization's activities or the nature of the medical device under consideration, the organization is not obligated to include that requirement in its quality management system. The rationale for such inapplicability is recorded by the organization as described in 4.2.2.

Conclusions/action items:

We are using this standard to align our final design with required quality and regularity affairs. Overall, ISO 13485:2016 sets out standards for managing quality in organizations involved in the production and distribution of medical devices and related services, ensuring compliance with customer requirements and relevant regulations. The document emphasizes the organization's responsibility for all relevant processes, justifications for exclusions, and the recording of any inapplicable requirements.

2024/2/5 CDC guidelines for infection control

Olivia Jaekle - Feb 28, 2024, 1:48 PM CST

Title: 2024/2/5 CDC guidelines for infection control

Date: 2024/2/5

Content by: Olivia Jaekle

Present: Olivia Jaekle

Cite: [1] “Guidelines Library | Infection Control | CDC,” Sep. 28, 2023. Available: https://www.cdc.gov/infectioncontrol/guidelines/index.html. [Accessed: Feb. 28, 2024]

Link: https://www.cdc.gov/infectioncontrol/guidelines/index.html

Goals:

- Content: Standard Precautions: Assume all patients are potentially infectious; includes hand hygiene, PPE use, safe injection practices, and sharps handling.
- Transmission-Based Precautions: Additional precautions for patients with known or suspected infections; includes contact, droplet, and airborne precautions.
- Hand Hygiene: Wash hands with soap and water or use alcohol-based hand sanitizers before and after patient contact, after touching surfaces, and before and after wearing gloves.
- Environmental Cleaning and Disinfection: Proper cleaning and disinfection of patient care areas, equipment, and surfaces using EPA-approved disinfectants.
- Respiratory Hygiene/Cough Etiquette: Promote covering mouth and nose when coughing or sneezing, proper tissue disposal, and hand hygiene.
- Safe Injection Practices: Use aseptic technique, new needles, and syringes for each injection, and avoid reusing single-dose vials for multiple patients.
- Personal Protective Equipment (PPE): Use appropriate PPE, including gloves, gowns, masks, and eye protection, based on anticipated exposure.
- Education and Training: Provide ongoing education and training on infection control practices, including hand hygiene, PPE use, and cleaning techniques.
- Surveillance and Monitoring: Implement surveillance systems to monitor healthcare-associated infections, identify trends, and implement interventions.

Conclusions/action items:

In conclusion, adherence to the Centers for Disease Control and Prevention (CDC) guidelines for infection control in healthcare settings is paramount for preventing the spread of infections among patients, healthcare workers, and visitors. These guidelines encompass comprehensive measures such as standard precautions, transmission-based precautions, hand hygiene, environmental cleaning, and safe injection practices. This is important for our project because we want to make sure our clients are safe and that our product is not creating any infections.

Action items:

- **Continuing researching for other standards and codes for safety instructions**
- **Look at standards and codes for service instructions**

2024/2/10 BS EN ISO 7153 Part 1

Olivia Jaekle - Feb 28, 2024, 4:01 PM CST

Title: ISO 7153-1:2016

Date: 2024/2/10

Content by: Olivia Jaekle

Present: Olivia Jaekle

Goals: Learn about ISO 7153-1:2016 for how blades are manufacutred in the medical device

Link: https://www.iso.org/standard/66850.html

Cite:

[1] 14:00-17:00, “ISO 7153-1:2016,” ISO. Accessed: Dec. 12, 2023. [Online]. Available: https://www.iso.org/standard/66850.html

Content:

ISO 7153-1:2016

Surgical instruments

Materials

Part 1: Metals

ISO 7153-1:2016 outlines the metals typically employed in the production of a range of standard surgical instruments, encompassing those utilized in general surgery, orthopaedics, and dentistry, among others.

While ISO 7153-1:2016 is not specifically designed for surgical instruments utilized in specialized applications like implantology and minimally invasive surgery, certain sections of the standard may still be relevant to these instruments.

Conclusions/action items:

We are using this standard for manufacturing blades. This standard gave us insight of how production level blades work and are dispersed.

2024/2/11 EPA guidlines

Olivia Jaekle - Feb 28, 2024, 4:14 PM CST

Title: EPA guidelines for waste

Date: 2024/2/11

Content by: Olivia Jaekle

Present: Olivia Jaekle

Link: https://www.epa.gov/laws-regulations/regulations

Cite:

O. US EPA, “Regulations,” Feb. 22, 2013. Available: https://www.epa.gov/laws-regulations/regulations. [Accessed: Feb. 28, 2024]

Goals: look at how to get rid of waste properly in terms of our device

Content:

- **Identification of Hazardous Waste: EPA criteria determine hazardous waste based on characteristics like ignitability, corrosivity, reactivity, and toxicity, alongside specific listings.**
- **Generator Requirements: Generators categorized as large, small, or conditionally exempt must adhere to specific waste management, record-keeping, and reporting standards.**
- **Transportation: Transporters must comply with packaging, labeling, manifesting, and placarding requirements to safely transport hazardous waste.**
- **Treatment, Storage, and Disposal Facilities (TSDFs): Facilities treating, storing, or disposing of hazardous waste need permits, adhering to stringent standards to prevent environmental contamination.**
- **Land Disposal Restrictions: Regulations restrict land disposal to minimize groundwater contamination, requiring treatment standards for certain hazardous wastes before disposal.**
- **Universal Waste: Certain common hazardous wastes, like batteries and mercury-containing equipment, are regulated under streamlined rules to simplify management.**
- **Enforcement: The EPA and state agencies enforce RCRA regulations through inspections, compliance monitoring, and penalties for non-compliance.**

Conclusions/action items:

In conclusion, the Environmental Protection Agency's (EPA) regulations on hazardous waste, governed by the Resource Conservation and Recovery Act (RCRA), establish rigorous standards for the identification, management, transportation, treatment, and disposal of hazardous waste. These regulations aim to protect human health and the environment by preventing pollution and minimizing risks associated with hazardous waste.

2024/3/10 Human vs. Pig Kidney

Olivia Jaekle - May 01, 2024, 9:07 AM CDT

Title: Human vs. Pig Kidney

Date: 2024/3/10

Content by: Olivia Jaekle

Present: Olivia Jaekle

Goals: Learn about the similarities between human and pig kidney

Cite: “Human/Pig Comparisons,” Academics. Accessed: March 10, 2024. [Online]. Available: https://www.goshen.edu/academics/biology/pigbook/human-pig-comparisons/

Link: https://www.goshen.edu/academics/biology/pigbook/human-pig-comparisons/#:~:text=of%20the%20FPDG.-,Internal%20Organs,%2C%20left%20lateral%2C%20and%20caudate.

Content:

Similarity to Human Structure

- Muscles:
  - Fetal pigs share almost identical muscle structures with humans, albeit with minor differences due to their quadrupedal nature.
  - Chest and abdominal muscles are comparable, though chest muscle attachments to the shoulder girdle differ slightly.
  - Hind limb muscles, like quadriceps femoris and hamstrings, mirror human anatomy, though some distinctions exist in the gluteal muscles.

- Internal Organs:
  - Thoracic and abdominal organs in pigs closely resemble those in humans, with slight variations.
  - Liver: Pig liver has five lobes compared to the human's four.
  - Intestines: Pig colon is spiral-shaped, unlike the human colon.
  - Adrenal glands: Positioned differently in fetal pigs, located near the aorta towards the cephalic end of the kidneys.
  - Other organs like the stomach, spleen, bile duct system, small intestines, kidneys, bladder, thymus, lungs, pericardium, vena cava, esophagus, and phrenic nerve are akin to human counterparts.

- Genitourinary Structures:
  - Uterus: Fetal pig uterus is bicornate, having two large horns in addition to the body, unlike the simplex human uterus.
  - Urogenital Sinus: Pigs possess a relatively lengthy urogenital sinus formed by the fusion of urethra and vagina, unlike humans where these structures have separate external openings.

- Blood Vessels:
  - Bicarotid trunk: Present in fetal pigs, where the brachiocephalic artery splits into the right subclavian artery and bicarotid trunk, which further divides into right and left common carotid arteries, unlike in humans.
  - Iliac arteries: Fetal pigs lack a common iliac artery, with internal and external iliac arteries branching directly from the aorta.

- Sheep Organs:
  - Sheep heart, eye, and brain resemble human counterparts in size and shape, with slight proportional differences in the brain.

- Embryological Note:
  - Notable differences in the veins draining the posterior chest wall between pigs and humans, affecting the development of the coronary sinus and hemiazygous vein.

Conclusions/action items:

Using this information the team will decided how to proceed with testing on pig kidneys since it is hard for us to meet with our client to use processed pig kidneys. Also there are major differences in the perinal fat so we may want to talk to our client about just sticking with chicken breasts until our next human kidney testing.

2024/3/15 Pig kidneys used in human

Olivia Jaekle - May 05, 2024, 3:24 PM CDT

Title: Pig kidney used in human

Date: 2024/3/15

Content by: Olivia Jaekle

Present: Olivia Jaekle

Goals: to prove that the human and pig kidney are similar for testing

Cite:“New study: Pig kidneys — for the first time — demonstrate ‘life-sustaining kidney function’ in a human,” UAB News. Accessed: March 15, 2024. [Online]. Available: https://www.uab.edu/news/health/item/13712-new-study-pig-kidneys-for-the-first-time-demonstrate-life-sustaining-kidney-function-in-a-human

Link: https://www.uab.edu/news/health/item/13712-new-study-pig-kidneys-for-the-first-time-demonstrate-life-sustaining-kidney-function-in-a-human

Content:

- Overview:
  - Genetically modified pig kidneys showcased "life-sustaining kidney function" in a human for the first time during a seven-day study, using standard immunosuppression drugs.
  - Published in JAMA Surgery, the study, conducted in Feb. 2023, signifies a major leap in xenotransplantation, offering hope for curing end-stage kidney disease and addressing the global organ shortage crisis.

- Lead Researcher:
  - Dr. Jayme Locke, director of UAB's Comprehensive Transplant Institute, led the study, emphasizing its groundbreaking nature and potential impact on organ transplantation.

- Study Details:
  - Conducted using the Parsons Model, a pre-clinical human brain death model, the study involved a recipient who had both native kidneys removed due to chronic kidney disease.
  - Ten gene-edited pig kidneys, termed UKidney™, were transplanted into the recipient.
  - The transplanted pig kidneys exhibited immediate urine production upon reperfusion and sustained normal kidney function throughout the study period, producing over 37 liters of urine within 24 hours.
  - Biopsies confirmed normal kidney histology without evidence of damage.

- Significance and Progress:
  - This study follows UAB's previous successful xenotransplant research and marks another milestone in xenotransplantation.
  - The Parsons Model studies provide crucial insights into pig-to-human kidney transplants, advancing the field and potentially offering a solution to the organ shortage crisis.

- Research Funding and Partnerships:
  - Supported by United Therapeutics Corporation and Revivicor, Inc., the study received grants and resources to develop innovative xenotransplantation programs.
  - Collaboration with Legacy of Hope and various departments within UAB facilitated the study's success.

- Future Implications:
  - Genetically modified pig kidneys, designed for reduced immune rejection, offer a promising solution to organ failure.
  - Xenotransplantation could alleviate the burden of organ shortage, potentially saving thousands of lives annually.
  - The study's success paves the way for further clinical trials and advancements in organ transplantation, emphasizing the importance of continued research in this field.

- Conclusion:
  - UAB's groundbreaking research in xenotransplantation demonstrates the potential for sustainable organ supplies and brings hope to patients worldwide.
  - The study's success underscores the importance of collaboration, innovative technologies, and the invaluable contributions of donors and their families to medical research.

Conclusions/action items:

From this study, they found that it was successful to transplant a genetically modified pig kidney into a human. This can be used towards are testing and see if there are things we can do to the pig kidney, like process them in a way so that we can mimic human tissue more closely.

2024/2/8 Silicone Mold

Olivia Jaekle - Feb 28, 2024, 4:18 PM CST

Title: Silicone Mold

Date: 2024/2/8

Content by: Olivia Jaekle

Present: Olivia Jaekle

Link: https://inmoov.fr/silicone-finger-tip-mold/

Cite: “Silicone Finger Tip Mold,” InMoov, Nov. 01, 2015. Available: https://inmoov.fr/silicone-finger-tip-mold/. [Accessed: Feb. 28, 2024]

Goals: Looking at a way to cap the blade

Content:

- Materials: Printed parts, scissors, silicone (either from a cartridge or two-component), clamp, brush, and wax, Vaseline, or dish soap.
- Prepare Mold: Brush wax, Vaseline, or dish soap on the mold parts to prevent silicone adherence. Assemble the mold using a clamp, ensuring correct alignment.
- Fill Mold: Fill each finger mold halfway with silicone, using a bathroom or window silicone cartridge or two-component silicone for faster curing.
- Press Third Part: Firmly press the third part of the mold onto the silicone-filled fingers, ensuring correct alignment.
- Cure Silicone: Allow the silicone to cure according to the product's instructions. This may take several days for some silicone types.
- Carefully Remove Mold: Open the mold carefully with a small screwdriver, being patient to avoid tearing the thin silicone.
- Trim Excess Silicone: Use scissors to cut excess silicone between each finger and trim close to the edges without making holes.
- Measure and Apply: Measure the desired length for each finger tip cover, cut cleanly, and apply onto the finger.

Following these steps will result in silicone finger tips that provide a better grip and cover sensors if needed, enhancing the functionality of the InMoov hand for grabbing and picking up objects.

Conclusions/action items: Was thinking of using this as inspiration for a blade cap. We were looking at using a silicone sealant as the material. Turns out the blade comes with a cap though so no need to pursue further research on this topic.

2024/2/26 3D-Printed Video Laryngoscope for Tracheal Intubation

Olivia Jaekle - Feb 28, 2024, 4:28 PM CST

Title: Evaluating the Usability of a 3D-Printed Video Laryngoscope for Tracheal Intubation of a Manikin

Date: 2024/2/26

Content by: Olivia Jaekle

Present: Olivia Jaekle

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10281522/

Cite: . T.Fonternel, H. van Rooyen, G. Joubert, and E. Turton, “Evaluating the Usability of a 3D-Printed Video Laryngoscope for Tracheal Intubation of a Manikin,” Med Devices (Auckl), vol. 16, pp. 157–165, Jun. 2023, doi: 10.2147/MDER.S405833. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10281522/. [Accessed: Feb. 28, 2024]

Goals: Look at journal articles to see if this may be one we would want to use to copy our format

Content:

Good:

Clear Objective Statement: The article clearly states its objective of evaluating the usability of a 3D-printed video laryngoscope compared to a standard device, providing context and rationale for the study.

Detailed Methods Section: The methods section provides a clear description of the study design, including participant selection, randomization, and ethical considerations, which is essential for reproducibility and understanding the study's validity.

Statistical Analysis: The statistical analysis is thorough, utilizing appropriate tests to compare outcomes between the two devices and providing detailed results with confidence intervals and p-values.

Comprehensive Results Presentation: Results are presented in tables and graphs, making them easy to interpret. The discussion of key findings is supported by data, enhancing the credibility of the conclusions.

Discussion of Limitations: The article acknowledges limitations such as the use of a manikin instead of human subjects and the absence of a time limit for intubation attempts, demonstrating transparency and a critical appraisal of the study's methodology.

Conclusion and Implications: The conclusion summarizes key findings and implications for future research and clinical practice, providing a clear takeaway message for readers.

Bad:

Lack of Visual Aids: While the article describes the design of the 3D-printed device, it could benefit from visual aids such as images or diagrams to help readers better understand its features and functionality.

Complex Language: Some sections of the article contain technical terminology and complex language that may be difficult for non-specialist readers to understand, potentially limiting its accessibility.

Insufficient Discussion of Previous Research: The article briefly mentions previous studies on 3D-printed medical devices but could provide a more comprehensive discussion of relevant literature to contextualize the current study and highlight its novelty and contribution to the field.

Data Sharing Statement: While the article includes a data sharing statement, it does not specify where the data will be available or provide any details on data accessibility, which may limit transparency and reproducibility.

Conclusions/action items:

I feel like overall it was a well written article. I think that some things we would need to have is more background in ours since our project has been going on for multiple years. I also think it is important for us to have images throughout once we have results to show our readers what exactly we are doing.

2022/2/9 Training Record- Chemical Safety and Biosafety Training

Olivia Jaekle - Feb 09, 2022, 9:39 PM CST

Title: Training Record

Date: 2022/2/9

Content by: Olivia Jaekle

Present: Olivia Jaekle

Goals: Showing that I have completed Biosafety Training and Chemical Saftey Training

Content:

WISCONSIN
UNIVERSITY OF WISCONSIN-MADISON

This certifies that Olivia Jaekle has completed training for the following course(s):

Course	Assignment	Completion	Expiration
Biosafety Required Training	Biosafety Required Training Quiz 2022	1/29/2022	
Chemical Safety: The OSHA Lab Standard	Final Quiz	1/25/2022	

Data Last Imported: 09/02/2022 09:30 PM

Conclusions/action items:

Make sure that these training stay updated and refer back to them when needed.

2022/2/19 Training Record-Green Permit

Olivia Jaekle - Feb 19, 2022, 5:09 PM CST

Title: Training Record- Green Permit

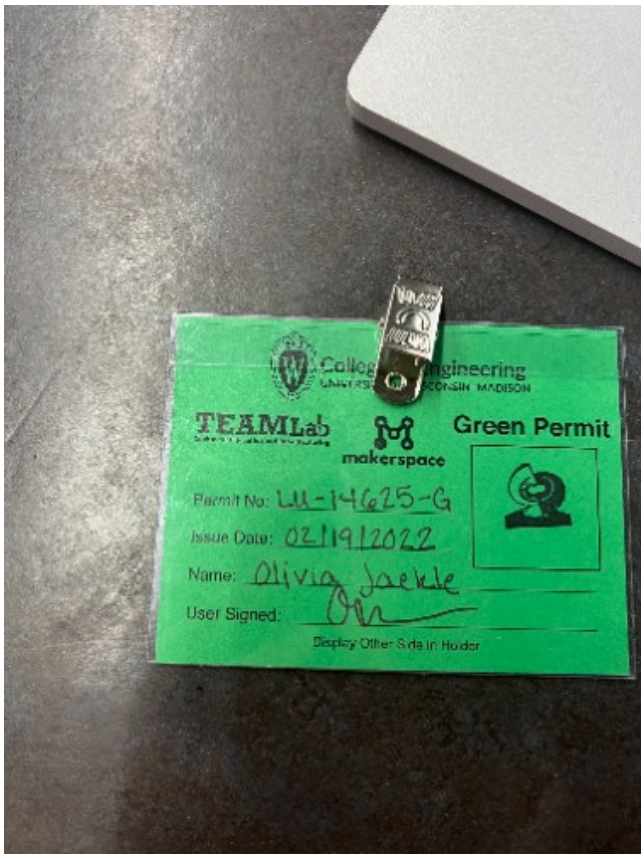
Date: 2022/2/19

Content by: Olivia Jaekle

Present: Olivia Jaekle

Goals: Showing that I have completed the Green Permit

Content:



Conclusions/action items:

Make sure that this training stays updated and refer back to it when needed.

2024/2/28 MR-guided vacuum biopsy

Olivia Jaekle - May 05, 2024, 11:49 AM CDT

Title: Multicenter study for the evaluation of a dedicated biopsy device for MR-guided vacuum biopsy of the breast

Date: 2024/2/28

Content by: Olivia Jaekle

Present: Olivia Jaekle

Goals: Learn about this journal and see if my team wants to use for our example journal

Content:

- Magnetic resonance mammography (MRM) is highly sensitive for detecting invasive breast carcinoma but has limited specificity.
- Indications for MRM include scar tissue differentiation, recurrence detection after therapy, diagnosis in patients with implants, primary tumor search in patients with unsuspicious findings, preoperative staging, neoadjuvant chemotherapy monitoring, and cases unsolvable by conventional methods.
- Approximately 70% of lesions detected by MRM are not visible by other imaging methods.
- MR-guided preoperative wire localization or minimally invasive percutaneous needle biopsy is necessary for precise diagnosis of small lesions detected by MRM.
- Vacuum biopsy (VB) is superior to core-needle biopsy for evaluating indeterminate or suspicious mammographic microcalcifications or small masses.
- A European multicenter study evaluated MR-guided VB on 341 lesions using a dedicated biopsy coil.
- MR-guided VB was performed using 1.0 T or 1.5 T scanners and 11-G needles.
- Patients referred for MR-guided VB had various indications, including lesion visibility only on MRM or one mammographic view.
- Histologic results were retrospectively correlated with MRI to ensure accuracy.
- VB was successful in most cases, with only 2% considered unsuccessful.
- Assessment of excision was sometimes impaired by bleeding or patient movement, but overall, VB yielded reliable results.
- Major side effects were rare, with most patients tolerating the procedure well.
- MR-guided VB combined with a dedicated biopsy coil offers accurate diagnosis of small lesions.
- Post-biopsy MR follow-up after 6 months is recommended for further verification of results.

Conclusions/action items:

I really liked this journal because it flowed really well. It was really easy to follow and use clear, concise language. One thing I would keep in mind is that their result images took up like 3 full pages. I feel like that is excessive but that is something my team and I can discuss on how to approach our results.

3/7 Properties of Acrylonitrile Butadiene Styrene (ABS)

Ellie Steger - Mar 12, 2024, 5:06 PM CDT

Title: Properties of Acrylonitrile Butadiene Styrene (ABS)

Date: 3/7

Content by: Ellie Steger

Present: ES

Goals: To find a material to use for our plunger.

Content:

ABS could be autoclavable as it has a melting point of 200 degrees Celcius, the autoclave only reaches a temperature of 140 degrees so the plunger will not melt. However, ABS is very porous, so it would not be properly sanitized through the autoclave because small particles of the resected kidney may remain inside of the plunger.

Conclusions/action items:

We will not move forward with ABS as a material for our plunger due to sanitization concerns. Instead, we will move forward making a

2024/02/23 Instructions For Use The Use Of Short And Long Corneal Trephine Blades A6816L to A6884L

Ellie Steger - Feb 28, 2024, 2:00 PM CST

Title: Corneal trephines, cutting blocks and artificial anterior chambers

Date: 02/23/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To understand what the user manual should look like based on user manuals for other tephine blades

Content:

- Altomed Trephines are designed for corneal trephination in donor or recipient corneas during ophthalmic procedures like keratoplasty.
- Single-use, sterile devices not intended for reuse, with a specific use-by date indicated by an hourglass symbol
- Trephine blades are made from surgical-grade stainless steel and are supplied sterile for single use. They can be held by hand or with an A6830 Handle for short blades.
- The document emphasizes the importance of handling the blades with care to avoid damage, not using excessive force, and the prohibition of re-sterilization or reuse to prevent infection risks and ensure patient safety.
- Altomed Trephines should be stored in their original packaging in normal room conditions, away from direct light and moisture, and are made from surgical stainless steel, which may contain trace elements of nickel but do not contain latex or phthalates.

Conclusions/action items: Note the symbols used on BS EN ISO 15223-1 and ASTM F 2503

Ellie Steger - Feb 28, 2024, 2:02 PM CST


altomed

Instructions For Use The Use Of Short
And Long Corneal Trephine Blades A6816L to A6884L

Download

ALT-I005-Trephines.pdf (165 kB)

2024/2/2 Corneal trephines, cutting blocks and artificial anterior chambers

Ellie Steger - Feb 28, 2024, 1:29 PM CST

Title: Corneal trephines, cutting blocks and artificial anterior chambers

Date: 02/2/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To understand corneal trephines and evaluate if the blades used would be appropriate for our purposes.

Content:

- The term "trephine" refers to a surgical instrument used for cutting circular sections of corneal tissue or bone, designed as a circular or cylindrical saw.
- Trephine blades are essential in corneal transplantation surgeries, including both penetrating keratoplasty (PKP) and posterior lamellar keratoplasty (PLK), such as Descemetorhexis with Endokeratoplasty (DXEK).
- Trephines can be categorized into two main groups: those with suction and those without suction. This distinction is based on the method used to adhere the trephine to the cornea during the cutting process.
- Suctionless trephines are characterized by a cylindrical metal blade, sharp on one end and blunt on the other, which is manipulated manually between the surgeon's fingers, typically the thumb and index finger. This type of trephine is rotated in clockwise and counterclockwise directions to cut the corneal tissue.
- The suctionless trephine can be used on both donor and recipient corneas. When used on donor corneas, it can cut the cornea from the endothelial side using a guillotine-type corneal punch or from the epithelial side using an artificial anterior chamber (AAC). Cutting from the epithelial side into the AAC requires the use of corneal microscissors to complete the cut after the initial trephine incision.
- It's crucial to maintain a perpendicular orientation to the central cornea during trephination to avoid irregular cuts. This is achieved by observing through the central opening of the trephine blade while cutting.
- Suctionless trephines offer the advantage of being usable on irregular or scarred host corneas where suction trephines might not be able to establish good suction.

Conclusions/action items: I believe that purchasing a pre-fabricated trephine blade could be effective for our device. The corneal cut is taken in the same manner as the coring biopsy.

Ellie Steger - Feb 28, 2024, 1:37 PM CST

[1] T. John, “Corneal trephines, cutting blocks and artificial anterior chambers,” *Corneal Surgery*, pp. 305–312, 2009. doi:10.1016/b978-0-323-04835-4.50041-0

2024/02/22 Medical Devices: Evidence and Research

Ellie Steger - Feb 28, 2024, 3:36 PM CST

Title: BMC Medical Research Methodology

Date: 02/22/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To find a suitable journal to submit our article to.

Content:

- I was looking into medical device journals to submit our coring biopsy device to.
- An international, peer-reviewed, open access journal that focuses on the evidence, technology, research, and expert opinion supporting the use and application of medical devices in the diagnosis, monitoring, treatment and management of clinical conditions and physiological processes.
- **Speed/ acceptance:**
  - **56** days average from submission to first editorial decision
  - **10** days average from editorial acceptance to publication
  - **49**% acceptance rate
- **itation metrics:**
  This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE).
  - **1.3** Impact Factor *
  - **3.0** CiteScore
  - **0.826** Source Normalized Impact per Paper (SNIP)
  - **0.329** Scimago Journal & Country Rank (SJR)

Conclusions/action items: We will present this journal as an idea to our client.

2024/02/26 BMC Medical Research Methodology

Ellie Steger - Feb 28, 2024, 3:30 PM CST

Title: BMC Medical Research Methodology

Date: 02/26/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To find a suitable journal to submit our article to.

Content:

- *One of our clients suggested looking into a journal focused on methodology*
- *BMC Medical Research Methodology* is an open access journal publishing original peer-reviewed research articles in methodological approaches to healthcare research. Articles on the methodology of epidemiological research, clinical trials and meta-analysis/systematic review are particularly encouraged, as are empirical studies of the associations between choice of methodology and study outcomes. *BMC Medical Research Methodology* does not aim to publish articles describing scientific methods or techniques: these should be directed to the BMC journal covering the relevant biomedical subject area.
- **2022 Citation Impact**
  4.0 - 2-year Impact Factor
  7.0 - 5-year Impact Factor
  2.055 - SNIP (Source Normalized Impact per Paper)
  1.778 - SJR (SCImago Journal Rank)
- **2022 Speed**
  34 days submission to first editorial decision for all manuscripts (Median)
  175 days submission to accept (Median)

Conclusions/action items: I believe that BMC Medical Research Methodology would be a good fit for our device

2024/02/28 Quantity and quality of nucleic acids extracted from archival formalin fixed paraffin embedded prostate biopsies

Ellie Steger - Feb 28, 2024, 3:50 PM CST

Title:

Quantity and quality of nucleic acids extracted from archival formalin fixed paraffin embedded prostate biopsies

Date: 02/26/24

Content by: Ellie Steger

Present: Ellie Steger

Goals: To find a journal article whose format we will mimic in our own.

Content:

- Abstract: Provides an overview of the study's background, methods, results, and conclusions. It highlights the challenge of extracting high-quality nucleic acids from FFPE tissues and compares the efficiency of five commercial nucleic acid extraction kits
- Background: Discusses the relevance of prostate cancer as a significant health issue and the potential of molecular studies to identify biomarkers for predicting prostate cancer mortality. It emphasizes the difficulty of extracting nucleic acids from FFPE tissues due to tissue fixation processes.
- Methods: Details the study population, the comparison of nucleic acid extraction kits, and the assessment of DNA/RNA quantity and quality from FFPE biopsies. It includes specific methodologies for assessing the efficiency of extraction kits, statistical analyses, and criteria for evaluating nucleic acid quality and quantity.
- Results: Presents findings from the assessment of nucleic acid extraction kits, including comparative trials for RNA and DNA extraction. It reports on the quantity and quality of DNA/RNA obtained from archival biopsies and identifies factors influencing nucleic acid quality, such as tissue age and tumor amount.
- Discussion: Interprets the results, discussing the impact of extraction kit choice on nucleic acid quantity and quality. It also considers the implications of the findings for molecular studies using archival FFPE tissues.
- Conclusions: Summarizes the study's main findings, emphasizing the importance of extraction kit selection for obtaining high-quality nucleic acids from FFPE prostate biopsies. It mentions the potential for molecular studies to proceed with archival samples.
- Additional Sections: Includes abbreviations, acknowledgements, funding, availability of data and materials, author contributions, ethics approval and consent to participate, consent for publication, competing interests, publisher’s note, and author details. These sections provide supplementary information regarding the study's execution, ethical considerations, and funding sources.

Conclusions/action items: After consulting with the team, we have decided to move forward with the format of this article

BMC Medical Research Methodology

RESEARCH ARTICLE Open Access

Quantity and quality of nucleic acids extracted from archival formalin fixed paraffin embedded prostate biopsies

Abstract

Background

Download

BMC_Prostate_Sample_Quality.pdf (1.18 MB)

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: