BME Design-Spring 2025 - ANA CLARA TOSCANO
Complete Notebook

PDF Version generated by

SOFIA YEATES-DELAHOZ

on

Apr 30, 2025 @07:47 PM CDT

Table of Contents

Team contact Information

ANA CLARA TOSCANO - Jan 24, 2025, 1:07 PM CST

Last Name	First Name	Role	E-mail	Phone	Office Room/Building
McClean	Megan	Advisor			
Ross	Andrew	Client	Aross@uwhealth.org	608263-1426	
Toscano	Ana	Leader	atoscano2@wisc.edu	6027027585	
Anand	Kshirin	Communicator	kmanand@wisc.edu	6083343121	
Yeates-Delahoz	Sofia	BSAC	yeatesdelaho@wisc.edu	4252297486	
Yeates-Delahoz	Sofia	BWIG	yeatesdelaho@wisc.edu	4252297486	
Cecon	Gabriela	BPAG	cecon@wisc.edu	6089825385	

Project description

ANA CLARA TOSCANO - Jan 24, 2025, 1:06 PM CST

Course Number: BME 301

Project Name: Needle navigator: support and control device for image-guided minimally invasive procedures

Short Name: Needle Navigator

Project description/problem statement:

Minimally invasive radiology procedures require delicate needle insertions under imaging guidance, demanding steady hands and precise angles—a challenge in constrained or awkward positions. This project challenges biomedical engineering students to conceive and prototype a device that maintains optimal needle alignment while providing adjustable support and intuitive control. By integrating principles of mechanical design, ergonomics, and medical safety, the solution should minimize operator strain and reduce the risk of procedural errors. Students will conduct user research, assess design feasibility, fabricate the device, and validate its performance through simulated or real-world testing. The final outcome will be a functional prototype addressing clinical needs for enhanced accuracy and comfort in image-guided procedures.

About the client:

Dr. Andrew Ross is a radiologist at the University of Wisconsin School of Medicine and Public Health. With extensive expertise in the field of radiology, Dr. Ross is dedicated to advancing medical imaging and improving patient care. He is affiliated with UW Health and collaborates with multidisciplinary teams to ensure the highest quality of diagnostic and therapeutic radiology services.

2025/2/3 First Client Meeting

KSHIRIN ANAND - Feb 03, 2025, 5:56 PM CST

Title: First Client Meeting

Date: 2/3/25

Content by: Rini

Present: Rini, Ana, Sofia

Goals: Answer client questions to gain better understanding of project scope and details

Content:

Please see the following attachments: "Client Meeting Questions" & "Client Meeting Notes: 2/3/25" for the client meeting that took place 2/3/25 at 2-2:30pm.

Conclusions/action items: Send client follow-up email to schedule times to observe procedures and send access to team website. Update Gabi about client meeting.

KSHIRIN ANAND - Feb 03, 2025, 4:00 PM CST

Client Meeting Questions

1. What are the deliverable expectations for this project? Design specifications?
2. What level of precision and control does the client expect from the device?
3. How much customization should the device allow for different procedures and uses?
4. What imaging modalities will the device need to be compatible with (e.g., ultrasound, fluoroscopy, CT, MRI)?
5. What are the critical safety concerns the client wants addressed?
6. How will the device be secured to the patient or the operating table?
7. What range of needle angles and insertion depths must the device support?
8. What are the potential sources of mechanical failure?
9. Should the design allow for single-hand operation, or is a two-handed approach acceptable?
10. What kind of testing scenarios will best simulate real-world use?
11. Should there be a trigger-style locking mechanism to hold needle alignment once positioned?
12. How adaptable should the device be for different patient anatomies and conditions?
13. Are there any patient demographics (age, size, or medical conditions) that may require special considerations in design?
14. What are the expected durability and maintenance requirements over the device's lifecycle?
15. What should be the method of alerting the operator about critical alignment issues or potential errors?
16. Are there any outstanding environmental factors, such as operating room temperature or humidity, that should be considered in the design?
17. What methods or processes of sterilization do you use regularly?
18. Should the device offer adjustable sensitivity for needle guidance, depending on the operator's experience level?
19. Once the needle path is defined and it goes inside the patient, does it require you to move it?

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Client_Meeting_Questions.pdf (63.1 kB)

KSHIRIN ANAND - Feb 03, 2025, 4:01 PM CST

Client Meeting Notes: 2/3/25

Random Notes about client:

- Works in radiology dept

Answers to questions:

- Longer, 6 inch needle
- Needles go from 2-6 inches
- Usually use 2 - 3.5 inch needle for certain injections
- Use X-ray guidance
- Lots of spine injections (for spine pain)
- Lumbar spine needle is easy to manipulate because of the soft tissue
- Struggle with cervical spine (inject in the neck and inject into the cervical spine) there are a lot of blood vessels close to the brain and if punctured, patient can have a stroke
- Needle is angled 45 degrees to the floor, standing up it flops down
- Currently taking a sterile clamp to hold the needle, take the X-ray to get to right angle
    - Challenging because the needle starts bending, hard for hand to steer
    - Want a better way to steer the needles
- Precision:
    - Free-hand device that augments the ease of holding it with the hand
    - Procedures are done pretty quickly
- Single-handed operation (look vaguely like a clamp)
    - Can slide through with the other hand and reach through
    - Have some type of sliding mechanism to slide the needle
- Would be nice to hold the needle shaft
- Find a way to anchor the hand to the table and modify the end to adjust the angle that would be favorable
- Size of the needle:
    - Cervical (25 gauge needle)
    - 22 gauge needle
- Trigger style would be nice, have some type of pressure that holds the needle (this is a potential design idea)
    - Some type of compressive material there that can accommodate for different diameter needles
    - Telfa pad?
- Client mentioned we could go watch procedure, can arrange a time for that
- Plastic, simple, and disposable so that it is discarded after each
    - Sterile packaging

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Client_Meeting_Notes__2_3_25.pdf (54.7 kB)

2025/2/27 Client Meeting #2

SOFIA YEATES-DELAHOZ - Mar 02, 2025, 4:43 PM CST

Title: Client Meeting #2

Date: 2/27/2025

Content by: Sofia Yeates-Delahoz

Present: Rini, Gabi, Sofia

Goals: To provide an update of the progress of our project with the client and hear Dr. Ross's feedback regarding our preliminary deliverables.

Link: N/A

IEEE Citation: N/A

Content:

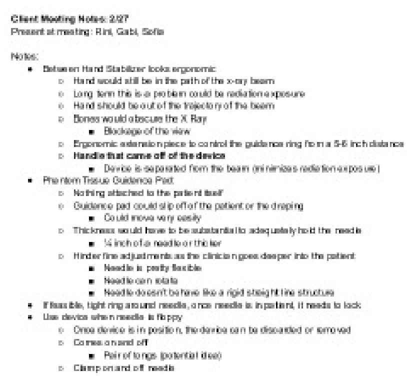
Meeting occurred over Teams on 2/27/25 at 9:00 AM.

To see the meeting notes, please review the attachment that is linked below.

Conclusions/action items:

Update Ana about the meeting. Start brainstorming ideas for the locking mechanism that will be used with the device.

SOFIA YEATES-DELAHOZ - Mar 02, 2025, 4:43 PM CST



Client Meeting Notes: 2/27
Present at meeting: Rini, Gabi, Sofia

Notes:
- Between Hand Stabilizer looks ergonomic
  - Hand would still be in the path of the x-ray beam
  - Long term this is a problem could be radiation exposure
  - Hand should be out of the trajectory of the beam
  - Bones would obscure the X Ray
    - Blockage of the view
  - Ergonomic extension piece to control the guidance ring from a 5-6 inch distance
  - **Handle that came off of the device**
    - Device is separated from the beam (minimizes radiation exposure)
- Phantom Tissue Guidance Pad
  - Nothing attached to the patient itself
  - Guidance pad could slip off of the patient or the draping
    - Could move very easily
  - Thickness would have to be substantial to adequately hold the needle
    - ¼ inch of a needle or thicker
  - Hinder fine adjustments as the clinician goes deeper into the patient
    - Needle is pretty flexible
    - Needle can rotate
    - Needle doesn't behave like a rigid straight line structure
- If feasible, tight ring around needle, once needle is in patient, it needs to lock
- Use device when needle is floppy
  - Once device is in position, the device can be discarded or removed
  - Comes on and off
    - Pair of tongs (potential idea)
  - Clamp on and off needle

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Client_Meeting_Notes__2_27_25.pdf (53.9 kB)

2025/4/8 X-Ray Fluoroscopy Needle Nav Device Testing

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:29 PM CDT

Title: X-Ray Fluoroscopy Needle Nav Device Testing

Date: 4/8/2025

Content by: Sofia Yeates-Delahoz

Present: Sofia, Rini, Gabi

Goals: To test out the device with Dr. Ross under XRay-Fluroscopy imaging.

Link: N/A

IEEE Citation: N/A

Content:

During this meeting:

- Testing of the device with a phantom under Xray fluoroscopy imaging was successful (see images below).
- There needs to be rubber attachments added to the device so that the needle is secured in place via the prongs.
- Future work idea: attach a bevel attachment to one of the ends of the prongs so that the needle can be rotated freely.
- Prongs are radiolucent under Xray fluoroscopy imaging -- this is good!

Conclusions/action items:

- Attach the rubber/silicone stoppers and continue working on the project.
- Create a survey to send out to radiologists at UW Health. Fabricate final prototypes.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:30 PM CDT

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IMG_7458.MOV (22.9 MB)

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:30 PM CDT

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NeedleNav_Phantom.MOV (3.64 MB)

2025/4/17 Client Meeting at UW Health

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:03 PM CDT

Title: Client Meeting

Date: 4/17/25

Content by: Sofia Yeates-Delahoz

Present: Sofia and Rini

Goals: To provide client with multiple prototypes for testing.

Link: N/A

IEEE Citation: N/A

Content:

Rini and Sofia went to meet Dr. Ross and give him multiple prototypes and a QR code for the survey. Dr. Ross shared the prototypes with some of his colleagues and some immediate feedback was given:

- Clamp part can be made for larger/smaller hand sizes in the future
- Provides easy stability
- Is comparable to the hemostat but is better since it reduces strain.

The radiologists were instructed to complete the survey with any thoughts and a couple prototypes were left behind so that the radiologists could learn how to use them with the phantoms.

Conclusions/action items:

Continue testing of the device.

2025/4/25 Client Meeting at Poster Session

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:06 PM CDT

Title: Client Meeting at Poster Session

Date: 4/25/25

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To present poster to our client.

Link: N/A

IEEE Citation: N/A

Content:

Dr. Ross came to our formal poster presentation at the poster session. Attached below is an image of Dr. Ross with the team!

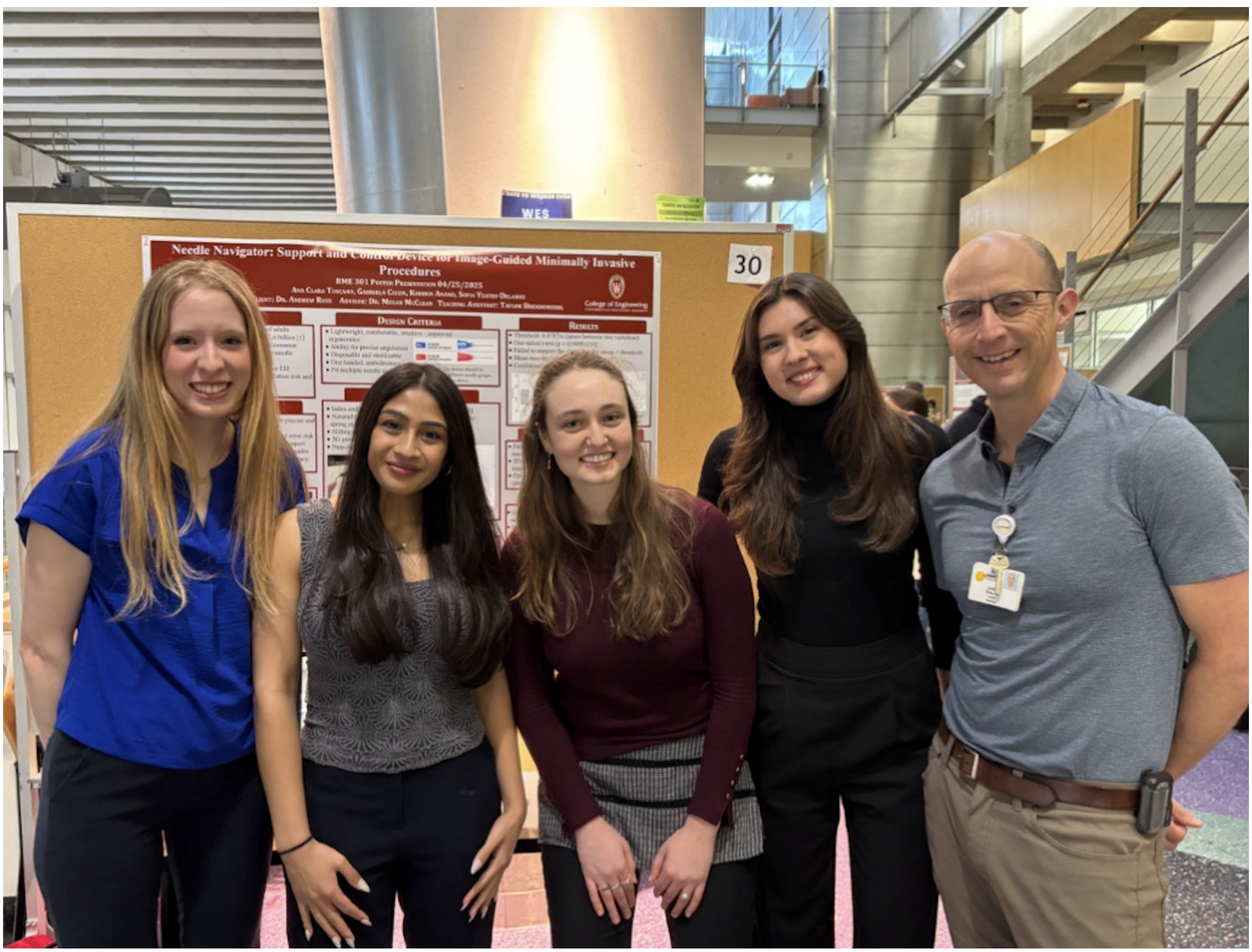


Figure 1: Image of team with the client Dr. Ross (on the right).

Conclusions/action items:

None. Stay in touch with Dr. Ross.

1/31/2025 Advisor Meeting 1

SOFIA YEATES-DELAHOZ - Feb 03, 2025, 5:43 PM CST

Title: 1/31/2025 Advisor Meeting 1

Date: 1/31/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: Meet with advisor and TA to discuss findings from literature search.

Content:

During this meeting each of the team members shared their findings of their literature search with the advisor.

Conclusions/action items: Continue conducting preliminary research and set up client meeting.

2/7/2025 - Advisor Meeting 2

SOFIA YEATES-DELAHOZ - Feb 11, 2025, 9:45 AM CST

Title: Advisor Meeting 2

Date: 2/7/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To present Week 2 literature search findings to the advisor and how they were incorporated into the PDS document.

Citation: N/A

Content:

During this meeting, each team member presented to Dr. Mcclean their research findings and how they were applicable to the PDS document.

Conclusions/action items:

Start working on the design matrix so that it is ready for the next advisor meeting. Continue research that is applicable to the project.

2/14/2025 - Advisor Meeting 3

SOFIA YEATES-DELAHOZ - Feb 26, 2025, 2:00 PM CST

Title: Advisor Meeting 3

Date: 2/14/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: Present research findings to advisor.

Link: N/A

IEEE Citation: N/A

Content:

During this weeks advisor, each team member presented their individual research to Taylor.

Conclusions/action items: Start preparing for the preliminary presentation.

2/28/2025 - Advisor Meeting 4

SOFIA YEATES-DELAHOZ - Mar 14, 2025, 9:09 AM CDT

Title: Advisor Meeting 4

Date: 2/28/25

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: Have individual consultations/meetings with advisor and TA.

Link: N/A

IEEE Citation: N/A

Content: N/A

During this meeting, each team member met individually with the advisor and TA to go over their semester's progress.

Conclusions/action items: None.

3/7/2025 - Advisor Meeting 5

SOFIA YEATES-DELAHOZ - Mar 14, 2025, 9:12 AM CDT

Title: Advisor Meeting 5

Date: 3/7/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To update our advisor and TA on the progress of the project.

Link: N/A

IEEE Citation: N/A

Content: N/A

During this meeting, we updated Dr. McClean and Taylor with our proposed final design idea. We asked for any input regarding the idea and they both asked some questions regarding the design and how it would work. They also suggested setting up a design consultation at the Team Lab to ask about material choices for the device.

Conclusions/action items: Set up design consultation at the team lab and conduct more research regarding 3D printed flexible materials.

3/14/2025 - Advisor Meeting 6

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:35 PM CDT

Title: Advisor Meeting 6

Date: 3/14/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To update our advisor and TA on the progress of the project.

Link: N/A

IEEE Citation: N/A

Content: N/A

During this meeting, we updated Dr. McClean and Taylor with our proposed fabrication plan for the development of the prototype for Show and Tell. We showed them the 3D printed parts and took in any advice for changes to the CAD model we could make to improve the prototype.

Conclusions/action items: Work on fabrication of the prototype to be ready for Show and Tell on 3/21/2025.

4/4/2025 - Advisor Meeting 7 with Taylor

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:42 PM CDT

Title: Advisor Meeting 7 with Taylor

Date: 4/4/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To update Taylor on the progress of our project.

Link: N/A

IEEE Citation: N/A

Content: N/A

During this meeting, we updated Taylor with the feedback that we received from Show and Tell before Spring Break. We showed her our prototype and also asked for any advice on how to make sure that the prongs of the Needle Navigator device were in the same plane. Taylor gave us some feedback and we decided we would have to modify the CAD file and print new prongs with the adjustment.

Conclusions/action items: Edit SolidWorks File and 3D print new prongs for the needle navigator device.

4/18/25 - Advisor Meeting 8

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:18 PM CDT

Title: Advisor Meeting 8

Date: 4/18/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To update our advisor and TA on the progress of the project.

Link: N/A

IEEE Citation: N/A

Content: N/A

During this meeting, we discussed our testing plans with Dr. McClean and Taylor. We asked for advice regarding testing outside of the survey testing in order to have quantifiable results for the poster.

Some ideas included:

- Compression testing
- Drop testing
- Needle placement testing
- Max failure load testing

Conclusions/action items:

Finalize testing plan and conduct testing with enough time to put the results on the poster.

2025/2/03-Team PDS Meeting

KSHIRIN ANAND - Feb 07, 2025, 12:05 AM CST

Title: Team PDS Meeting

Date: 2/3/25

Content by: Rini

Present: Team

Goals: To discuss client meeting from earlier today and split up PDS into sections.

Content:

PDS template was created and sections assigned.

Conclusions/action items: Attach submitted PDS.

KSHIRIN ANAND - Feb 07, 2025, 12:05 AM CST

BME Design

Product Design Specifications

Project Title: Needle Navigator: support and control device for image-guided minimally invasive procedures

Client: Dr. Andrew Ross

Advisor: Dr. Megan Modean

Lab Section: Lab 304

TA: Taylor Brendemuehl

Team:

Leader: Ana Toscano
Communicator: Kshirin (Rini) Anand
BSAC,BWIG: Sofia Yeates-Delahoz
BPAG: Gabriela de Vasconcellos Cecon

1

Download

Needle_Navigator_Product_Design_Specifications_PDS_.pdf (645 kB)

2025/2/10 - Team Design Matrix Meeting

SOFIA YEATES-DELAHOZ - Feb 11, 2025, 9:38 AM CST

Title: Team Design Matrix Meeting

Date: 2025/2/10

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: Meet with the team to discuss three preliminary design ideas as well as brainstorm the design matrix criteria.

Citation: N/A

Content:

During this meeting, we brainstormed three preliminary design ideas that are going to be incorporated into the design matrix. We also listened to Ana's inputs from her observing the cervical spine injection procedure on 2/10/2025 at UW Health.

Design ideas: The names of these design ideas are subject to change.

- Between Finger Stabilizer
- Phantom Tissue Guidance Pad
- Modified Scalp Vein Needle

During the meeting, the team also discussed what criteria would be relevant to the design matrix and assigned a specific weighting to each criteria as follows:

- Safety (20)
- Cost (5)
- Ergonomics (30)
- Ease of Use (10)
- Effectiveness (35)

We split up the sections of the design matrix in order for it to be ready for submission at the end of the week. As a team, we discussed next steps and goals for the upcoming week.

Conclusions/action items:

Start working on the design matrix individually and seek help from each other if needed.

Procedure Viewing:

- Sofia: 2/11/25 at 11:45am
- Rini and Gabi: 2/12/15 at 1pm

2025/2/20 - Team Preliminary Presentation Practice Meeting

SOFIA YEATES-DELAHOZ - Feb 26, 2025, 1:57 PM CST

Title: Team Preliminary Presentation Practice Meeting

Date: 2/20/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To practice presenting the preliminary presentation before the presentation date on 2/21.

Link: N/A

IEEE Citation: N/A

Content: N/A

During this meeting, we made some final modifications to the preliminary presentation. We then practiced presenting the presentation multiple times to ensure that everything flowed smoothly and that the presentation was under the time limit of 10 minutes.

Conclusions/action items:

Present at the preliminary presentation on 2/21. Submit slides to canvas and website!

2025/2/24 Brainstorming Design Ideas Team Meeting

SOFIA YEATES-DELAHOZ - Mar 14, 2025, 8:59 AM CDT

Title: Brainstorming Design Ideas Team Meeting

Date: 3/3/2025

Content by: Sofia Yeates-Delahoz

Present: Team

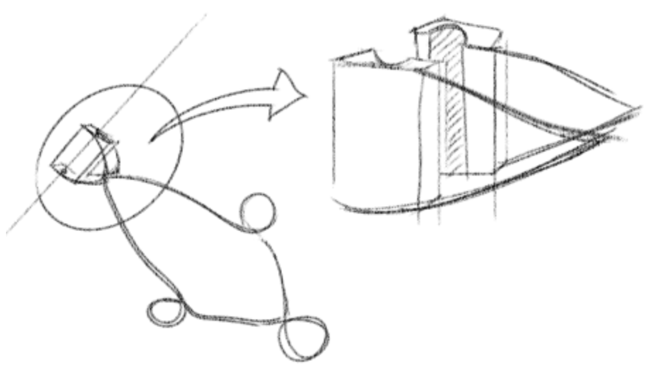
Goals: To brainstorm a new design idea for our final design that includes feedback from the meeting with our client.

Link: N/A

IEEE Citation: N/A

Content:

During this meeting, we used the notes from the client meeting and our client's input and advice to come up with a new final design. The proposed final design was drawn by Gabi. The team brainstormed and discussed potential options for materials. The team also worked on creating a timeline for the remainder of the semester to stay on track with the course of the project.



Conclusions/action items: Begin to work on the CAD for the final design. Research materials available at the Makerspace for the "soft" material.

2025/2/26 Diversity, Inclusion, and Universal Design Considerations

ANA CLARA TOSCANO - Feb 26, 2025, 2:39 PM CST

Title: Diversity, Inclusion, and Universal Design Considerations

Date: February 26, 2025

Content by: Gabriela, Ana, Sofia, Rini

Present: Gabriela, Ana, Sofia, Rini

Goals: Perform an analysis on Diversity, Inclusion, and Universal Consideration and create a action plan to address the 7 ethical principles in the Needle Naviator design considerations.

Link: Code of Conduct | 2025 CMBE Conference

Content:

Title: Diversity, Inclusion, and Universal Design Considerations

Date: February 26, 2025

Content by: Gabriela, Ana, Sofia, Rini

Present: Gabriela, Ana, Sofia, Rini

Goals: Review how diversity and inclusion plays a role in biomedical engineering design

Content:

What does Diversity in Engineering mean in engineering design? (brainstorm):

- Account for different settings, barriers, challenges, backgrounds
- Consider the accessibility of the product/device
- Consider cost/financial classes
- Accessible for different ages and cultures
- Consider how certain ethnicities are predisposed to certain medical conditions and how design could potentially account for that

What does Universal Design mean?

- Design for outliers
- Applies to a universal population
- Provides consistent quality across all groups of a population
- Maximize adjustability
- Account for individual differences
- Have a target audience, but cover all possible users
- Usable by all with no adaptations needed
- Using understandable language and universal symbols

Needle Navigator Design Critiques:

1. Equitable use:

- Needle navigator device needs to be used by people with different hand sizes
    - Male and female surgeons may have different hand sizes

2. Flexibility in Use:

- Should have an adjustable mechanism to accommodate for different hand sizes

3. Simple and Intuitive Use:

- Device needs to be simplified to essential components

4. Perceptible Information

- Design needs to be efficient and effective for the user
- Design needs to allow for the radiologist to still be able to use X Ray fluoroscopy guidance throughout course of procedure

5. Tolerance for Error

- Testing needs to be done to test for tolerance of needle placement

6. Low Physical Effort

- The design does focus on reducing strain for the operator so it does require relative low physical effort
- Testing will make sure this is reached

7. Size and Space for Approach and Use

- If the device is under sterilization, basket/sterilized packaging needs to allow to operator to hold the device without breaking the sterilization

Ethical Considerations:

- If your design does not account for all users during testing then your testing is not ethical
- Testing needs to be done with multiple groups of people
- Design shouldn't offer different levels of quality of treatment based on race, gender, ethnicity, etc
- Inclusivity is important to maintain an ethical device

Conclusions/action items:

- What components of your design can be improved?
    - We can improve equitable use and tolerance for error, as well as adjustability.
- Which of the 7 principles are you addressing?
    - We have in mind all 7 principles, there are just some extra adjustments we should focus on during testing and adapt our design from our testing results.
- How can you make these improvements?
    - By implementing an adjustable mechanism to account for different hand sizes
    - Ensuring the sliding mechanism is steady but smooth and that the locking mechanism works properly for low physical effort
    - Making sure packaging allows the operator to hold the device without breaking sterilization

2025/3/10 Team Timeline Meeting

SOFIA YEATES-DELAHOZ - Mar 14, 2025, 9:04 AM CDT

Title: 3/10/2025

Date: Team Timeline Meeting

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To discuss our current progress on the project and evaluate next steps needed in order to be prepared for Show and Tell.

Link: N/A

IEEE Citation: N/A

Content:

During the meeting, we discussed what we wanted to get accomplished this week and set a timeline for the week for when to work on the project together. We decided to set up a meeting with the Team Lab for a design consultation to gain more insight into how we can design and develop the prototype.

Conclusions/action items:

Start working on the CAD and attend the design consultation meeting at the Team Lab.

2025/03/12 Design Drawings

Gabriela Cecon - Mar 14, 2025, 9:40 AM CDT

Title: Design Drawings

Date: 03/12/2025

Content by: Gabriela Cecon

Present: All

Goals: To outline the progress of our design ideas and their corresponding drawings.

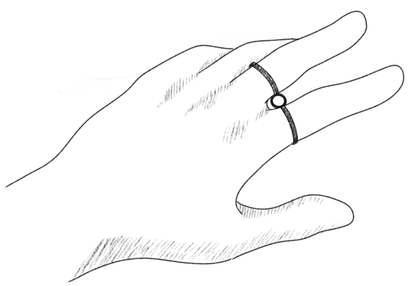
Link: N/A

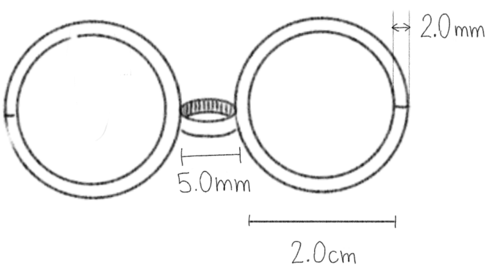
IEEE Citation: N/A

Content:

Preliminary Design 1 - Between Finger Stabilizer

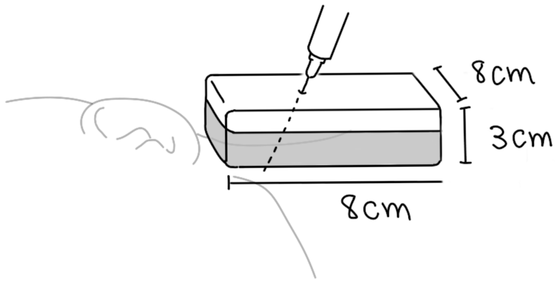
- Consists of two rings that are interconnected via a separate ring that is rotated 90° perpendicular to the two large rings
- The large rings are for the index and middle finger to be inserted in order for the clinician to guide the needle with their fingers
- The hole in between the two rings is where the needle will be inserted into, in which a locking mechanism will hold the needle in place throughout the course of the procedure
- Must be compatible with surgical-grade gloves and must not allow for any tears of gloves during the procedure
- Must also be compatible with the X Ray fluoroscopy guidance to keep needle trajectory visibility clear during the needle injection





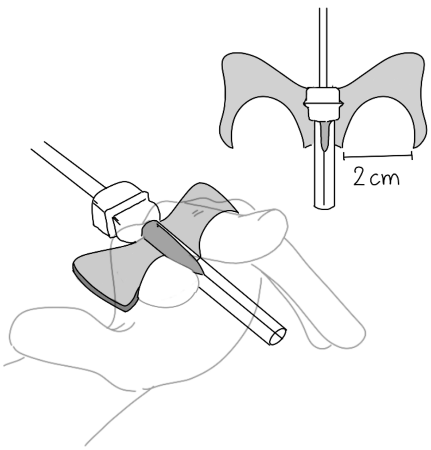
Preliminary Design 2 - Phantom Tissue Guidance Pad

- Provide a backup check of the needle angle and alignment prior to injection into the patient
- The clinician will insert the properly aligned needle into the phantom tissue pad which will be placed above the injection site of the patient
    - If the needle alignment is correct in the Phantom Tissue Guidance Pad, the clinician will insert the needle into the patient and perform the injection
- The advantage of this design is that the material properties of the phantom tissue provide additional stability to the needle when compared to the thin layer of human tissue where doctors insert the needle to check for path alignment, minimizing the need for repeated adjustments



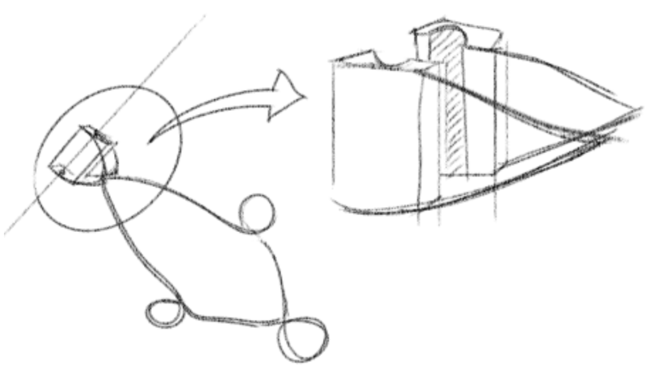
Preliminary Design 3 - Modified Scalp Vein Needle

- Modification of a scalp vein needle device that is commonly used in the market for the collection of blood
- The main modification of the proposed Modified Scalp Vein Needle device is that the flaps on the needle will be rotated 90° perpendicular to the needle
- The needle will be inserted in between the flaps of the modified scalp vein needle and will be controlled via the middle and index fingers
- This device will be customizable to accommodate a range of needle sizes for the different injection procedures



Design 4 - after meeting with client:

- This design consists of a spring clamp mechanism that is naturally in compression to hold the needle
- The jaws will be made of a soft material to avoid breaking the needle
- The design of the springs and the overall aesthetics are still to be fully defined



Conclusions/action items:

- Gather feedback from the design advisor and discuss possible changes
- Finish CAD model of the device
- Print a prototype for show and tell

2025/3/17 3D Scan Meeting at Makerspace

SOFIA YEATES-DELAHOZ - Mar 19, 2025, 1:30 PM CDT

Title: 3D Scan Meeting at Makerspace

Date: 3/17/2025

Content by: Sofia Yeates-Delahoz

Present: Sofia and Ana

Goals: To 3D scan the needle hub of the spinal needle.

Link: N/A

IEEE Citation: N/A

Content:

Ana and I went to the Makerspace to attempt to 3D scan the needle hub of the spinal needle as pictured below. The purpose of this was to get the dimensions of the needle hub in order to develop and design our needle navigator device. The 3D scan was unsuccessful as the needle hub is too small for the 3D scanning device to accurately read and measure the dimensions of the hub. The staff at the Makerspace suggested to use a caliper to measure the dimensions and to reach out to the manufacturer (BD).

Ana and I went to the TeamLab at ECB to measure the dimensions of the needle hub using a caliper.

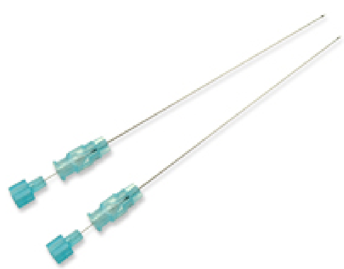


Figure 1: Surgical spinal needle. The teal "cap" is the needle hub.

Conclusions/action items:

Reach out to BD manufacturing for the dimensions of the needle hub.

2025/3/17 Team Meeting - Show and Tell Plan

SOFIA YEATES-DELAHOZ - Mar 19, 2025, 8:02 AM CDT

Title: Team Meeting - Show and Tell Plan

Date: 03/19/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To make a plan for show and tell which will happen on 3/23/25.

Link: N/A

IEEE Citation: N/A

Content: N/A

During this meeting, the team met and discussed what was needed to be done in order to be prepared for show and tell. We went over the CAD model that we designed on 3/14/25.

We also planned out when to 3D print the model and when we would attempt to assemble the prototype. The group also plans to reach out to BD medical device company in order to get the dimensions for the spinal needle hub since the 3D scan at the Makerspace was unsuccessful.

Additionally, the team made plans to find a test tube clamp in order to machine it and cut it at the desired location in order to work with the device. If this is not possible by Show and Tell Date, the team will create a prototype out of cardboard to model the test tube clamp.

Conclusions/action items:

- Email BD
- Print out prototype
- Attempt to assemble prototype at TeamLab
- Find a test tube clamp

2025/3/21 Show and Tell

Gabriela Cecon - Mar 31, 2025, 3:49 PM CDT

Title: Show and Tell

Date: 03/21/2025

Content by: Gabriela Cecon

Present: All

Goals: To document the feedback received during show and tell

Content:

Show and Tell Notes 3/21/25

- make 3D part thicker
- ID stabilizer
- feed one of the "holders" through the other
- make it thicker so there is more stability
- more absorbent material w/ better grip
- "helping hands" idea
  - ↳ set of clips
  - ↳ "soldering"
- add a track so that when it's squeezed together it follows the track - SAME PLANE
- push to unlock
- flattening the end
  - ↳ sanding so that there is more grip
- clear resin for 3D printed
  - ↳ Loctite (glue)

Conclusions/action items:

- Do research on the suggested implementations

2025/3/31 Team Meeting - Planning

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 11:53 AM CDT

Title: Team Meeting - Planning

Date: 3/31/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To plan out the rest of the semester and begin a draft of the executive summary that is due later in the week (4/3).

Link: N/A

IEEE Citation: N/A

Content:

During this meeting, the team discussed and split up the draft of the executive summary for the design awards competition. The team chose to compete in the Tong Award competition.

The team also modified the timeline in order to make sure that everything is complete by the end of the semester.

Conclusions/action items:

Work on the draft of the executive summary and continue working on the project.

2025/4/7 Team Meeting

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:15 PM CDT

Title: Weekly Team Meeting

Date: 4/7/25

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To discuss the executive summary and also discuss further fabrication of the device and any modifications that need to be made.

Link: N/A

IEEE Citation: N/A

Content:

The team planned to create more prototypes with the new CAD file that included the ridges so that the prongs would be on the same plane. The plan was to create the prototypes that were modified after show and tell in order to give them to Dr. Ross and begin testing.

The team also read the comments from the executive summary draft and started making changes in order to finalize the executive summary.

Conclusions/action items:

Fabricate updated prototype and meet with Dr. Ross.

2025/4/14 Team Meeting

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:11 PM CDT

Title: Weekly Team Meeting

Date: 4/14/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To prepare final testing and develop a plan for fabrication by the end of the week.

Link: N/A

IEEE Citation: N/A

Content:

During this meeting, the team discussed the fabrication of the remaining prototypes. There were six prototypes that were built the following day after the meeting. These prototypes were planned to be given to our client Dr. Ross on Thursday 4/17/25 in order for him to conduct testing and pass the devices on to his colleagues. The team started brainstorming other means of testing the device in order to have quantifiable results for the final deliverables. The team also created a survey for the radiologists to fill out with their opinions on the Needle Navigator device.

Conclusions/action items:

Fabricate the remaining devices and give them to the client. Begin testing and finalize the survey.

2025/4/21 Team Meeting

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:08 PM CDT

Title: Weekly Team Meeting

Date: 4/21/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To prepare for the poster presentation at the end of the week and wrap up any final testing of the device.

Link: N/A

IEEE Citation: N/A

Content:

During this team meeting, the team worked on the final poster and decided to have it finalized by Wednesday 4/23/2025 in order to have time to print the poster and get it peer reviewed in class. We also came up with the circle accuracy test idea in order to have a means of results that could be quantified and displayed graphically since the survey results weren't enough to plot on a graph.

The team developed the circle accuracy test with Rini and Sofia each having a Needle Navigator device they would let their friends test out. Gabi was planned to run all the statistical testing and analysis on RStudio.

Conclusions/action items:

Complete Circle Accuracy Testing and work on the final poster.

2025/4/23 Poster Presentation and Tong Pitch Practice Meeting

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 4:43 PM CDT

Title: Poster Presentation and Tong Pitch Practice Meeting

Date: 4/23/2025

Content by: Sofia Yeates-Delahoz

Present: Rini, Ana, Sofia

Goals: To practice for the poster presentation and Tong Pitch.

Link: N/A

IEEE Citation: N/A

Content:

During this meeting the team worked on making final edits for the poster. Ana and Sofia worked on splitting up the pitch for the Tong Design Competition.

Conclusions/action items:

Print out poster and practice presentation independently.

2025/4/24 Poster Presentation Practice Meeting

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:45 PM CDT

Title: Poster Presentation Practice Meeting

Date: 4/24/25

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To practice the presentation for the final poster presentation.

Link: N/A

IEEE Citation: N/A

Content:

During this meeting, the group made some final edits to the poster and then submitted the reprint for the poster. The team practice the presentation multiple times in order to be ready for the poster session.

Conclusions/action items:

Pick up poster and attend poster session!

Materials and Expenses Sheet

Gabriela Cecon - Apr 27, 2025, 3:27 PM CDT

Title: Materials and Expenses Sheet

Date: 03/2025 - 05/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To document the materials used during the prototyping and fabrication process and the expenses associated with them.

Content:

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Category 1										
Needle Holder Jaws	3D-printed PLA needle holder jaws	UW-Madison Makerspace	N/A	N/A	N/A	03/19/2025	2	$0.28	$0.57	N/A
Test Tube Clamp	Labs Stoddard Test Tube Clamp, Stainless Steel with Finger Grips, 6'' Length	SUCOHANS	SUCOHANS-TBC-Unique-Identifier	N/A	N/A	03/19/2025	10	$1.43	$14.28	https://a.co/d/iC2k5td
Needle Holder Jaws #2	3D-printed PLA needle holder jaws	UW-Madison Makerspace	N/A	N/A	N/A	04/01/2025	6	$0.12	$0.73	N/A
Epoxy Adhesive Glue	Hubble Bubble Extra Fast Setting Epoxy	Hardman	4001	N/A	N/A	04/07/2025	1	$1.25	$1.25	N/A
Adhesive Bumpers	Adhesive Rubber Bumpers	ONUEMP	43239-160262	N/A	N/A	04/05/2025	304	$0.03	$9.99	https://a.co/d/43RNYro
								TOTAL:	**$26.82**	

Conclusions/action items:

- For future work:
    - Do further research and attempt fabrication using carbon fiber instead of PLA.
    - Upgrade any necessary materials.

04/15/2025 Fabrication Plan

Gabriela Cecon - Apr 27, 2025, 3:33 PM CDT

Title: Fabrication Plan

Date: 04/15/2025

Content by: Rini Anand

Present: Whole group

Goals: To outline the fabrication plan for the needle navigator prototype.

Content:

Prepare the 3D Print

1. Export the SolidWorks file as a .stl format.
2. Upload the file to Bambu Studio to configure print settings, including material selection, printer type, infill density, layer height, part orientation, and support structures.
3. Review the estimated cost and proceed with payment for the 3D-printed part.

Modify the Test Tube Clamp

1. Secure the test tube clamp in a vise at full extension.
2. Use heavy-duty wire cutters to trim both ends of the clamp at the base of the rectangular end.
3. Remove the clamp from the vise and grit the cut edges using sandpaper.

Assemble the Components

1. Use a rotating forcing to fix the ends of the test tube clamp into the hole of the 3D-printed parts, ensuring proper interlocking.
2. Attach rubber material to the ends of the 3D-printed parts using pre-existing adhesive.

Conclusions/action items:

- Finalize fabricating the prototypes
  - Deliver part of them to the client for clinicians to try and fill out the survey
  - Perform additional testing on the ones the group keeps

04/23/2025 Testing Protocol

Gabriela Cecon - Apr 27, 2025, 2:50 PM CDT

Title: Testing Protocol

Date: 04/23/2025

Content by: Whole group

Present: Whole group

Goals: To establish a testing protocol for the accuracy and stability of the needle navigator prototype.

Content:

Objective: To determine the accuracy and repeatability of the Needle Navigator in guiding needle positioning by evaluating the maximum deviation from a defined trajectory.

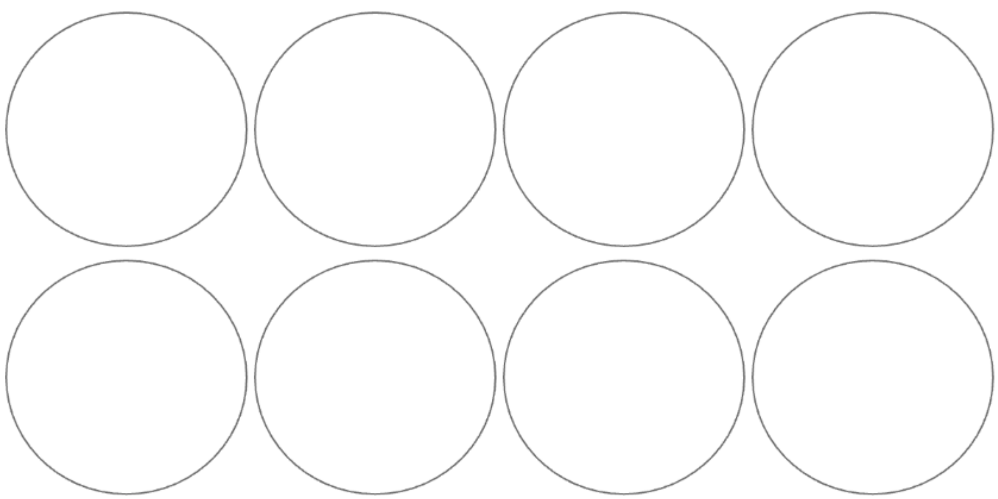
Materials:

- Needle navigator prototype
- Standard pen
- Paper with printed circles
- Flat drawing surface
- ImageJ software statistical analysis

Overall Setup:

- Hold a pencil with the device and align it above the printed test sheet.
- Task: Each participant will attempt to trace directly over the printed circular paths using the device, attempting to match the line as closely as possible.
- Metric Recorded: For each trial, record maximum deviation from the line (inches).
- Each participant will complete 4 trials.

Example From Testing Sheet:



Conclusions/action items:

- Gather data from participants and calculate maximum deviation using ImageJ
- Run a statistical analysis on the data

04/23/2025 Accuracy Testing Raw Data

Gabriela Cecon - Apr 27, 2025, 3:22 PM CDT

Title: Accuracy Testing Raw Data

Date: 04/23/2025

Content by: Sofia and Rini

Present: Sofia and Rini

Goals: To document the accuracy testing results conducted with the needle navigator prototype.

Content:

Participant #	Max Deviation (in)				Mean Max Deviation (in)
	Trial 1	Trial 2	Trial 3	Trial 4	
1	0.303	0.124	0.403	0.08	0.2275
2	0.081	0.088	0.113	0.085	0.09175
3	0.064	0.058	0.068	0.079	0.06725
4	0.051	0.064	0.034	0.04	0.04725
5	0.116	0.049	0.068	0.058	0.07275
6	0.16	0.174	0.109	0.073	0.129
7	0.08	0.114	0.106	0.052	0.088
8	0.071	0.063	0.083	0.073	0.0725
9	0.147	0.072	0.046	0.188	0.11325
10	0.089	0.088	0.086	0.112	0.09375
11	0.126	0.112	0.164	0.145	0.13675
12	0.128	0.084	0.13	0.073	0.10375
13	0.176	0.127	0.119	0.137	0.13975
14	0.065	0.089	0.085	0.109	0.087
15	0.12	0.081	0.153	0.102	0.114
Total					0.1056166667

Conclusions/action items:

- Perform statistical analysis on the experimental data.

04/23/2025 Statistical Analysis

Gabriela Cecon - Apr 27, 2025, 3:12 PM CDT

Title: Statistical Analysis

Date: 04/23/2025

Content by: Gabriela Cecon

Present: Whole group

Goals: To outline the statistical analysis conducted on the data gathered from testing.

Content:

One-tail t-test of the experimental values (using the mean maximum deviation in inches among all participants):

- The threshold used (0.0787402 in) refers to the space between the dura, which is the maximum margin of error of the needle placement without risk of complications.
- Null hypothesis: The experimental mean is equal to or higher than the threshold.
- Alternative hypothesis: the experimental mean is lower than the threshold.

```
data <- read.csv("~/Downloads/BME301 accuracy testing data - Sheet1.csv", header = FALSE)

values <- data[[1]]

# one tail t-test
t.test(values, mu = 0.0787402, alternative ="less")

hist(values, main="Mean Max Deviation
     ")
shapiro.test(values)  # Shapiro-Wilk test for normality
```

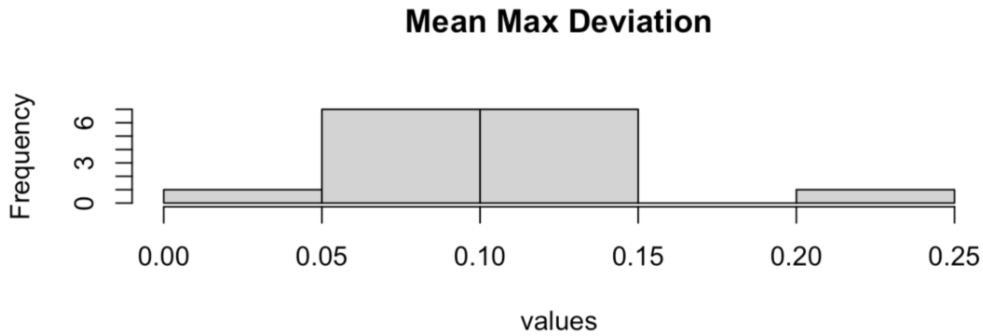
10:56 (Top Level)

Console | Terminal | Background Jobs

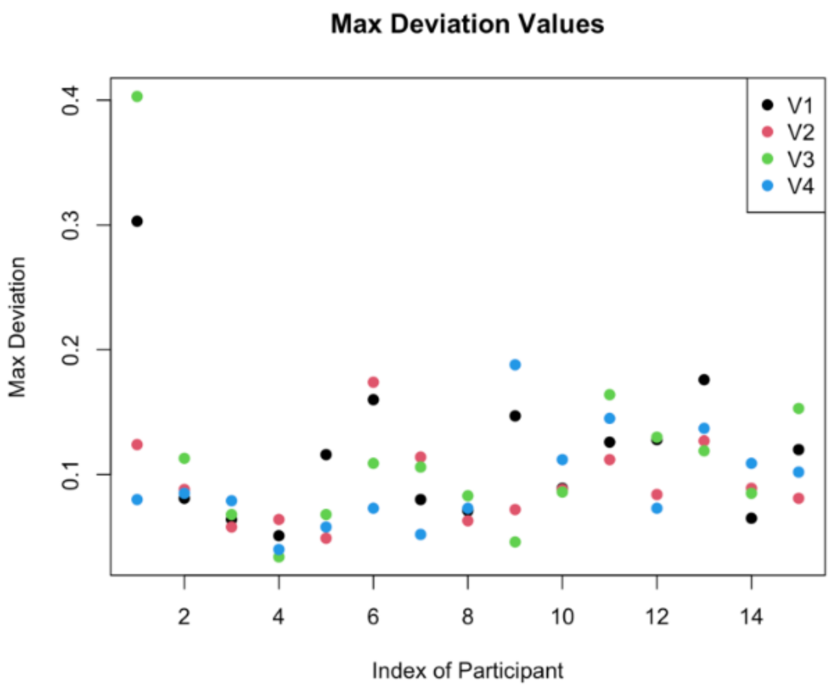
R 4.5.0 · ~/

```
>
> # one tail t-test
> t.test(values, mu = 0.0787402, alternative ="less")

        One Sample t-test

data:  values
t = 2.5965, df = 15, p-value = 0.9899
alternative hypothesis: true mean is less than 0.0787402
95 percent confidence interval:
      -Inf 0.1237625
sample estimates:
mean of x
0.1056167
```

Histogram of Mean Max Deviation (all data points):

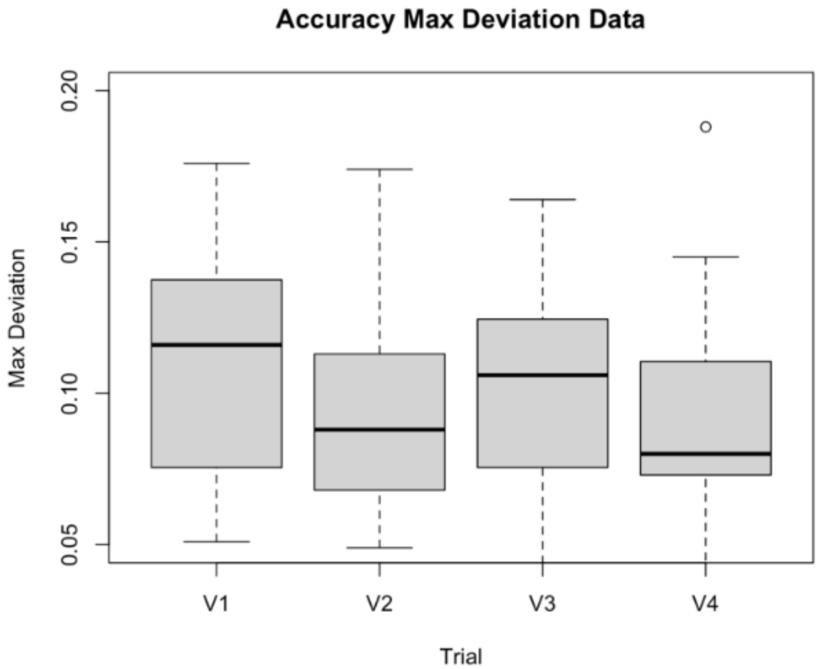


Scatter Plot of Mean Max Deviation (all data points):



where V1-V4 are each of the 4 trials conducted per participant.

Boxplot of Max Deviation (all data points):



Conclusions/action items:

- The t-test result showed that we failed to reject the null hypothesis, since the experimental maximum deviation mean was higher than the safety threshold.
- Further testing must be done with radiologists with more training and dexterous movement.

04/30/2025 Radiologist Survey

Gabriela Cecon - Apr 30, 2025, 6:02 PM CDT

Title: Radiologist Survey

Date: 04/30/2025

Content by: Gabriela Cecon

Present: All group

Goals: To gather feedback from radiologists on ergonomics, ease of use, effectiveness, and safety of the device.

Content:

Questions:

1. After a typical procedure, rate your hand/wrist fatigue level on a scale of 1-5.
2. After performing the procedure with the new tool, rate your hand/wrist fatigue level on a scale of 1-5.
3. Rate the grip comfort of the new cervical injection tool on a scale of 1-5.
4. Rate the weight balance of the tool on a scale of 1-5.
5. Estimate the reduction in procedure time compared to standard tools (0%, 1-25%, 26-50%, 51-75%, or >75%).
6. In general, how would you rate the device? (on a scale of 1-5)
7. (Open Ended) Do you have any suggestions/ concerns/ comments? If the procedure was timed, enter here.

Timestamp	After a typical procedure, rate your hand/wrist fatigue level on a scale of 1-5.	After performing the procedure with the new tool, rate your hand/wrist fatigue level on a scale of 1-5.	Rate the grip comfort of the new cervical injection tool.	Rate the weight balance of the tool on a scale of 1-5.	Estimate the reduction in procedure time compared to standard tools.	In general, how would you rate the device?	Do you have any suggestions/ concerns/ comments? If the procedure was timed, enter here.
4/18/2025 14:03:33	3	5	5	4	1-25%	5	The new device feels much more comfortable in my hands than a standard pair of forceps. I appreciate how smoothly it hinges and that the silicone offers good grip on the object you're holding.

Table 1: Radiologist Survey Raw Data

Conclusions/action items:

- Interview a larger sample size of radiologists
- Add questions about procedure time to analyze quantitative data

PDS Document

SOFIA YEATES-DELAHOZ - Mar 02, 2025, 4:47 PM CST

Title: Product Design Specifications (PDS) Document

Date: 3/2/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To provide documentation of the PDS document in LabArchives for future reference.

Link: N/A

IEEE Citation: N/A

Content:

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Mar 02, 2025, 4:47 PM CST

BME Design

Product Design Specifications

Project Title: Needle Navigator: support and control device for image-guided minimally invasive procedures

Client: Dr. Andrew Ross

Advisor: Dr. Megan Modean

Lab Section:

TA: Taylor Brendemuehl

Team:

Leader: Ana Toscano
Communicator: Kahirin (Rini) Anand
BSAC, BWIG: Sofia Yeates-Delahoz
BPAG: Gabriela de Vasconcellos Cecon

1

Download

Needle_Navigator_Product_Design_Specifications_PDS_.pdf (426 kB)

Needle Navigator Design Matrix

SOFIA YEATES-DELAHOZ - Mar 02, 2025, 4:45 PM CST

Title: Needle Navigator Design Matrix

Date: 2/26/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To provide documentation for the design matrix.

Link: N/A

IEEE Citation: N/A

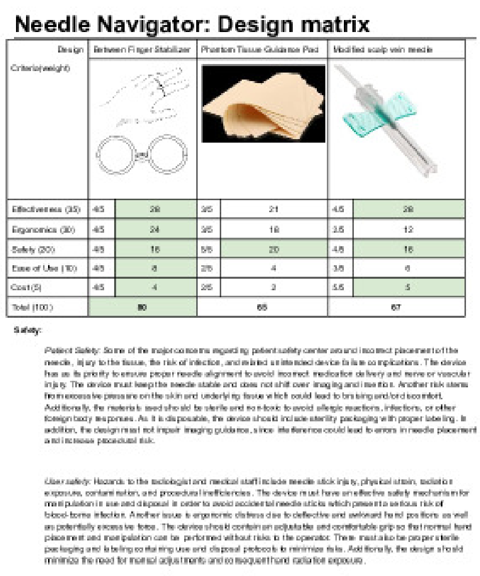
Content:

Attached below is the document containing the design matrix for the three preliminary design ideas for the Needle Navigator device.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Mar 02, 2025, 4:45 PM CST



Needle Navigator: Design matrix

Design / Criteria(weight)	Between Finger Stabilizer		Phantom Tissue Guidance Pad		Modified scalp vein needle	
Effectiveness (35)	4/5	28	3/5	21	4/5	28
Ergonomics (30)	4/5	24	3/5	18	2/5	12
Safety (20)	4/5	16	5/5	20	4/5	16
Ease of Use (10)	4/5	8	2/5	4	3/5	6
Cost (5)	4/5	4	2/5	2	5/5	5
Total (100)	80		65		67	

Safety:

Patient Safety: Some of the major concerns regarding patient safety center around incorrect placement of the needle, injury to the tissue, the risk of infection, and related unintended device failure complications. The device has as its priority to ensure proper needle alignment to avoid incorrect medication delivery and nerve or vascular injury. The device must keep the needle stable and does not shift over imaging and insertion. Another risk stems from excessive pressure on the skin and underlying tissue which could lead to bruising and/or discomfort. Additionally, the materials used should be sterile and non-toxic to avoid allergic reactions, infections, or other foreign body responses. As it is disposable, the device should include sterility packaging with proper labeling. In addition, the design must not impair imaging guidance, since interference could lead to errors in needle placement and increase procedural risk.

User safety: Hazards to the radiologist and medical staff include needle stick injury, physical strain, radiation exposure, contamination, and procedural inefficiencies. The device must have an effective safety mechanism for manipulation in use and disposal in order to avoid accidental needle sticks which present a serious risk of blood-borne infection. Another issue is ergonomic distress due to deflective and awkward hand positions as well as potentially excessive force. The device should contain an adjustable and comfortable grip so that normal hand placement and manipulation can be performed without risks to the operator. There must also be proper sterile packaging and labeling containing use and disposal protocols to minimize risks. Additionally, the design should minimize the need for manual adjustments and consequent hand radiation exposure.

1

Download

Needle_Navigator_Design_Matrix.pdf (488 kB)

Preliminary Presentation

SOFIA YEATES-DELAHOZ - Mar 02, 2025, 4:46 PM CST

Title: Preliminary Presentation PDF

Date: 02/27/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To provide the document of the preliminary presentation for refrence.

Link: N/A

IEEE Citation: N/A

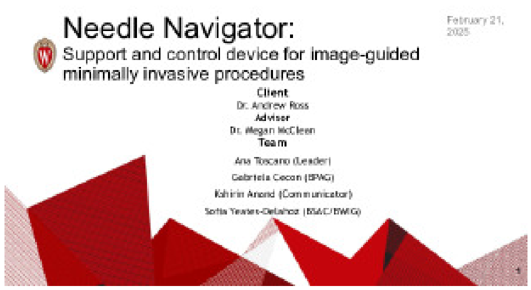
Content:

Attached below is the preliminary presentation pdf.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Feb 27, 2025, 8:51 AM CST



Download

Needle_Navigator_Preliminary_Presentation.pdf (1.18 MB)

Preliminary Report

SOFIA YEATES-DELAHOZ - Mar 02, 2025, 4:46 PM CST

Title: Preliminary Report Document

Date: 02/27/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide file of preliminary report in Lab Archives for reference.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the Preliminary Report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Feb 27, 2025, 8:50 AM CST

BME Design

Needle Navigator Preliminary Report

Project Title: Needle Navigator: support and control device for image-guided minimally invasive procedures

Course Name: BME 301

Date: 02/26/25

Client: Dr. Andrew Ross, University of Wisconsin School of Medicine and Public Health

Advisor: Dr. Megan McClean, University of Wisconsin-Madison Department of Biomedical Engineering

Lab Section: 304

TA: Taylor Brendemuehl

Team:

Leader: Ana Toscano, atoscano2@wisc.edu
Communicator: Kshirin (Rini) Anand, kanand@wisc.edu
BSAC, BWIG: Sofia Yeates-Delahoz, yeatesdelaho@wisc.edu
BPAG: Gabriela de Vasconcellos Cecon, cecon@wisc.edu

1

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Needle_Navigator_Preliminary_Report.pdf (2.21 MB)

Project Timeline

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:11 PM CDT

Title: Project Timeline

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To provide the document for the project timeline.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the project timeline that was used by the team during the last half of the semester.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:11 PM CDT

April 2025

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
*Turn in *Meetings *Team Deadline (TBD)	Team Meeting Final CAD	1 Print CAD	2 Lecture	3 Exec Sum Draft Assemble Final	4 - BSAC Advisor	5 Testing Plan?
6 Testing Plan?	7 Team Meeting	8 Ethics Activity Start Testing	9 Lecture	10 Iterate prototype	11- EXPO	12
13	14 Team Meeting Testing?	15 Testing?	16 Lecture Start Final Deliverables (Poster)	17	18 - BSAC Advisor Exec Sum Final - Noon End testing	19
20	21 Team Meeting	22 Poster Draft (1 per)	23 Lecture	24	25 Final Poster Session	26
27	28 Team Meeting Review Final Deliverables	29	30 Final Deliverables (Reflection due Sun)			

statistical tests suggested (quantitatively - p-values, r-squared) - what the results show me? On average the standard deviation

- Update PDS
- Update Executive Summary
- Work on the Final Report
- Work on the Final Poster

Download

Needle_Navigator_Project_Timeline.pdf (102 kB)

Needle Navigator Final Poster

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:09 PM CDT

Title: Needle Navigator Final Poster

Date: 4/25/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To provide the pdf to the Final Poster.

Link: N/A

IEEE Citation: N/A

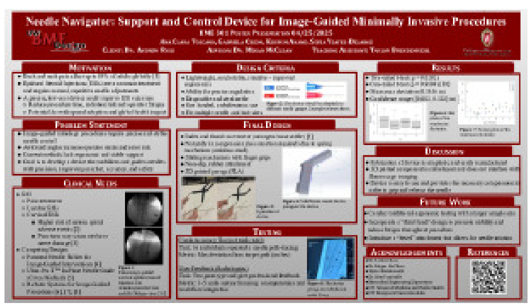
Content:

Attached below is the pdf to the Final Poster.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:09 PM CDT



Download

BME_Needle_Navigator_Poster.pdf (1.59 MB)

Executive Summary

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 12:19 PM CDT

Title:

Date:

Content by:

Present:

Goals:

Link:

IEEE Citation:

Content:

Conclusions/action items:

Engineering Ethics Assignment

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 5:08 PM CDT

Title: Engineering Ethics Assignment

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To consider the ethics in engineering and in the needle navigator device.

Link: N/A

IEEE Citation: N/A

Content: N/A

This assignment was to learn more about ethics in engineering. The team considered what ethics must be considered in the development of the Needle Navigator device and compiled them into this document attached below.

Conclusions/action items:

Continue considering ethics at all stages of the design and development process.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 5:09 PM CDT

Names: Ana, Rini, Gabi, Sofia

Ethics in engineering

The medical device dilemma

Download

Ethics_in_engineering.pdf (261 kB)

Executive Summary Pitch

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 5:10 PM CDT

Title: Executive Summary Pitch

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: Team

Goals: To prepare the executive summary pitch to the judges for the Tong Award.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the document with an outline of the executive summary pitch that will be presented to the judges.

Conclusions/action items:

Practice the pitch and present it to judges at the poster presentation.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 5:11 PM CDT

The **Needle Navigator** is a cost-effective, single-use device designed to enhance **precision, stability, and ergonomics** in minimally invasive spine procedures. It addresses a clear gap in current solutions: while existing devices tend to be **limited by high cost, and only function for specific procedures or even needle sizes.**

Our device bridges this gap. The Needle Navigator ensures intuitive control and improved procedural efficiency for radiologists. It supports a **range of needle gauges** and is **adaptable to different procedural techniques**, making it more inclusive across clinical settings.

Importantly, it is **easily manufacturable** at a cost of under $2 per unit, which makes it highly scalable and **affordable**, especially compared to competing designs. Because it's **disposable and compact**, it fits directly into existing workflows.

In terms of market potential, the global demand for minimally invasive procedures—especially for **cervical radiculopathy and spine pain management**—is rapidly growing. This device offers a **simple, scalable solution** that lowers the barrier for adoption across hospitals and outpatient clinics.

The **Needle Navigator** addresses a critical and growing need in the **$12.3 billion global interventional radiology market** (2022), projected to grow at **7.3% CAGR through 2030**. In parallel, the **minimally invasive spine surgery market** is expected to reach **$20 billion by 2025**, driven by rising demand for procedures that treat conditions like **cervical radiculopathy**, which affects nearly **6.8 million people globally** each year. The **clinical value, user-centered design, and commercial viability** of the design can position it as a standard tool in image-guided spine procedures.

Download

Executive_Summary_Pitch.pdf (51.7 kB)

Needle Navigator Prongs - 3/17/25

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:54 PM CDT

Title: Needle Navigator Prongs CAD File

Date: 3/17/25

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To provide the file for the SolidWorks part.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the SolidWorks file.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:55 PM CDT

Download

Needle_Nav_3_17_25_.SLDPRT (73.8 kB)

Needle Navigator Prongs - 3/19/25

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:55 PM CDT

Title: Needle Navigator Prongs CAD File

Date: 3/19/25

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To provide the file for the SolidWorks part.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the SolidWorks file.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:56 PM CDT

Download

needle_nav_updated_dimensions.SLDPRT (83.6 kB)

Needle Navigator Prongs - 4/1/25

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:58 PM CDT

Title: Needle Navigator Prongs CAD File

Date: 4/1/25

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To provide the file for the SolidWorks part.

Link: N/A

IEEE Citation: N/A

Content:

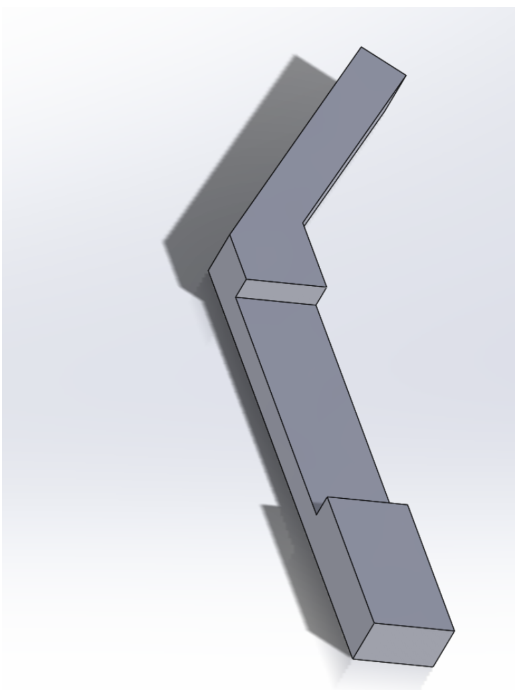


Figure 1: Solidworks image of the prong.

Attached below is the SolidWorks file.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:57 PM CDT

Download

needle_nav_updated_4.1.SLDPRT (76.8 kB)

Needle Navigator Prongs - 4/15/25

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 6:59 PM CDT

Title: Needle Navigator Prongs CAD File

Date: 4/15/25

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To provide the file for the SolidWorks part.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the SolidWorks file for the most recent design.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:00 PM CDT

Download

needle_nav_updated_4.15_final_design.SLDPRT (93.4 kB)

Progress Report 1

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:23 PM CDT

Title: Progress Report 1

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

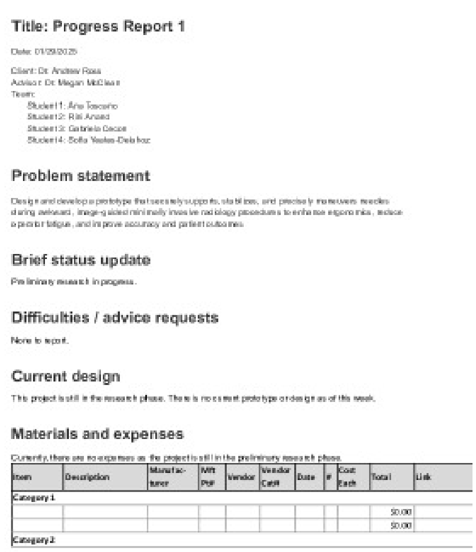
Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:23 PM CDT



Title: Progress Report 1

Date: 01/29/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Rati Anand
Student 3: Gabriela Cecce
Student 4: Sofia Yeates-Delahoz

Problem statement

Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during awkward, image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

Preliminary research in progress.

Difficulties / advice requests

None to report.

Current design

This project is still in the research phase. There is no current prototype or design as of this week.

Materials and expenses

Currently, there are no expenses as the project is still in the preliminary research phase.

Item	Description	Manufac-turer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Category 1										
									$0.00	
									$0.00	
Category 2										

Download

01_30_2025_-_Progress_Report_1.pdf (169 kB)

Progress Report 2

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:24 PM CDT

Title: Progress Report 2

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

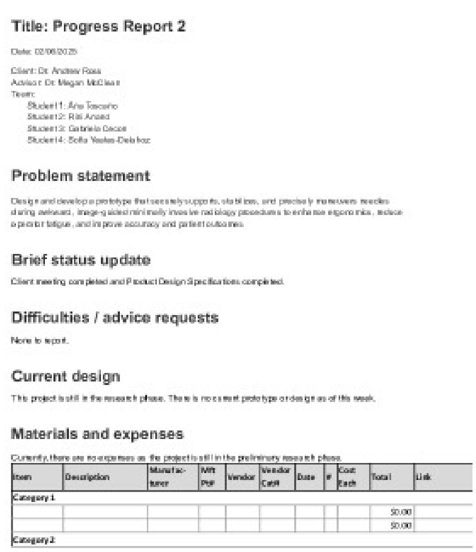
Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:24 PM CDT



Title: Progress Report 2

Date: 02/06/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Rithi Anand
Student 3: Gabriela Cecco
Student 4: Sofia Yeates-Delahoz

Problem statement

Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during awkward, image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

Client meeting completed and Product Design Specifications completed.

Difficulties / advice requests

None to report.

Current design

This project is still in the research phase. There is no current prototype or design as of this week.

Materials and expenses

Currently, there are no expenses as the project is still in the preliminary research phase.

Item	Description	Manufac-turer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Category 1										
									$0.00	
									$0.00	
Category 2										

Download

02_06_2025_-_Progress_Report_2.pdf (132 kB)

Progress Report 3

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:25 PM CDT

Title: Progress Report 3

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:27 PM CDT

Title: Progress Report 3

Date: 02/13/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Rishi Anand
Student 3: Gabriela Cecce
Student 4: Sofia Yeates-Delahoz

Problem statement

Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during awkward, image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

The team watched several cervical injection procedures this week to gain insight on the procedure. The team is currently working on the design matrix for the device.

Difficulties / advice requests

None to report.

Current design

This project is still in the research phase. There is no current prototype or design as of this week.

Materials and expenses

Currently, there are no expenses as the project is still in the preliminary research phase.

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Category 1										
									$0.00	
									$0.00	

[Download](#)

02_13_2025_-_Progress_Report_3.pdf (135 kB)

Progress Report 4

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:27 PM CDT

Title: Progress Report 4

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:28 PM CDT

Title: Progress Report 4

Date: 02/20/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Riti Anand
Student 3: Gabriela Cecon
Student 4: Sofia Yeates-Delahoz

Problem statement

Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during awkward, image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

Team presented the oral preliminary presentation and is brainstorming alternate design ideas as a result of client feedback.

Difficulties / advice requests

None to report.

Download

02_20_2025_-_Progress_Report_4.pdf (398 kB)

Progress Report 5

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:28 PM CDT

Title: Progress Report 5

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:28 PM CDT

Title: Progress Report 5

Date: 02/27/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Riti Anand
Student 3: Gabriela Cecco
Student 4: Sofia Yeates-Delahoz

Problem statement

Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during awkward, image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

Team presented the oral preliminary presentation and is brainstorming alternate design ideas as a result of client feedback.

Difficulties / advice requests

None to report.

[Download](#)

02_27_2025_-_Progress_Report_5.pdf (480 kB)

Progress Report 6

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:29 PM CDT

Title: Progress Report 6

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

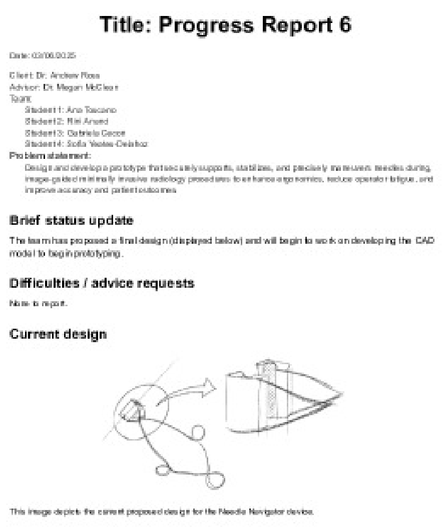
Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:29 PM CDT



Title: Progress Report 6

Date: 03/06/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Rini Anand
Student 3: Gabriela Gecce
Student 4: Sofia Yeates-Delahoz
Problem statement:
Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

The team has proposed a final design (displayed below) and will begin to work on developing the CAD model to begin prototyping.

Difficulties / advice requests

None to report.

Current design

This image depicts the current proposed design for the Needle Navigator device.

Download

03_06_2025_-_Progress_Report_6.pdf (378 kB)

Progress Report 7

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:29 PM CDT

Title: Progress Report 7

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

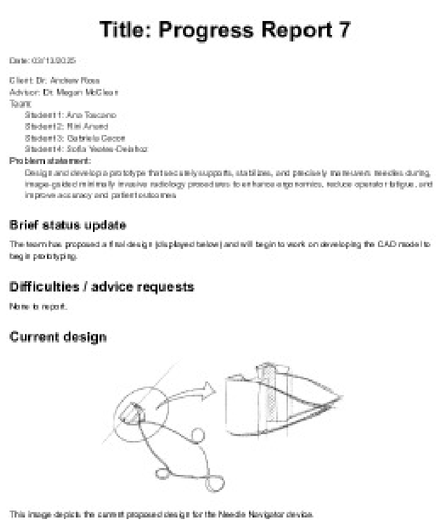
Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:29 PM CDT



Title: Progress Report 7

Date: 03/13/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Rini Anand
Student 3: Gabriela Cecce
Student 4: Sofia Yeates-Delahoz

Problem statement:
Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

The team has proposed a final design (displayed below) and will begin to work on developing the CAD model to begin prototyping.

Difficulties / advice requests

None to report.

Current design

This image depicts the current proposed design for the Needle Navigator device.

Download

03_13_2025_-_Progress_Report_7.pdf (378 kB)

Progress Report 8

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:30 PM CDT

Title: Progress Report 8

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:30 PM CDT

Title: Progress Report 8

Date: 03/20/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Rini Anand
Student 3: Gabriela Gecce
Student 4: Sofia Yeates-Delahoz
Problem statement:
Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

A preliminary CAD model was developed with SolidWorks and printed at UW-Madison Makerspace. Then a test tube holder was cut to fit. After that, a hole was drilled into the plastic pieces and hot glued onto the metal. Foam was also hot glued onto the end.

Difficulties / advice requests

None to report.

Current design

These images depict the current proposed design for the Needle Navigator device.

Download

03_20_2025_-_Progress_Report_8.pdf (906 kB)

Progress Report 9

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:31 PM CDT

Title: Progress Report 9

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:31 PM CDT

Title: Progress Report 9

Date: 04/03/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Riri Anand
Student 3: Gabriela Cecce
Student 4: Sofia Yeates-Delahoz
Problem statement:
Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

After the "Show-and-Tell" event, our group got advice and feedback from TAs and upperclassmen to aid in our design. We are currently implementing and fabricating a new prototype for upcoming testing.

Difficulties / advice requests

None to report.

Current design

A preliminary CAD model was developed with *SolidWorks* and printed at UW-Madison Makerspace. Then a test tube holder was cut to fit. After that, a hole was drilled into the plastic pieces and hot glued onto the metal. Foam was also hot glued onto the end.

Download

04_03_2025_-_Progress_Report_9.pdf (752 kB)

Progress Report 10

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:31 PM CDT

Title: Progress Report 10

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

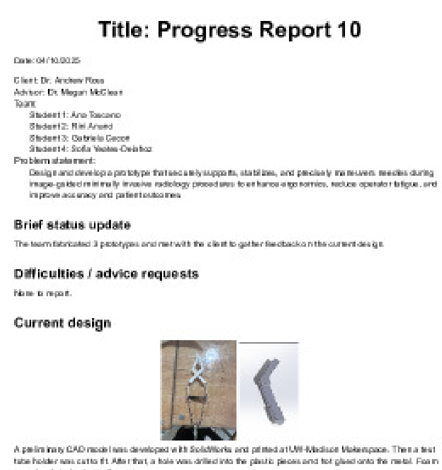
Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:32 PM CDT



Title: Progress Report 10

Date: 04/10/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Riri Anand
Student 3: Gabriela Cecce
Student 4: Sofia Yeates-Delahoz
Problem statement:
Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

The team fabricated 3 prototypes and met with the client to gather feedback on the current design.

Difficulties / advice requests

None to report.

Current design

A preliminary CAD model was developed with *SolidWorks* and printed at UW-Madison Makerspace. Then a test tube holder was cut to fit. After that, a hole was drilled into the plastic pieces and hot glued onto the metal. Foam was also hot glued onto the end.

Download

04_10_2025_-_Progress_Report_10.pdf (747 kB)

Progress Report 11

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:32 PM CDT

Title: Progress Report 11

Date: 4/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: Provide documentation of progress report.

Link: N/A

IEEE Citation: N/A

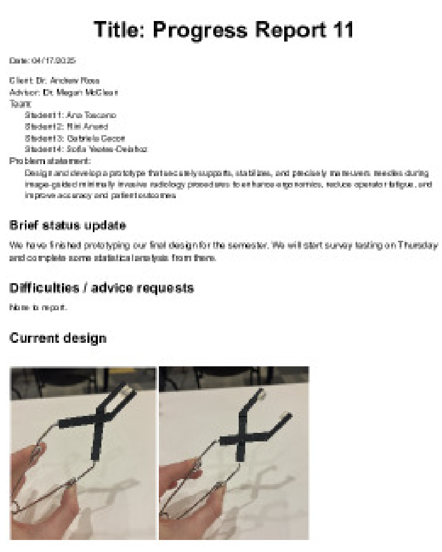
Content:

Attached below is the progress report.

Conclusions/action items:

None.

SOFIA YEATES-DELAHOZ - Apr 30, 2025, 7:32 PM CDT



Title: Progress Report 11

Date: 04/17/2025

Client: Dr. Andrew Ross
Advisor: Dr. Megan McClean
Team:
Student 1: Ana Toscano
Student 2: Rini Anand
Student 3: Gabriela Cecce
Student 4: Sofia Yeates-Delahoz
Problem statement:
Design and develop a prototype that securely supports, stabilizes, and precisely maneuvers needles during image-guided minimally invasive radiology procedures to enhance ergonomics, reduce operator fatigue, and improve accuracy and patient outcomes.

Brief status update

We have finished prototyping our final design for the semester. We will start survey testing on Thursday and complete some statistical analysis from there.

Difficulties / advice requests

None to report.

Current design

[Download](#)

04_17_2025_-_Progress_Report_11.pdf (2.74 MB)

2025/01/29 - Image-Guided Needle Procedures Research

ANA CLARA TOSCANO - Jan 29, 2025, 9:52 PM CST

Title: Summary of Key Points from the Review on Tissue-Mimicking Materials in Image-Guided Needle-Based Interventions

Date: 01/29

Content by: Ana Toscano

Present: Ana Toscano

Link: Tissue mimicking materials in image-guided needle-based interventions_ A review

Citation:

Li, Pan, et al. “Tissue Mimicking Materials in Image-Guided Needle-Based Interventions: A Review.” *Materials Science and Engineering: C*, vol. 93, 10 Sept. 2018, pp. 1116–1131, www.sciencedirect.com/science/article/pii/S0928493118304545?via%3Dihub, https://doi.org/10.1016/j.msec.2018.09.028.

Goals: Guide Material Selection for Specific Medical Applications - Differentiate between materials optimized for needle-tissue interaction, ultrasound imaging, and photoacoustic imaging.

Content:

1. Importance of Tissue-Mimicking Materials in Image-Guided Procedures

- Essential for minimally invasive surgeries (e.g., biopsies, brachytherapy, and interventional radiology).
- Training phantoms (TMMs) are necessary for medical trainees to practice procedures.

2. Imaging Techniques in Image-Guided Procedures

- Common imaging modalities: MRI/CT (high-resolution), and ultrasound (real-time and non-ionizing radiation).

3. Key Material Properties for TMMs

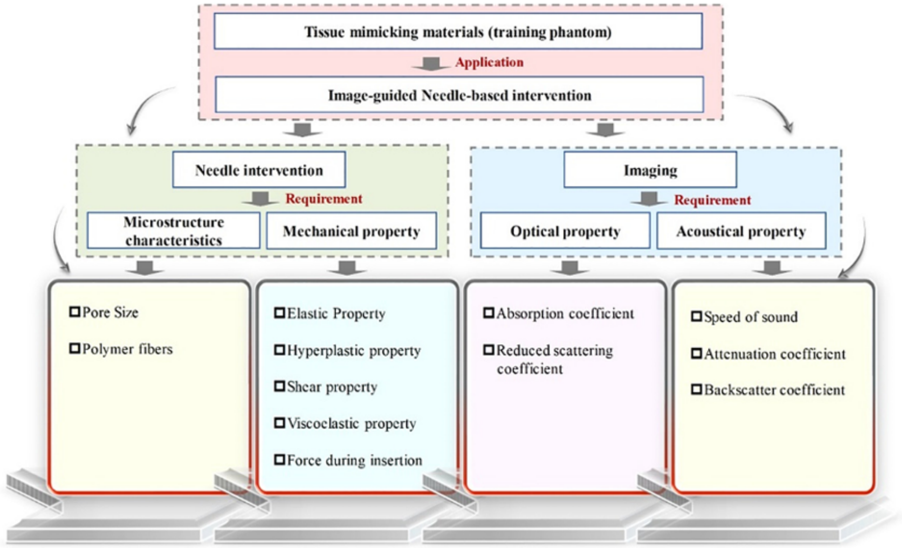


Fig. 1. The framework of the review content showing the connection of the microstructure characteristics, mechanical properties, optical properties, and acoustical properties of the tissue mimicking materials in image-guided needle-based intervention.

4. Common Base Materials for TMMs

- Polyvinyl Alcohol (PVA): Hydrophilic, biocompatible, tunable via freeze-thaw cycles.
- Polyvinyl Chloride (PVC): Used in soft plastics, tunable stiffness, good for ultrasound imaging.
- Gelatin: Low cost, widely used for ultrasound training, but lacks long-term stability.
- Agar/Agarose: Good for ultrasound applications, stable in high water content environments.
- Silicone: Used for long-term phantoms but lacks ultrasound compatibility.

7. Applications and Selection Guidelines

- For Needle-Tissue Interaction Studies: PVA-based materials are preferred due to their tunable mechanical properties.
- For Ultrasound Imaging Training: Gelatin and agar are commonly used due to their acoustic similarities with human tissues.
- For Photoacoustic Imaging: PVC-based materials with optical additives like TiO_2 and carbon black are suitable.

Conclusions/action items: The literature review provides a structured approach to material selection based on procedural priorities - whether optimizing needle insertion mechanics or enhancing imaging clarity.

For a support and control device like the Needle Navigator, mechanical properties such as needle insertion force, elasticity, and viscoelastic response are key factors to ensure the device performs as expected. At the same time, imaging properties must align with clinical modalities (ultrasound, CT, MRI) to validate guidance precision. This comparative review guides material selection for prototyping and testing.

2025/01/30 - Needle Deflection Research

ANA CLARA TOSCANO - Jan 31, 2025, 12:31 PM CST

Title: Needle-tissue interactive mechanism and steering control in image-guided robot-assisted minimally invasive surgery: a review

Date: 01/30

Content by: Ana Toscano

Present: Ana Toscano

Link: Needle-tissue interactive mechanism and steering control in image-guided robot-assisted minimally invasive surgery: a review | Medical & Biological Engineering & Computing

Citation:

Li, Pan, et al. "Needle-Tissue Interactive Mechanism and Steering Control in Image-Guided Robot-Assisted Minimally Invasive Surgery: A Review." *Medical & Biological Engineering & Computing*, vol. 56, no. 6, 21 Apr. 2018, pp. 931–949, https://doi.org/10.1007/s11517-018-1825-0. Accessed 29 Apr. 2023.

Goals: Learn the mechanics of needle-tissue interaction and needle steering control in image-guided robot-assisted minimally invasive surgery.

Content:

Main points: How flexible needles interact with soft tissues, the challenges of needle deflection, and the need for accurate path planning and real-time steering control.

The study provides an in-depth look at force modeling, surgical simulation, path planning, and steering techniques, discussing their applications in medical robotics.

1. Needle-Tissue Interaction & Force Modeling

- Soft tissues are nonlinear and deformable, requiring precise force models to predict needle behavior.
- Interaction forces can be divided into:
  - Stiffness force – Tissue resistance before rupture.
  - Friction force – Resistance along the needle shaft.
  - Cutting force – Force needed to penetrate soft tissue.
  - Fracture force – Sudden force drop when tissue ruptures.

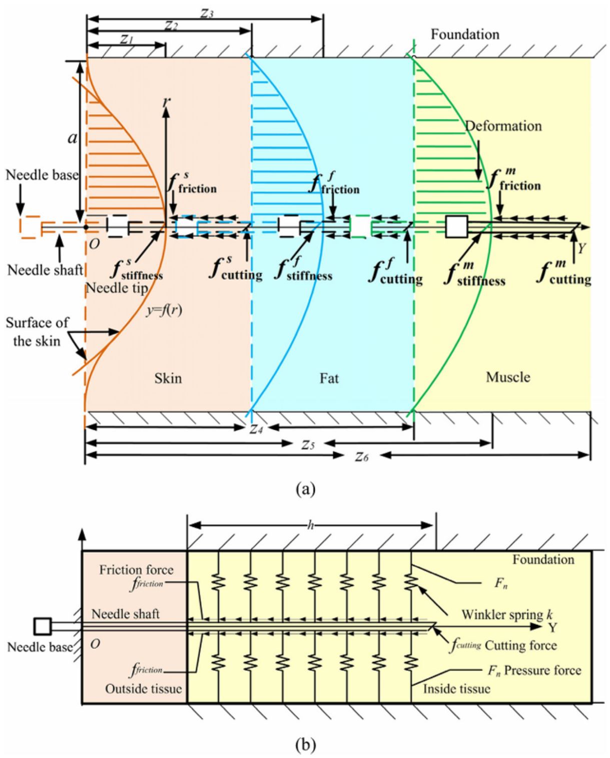


Fig. 3 Stiffness force and friction force of the needle-tissue interaction biomechanical model. **a** Contact model prior to the rupture event. **b** Friction force using modified Winkler foundation after the rupture event [61]

- **Mathematical Force Models:**
  - Okamura Model (2004, 2005): Combines stiffness, friction, and cutting forces.
  - Hunt-Crossley Model: Captures nonlinearity of soft tissues.
  - Energy-based Fracture Model (Mahvash et al.): Uses strain energy concentration to predict rupture.

Important Formulas:

1. **Stiffness Force Model:**
   - $$f_{\text{stiffness}} = \frac{2}{\pi} E r \tan(\alpha) h^2$$
2. **Friction Force Model:**
   - $$f_{\text{friction}} = \mu F_n$$
3. **Fracture Force Model:**
   - $$f_n \propto \sqrt{\frac{K_c A_c}{R}}$$

2. Surgical Simulations for Needle Insertion

- **Computer simulations:** predict needle trajectory and tissue deformation.

- Hyperelastic models (Neo-Hookean, Mooney-Rivlin) for soft tissue elasticity.
- Viscoelastic models (Kelvin-Voigt, Prony series) for tissue relaxation effects.
- Finite Element Models (FEM) predict tissue response to needle insertion.

3. Path Planning for Flexible Needles

- Goal: Ensure accurate targeting while avoiding critical structures (nerves, blood vessels).
- Current path planning techniques:
  - Numerical Methods: Use probability and optimization models to compute the best path.
  - Inverse Kinematics: Calculates optimal needle angles based on the desired target location.
  - Search-Based Algorithms:
    - Artificial Potential Fields: Uses attraction-repulsion models to guide the needle.
    - Rapidly Exploring Random Trees (RRT): Finds multiple feasible paths and selects the best one.

4. Steering Control of Flexible Needles

- Main Steering Challenge: Needles naturally bend due to asymmetric forces from their bevel tip.
- Key Steering Models:
  - Webster's Nonholonomic Model (2006): Treats the needle like a car with restricted turning angles.
  - Energy-Based Steering Model (Misra et al.): Incorporates tissue elasticity and rupture forces.
  - Duty-Cycled Spinning (Minhas et al.):
    - Alternates rotation and insertion to adjust trajectory dynamically.
- **Key Steering Formula (Needle Tip Position in 3D):**

$$n(t) = R_{ab}(t) l_2 e_3 + p_{ab}(t)$$

where:

- R_{ab} = Rotation matrix,
- l_2 = Needle length segment,
- e_3 = Unit vector.

Conclusions/action items: The device must account for needle deflection, tissue resistance, and deformation forces. Force models can help design feedback mechanisms to improve stability. Further research must be made on **duty-cycled spinning, adaptive trajectory corrections, and haptic feedback**.

2025/02/12- Research on Procedure and Fine Adjustments

ANA CLARA TOSCANO - Feb 13, 2025, 9:17 PM CST

Title: New Optimal Needle Entry Angle for Cervical Transforaminal Epidural Steroid Injections

Date: 02/12

Content by: Ana Toscano

Present: Ana Toscano

Goals: Provide valuable information about the importance of needle design and angulation in cervical procedures, which can inform the development of ergonomic needle designs.

Citation:

Karm, Myong-Hwan, et al. “New Optimal Needle Entry Angle for Cervical Transforaminal Epidural Steroid Injections: A Retrospective Study.” *International Journal of Medical Sciences*, vol. 14, no. 4, 1 Jan. 2017, pp. 376–381, pmc.ncbi.nlm.nih.gov/articles/PMC5436480/, https://doi.org/10.7150/ijms.17112. Accessed 14 Feb. 2025.

Content:

This study investigates the optimal needle entry angles for cervical transforaminal epidural steroid injections (CTFESI) and cervical selective nerve root blocks (CSNRB) using fluoroscopically guided anterior oblique approaches. The researchers measured angles at various cervical levels (C3-4 through C7-T1) in 190 patients, finding that the optimal entry angle averaged slightly less than 50 degrees. These findings can inform ergonomic needle design by highlighting the importance of accommodating specific insertion angles to enhance procedural accuracy and safety.

Researchers compared two approaches:

- **Conventional Transforaminal Approach Line (CTAL)** – A commonly used needle insertion angle (~50°).
- **New Transforaminal Approach Line (NTAL)** – A proposed safer alternative (~70°).

Key findings:

- NTAL consistently maintained a greater distance from the VA than CTAL ($P < 0.001$).
- NTAL reduced the risk of VA, internal carotid artery (ICA), and internal jugular vein (IJV) penetration, with zero cases of VA puncture.
- The NTAL method prioritizes the superior articular process (SAP) over the neural foramen (NF) for better safety.

Conclusions/action items: The study concludes that a 70° entry angle (NTAL) is safer than the conventional 50° (CTAL) angle for avoiding vascular injuries. Further clinical trials are needed to validate NTAL’s safety in practice.

2025/01/29 - Needle guidance systems Research

ANA CLARA TOSCANO - Jan 29, 2025, 10:37 PM CST

Title: Summary: Review of Robotic Needle Guide Systems for Percutaneous Intervention

Date: 01/29

Content by: Ana Toscano

Present: Ana Toscano

Link: Review of Robotic Needle Guide Systems for Percutaneous Intervention | Annals of Biomedical Engineering

Citation:

Kulkarni, Pankaj, et al. “Review of Robotic Needle Guide Systems for Percutaneous Intervention.” *Annals of Biomedical Engineering*, vol. 47, no. 12, 31 July 2019, pp. 2489–2513, https://doi.org/10.1007/s10439-019-02319-9. Accessed 30 Jan. 2025.

Goals: Compare interventions - Organize and analyze robotic needle guidance systems used in MRI, CT, ultrasound (US), and multi-imager-compatible setups.

Content:

*Note: percutaneous interventions—procedures requiring needle insertion through the skin for purposes like biopsy, drug delivery, and tumor ablation.

1. **Imaging Modalities**
   - Most systems use MRI, CT, or Ultrasound (US) for real-time guidance, though some function without image feedback.
   - MRI-guided systems dominate recent research due to their superior soft-tissue visualization.
2. **Robotic Systems**
   - Robots provide manual assistance (e.g., needle guides) or fully automated needle placement.
   - MRI-compatible robots often use pneumatic, piezoelectric, or ultrasonic actuation to avoid magnetic interference.
   - CT and US systems use DC motors, hydraulic, and pneumatic actuators.
3. **Material Considerations**
   - MRI-compatible robots use plastics (PEEK, Delrin, ABS), non-ferrous metals (titanium, brass, copper), and ceramics.
   - CT systems require X-ray transparency, using carbon fiber and polymers.
4. **Image Compatibility & Performance**
   - MRI robots undergo signal-to-noise ratio (SNR), image distortion, and homogeneity tests.
   - CT robots are evaluated for artifact production.

CT Robotic System Examples

- Motorized needle positioning robots that operate outside the CT scanner and are manually adjusted after CT confirmation.
- Image-tracked robotic arms that adjust needle trajectories before insertion, based on pre-acquired CT scans.
- Robot-assisted C-arm fluoroscopy systems, which combine real-time x-ray guidance with robotic precision.

Robotic System Examples

- Teleoperated US-guided robots, where an operator controls the robotic arm remotely.
- Needle insertion guides with robotic precision, allowing for steady and accurate movement even with patient motion.
- Robotic-assisted freehand US scanning systems to improve reproducibility in image acquisition.

Conclusions/action items: These insights contribute to understanding the design considerations of the project. Each imaging modality imposes unique requirements on robotic systems, affecting material selection, actuation methods, and system integration.

CT Design Considerations

- CT imaging involves ionizing radiation, requiring low-radiation-exposure workflows.
- Robot positioning must be precise since real-time CT imaging is limited.
- High-density metal components can cause artifacts in CT images, necessitating the use of low-density radiolucent materials

Ultrasound (US)- Design Considerations

- Ultrasound is real-time, which enables dynamic tracking but requires the robot to compensate for tissue movement.
- Contact-based imaging means the robotic system must stabilize and maintain proper probe-to-skin contact.
- Acoustic coupling materials must be considered to ensure image clarity.

2025/01/30 - Assessment of Needle Guidance Devices Research

ANA CLARA TOSCANO - Jan 30, 2025, 1:05 PM CST

Title: Assessment of Needle Guidance Devices for Their Potential to Reduce Fluoroscopy Time and Operator Hand Dose during C-Arm Cone-Beam Computed Tomography–guided Needle Interventions

Date: 01/30

Content by: Ana Toscano

Present: Ana Toscano

Link: [Assessment of needle guidance devices for their potential to reduce fluoroscopy time and operator hand dose during C-arm cone-beam computed tomography-guided needle interventions - PubMed]

Citation:

Kroes, Maarten W., et al. "Assessment of Needle Guidance Devices for Their Potential to Reduce Fluoroscopy Time and Operator Hand Dose during C-Arm Cone-Beam Computed Tomography–Guided Needle Interventions." *Journal of Vascular and Interventional Radiology*, vol. 24, no. 6, June 2013, pp. 901–906, https://doi.org/10.1016/j.jvir.2013.02.037. Accessed 30 Nov. 2021.

Goals: The primary goal is to compare needle guidance systems. The study evaluates their ability to reduce fluoroscopy time and operator hand dose during CT-guided needle interventions.

Content:

The freehand technique was compared with two needle holders and a ceiling-mounted laser guidance system, used separately and in combination.

Important Findings

- Fluoroscopy Time Reduction:
  - Freehand technique: 50 seconds (31–98 s).
  - Laser guidance (alone or combined with needle holders): Reduced fluoroscopy time to ~30 seconds ($P < 0.02$).
  - Needle holders alone: No significant reduction in fluoroscopy time.
- Operator Hand Dose Reduction: (dose reduction is good)
  - Freehand technique: 275 mSv (20–603 mSv).
  - Laser guidance (alone or combined with holders): Reduced dose to ≤36 mSv ($P < 0.001$).
  - Needle holders alone: No significant reduction in hand dose.
- Procedure Time**:**
  - Laser guidance prolonged procedure time by only a few minutes, which is unlikely to impact clinical workflow.
- **Accuracy:**
  - No significant differences in accuracy between techniques.

Conclusions/action items: Laser guidance significantly reduces radiation exposure by decreasing both fluoroscopy time and operator hand dose without compromising accuracy. Compared to the freehand technique, laser-guided interventions offer a safer, more efficient, and equally precise alternative while maintaining tactile feedback for the operator. The reduced need for corrective needle manipulations helps prevent direct exposure to the primary X-ray beam, making procedures safer for interventional radiologists.

Future Considerations: **Automated laser-assisted targeting** to provide visual guidance for optimal needle alignment before the first insertion

2025/02/12- Research on Navigation System for Needle Guidance

ANA CLARA TOSCANO - Feb 13, 2025, 8:56 PM CST

Title: Ultrasound-guided needle tracking with deep learning: A novel approach with photoacoustic ground truth

Date: 02/12

Content by: Ana Toscano

Present: Ana Toscano

Goals: During the procedure, I noticed the team spent the longest time determining where to place the needle and making it. I decided to research an interface we could incorporate for the design.

Citation:

Hui, Xie, et al. "Ultrasound-Guided Needle Tracking with Deep Learning: A Novel Approach with Photoacoustic Ground Truth." *Photoacoustics*, vol. 34, 1 Dec. 2023, p. 100575, www.sciencedirect.com/science/article/pii/S2213597923001283?via%3Dihub, https://doi.org/10.1016/j.pacs.2023.100575. Accessed 24 Apr. 2024.

Content:

1. Importance of FD-CT-Guided Robotic Navigation

- **Flat Detector CT (FD-CT) imaging** provides high-resolution, real-time 3D visualization, improving precision in needle placement.
- **Robotic-assisted needle guidance** reduces operator variability and enhances procedural accuracy, particularly in complex anatomical regions.

2. Deep Learning Integration for Needle Tracking

- **Photoacoustic (PA) imaging** combined with deep learning models like **UIU-Net** improves real-time needle visibility in FD-CT-guided procedures.
- AI-driven segmentation enhances **needle localization**, reducing the need for repeated scans and manual adjustments.

3. Potential Enhancements

- **Material optimization** to ensure CT visibility and compatibility with robotic systems.
- **Real-time tracking algorithms** to adjust stabilization dynamically during the procedure.
- **Force-feedback integration** for robotic-assisted needle guidance, minimizing resistance and improving tactile control.

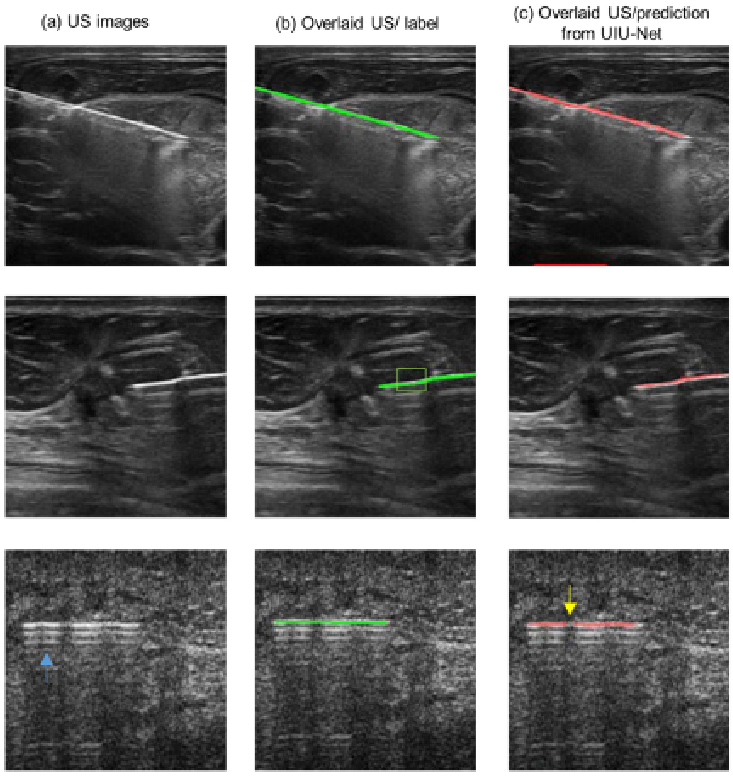


Fig. 6. Representative images with needle insertions into the human body. (a) conventional US images, (b) overlaid US image with ground truth (manual label shown in green), (c) overlaid US image with prediction from UIU-Net.

Conclusions/action items: We could integrate the device with robotic FD-CT-guided systems to ensure precise needle angulation and fixation. During the procedure, I noticed the team spent the longest time determining where to place the needle and making it. We could discuss a way the Between Finger Stabilizer could serve as an interface between manual handling and robotic assistance, improving usability.

2025/02/12 - Research on Smartphone-Guided Needle Angle Selection

ANA CLARA TOSCANO - Feb 13, 2025, 9:07 PM CST

Title: Smartphone-Guided Needle Angle Selection During CT-Guided Procedures

Date: 02/12

Content by: Ana Toscano

Present: Ana Toscano

Goals: This study presents a smartphone-based guidance system with real-time feedback designed to assist in needle angle selection during CT-guided interventions.

Citation:

Xu, Sheng, et al. “Smartphone-Guided Needle Angle Selection during CT-Guided Procedures.” *American Journal of Roentgenology*, vol. 210, no. 1, 1 Jan. 2018, pp. 207–213, https://doi.org/10.2214/ajr.17.18498. Accessed 22 Feb. 2024.

Content:

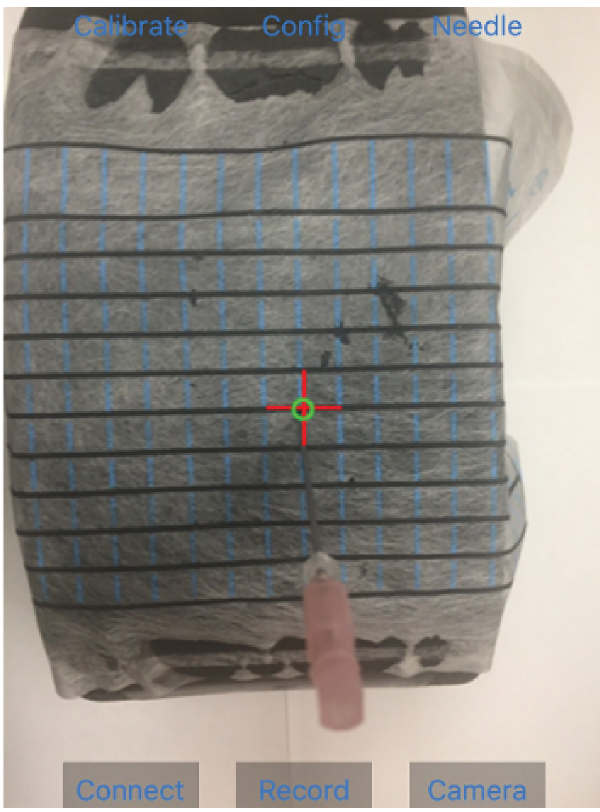


Fig. 6B —Photographs show smartphone in Bull's-Eye View mode. Config = Configure.

B, Step 2: Hold camera perpendicular to needle path (*circle over cross*).

1. Angle Guidance in Two Modes:
    - Guideline Mode: Displays a green reference line on the smartphone screen to visually compare with the needle’s actual angle.
    - Bull’s-Eye View Mode: When held perpendicular to the needle path, the screen provides a targeting crosshair, ensuring the hub aligns with the tip.
2. One-Touch Calibration:
    - The smartphone is calibrated by touching its edge to the CT table, aligning its coordinate system with the CT scanner’s.
3. Experimental Results:

  - Significantly reduces targeting error and enhances needle placement accuracy compared to CT-only guidance.
- Low-cost and widely available (compatible with standard smartphones).
- Does not require additional disposable materials
- Reduces reliance on the physician's visuospatial ability, making it particularly beneficial for less-experienced operators. (training)

Limitations & Future Improvements:

- Manual smartphone handling may require a passive holder or smart glasses for better usability.

Conclusions/action items: This smartphone-based navigation system could be combined with your needle stabilizer. This hybrid approach would offer a high-precision, low-cost, and user-friendly solution for cervical injections and other image-guided interventions.

2025/02/12- Research comparing smartphone and virtual reality glasses

ANA CLARA TOSCANO - Feb 14, 2025, 12:09 PM CST

Title: Smartphone- versus smartglasses-based augmented reality (AR) for percutaneous needle interventions: system accuracy and feasibility study

Date: 02/12

Content by: Ana Toscano

Present: Ana Toscano

Goals: Determine a good interface to combine to the physical design

Citation:

Li, Ming, et al. “Smartphone- versus Smartglasses-Based Augmented Reality (AR) for Percutaneous Needle Interventions: System Accuracy and Feasibility Study.” *International Journal of Computer Assisted Radiology and Surgery*, vol. 15, no. 11, 30 July 2020, pp. 1921–1930, https://doi.org/10.1007/s11548-020-02235-7.

Content: This study evaluates an augmented reality (AR) platform for percutaneous needle interventions, comparing its use on smartphones (iPhone 7) and smartglasses (HoloLens 1). The goal was to assess the accuracy, feasibility, and efficiency of both AR devices in guiding needle placement compared to conventional CT-guided freehand navigation.

Methods

- The AR system was designed to overlay preprocedural imaging data and planned needle trajectories onto the patient in real time.
- A 3D-printed phantom was used to evaluate system accuracy, measuring target overlay errors (distance between actual and virtual targets) and needle overlay angles (difference between actual and virtual needle paths).
- Three operators placed needles into targets using iPhone AR, HoloLens AR, and CT-guided freehand.
- Needle placement accuracy and time were measured using post-placement CT scans.

Results

- Accuracy: Both AR devices had comparable target overlay accuracy (~1.75mm error) and needle overlay angle accuracy (~0.3° error).
- Needle placement error:
  - iPhone AR: 2.58 ± 1.04mm (most precise)
  - HoloLens AR: 3.61 ± 2.25mm
  - CT-guided freehand: 15.92 ± 8.06mm (least precise)
- Needle placement time:
  - iPhone AR: 87 ± 17s
  - HoloLens AR: 71 ± 27s
  - CT-guided freehand: 19 ± 17s (fastest but least accurate)

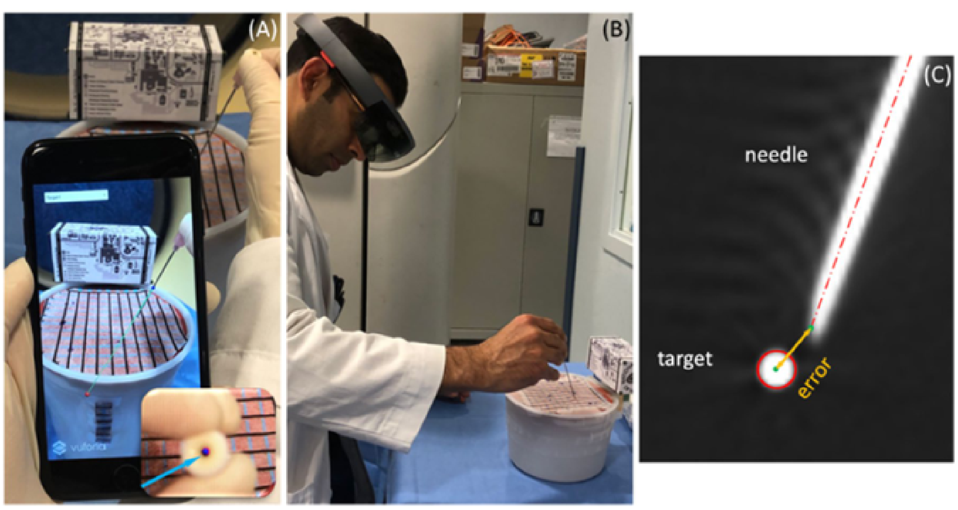


Fig. 4 Workflow for experiment 2: comparison of needle placement performance. **a** Smartphone-guided needle placement. The needle was advanced along its planned AR path. Accurate alignment is indicated by the superimposition of the needle (silver) and AR trajectory (green). The inset image shows the bull's eye view, in which the AR needle path, target (red dot), and needle end (blue dot) are superimposed in the center of the needle hub. **b** Smartglasses-guided needle placement. **c** Postoperative measurement of needle placement error, defined as the distance from the needle tip to the center of the target bead (red circle)

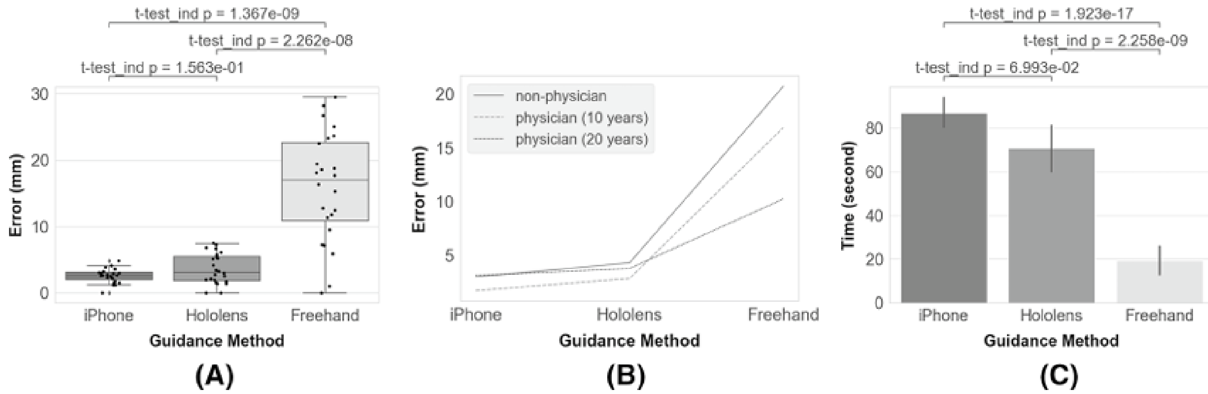


Fig. 7 Results of experiment 2: comparison of needle placement performance. **a** Comparative box-and-whisker plot of the needle placement error for the AR smartphone, AR smartglasses, and CT-guided freehand navigation. Each dot represents a measurement of error for each insertion. **b** Spaghetti plot showing the needle placement error for operators of various experience. **c** Comparative bar graph of the needle placement time for the AR smartphone, AR smartglasses, and CT-guided freehand navigation. Results are shown as mean ± SD

Conclusions/action items: Smartphone-based AR provided better precision but required holding the device, increasing procedure time. Smartglasses offered hands-free operation but had limitations in the field of view and depth perception, making needle alignment more difficult.

2025/02/06 - Research on Environment Specification

ANA CLARA TOSCANO - Feb 07, 2025, 12:39 PM CST

Title: Needle-based injection systems for medical use - Requirements and test methods

Date: 2025/02/06

Content by: Ana Toscano

Present: Ana Toscano

Goals: Determine requirements for the device - specifically in the section of environment. The parameters will be useful in our design matrix

Link: [ISO - 11608-1 - Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems | GlobalSpec]

Citation:

“ISO - 11608-1 - Needle-Based Injection Systems for Medical Use — Requirements and Test Methods — Part 1: Needle-Based Injection Systems | GlobalSpec.” *Globalspec.com*, 2022, standards.globalspec.com/std/14505709/11608-1. Accessed 6 Feb. 2025.

Content:

1. **Scope & Applicability**
    - Covers **needle-based injection systems (NISs)** for single-patient use in intradermal, subcutaneous, or intramuscular drug delivery.
    - Includes **single and multi-dose systems**, both disposable and reusable.
    - Applies to devices with **pre-filled, user-filled, replaceable, or non-replaceable containers**.
2. **General Design Requirements**
    - Ensures **safe and effective use** with a focus on **ergonomics and user safety**.
    - Minimizes **risk of accidental needle sticks** and enhances usability.
3. **Performance Requirements**
    - **Dose Accuracy:** Must deliver the intended dose within defined accuracy limits.
    - **Functional Stability:** Device must maintain performance over its **shelf life** and **intended usage conditions**.
4. **Testing & Verification**
    - **Dose Accuracy Testing:** Confirms dose delivery within tolerance levels.
    - **Environmental Testing:** Ensures performance in varying temperature and humidity conditions.
    - **Mechanical Testing:** Evaluates robustness through **shock, vibration, and durability tests**.
    - **Usability Testing:** Assesses **activation force, user interaction, and instruction clarity**.

5. **Risk Management**
    - **ISO 14971:2019 compliance**: Requires a **risk-based approach** in design and development.
    - Identifies potential **hazards, assesses risks, and implements mitigations**.

6. **Labeling & Information**

    - Requires **clear labeling and instructions** for safe use.
    - Must include **device identification, usage instructions, and limitations**.

7. **Integration with Other Standards**

    - **ISO 11608 series**includes additional parts:
        - **Part 2:** Double-ended pen needles
        - **Part 3:** Containers and integrated fluid paths
        - **Part 4:** Needle-based injection systems with electronics
        - **Part 5:** Automated functions
        - **Part 6:** On-body delivery systems
        - **Part 7:** Accessibility for visually impaired users

Conclusion

Adhering to **ISO 11608-1:2022** ensures compliance with **international standards** for **safety, performance, and quality** in needle-based injection systems.

Conclusions/action items:

2025/02/06 - Research on Possible Environment Requirement

ANA CLARA TOSCANO - Feb 06, 2025, 9:19 PM CST

Title: Comparative Table of Operating Table and Radiology Patient Placement Heights

Date: 2025/02/06

Content by: Ana Toscano

Present: Ana Toscano

Goals: Research on structural Integrity and Mechanical Resilience of Cirurgical Device Under Impact and Vibration

Citation:

1. **“STERIS 4085 General Surgical Table.”** Avante Health Solutions, 2025, www.avantehs.com/learn/buying-guides/surgical-table-brand-comparison. Accessed 6 Feb. 2025.

2. **“Maquet 1180 Series (Magnus) Surgical Table.”** Meditek, 2025, www.meditek.ca/general-surgery-table-review-comparison-popular-brands-models. Accessed 6 Feb. 2025.

3. **“Skytron 3603 Surgical Table Overview.”** Didage, 2025, www.didage.com/blogs/news/what-to-know-about-used-surgical-tables. Accessed 6 Feb. 2025.

4. **“STERIS 7080 General Surgical Table for Operating Rooms.”** Steris.com, 2025, www.steris.com/healthcare/products/surgical-tables/steris-7080-general-surgical-table. Accessed 6 Feb. 2025.

5. **“Radiology Exam Tables for Patient Positioning.”** RadiologyInfo.org, 2025, www.radiologyinfo.org. Accessed 6 Feb. 2025.

6. **“Fluoroscopy Patient Table Specifications.”** Siemens Healthineers, 2025, www.siemens-healthineers.com. Accessed 6 Feb. 2025.

7. **“MRI Scanner Table Design and Specifications.”** GE Healthcare, 2025, www.gehealthcare.com. Accessed 6 Feb. 2025.

8. **“CT Scanner Table Features and Adjustability.”** Philips Healthcare, 2025, www.usa.philips.com/healthcare. Accessed 6 Feb. 2025.

Content:

Table/Surface Name	Height Range (meters)	Key Features	Source
STERIS 4085 General Surgical Table	0.66 – 1.14 m	Versatile for multiple specialties, 30°/30° Trendelenburg, 1,100 lb capacity	Avante Health Solutions
Maquet 1180 Series (Magnus)	0.53 – 1.23 m	Wide height range, X-ray compatible, inclination angles up to 80°	Meditek
Skytron 3603 Surgical Table	0.52 – 1.00 m	High articulation capacity, 40° Trendelenburg, 35° lateral tilt	Didage
STERIS 7080 General Surgical Table	0.56 – 1.14 m	22" (0.56 m) longitudinal slide, 700 lb capacity, 45° Trendelenburg	**"STERIS 7080 General Surgical Table for Operating Rooms." Steris.com, 2025,** www.steris.com/healthcare/products/surgical-tables/steris-7080-general-surgical-table**. Accessed 6 Feb. 2025.**
Radiology Exam Tables (General Use)	0.46 – 1.02 m	Adjustable height, padded for patient comfort	RadiologyInfo.org
Fluoroscopy Patient Table	0.63 – 1.22 m	Movable patient surface, motorized height adjustment for imaging precision	Siemens Healthineers
MRI Scanner Table	0.46 – 0.86 m	Low height for easy patient access, slides into scanner bore	GE Healthcare
CT Scanner Table	0.56 – 0.97 m	Raises/lowers automatically, motorized movements for precision	Philips Healthcare

Conclusions/action items: The device must also be mechanically resilient, and capable of withstanding minor handling impacts, such as drops from a standard table height (~1.14m) and vibrations during transport.

2025/02/06 - Hand measurement Ergonomics

ANA CLARA TOSCANO - Feb 06, 2025, 8:38 PM CST

Title: Research on Hand Measurement Ergonomics

Date: 2025/02/06

Content by: Ana Toscano

Present: Ana Toscano

Goals: Determine key characteristics the device must have to accommodate various sizes.

Citation:

Wang, Ching-yi, and Deng-chuan Cai. "Hand Tool Handle Design Based on Hand Measurements." *MATEC Web of Conferences*, vol. 119, 2017, p. 01044, www.matec-conferences.org/articles/matecconf/pdf/2017/33/matecconf_imeti2017_01044.pdf, https://doi.org/10.1051/matecconf/201711901044. Accessed 15 Oct. 2019.

Content:

This study aims to establish ergonomic guidelines for designing hand tool handles based on anthropometric hand measurements (values: improve grip comfort and efficiency while reducing musculoskeletal strain).

Key Findings

1. **Handle Design Considerations**
    - Handle dimensions should be based on **hand length and handbreadth**.
    - The **minimum handle length should be 100 mm** to accommodate 95% of workers.
    - The ideal **width-to-length ratio** of the handle cross-section is **1:1.25**.
    - The handle diameter should range between **30 mm to 40 mm** for optimal comfort.
    - The **grip diameter should be about 19.7% of hand length** for an ergonomic fit.
2. **Handle Slope and Grip Angles**
    - Pistol-shaped handles should have a **78° tilt**.
    - A **20° to 40° tilt** in hammer handles can reduce wrist strain.
    - For linear handles, the **grip central line and forearm shaft** should form a **110° angle**.

Methodology

- **Participants:** 60 adults (30 male, 30 female), average age 31.2 years.
- **Hand Measurements:** Taken using a caliper on the right hand.
- **Key Measurements:**
    - **Hand length**
    - **Handbreadth**

- **Grip breadth (inside width and length diameters)**

Results & Discussions

1. **Hand Dimensions**

- **Average Hand Length:**
  - Males: **187.9 mm**, Females: **167.9 mm**.
- **Average Hand Breadth:**
  - Males: **83.6 mm**, Females: **75.2 mm**.

Conclusions/action items:

Table 2. The results of hand dimensions (unit: mm) (standard deviation of the mean in parentheses).

item		This study		Wang et al. (2002)
male	A hand length	187.9	(7.9)	183
	B hand breadth (four fingers)	83.6	(4.8)	86
	C grip breath inside width diameter	44.5	(5.3)	-
	D grip breath inside length diameter	35.6	(4.9)	-
female	A hand length	167.9	(6.6)	167
	B hand breadth (four fingers)	75.2	(6.2)	75
	C grip breath inside width diameter	32.2	(4.5)	-
	D grip breath inside length diameter	25.7	(5.0)	-
all	A hand length	177.9	(12.4)	175
	B hand breadth (four fingers)	79.4	(6.9)	80.5
	C grip breath inside width diameter	38.3	(7.9)	-
	D grip breath inside length diameter	30.7	(7.0)	-

Note for brainstorming: The device must be comfortable for both left- and right-handed radiologists. Additionally, to enhance stability, the design should minimize wrist strain, and maintain a neutral wrist position during use.

2025/02/06- Percutaneous Image-guided Needle Biopsy of Musculoskeletal Tumors: Technical Tips

ANA CLARA TOSCANO - Feb 06, 2025, 9:45 PM CST

Title: Percutaneous Image-guided Needle Biopsy of Musculoskeletal Tumors:Technical Tips

Date: 2025/02/06

Content by: Ana Toscano

Present: Ana Toscano

Goals: Understand Radiology Procedures

Citation:

Hasegawa, Takaaki, et al. “Percutaneous Image-Guided Needle Biopsy of Musculoskeletal Tumors: Technical Tips.” *Interventional Radiology*, vol. 6, no. 3, 1 Nov. 2021, pp. 75–82, https://doi.org/10.22575/interventionalradiology.2020-0030. Accessed 12 Mar. 2023.

Content:

- **Indications for Image-Guided Biopsy:**
    - Differentiating benign from malignant lesions.
    - Confirming metastases or acquiring samples for genetic mutation analysis.
    - Diagnosing multiple myeloma and infections.
    - Evaluating enlarging soft tissue tumors or suspected malignant lymphomas.
- **Contraindications:**
    - Uncorrected coagulopathy.
    - Lack of a safe access route.
    - Inability to obtain patient consent.
- **Techniques and Imaging Modalities:**
    - **Bone Biopsy:** CT is the preferred imaging modality due to its clarity in visualizing bone structures, while fluoroscopy, ultrasound, and MRI can also be used. Percutaneous bone biopsy has a diagnostic accuracy of 77%-94%, with higher success rates for osteolytic lesions.
    - **Soft Tissue Tumor Biopsy:** Typically performed under ultrasound for superficial lesions and CT for deep lesions. Core-needle biopsy is preferred for its reduced invasiveness, though surgical biopsy remains necessary in certain cases.
- **Enhancing Biopsy Success:**
    - Using appropriate needle sizes (11-20 gauge) based on lesion type.
    - Applying hydrodissection (injecting saline or lidocaine) to displace critical structures and secure a safer puncture route.
    - Rotating the biopsy needle for improved accuracy, particularly in osteoblastic lesions.

Conclusions/action items: Surgical biopsy remains highly accurate but is invasive, making percutaneous needle biopsy the preferred initial approach due to its lower invasiveness and increasing opportunities in minimally invasive medicine.

2025/03/13- Patent Image Guided Surgery System

ANA CLARA TOSCANO - Mar 13, 2025, 9:51 PM CDT

Title: Patent Image Guided Surgery System

Date: 03/13/2025

Content by: Ana Toscano

Present: Ana Toscano

Goals: Summary of European Patent EP 0 836 438 B1: Image-Guided Surgery System

Link: EP 0836438 B1 - image guided surgery system | The Lens

IEEE Citation:

Bosman, Jeroen, et al. *The OA Diamond Journals Study. Part 1: Findings*. 9 Mar. 2021, https://doi.org/10.5281/zenodo.4558704. Accessed 13 May 2025.

Content:

The patent EP 0 836 438 B1 describes an image-guided surgery system designed to enhance precision in medical procedures by utilizing position detection and visualization technologies. The system provides real-time tracking of surgical instruments and overlays important visual markers on pre-stored images of the patient.

Key Features:

1. Indicator System – Incorporates a visible marker in the measurement field to guide the surgeon.
2. Light Source for Tracking – Uses a semiconductor laser or infrared emitting diode (LED) to generate the marker.
3. Data Processing & Superimposition – The system's data processor overlays key visual elementson the stored image, including:
   - The center of the measurement region.
   - The contour of the measurement field.
   - Real-time images of the patient aligned with stored images for better accuracy.
4. Enhanced Visualization – The system can project a visible marker at the center of the measuring region, improving alignment and tracking.

Conclusions/action items: The analysis of European Patent EP 0 836 438 B1 (expired) confirms that there is prior art relevant to the proposed project design for a needle alignment device in minimally invasive radiology. The patent details an image-guided system that enhances precision using real-time position detection and visualization technologies, which align with the objectives of this project. Understanding this prior art will help refine the innovation, ensure compliance with patent laws, and potentially highlight areas for improvement that enhance usability, adaptability, and effectiveness in real-world medical applications.

2025/03/13- Active Patent Hand Support Device

ANA CLARA TOSCANO - Mar 13, 2025, 10:08 PM CDT

Title: Active Patent Hand Support Device

Date: 03/13/2025

Content by: Ana Toscano

Present: Ana Toscano

Goals: Summary of US Patent No. 12,138,956 B1 - Paint-Edging Hand Steadying Device

Link: **US 2013/0120281 A1 - Methods and Apparatus for Natural Media Painting Using Touch-and-Stylus Combination Gestures | The Lens**

IEEE Citation:

Bosman, Jeroen, et al. *The OA Diamond Journals Study. Part 1: Findings*. 9 Mar. 2021, https://doi.org/10.5281/zenodo.4558704. Accessed 10 Dec. 2023.

Content:

Key Features:

1. Hand-Supporting Body: Provides stability for precise paint application.
2. Concave Surface: Helps guide movement along the painting surface.
3. Ergonomic Design: Reduces strain and improves comfort during extended use.
4. Adaptability: Suitable for both straight and curved painting applications.

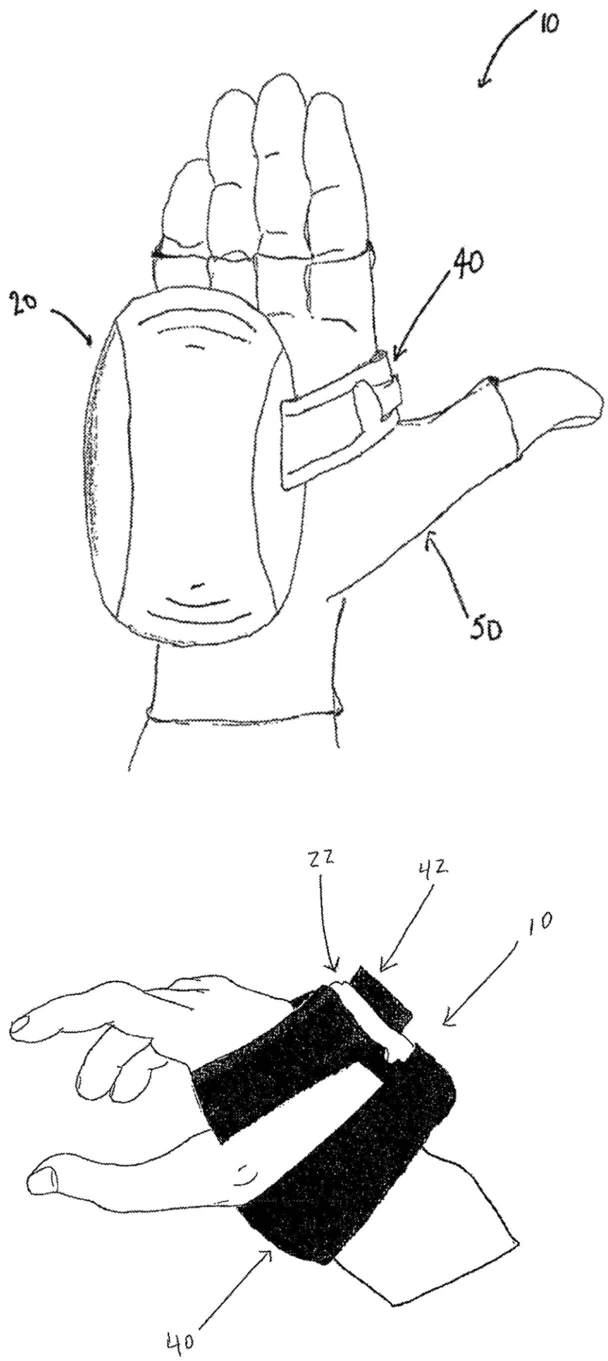


Figure 20

Claim Section:

1. Touch and Gesture Detection: Differentiates stylus motions (twisting, rotating, pressing) from touch inputs (finger, hand).
2. Context-Aware Interaction: Adjusts software settings based on ongoing tasks (e.g., aiding in painting operations).
3. Distance Sensitivity: Determines whether the stylus is near the tablet to modify responses accordingly.
4. Multi-Mode Capabilities: Supports zoom, panning, snapping to grid, and precise detailing modes.

Conclusions/action items: The Paint-Edging Hand Steadying Device (US Patent No. 12,138,956 B1) is an active patent, meaning that any similar stabilizing mechanisms designed for minimally invasive radiology procedures must be approached with caution to avoid potential infringement. While this patent specifically applies to paint edging, the underlying principles of hand stabilization, ergonomic support, and guided movement could overlap with designs intended for medical applications.

2025/04/20 - Material Specification

ANA CLARA TOSCANO - Apr 28, 2025, 12:40 PM CDT

Title:
Material characterization and biocompatibility of polycarbonate-based polyurethane for biomedical implant applications

Date:
04/28

Content by:
Ana Toscano

Present:
Ana Toscano

Goals:
Determine Young's Modulus for PDS (Polycarbonate-based polyurethane for biomedical use)

Link:
Material characterization and biocompatibility of polycarbonate-based polyurethane for biomedical implant applications

IEEE Citation:
A. Shakoor, S. Ahmad, M. Z. Iqbal, M. K. Iqbal, and N. A. Siddiqui, "Material characterization and biocompatibility of polycarbonate-based polyurethane for biomedical implant applications," *Heliyon*, vol. 10, no. 4, Apr. 2025, Art. no. e26990. [Online]. Available: https://www.sciencedirect.com/science/article/pii/S2046206925006990

Content:
This paper focuses on the mechanical characterization and biocompatibility of polycarbonate-based polyurethane (PCU) materials intended for biomedical implant applications. The study highlights that the polycarbonate-based polyurethane exhibits a Young's modulus in the range of approximately **2.0 to 3.5 GPa**, aligning with mechanical properties desirable for biomedical implants requiring a balance of flexibility and structural support. The material also showed good biocompatibility results with minimal cytotoxicity, supporting its potential for clinical use. The mechanical properties make this polymer suitable for applications requiring moderate flexibility with sufficient stiffness to maintain structural integrity, such as in injection stabilization devices.

Conclusions/action items:

- Confirm that the material's Young's modulus (2.0–3.5 GPa) meets the mechanical requirements for a cervical injection stabilizer.
- Evaluate sterilization compatibility.

2025/02/26- Research on Demographics and Global Impact

ANA CLARA TOSCANO - Feb 26, 2025, 11:53 AM CST

Title: Epidural Steroids for Cervical and Lumbar Radicular Pain and Spinal Stenosis Systematic Review Summary

Date: 02/26

Content by: Ana Toscano

Present: Ana Toscano

Goals: Determine demographics of ESI procedures

Link: Epidural Steroids for Cervical and Lumbar Radicular Pain and Spinal Stenosis Systematic Review Summary

IEEE Citation:

Armon, Carmel, et al. "Epidural Steroids for Cervical and Lumbar Radicular Pain and Spinal Stenosis Systematic Review Summary." *Neurology*, vol. 104, no. 5, 12 Feb. 2025, https://doi.org/10.1212/wnl.0000000000213361.

Content:

Demographics of Epidural Steroid Injection (ESI) Procedures

1. Prevalence of Lower Back and Neck Pain
    - Lower back pain affects 50%–80% of adults during their lifetime.
    - In 2013, lower back and neck pain accounted for $87.6 billion in healthcare spending, ranking third after diabetes and ischemic heart disease.
2. Incidence of Radiculopathy and Spinal Stenosis
    - Lumbar radiculopathy: 486 cases per 100,000 person-years.
    - Cervical radiculopathy: 83 cases per 100,000 person-years.
    - While most cases resolve naturally, only 33%–50% of spinal stenosis patients improve over time.
3. Utilization of ESI Procedures
    - ESIs are frequently used for radicular pain and spinal stenosis.
    - Medicare data shows that while utilization rates per 100,000 people have declined slightly, the absolute number of procedures remains high due to population growth.
4. Efficacy and Limitations
    - ESIs probably reduce short-term pain and disability in lumbar radiculopathy but have insufficient evidence for long-term pain relief.
    - For lumbar spinal stenosis, ESIs may reduce disability but do not provide significant pain relief.
    - There is limited data for cervical spinal stenosis, with no conclusive studies confirming ESI effectiveness.
5. Impact on Surgery and Long-Term Outcomes
    - There is no significant evidence that ESIs reduce the need for surgery.
    - ESIs are sometimes administered repeatedly, though long-term steroid use carries risks, including epidural lipomatosis, which can worsen spinal stenosis.
6. Adverse Events and Safety Concerns
    - Complications occur in 2.4% to 16.8% of cases, with injection site pain, numbness, and increased pain being most common.
    - Serious complications are rare but possible, including epidural hematomas, nerve injury, stroke, blindness, paralysis, and even death.
    - The FDA issued a warning in 2014 about potential severe risks associated with ESIs.
7. Cost-Effectiveness

- Some studies show small cost savings due to improved productivity, while others report no significant differences between ESIs and standard medical management.

Conclusions/action items: ESIs are widely used for treating lumbar and cervical radiculopathy and spinal stenosis, but their effectiveness is mostly short-term, and long-term pain relief remains uncertain. While ESIs are commonly performed, they do not significantly reduce the need for surgery and carry potential risks, including rare but severe complications. More research is needed to determine long-term benefits and cost-effectiveness.

2025/02/26- Research on Demographics Lubar Steroid Injection

ANA CLARA TOSCANO - Feb 26, 2025, 12:33 PM CST

Title:

Date:

Content by:

Present:

Goals:

Link: Assessment: Use of epidural steroid injections to treat radicular lumbosacral pain

IEEE Citation:

Armon, C., et al. “Assessment: Use of Epidural Steroid Injections to Treat Radicular Lumbosacral Pain: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.” *Neurology*, vol. 68, no. 10, 5 Mar. 2007, pp. 723–729, https://doi.org/10.1212/01.wnl.0000256734.34238.e7.

Content:

1. Prevalence and Economic Burden
    - Chronic back pain affects 50%–80% of adults in their lifetime.
    - The economic impact is significant, with $90.7 billion spent on back pain treatments in the U.S. in 1998 alone.
    - Spinal pain treatments, including ESIs, spinal cord stimulation, and intrathecal narcotics, cost at least $13 billion in 1990, growing at 7% annually.
    - In 1999, Medicare Part B claims included:
        - $49.9 million for lumbar ESIs
        - $8.5 million for lumbar facet or peri-facet joint injections
        - $5.6 million for cervical or thoracic ESIs
2. Efficacy and Clinical Limitations
    - Short-term pain relief: ESIs may provide pain relief between 2 and 6 weeks post-injection.
    - Limited long-term effectiveness: ESIs do not reduce long-term pain beyond 3 months and have no impact on function or the need for surgery.
    - Cervical radiculopathy: There is insufficient data to support the use of ESIs for cervical radicular pain.
3. Complication Rates and Safety Concerns
    - Minor complications: Occur in 2.4%–16.8% of cases, including transient headaches, injection site pain, and increased back pain.
    - Severe complications (rare but reported cases):
        - Aseptic meningitis, bacterial meningitis, arachnoiditis, epidural abscess, spinal hematoma, and nerve injury.
        - Stroke, paralysis, and death have been linked to cervical ESIs.
    - Radiation exposure from fluoroscopic guidance is a concern, but levels remain within safety limits if proper procedures are followed.
4. Comparison to Other Treatments
    - ESIs have not been proven to prevent surgery, and their effectiveness may be overstated due to placebo effects or temporary symptom relief.
    - Better-designed studies are needed to evaluate the true benefit of ESIs compared to alternative treatments, such as physical therapy, pain management strategies, or surgical interventions.

Conclusions/action items: ESIs are widely used despite limited long-term benefits. They may provide short-term relief, but their effectiveness beyond 3 months is questionable, and they do not reduce the need for surgery. Additionally, complications, costs, and safety concerns highlight the need for improved precision and alternative treatment options.

2025/03/13- Historical Background

ANA CLARA TOSCANO - Mar 13, 2025, 9:25 PM CDT

Title: Historical Background

Date: 2025/03/13

Content by: Ana Toscano

Present: Ana Toscano

Goals: Historical Background

Link: bhc1991n09p037.pdf

IEEE Citation:

Williams, William D. "The Stoddard Test Tube Clamp." *Bulletin for the History of Chemistry*, vol. 9, 1991, pp. 38-39.

Content:

The article discusses the history and development of the Stoddard Test Tube Clamp, invented by John T. Stoddard around 1890. Before its invention, various types of test tube holders were used, including twisted paper clamps, metal slide clamps, wooden nippers, and rubber-band-based clamps. However, these designs were often inconvenient or unreliable.

Stoddard, a chemistry professor at Smith College, designed a spring brass wire clamp that could securely hold test tubes of different sizes and resist deterioration from rubber band failure. His design was quickly adopted and became widely available through chemical supply catalogs starting in 1893. Over time, some suppliers continued to attribute the clamp to Stoddard, while others omitted his name.

Beyond his contributions to laboratory equipment, Stoddard was a well-regarded educator and author of chemistry textbooks, as well as a book on billiards. His legacy continues in the Stoddard Hall building at Smith College, named in his honor.

Conclusions/action items:

Understanding the historical development of the Stoddard Test Tube Clamp provides valuable insight into the evolution of laboratory equipment and its impact on scientific research. Just as Stoddard’s clamp refined laboratory techniques, our work aims to contribute meaningful advancements by critically evaluating existing methodologies and developing more effective solutions.

2025/03/13- TPU 95A Research

ANA CLARA TOSCANO - Mar 13, 2025, 10:21 PM CDT

Title: TPU 95A Research

Date: 2025/03/13

Content by: Ana Toscano

Present: Ana Toscano

Goals: Determine what material would be appropriate for the prototype of the final design

Link: [Design and characterization of 3D-printed TPU-based lattice structures. Application to methodology for the design of personalized therapeutic products | Emerald Insight]

IEEE Citation:

Sergio, et al. "Design and Characterization of 3D-Printed TPU-Based Lattice Structures. Application to Methodology for the Design of Personalized Therapeutic Products." *Rapid Prototyping Journal*, vol. 30, no. 11, 26 Mar. 2024, pp. 72–86, https://doi.org/10.1108/rpj-08-2023-0287. Accessed 9 Nov. 2024.

Content:

The study investigates 3D-printed TPU-based lattice structures for personalized therapeutic products, focusing on geometric, material, and manufacturing variables that influence compressive behavior. The research employs extrusion-based additive manufacturing and mechanical testing to analyze stiffness variations.

Key findings include:

Table 1 Main materials properties

Material	Filament diameter (mm)	Density (g/cm^3)	Tensile strength (MPa)	Printing temperature (°C)	Shore a Hardness
TPE 82 A	1.75	1.17	43	215 – 250	82 A
Reciflex	1.75	1.22	45	220 – 235	92 A
TPU 95 A	1.75	1.08	55	215 – 250	95 A

Source: Table by authors

Table 2 Main manufacturing variables

Variables	Value
Layer height (mm)	0.2
Layer width (mm)	0.4
Printing temperature (°C)	220
Bed temperature (°C)	35
Printing speed (mm/s)	20
Displacement speed (mm/s)	180
Retraction	Enabled
Retraction distance (mm)	3.5
Retraction speed (mm/s)	40

Source: Table by authors

Conclusions/action items: The geometric and material properties can be optimized to meet individualized needs.

Thermoplastic polyurethane is known for its flexibility and durability. It is commonly used in medical applications and should not interfere with X-rays.

- Young’s modulus decreases as unit cell size increases, with more significant effects at higher unit cell thickness and lower layer heights.
- Material hardness (Shore A) impacts stiffness variations, with softer materials (TPE 82A, Reciflex) showing greater changes compared to TPU 95A, which remains more stable.
- Different configurations can achieve similar stiffness levels, allowing for flexibility in design adjustments for patient-specific applications.
- Schwarz topology supports a wide range of stiffness values, making it effective for customization.

2025/03/13- Research on PETG

ANA CLARA TOSCANO - Mar 13, 2025, 10:34 PM CDT

Title: Experimental research on the mechanical characteristics of fused deposition modelled ABS, PLA and PETG specimens printed in 3D

Date: 2025/03/13

Content by: Ana Toscano

Present: Ana Toscano

Goals: Summary of PETG and PLA Mechanical Characteristics from Experimental Research:

Link: Experimental research on the mechanical characteristics of fused deposition modelled ABS, PLA and PETG specimens printed in 3D - ScienceDirect

IEEE Citation:

Durga, V, et al. “Experimental Research on the Mechanical Characteristics of Fused Deposition Modelled ABS, PLA and PETG Specimens Printed in 3D.” *Materials Today: Proceedings*, 1 July 2023, https://doi.org/10.1016/j.matpr.2023.06.343. Accessed 12 Aug. 2023.

Content:

Table 1
Properties of different thermoplastics.

Properties	PLA	ABS	PETG
Density (g/cm^3)	1.25	1.04	1.23
Tensile Strength (MPa)	65	43	49
Flexural Strength (MPa)	97	66	70
Extrusion Temperature (^0C)	190–210	220–260	230–250
Recyclability	Yes	Yes	Yes
Biodegradability	Yes	No	No
Flume Toxicity	Less	Medium	Less

Table 3
Obtained readings of Vickers hardness test.

Specimen	Load Applied in grams (F)	Trails	Length of Indentation in mm (D)			Hardness value
			D_1 (mm)	D_2 (mm)	D_{mean}	$HV = \frac{1.854F}{(Dmean)^2}$
PLA	50 gm	Trail-1	80.46	72.48	76.47	15.8
		Trail-2	78.99	79.79	79.39	15
		Trail-3	80.09	76.85	78.47	15
ABS	50 gm	Trail-1	73.78	76.56	75.17	16.4
		Trail-2	83.52	107.36	95.44	10.1
		Trail-3	88.64	89.44	89.04	11.6
PETG	50 gm	Trail-1	99.38	98.49	98.935	9.4
		Trail-2	103.7	97.02	100.36	9.2
		Trail-3	95.73	95.65	95.69	10

5

- Hardness:

  PLA: 15.8 HV (higher than PETG but slightly lower than ABS) PETG: 10 HV (lower hardness, making it more flexible)

- Surface Roughness:

  PLA has the smoothest surface among the tested materials. PETG has moderate surface roughness, better than ABS but not as smooth as PLA.

- Microstructure and Strength:

  PLA: Higher crystalline organization, leading to increased stiffness and tensile strength. PETG: Molecular chains are neatly packed, providing stiffness and strength, but less stiff than PLA.

- Flexibility and Toughness:

  PETG: Good impact strength, toughness of 31.5 kJ/m², but lower stiffness than PLA. PLA: More rigid than PETG, stiffness ~2050 MPa.

- Heat Resistance:

  PETG: 69°C heat resistance, making it more temperature-resistant than PLA. PLA: Lower heat resistance (~55°C - 60°C), prone to deformation under heat.

- Water Absorption:

  PETG: 0.40% absorption, relatively low. PLA: Higher than PETG, making it more susceptible to moisture-related degradation.

Conclusions/action items:

- PETG is a strong candidate for X-ray applications due to its transparency, chemical resistance, and moderate flexibility. It is also non-reactive, making it safer for biomedical and medical imaging devices.
- PLA offers better dimensional accuracy and stiffness, making it ideal for precise, rigid structures but may be less durable in applications requiring impact resistance or long-term stability.
- For X-ray transparent and non-reactive applications, PETG is the better choice due to its superior impact resistance, durability, and chemical stability.

2025/02/27- Design Idea and Hospital Visit

ANA CLARA TOSCANO - Apr 30, 2025, 7:46 PM CDT

Title: Design Idea

Date: 02/27

Content by: Ana Toscano

Present: Ana Toscano and Dr Ross

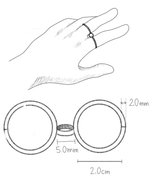
Goals: Learn more about the procedure of Spinal injections and brainstorm ideas

Content:

After observing the procedure, I stayed to discuss insights with Dr. Ross and the staff.

During our conversation, we brainstormed and developed the concept of a **"between-fingers" design** to enhance needle stabilization and control.

(Drawing by Gabi)



Conclusions/action items:

Research ergonomic considerations to ensure comfort and usability across different hand sizes. The main problem is that the hand is in the direct path of the radiation.

2025/02/13- Presentation Lecture Advice

ANA CLARA TOSCANO - Apr 30, 2025, 7:40 PM CDT

Title: Presentation Advice

Date: 02/13/25

Content by: Ana Toscano

Present: All group

Goals: Prepare for poster presentation

Engagement & Delivery:

Practice thoroughly to ensure smooth delivery and timing.

Highlight the impact of your project (“Why does this matter?”).

Maintain energy and enthusiasm; make eye contact (avoid reading from the screen).

Emphasize key takeaways; skip deep technical explanations unless asked.

Graphics & Visuals:

Use clear, well-labeled CAD images/sketches with dimensions and scales included.

Simplify visuals—remove cluttered backgrounds or unnecessary details.

Graphs only (no raw data tables); present summarized results with statistics (e.g., averages ± standard deviations, ≥3 replicates).

Common Errors to Avoid:

Overly nested bullet points (keep hierarchy simple).

Raw data tables (always summarize visually).

Unlabeled or low-quality images—always include clear labels and dimensions.

Conclusions/action items: Implement in poster presentation

2054/01/30 - “Assessment of Needle Guidance Devices for Their Potential to Reduce Fluoroscopy Time and Operator Hand Dose during C-Arm Cone-Beam Computed Tomography–guided Needle Interventions”

KSHIRIN ANAND - Jan 31, 2025, 10:55 AM CST

Title: “Assessment of Needle Guidance Devices for Their Potential to Reduce Fluoroscopy Time and Operator Hand Dose during C-Arm Cone-Beam Computed Tomography–guided Needle Interventions”

Date: 1/30/25

Content by: Rini

Present: None

Goals: Understand the different techniques and devices used in CT Fluroscopy

Content: M. W. Kroes et al., “Assessment of Needle Guidance Devices for Their Potential to Reduce Fluoroscopy Time and Operator Hand Dose during C-Arm Cone-Beam Computed Tomography–guided Needle Interventions,” Journal of Vascular and Interventional Radiology, vol. 24, no. 6, pp. 901–906, Jun. 2013, doi: 10.1016/j.jvir.2013.02.037.

Techniques used in study:

1. Freehand Technique
    - The operator manually guides the needle into the target using real-time fluoroscopy feedback.
    - This method requires frequent adjustments to align the needle with the planned path.
    - It serves as the baseline comparison for other techniques.
2. Needle Holders (Mechanical Guidance Devices)
   These devices are designed to assist with maintaining a fixed needle angle during placement. Two commercially available holders were tested:
    - SeeStar (AprioMed, Sweden):
        - Features a metallic needle guide that is visible under fluoroscopy.
        - Helps maintain a fixed trajectory but still requires manual adjustments.
        - Can be repositioned but remains attached to the needle during advancement.
    - Simplify (NeoRad AS, Norway):
        - Allows for rotation and angulation while keeping the needle stable.
        - Unlike SeeStar, it can be detached without removing the needle.
        - Aims to reduce excessive movement and improve handling.
3. Laser Guidance (SimpliCT, NeoRad AS, Norway)
    - A ceiling-mounted laser guidance system projects a visible laser beam to indicate the planned needle path.
    - The system is self-leveling and aligned with the operating table.
    - It helps the operator precisely align the needle before insertion, reducing reliance on fluoroscopy.
    - The maximum allowable angulation for this system is 45 degrees in both axial and craniocaudal directions.
4. Combination Techniques (Laser Guidance + Needle Holders)
    - SimpliCT + SeeStar
        - Combines the laser guidance system with the SeeStar needle holder.
        - The laser provides initial alignment, while SeeStar maintains the trajectory during insertion.
    - SimpliCT + Simplify
        - Uses laser guidance along with the Simplify needle holder.

- The laser ensures initial placement accuracy, and Simplify stabilizes the needle while allowing for some adjustments.

How the techniques were evaluated:

- Operators performed interventions using each technique three times.
- Fluoroscopy time, procedure time, radiation dose to the hand, and accuracy (needle tip deviation) were measured.
- The laser guidance system aimed to reduce the need for fluoroscopy by providing visual feedback without x-ray exposure.

Key Findings for Each Technique:

Technique	Fluoroscopy Time	Hand Dose	Procedure Time	Accuracy
Freehand	50 sec	275 mSv	1.9 min	1.2 mm
SeeStar (needle holder)	67 sec (NS)	298 mSv (NS)	2.8 min (NS)	0.4 mm (NS)
Simplify (needle holder)	59 sec (NS)	167 mSv (NS)	3.1 min (↑)	0.9 mm (NS)
SimpliCT (laser)	31 sec (↓)	33 mSv (↓)	2.9 min (↑)	0.2 mm (NS)
SimpliCT + SeeStar	30 sec (↓)	36 mSv (↓)	3.6 min (↑)	0.2 mm (NS)
SimpliCT + Simplify	29 sec (↓)	32 mSv (↓)	3.5 min (↑)	0.3 mm (NS)

(↓ = significantly lower, ↑ = significantly higher, NS = not significant)

Key Takeaways:

- Laser guidance (SimpliCT) significantly reduced fluoroscopy time and hand radiation dose.
- Needle holders alone did not provide significant improvements in fluoroscopy time or radiation reduction.
- All tested techniques maintained high accuracy.
- Laser guidance slightly increased procedure time but provided safer needle placement.

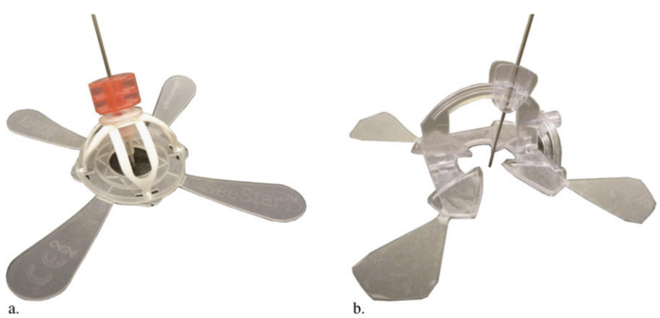


Figure 2. The two different types of needle holders used for assisting the operator in needle placement. **(a)** SeeStar. **(b)** Simplify. (Available in color online at *www.jvir.org*.)

Figure 3. Schematic presentation of the laser guidance setup. The guiding laser of SimpliCT is aimed along a planned needle path of 30 degrees in the axial direction (straight line), while the plane laser is aligned to the operating table (dashed line). The C-arm is positioned in progress view. (Available in color online at *www.jvir.org*.)

Conclusions/action items:

Look more into 1+ of the devices/techniques used within the study.

KSHIRIN ANAND - Jan 31, 2025, 1:39 AM CST

http://pubmed.ncbi.nlm.nih.gov/23602061/ - Link to article since no PDF available.

2054/01/30 - “The use of needle holders in CTF guided biopsies as a dose reduction tool”

KSHIRIN ANAND - Jan 31, 2025, 10:55 AM CST

Title: “The use of needle holders in CTF guided biopsies as a dose reduction tool”

Date: 1/30/25

Content by: Rini

Present: None

Goals: Understand the devices and techniques used within this study

Content: S. Sarmento et al., “The use of needle holders in CTF guided biopsies as a dose reduction tool,” J Appl Clin Med Phys, vol. 19, no. 1, pp. 250–258, Nov. 2017, doi: 10.1002/acm2.12234.

Techniques used in study:

The study evaluated different techniques for performing CT fluoroscopy (CTF)-guided biopsies, focusing on radiation exposure to the hands of interventional radiologists (IRs). The techniques included:

1. Quick-Check (QC) Method (Intermittent Imaging, No Needle Holder)
    - The quick-check (QC) method is an imaging technique that uses intermittent CT fluoroscopy scans to check needle position.
    - The needle is advanced when the beam is OFF, minimizing radiation exposure to the operator’s hands.
    - This method is most effective in reducing hand dose but is not always suitable for complex biopsies that require real-time adjustments.
2. Quick-Check + Needle Holder (QC + NH)
    - A needle holder (NH) (e.g., a 20 cm towel clamp) was used to grasp and stabilize the needle from a safe distance (at least 10 cm from the radiation beam).
    - This technique reduces the need for direct hand contact with the needle during irradiation, leading to lower radiation exposure.
    - Disadvantage: NH can reduce tactile feedback, making fine adjustments more difficult, especially with thinner needles.
3. Quick-Check + Side-Handle Manipulation (QC + SH)
    - In challenging biopsies, the IR occasionally manipulated the needle using a side-handle to maintain precision.
    - This method puts the operator’s hand closer to the direct beam, significantly increasing radiation exposure.
    - Only used in about 8% of cases, but accounted for ~70% of total hand dose.

Study Results:

1. Reduction in Hand Exposure:

- The introduction of needle holders significantly reduced hand exposure.
- Before using NH: Higher radiation doses, particularly in the dominant (left) hand.
- After using NH:
    - Overall hand dose was reduced by more than half.
    - Right-hand exposure remained low, confirming that the left hand is most at risk during biopsies.

Technique	Max Hand Dose per Procedure (Hp(0.07))	Mean Hand Dose per Procedure	% of Procedures
QC (No NH, Intermittent Imaging)	0.35 mSv	0.05 mSv (Lowest)	30%
QC + NH (Needle Holder)	24.47 mSv	1.52 mSv (Significantly Reduced)	56%
QC + SH (Side-Handle Manipulation)	42.89 mSv	13.07 mSv (Highest)	14%

- QC alone resulted in the lowest hand dose (<1 mSv per procedure).
- QC + NH significantly reduced exposure, but some biopsies still required QC + SH, leading to occasional high doses (>10 mSv).

2. Fingertip Exposure and High-Risk Cases:

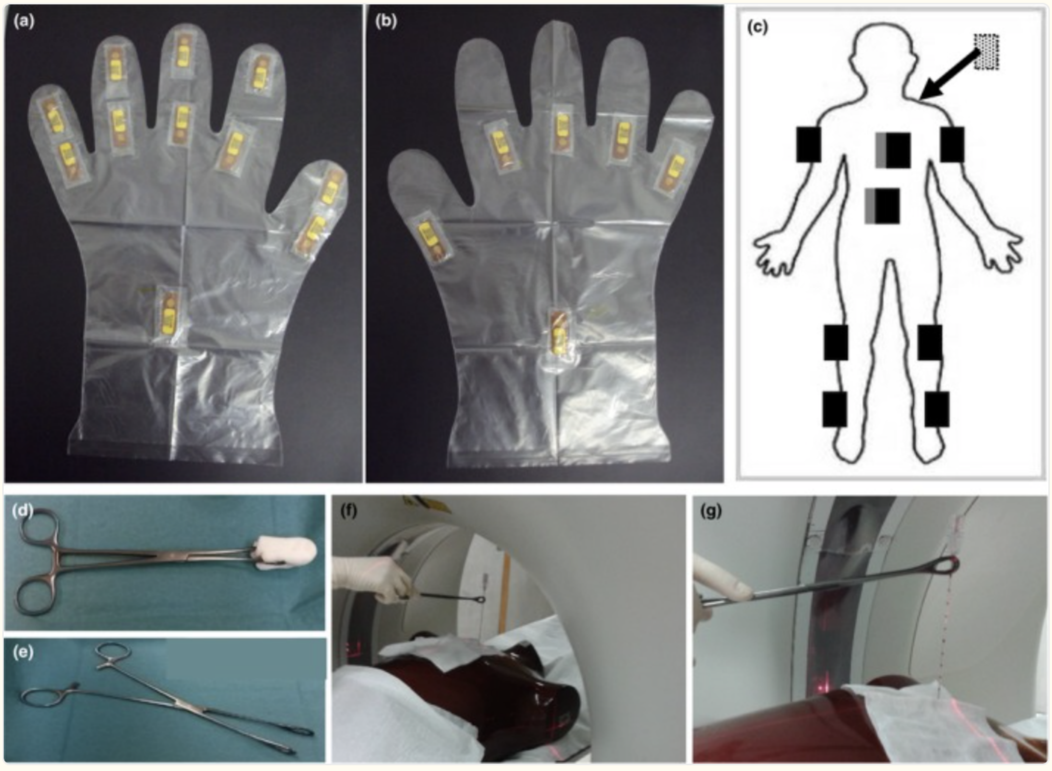
- Fingertips received the highest doses (up to 20 times more than the back of the hand).
- 8% of biopsies accounted for nearly 70% of the total hand dose, mostly due to side-handle manipulation (QC + SH).
- Even with NH, some procedures had exposures of 5–30 mSv, likely due to improper positioning of the holder or operator error.

3. Impact on Procedure Time and Patient Exposure:

- CT Fluoroscopy Time:
  - Increased by 9 seconds on average after NH introduction.
  - Did not significantly increase total procedure time but resulted in slightly higher patient skin doses (additional 0.04 Gy).
  - Still well below safety thresholds.
- Patient Radiation Dose:
  - Estimated maximum skin dose of 0.4 Gy (below the 2 Gy threshold for radiation injury).
  - The slight increase in fluoroscopy time (due to NH use) was not a major concern for patient safety

Key takeaways:

- Needle holders (NH) effectively reduce hand exposure, especially in procedures requiring real-time manipulation.
- The quick-check (QC) method alone remains the safest technique for hand radiation protection.
- Side-handle manipulation (QC + SH) is still needed for difficult biopsies, but it causes the highest hand exposure (~70% of total dose).
- Continuous hand monitoring is essential to detect unexpected high-dose cases and prevent cumulative radiation exposure.



Conclusions/action items:

Look further into the most standard needle holder on the market.

KSHIRIN ANAND - Jan 31, 2025, 1:35 AM CST

RADIATION PROTECTION & REGULATIONS

WILEY

The use of needle holders in CTF guided biopsies as a dose reduction tool

Sandra Sarmento[1] | Joana S. Pereira[2,3] | Maria José Sousa[4] | Luís T. Cunha[1] | Anabela G. Dias[1] | Miguel F. Pereira[2,3] | Augusto D. Oliveira[2,3] | João V. Cardoso[2] | Luís M. Santos[2] | João A.M. Santos[1,5] | João G. Alves[2,3]

Abstract

Purpose: The purpose of this study was to evaluate the efficacy of needle holders in reducing staff hand exposure during biopsies guided by computed tomography fluoroscopy (CTF), through the analysis of data acquired during a detailed monitoring study, undertaken in parallel with an ongoing optimization process to reduce hand irradiation.

Methods: Hand monitoring was performed with 11 extremity detectors, two per finger (base and tip) and one on the back of the wrist, for the left (dominant) hand, during two series of biopsies with comparable characteristics. The first series (47 biopsies) were performed with only quick-check method (QC) and occasional side-handle (SH) manipulation of the needle. The second series (63 biopsies) were performed after introducing needle holders (NH) in the course of an optimization process.

Results: Choice of technique (QC, QC + NH, QC + SH) by the interventional radiologist (IR) was related to biopsy difficulty. Measured hand exposure was low (< 1 mSv) for all QC-only procedures, and for most of the QC + NH procedures. Occasional side-handle manipulation still occurred during challenging biopsies, so that 8% of biopsies in the second series accounted for ~70% of total fingertip dose (~90 mSv). The methodology used allowed a detailed insight into the dose reduction achievable with needle holders during real procedures, without the limitations of phantom measurements.

Conclusions: Needle holders proved effective in reducing mean hand exposure during clinical procedures where real-time manipulation was necessary. Occasional side-handle manipulation was found to contribute disproportionately to hand exposure. This highlights the importance of individual hand monitoring during CTF guided procedures.

KEY WORDS

CTF-guided biopsies, dosimeters, hand monitoring, interventional radiology, needle holders, radiation exposure

[Download](#)

Sarmento_et_al._-_2017_-_The_use_of_needle_holders_in_CTF_guided_biopsies_a.pdf (603 kB)

2054/01/30 - Connections Between Technique Assessment Papers

KSHIRIN ANAND - Jan 31, 2025, 1:08 AM CST

Title: Connections between technique assessment literature (“Assessment of Needle Guidance Devices for Their Potential to Reduce Fluoroscopy Time and Operator Hand Dose during C-Arm Cone-Beam Computed Tomography–guided Needle Interventions” & “The use of needle holders in CTF guided biopsies as a dose reduction tool”)

Date: 1/30/25

Content by: Rini

Present: None

Goals: Make connections between both studies to gain insights about common/different findings

Content:

Similar Techniques:

Technique	CTF-Guided Biopsies Study	CBCT-Guided Interventions Study
Freehand Needle Placement	Used in quick-check (QC) method with intermittent imaging	Used in standard CBCT interventions, requiring frequent fluoroscopy adjustments
Needle Holders	Used towel clamps (20 cm) to hold the needle at a safe distance	Used SeeStar and Simplify mechanical needle holders for stability
Laser Guidance	Not tested in CTF study	Used SimpliCT laser guidance to pre-align the needle before insertion
Side-Handle Manipulation	Used when manual adjustments were needed for difficult biopsies	Corrective manipulations in CBCT increased radiation exposure
Fluoroscopy Reduction Strategies	Used intermittent imaging (Quick-Check method) to minimize hand exposure	Used laser alignment to reduce dependency on real-time fluoroscopy

Key Takeaways from Comparison:

- Both studies confirmed that needle guidance (either mechanical holders or laser systems) reduces hand exposure.
- Needle holders in CTF and laser guidance in CBCT reduced fluoroscopy time, but did not eliminate high-dose cases.
- Side-handle manipulation (CTF) and corrective adjustments (CBCT) remain major contributors to excessive radiation exposure.
- Guidance systems slightly increased procedure time but did not affect accuracy.

Conclusions/action items: None

2025/02/13- Cervical Injection Procedure

KSHIRIN ANAND - Feb 13, 2025, 7:39 PM CST

Title: Cervical Injection Procedure Overview

Date: 02/13/2025

Content by: Rini

Present: None

Goals: Review the procedure.

Citation: "Cervical-Epidural.pdf." Accessed: Feb. 13, 2025. [Online]. Available: https://radiology.wisc.edu/wp-content/uploads/2017/11/Cervical-Epidural.pdf

"Pain management injection procedures." Accessed: Feb. 13, 2025. [Online]. Available: https://patient.uwhealth.org/education/pain-management-injection-procedures

Content:

Summary: UW Health - The Day of the Procedure

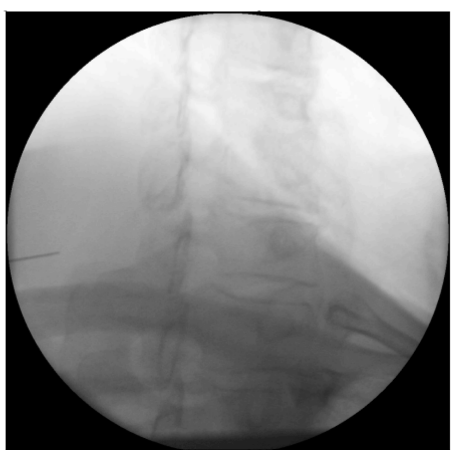
- You will change into a hospital gown and have an IV started.
  - Normal clothing, dressing applied
- Medical history, current health, and medications will be reviewed. A pain diagram will be filled out.
- A healthcare provider will explain the procedure, risks, and answer any questions before you sign a consent form.
- Family/friends can be with you before and after, but not during the procedure.
- The procedure takes place in an operating room with an X-ray machine. A sedative will be given, but you will remain awake.
  - Some kind of local anesthetic
- You will lie on your stomach (low-back injection) or side (neck injection), and vital signs will be monitored.
  - Laid on back, turned opposite side to where injection was occurring
- The injection area will be cleaned, covered with a sterile drape, and a needle guided by X-ray will be positioned near the spine.
  - Went in increments until needle had enough "property"
  - Had to adjust the needle many times because of patient moving or needle slipping
  - Needle has to stay in same position for extended time
- Contrast dye will confirm needle placement before injecting local anesthetic and steroids.
  - Additional moving of needle - attach needle-to-liquid device
- You must stay still and minimize talking. The procedure lasts 30-45 minutes.

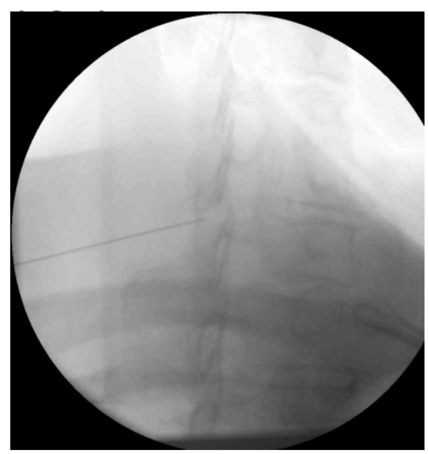
Musculoskeletal Imaging and Intervention Section Imaging Procedures Cervical Epidural:

- The initial **target is at the mid portion of the lower of the two target vertebral bodies and midway between the pedicle and spinous process**.
- A **22-gauge Tuohy needle is the preferred needle** because its blunt tip tends to push firm objects away, decreasing the risk of puncturing the dura. The Tuohy needle is inserted with cephalad angulation and advanced toward the interlaminar space with additional slight medial angulation.

- The tube is rotated to the contralateral oblique projection, approximately 45 degrees opposite the side of the needle entrance, until the laminae take on a shingled appearance. As the needle is advanced, its **position should be checked in the AP projection periodically** to verify that it is appropriately directed toward the midline.
- In this contralateral oblique projection, the remainder of the needle advancement i**s done with a slow advancement with intermittent fluoroscopy**. Contrast “puffs” are performed once through the ligamentum flavum. Inject 1 cc Omnipaque 300 to confirm epidural position in both the AP and oblique projections. **Epidural contrast should flow freely from the needle and outline the dura and cervical nerve roots.** If the contrast instead has a diluted appearance and wraps around the spinal cord, simulating a myelogram, intrathecal injection is likely. The procedures hould be terminated and reattempted in about seven days. Rarely, the contrast conforms to a tubular or serpentine pattern and washes away, due to needle position in an epidural vein. Often a minute adjustment to the needle tip will extricate it from the vessel. If the needle adjustment is unsuccessful, injection at a different level should be attempted.
- 2 cc of Kenalog-40 (80 mg) is instilled for an average-sized adult. An additional 3 mlof 0.25% preservative-free lidocaine is added.

Proper Placement





1. Proper placement

2. Too early

3. Too late

Conclusions/action items: None.

KSHIRIN ANAND - Feb 13, 2025, 7:25 PM CST

Musculoskeletal Imaging and Intervention Section Imaging Procedures

Cervical Epidural

INDICATIONS

- Multilevel spine disease, especially acquired spinal or foraminal stenosis
- Herniated disk with nerve root irritation as an alternative to a focal nerve block

RISKS

- Pain
- Hematoma
- Allergic reaction
- Epidural abscess
- Transient hypotension (only with anesthesia injection)
- Intrathecal injection (arachnoiditis, meningitis)

CONTRAINDICATIONS

- Local skin infection
- Concurrent illness (e.g. cold, flu)

PREPROCEDURE COUNSELLING

- Discuss patient's symptoms and results of prior injections
- Take brief past medical and surgical history including allergies
- Explain the procedure in detail
- Explain the expectations of the procedure
    - Can expect some immediate relief for a few hours due to lidocaine 0.25% with return of pain later in the day
    - Should expect some result within 1 – 2 day
    - Can likely expect 6 – 8 weeks of pain improvement and/or relief. There is a broad range of potential results from resolution of pain to no change in symptoms.
- Explain activity limitations post procedure
- Take it easy the remainder of the day, can return to routine activity the following day

PREREQUISITES

- Directed history is taken including symptoms, previous surgery, prior injections, allergy history, and other medical conditions including cardiac disease and diabetes
- Patient accompanied by someone to drive home.

Download

Cervical-Epidural.pdf (17.7 MB)

2025/01/30 - “AprioMed SeeStar"

KSHIRIN ANAND - Jan 31, 2025, 1:30 AM CST

Title: AprioMed SeeStar

Date: 1/30/25

Content by: Rini

Present: None

Goals: Look at IFU, description, and specifications for common needle guiding device on market.

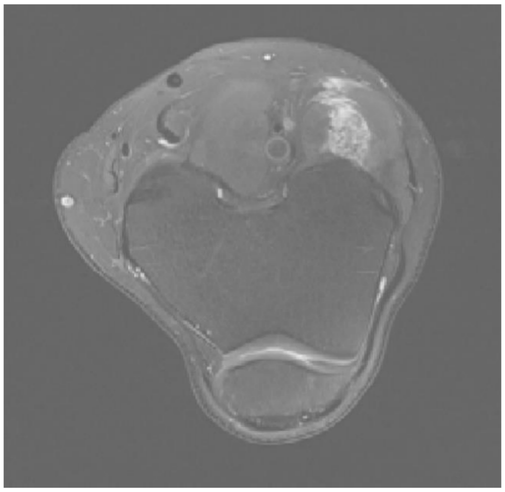
Content: “SeeStar IFU.pdf.” Accessed: Jan. 29, 2025. [Online]. Available: https://apriomed.com/wp-content/uploads/29600.pdf, “SeeStar Case.pdf.” Accessed: Jan. 29, 2025. [Online]. Available: https://apriomed.com/wp-content/uploads/29137.pdf

Description:

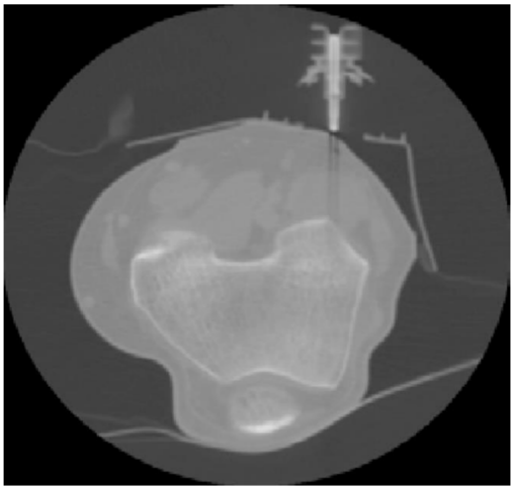
- Visualization and Adjustment: Enables visualization and adjustment of the planned CT-guided biopsy before needle insertion.
- Reduced Needle Manipulations: Helps reduce the number of needle manipulations during procedures.
- Support for Superficial Punctures: Assists in supporting the needle during superficial punctures.
- Maintains Needle Direction: Maintains the direction of the needle during puncture.

Product Specs: The SeeStar® is available in various sizes to accommodate different needle gauges:

- 12 Gauge (Blue): Suitable for needle sizes 12 and 13 gauge.
- 14 Gauge (Green): Suitable for needle sizes 14 and 15 gauge.
- 17 Gauge (Pink): Suitable for needle sizes 17 and 18 gauge.
- 20 Gauge (Yellow): Suitable for needle sizes 20 and 21 gauge.



Pre-procedure MRI



SeeStar® Localization

IFU:

“DIRECTIONS FOR USE

SeeStar® can be used to simplify and improve the precision of the regular procedure for CT guided puncture.

• Apply local anaesthetic.
• Make a small skin incision prior to the puncture.
• The entry point is determined and marked along the laser line. SeeStar is applied with the tip of the needle guide directly over the entry point and the hub open (Fig.1)
• Make sure the needle guide is in the image plane by centering/aligning the proximal end of the metal needle guide with the laser line (Fig.1). The linear artefact visible in the CT image marks the puncture route through the body/ the intended needle path. (Fig.2)
• The angle of the needle guide is adjusted in order to reach the target and the needle guide is locked in the desired position by tightening the hub.
• If repeat punctures are required from the same area, the SeeStar® can be left in its position. Other areas can also be punctured from the same entry point by angling the needle guide.”

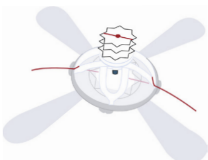


Fig. 1

Fig. 2

Fig. 3

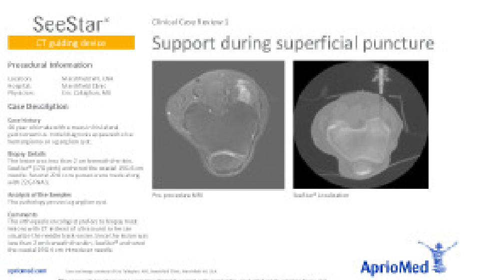
Instructional Video

[SeeStar®]

Conclusions/action items:

Potentially find patent, look into other devices on the market.

KSHIRIN ANAND - Jan 31, 2025, 1:34 AM CST


SeeStar®
CT guiding device
Support during superficial puncture
Procedural Information
Case Description
AprioMed

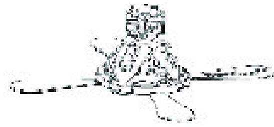
[Download]

29137.pdf (181 kB)

KSHIRIN ANAND - Jan 31, 2025, 1:35 AM CST

SeeStar®

Guiding Device



(EN) Instruction for use
(SV) Bruksanvisning
(NL) Handleiding
(FR) Mode d'emploi
(ES) Instrucciones de uso
(IT) Istruzioni per l'uso
(DE) Gebrauchsanweisung
(NO) Bruksanvisning

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29600.pdf (1.1 MB)

2025/01/30 - “Remotely Held Needle Guide for CT Fluoroscopy, US9259195B2"

KSHIRIN ANAND - Jan 31, 2025, 1:30 AM CST

Title: Remotely Held Needle Guide for CT Fluoroscopy, Patent US9259195B2

Date: 1/30/25

Content by: Rini

Present: None

Goals: Discover patent into needle guide device that minimizes radiation exposure.

Content: “Remotely Held Needle Guide for CT Fluoroscopy, US9259195B2.pdf.” Accessed: Jan. 29, 2025. [Online]. Available: https://patentimages.storage.googleapis.com/4d/93/0b/8250043468c4b3/US20060149147A1.pdf

This patent describes a device designed to enhance the precision and safety of interventional medical procedures performed under CT fluoroscopy guidance. This device allows medical professionals to manipulate interventional implements(biopsy needles or ablation probes) remotely, therefore reducing radiation exposure to both the patient and the operator.

Key featuers:

- Remote operation: The apparatus enables the operator to control the interventional implement from a distance, minimizing direct exposure to radiation during procedures.
- Gripping/holding mechanism: It includes a gripping area for manual control and a holding area to securely position the interventional implement along a selected linear path.
- Linear movement: The design facilitates the translation of the interventional implement along a predetermined path, ensuring accurate placement within the patient's body.
- Compatibility: The guide apparatus is intended for use with imaging devices like CT scanners, integrating seamlessly into existing medical imaging workflows.

Advantages:

- Better Safety: By allowing remote operation, the device reduces the need for the operator to be in close proximity to the patient during radiation exposure, thereby decreasing radiation risks.
- Improved Precision: The apparatus provides tactile feedback and precise control over the interventional implement, leading to more accurate procedures.
- Real time monitoring: Operators can continuously monitor and adjust the procedure using real-time imaging, ensuring optimal outcomes.

This patent represents a significant advancement in image-guided interventional procedures, offering a safer and more precise method for performing minimally invasive surgeries under CT fluoroscopy guidance.

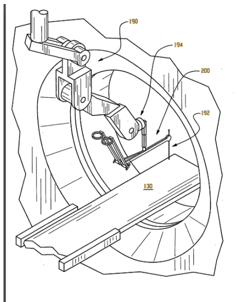
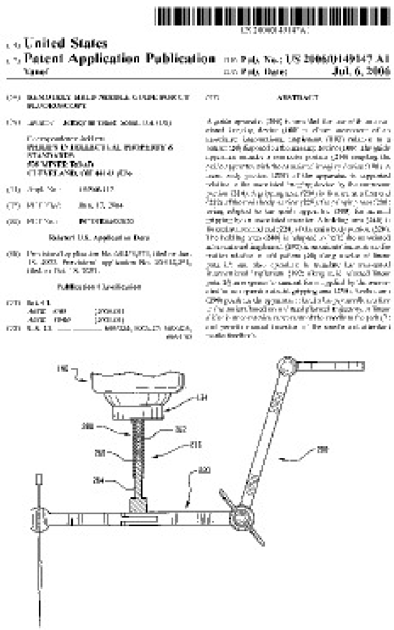


Fig. 2

Conclusions/action items:

Continue patent research on needle guides.

KSHIRIN ANAND - Jan 31, 2025, 1:34 AM CST



United States

Patent Application Publication

Pub. No.: US 2006/0149147 A1

Pub. Date: Jul. 6, 2006

ABSTRACT

[Download](#)

US20060149147A1.pdf (1.44 MB)

2025/02/07-Weight Research (Compiled)

KSHIRIN ANAND - Feb 07, 2025, 12:11 AM CST

Title: PDS Weight Research

Date: 02/07/2025

Content by: Rini

Present: None

Goals: Document compiled research on weight specifications for Needle Holder design

Citation: In content

Content:

[9] The4, "What Size Needle Holder to Use: A Complete Guide for Precision and Efficiency," Artman Instruments. Accessed: Feb. 05, 2025. [Online]. Available: https://artmaninstruments.com/blogs/our-blogs/what-size-needle-holder-to-use-a-complete-guide

Weight considerations: 1 hand, either right or left

Want to keep weight similar if not a bit less than standard needle holder

Lower weight is better for intricate procedures and heavier weight is for more robust procedures

[10] "Mayo-Hegar Needle Holder| Length-cm| 14cm," Gynex Corporation. Accessed: Feb. 05, 2025. [Online]. Available: https://www.gynexcorporation.com/product/mayo-hegar-needle-holder-2/

Standard needle holder being used is approximately 170g

Conclusions/action items: Summarize in PDS.

2025/02/07-Materials Research (Compiled)

KSHIRIN ANAND - Feb 07, 202

Title: PDS Materials Research

Date: 02/07/2025

Content by: Rini

Present: None

Goals: Document compiled research on material specifications for Needle Holder design

Citation: In content

Content:

[11] T. Y. Team, "How Device Materials Affect Medical Imaging | Yasui Co., Ltd." Accessed: Feb. 05, 2025. [Online]. Available: https://yasuico.com/medical materials-imaging/

Medical-grade plastics have many different functions in medicine such as durability, low cost, and lightweight for procedure

Polycarbonates are high-impact and have temperature-resistant properties. Used in alot of surgical instruments.

Polypropylene is durable and resistant to steam sterilization, so it's widely used in surgical dressing and single-use medical equipment.

Polyethylene is common in medical implants because it's resistant to impact and chemicals

[12] "Sorting Recyclable Plastics by Density," Chemistry LibreTexts. Accessed: Feb. 05, 2025. [Online]. Available: https://chem.libretexts.org/Ancillary_Materials/Exemplars_and_Case_Studies/Exemplars/Environmental_and_Green_chemistry/Sorting_Recyclable_Plastic

Propylene 0.9-0.92 g/cm3

HDPE 0.94-0.96 g/cm3

[13] E. A. Campbell and C. D. Wilbert, "Foreign Body Imaging," in StatPearls, Treasure Island (FL): StatPearls Publishing, 2025. Accessed: Feb. 05, 2025 Available: http://www.ncbi.nlm.nih.gov/books/NBK470294/

The CT procedure has pros and cons; pro: can identify tissue densities and processes for inflammation, con: have a high radiation dosage to the patient

[14] "Medical Plastic | Learn About Plastics Used in Medical Devices and Procedures - A&C Plastics." Accessed: Feb. 05, 2025. [Online]. Available: https://www.acplasticsinc.com:443/informationcenter/r/medical-uses-for-plastic-materials

Polycarbonate. Polycarbonate is a medical plastic that is easy to sanitize. This material provides good UV protection and doesn't deform from exposure to h temperatures or steam. Polycarbonate sheets are common for signage and panels.

Polypropylene. This plastic is resistant to impact and corrosion. It's more durable than other plastics, and you'll find it in orthotics and prosthetics. Polypropy go-to option for weight-bearing prosthetics due to its resistant properties.

Acrylonitrile butadiene styrene (ABS). ABS plastic sheets are durable and tough, providing a clean aesthetic appearance that is perfect for medical environr

Polyethylene terephthalate glycol (PETG). PETG is a material that is safe to use in contact with food. It's a common plastic used in the food prep area of cli hospitals, but you'll also find PETG sterilization trays.

Polyethylene. The usefulness of plastics in the medical field includes manufacturing implants. Polyethylene is a plastic that healthcare providers can sterili material that doesn't degrade over time, which makes it ideal for implants.

Polymethyl methacrylate. This material has properties similar to glass. It can transmit light and reflect a beam of light, which makes it a good option for endo implants.

Polyvinyl chloride (or PVC). You'll find PVC in different forms in the medical field. One type is a rigid material with excellent tensile strength, and another for alternative to rubber. When it comes to PVC, the uses of plastic include catheters and IV bags.

[15] M. H. Kudzin, D. Piwowarska, N. Festinger, and J. J. Chruściel, "Risks Associated with the Presence of Polyvinyl Chloride in the Environment and Me Disposal and Utilization," Materials (Basel), vol. 17, no. 1, p. 173, Dec. 2023, doi: 10.3390/ma17010173.

As plastics break down, they generate microplastics that accumulate in the environment and living organisms, eventually entering the food chain. The prese poly(vinyl chloride) (PVC) in soil and water poses a significant threat to ecosystems worldwide. Due to their durability and lightweight nature, microplastic pa easily transported by water and air, ultimately settling in the soil. Consequently, microplastic pollution impacts the entire ecosystem. Since microplastics are detected in both tap and bottled water, humans are also exposed to their potential harmful effects.

[17] "Tensile Property Testing of Plastics." Accessed: Feb. 06, 2025. [Online]. Available: https://www.matweb.com/reference/tensilestrength.aspx

Polycarbonate has a ultimate tensile strength of 70 MPa, 100 % elongation, and 2.6 tensile modulus GPa.

[18] "Comparison of Grip Strength Among 6 Grip Methods - ScienceDirect." Accessed: Feb. 06, 2025. [Online]. Available: https://www.sciencedirect.com/science/article/pii/S0363502314008922?via%3Dihub

Article outlines finger strength between index, middle, ring, and pinky finger to thumb. They use a dynamometer as their tool to measure. They conclude inc has generally the highest strength and the 5 finger (full grip) was the largest value in strength. The grip value can be used to calculate possible deformation

[19] "Grip Strength in Healthy Caucasian Adults: Reference Values - ScienceDirect." Accessed: Feb. 06, 2025. [Online]. Available: https://www.sciencedirect.com/science/article/pii/S0363502308000129

Table 6: Grip Strength Regression Equations

Side	Adjusted R^2	Regression Equation
R	0.762	$y = 21.57 - 16.14 \times \text{Female} - 3.13 \times 10^{-5} \times \text{Age}^3 + 3.15 \times 10^{-6} \times \text{Height}^3 + 0.74 \times \text{BMI} - 2.32 \times 10^{-4} \times \text{BMI}^3$
L	0.752	$y = 13.90 - 16.36 \times \text{Female} + 1.26 \times \text{Age} - 2.32 \times 10^{-2} \times \text{Age}^2 + 1.01 \times 10^{-4} \times \text{Age}^3 + 2.35 \times 10^{-6} \times \text{Height}^3 + 0.16 \times \text{BMI}$

y, predicted grip strength; R^2, amount of variance accounted for by the model; Age (years); Height (cm); Female = 0 for male patient; Female = 1 for female patient.

Table 6 might be helpful to calculate average grip strength of operators to compare with deformation of material

Table 7: Reference Values for Male Grip Strength

Age (y)	Right Grip Strength (kg)				Left Grip Strength (kg)			
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum
20–29	53	8	36	70	51	8	29	65
30–39	54	10	36	83	52	9	33	77
40–49	54	7	34	70	52	8	28	70
50–59	51	9	29	79	49	8	27	73
60–69	45	7	32	63	43	7	29	65
70–79	38	9	17	51	35	8	16	47
80–95	31	8	16	44	28	7	18	42

Table 8: Reference Values for Female Grip Strength

Age (y)	Right Grip Strength (kg)				Left Grip Strength (kg)			
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum
20–29	32	5	19	44	30	5	16	42
30–39	33	5	21	49	32	5	22	45
40–49	32	6	19	46	30	5	19	44
50–59	28	5	14	39	27	5	13	38
60–69	26	5	10	40	25	5	11	36
70–79	21	4	12	29	20	4	9	27
80–95	16	4	10	27	15	4	9	25

Average values for males or females, right or left hand, also based on age

[20] F. E. Boas and D. Fleischmann, "CT artifacts: causes and reduction techniques," Imaging in Medicine, vol. 4, no. 2, pp. 229–240, Apr. 2012.

If metal will have to be used, then there is techniques to correct for artifact: iterative construction and metal deletion methods

[21] ProPlate, “What metals are commonly used to enhance the radiopacity of catheter components?,” ProPlate®. Accessed: Feb. 05, 2025. [Online]. Ava
https://www.proplate.com/what-metals-are-commonly-used-to-enhance-the-radiopacity-of-catheter-components/

Metals are used to increase radiopacity because of their material composition that absorbs and scatters radiation

[22] “Johns Hopkins researchers solve imaging scan problems caused by metal implants - Johns Hopkins Biomedical Engineering.” Accessed: Feb. 05, 2
Available: https://www.bme.jhu.edu/news-events/news/johns-hopkins-researchers-solve-imaging-scan-problems-caused-by-metal-implants/

Metal is a “huge pain” for radiologists so it should be avoided in the design as much as possible.

Conclusions/action items: Summarize in PDS.

2025/02/07-Aesthetics, Appearance, and Finish Research (Compiled)

KSHIRIN ANAND - Feb 07, 2025, 12:20 AM CST

Title: PDS Aesthetics, Appearance, and Finish Research

Date: 02/07/2025

Content by: Rini

Present: None

Goals: Document compiled research on Aesthetics, Appearance, and Finish specifications for Needle Holder design

Citation: In content

Content:

[23] "Looking Good Matters for Devices, Too." Accessed: Feb. 05, 2025. [Online]. Available: https://www.mddionline.com/digital-health/looking-good-matters-for-devices-too

While functionality, safety, and durability are critical, aesthetics play a larger role than the medical device industry often admits.

A well-designed medical device integrates function, human factors (usability), and aesthetics to create value.

Devices must appeal to multiple groups: healthcare providers, patients, purchasing agents, and investors.

1. Ensuring the device meets clinical and performance requirements.

2. Making the device intuitive and easy to use.

3. Impacting perception, user experience, and brand identity.

Donald Norman's three levels of beauty:

1. Immediate, subconscious attraction to form.

2. How the device looks and feels during use.

3. The personal, subjective interpretation of its aesthetics.

Aesthetic consistency across product lines builds recognition and trust.

User & Patient Perception:

Associate well-designed devices with reliability and quality.

Aesthetic design can reduce anxiety and improve confidence in treatment.

As patients increasingly interact with devices, aesthetics will become a competitive advantage.

Conclusions/action items: Summarize in PDS.

2025/02/07-Quantity Research (Compiled)

KSHIRIN ANAND - Feb 07, 2025, 12:21 AM CST

Title: PDS Quantity Research

Date: 02/07/2025

Content by: Rini

Present: None

Goals: Document compiled research on quantity specifications for Needle Holder design

Citation: In content

Content:

[16] "3D Printer Cost Calculator," Design Innovation Lab. Accessed: Feb. 05, 2025. [Online]. Available: https://making.engr.wisc.edu/3dprint-cost/

From the makerspace, polycarbonate filament to 3D print is 5 cents per gram which is one of the cheapest option they have which contributes to keeping our low cost

Doing some math, at 170g, we can get about 35 devices printed within 300 budget

[24] "Significance, Errors, Power, and Sample Size: The Blocking and Tackling of Statistics - PubMed." Accessed: Feb. 05, 2025. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/29346210/

30 is a widely accepted sample size to calculate statistical significance.

Conclusions/action items: Summarize in PDS.

2025/02/13- Hand Tool Handle Design Based on Hand Measurements

KSHIRIN ANAND - Feb 13, 2025, 7:38 PM CST

Title: Hand tool handle design based on hand measurements

Date: 02/13/2025

Content by: Rini

Present: None

Goals: Understand and implement recommended specifications for hand held devices

Citation: C. Wang and D. Cai, “Hand tool handle design based on hand measurements,” MATEC Web Conf., vol. 119, p. 01044, 2017, doi: 10.1051/matecconf/201711901044.

Content:

Provides guidelines for hand tool handle design based on anthropometric hand measurements to improve user comfort and ergonomics.

Handle design considerations

- Handle design should be based on users’ hand length and breadth.
- Gender differences affect handle size preference.
- The optimal handle cross-section is elliptical rather than cylindrical.
- The best ratio of handle cross-section width to length is **1:1.25**.

Recommended dimensions

- Handle Diameter:
  - Ideal range: **30-40 mm**, though studies suggest **25-50 mm** may accommodate more users.
  - Should be about **19.7% of hand length**.
- Handle Length:
  - Minimum **100 mm**, as 95% of workers have a palm width below this threshold.
- Handle Slope:
  - Pistol-shaped handles should be tilted at **78°**.
  - Hammer handles should be **slightly curved (10°)** or tilted **20-40°** to reduce wrist strain.

Anthropometric (measurements and proportions of the human body) data from study

- 60 participants (30 male, 30 female).
- Average hand length: 177.9 mm (males: 187.9 mm, females: 167.9 mm).
- Average hand breadth: 79.4 mm (males: 83.6 mm, females: 75.2 mm)

Ergonomic considerations

- Handle size should account for gender-based differences.
- Properly designed handles improve grip comfort and reduce musculoskeletal strain.
- Elliptical cross-sections provide better force distribution and grip efficiency.

Conclusions/action items: Possibly implement in design process.

KSHIRIN ANAND - Feb 13, 2025, 6:22 PM CST

MATEC Web of Conferences 119, 01044 (2017) DOI: 10.1051/matecconf/201711901044
IMETI 2016

Hand tool handle design based on hand measurements

Ching-yi Wang[1*] and Deng-chuan Cai[2]

[1]Department of Industrial Design, Tatung University, Taipei City 104, Taiwan
[2]National Yunlin University of Science and Technology, Douliou, Yunlin City 64002, Taiwan

Abstract. This study provides a tool handle design guideline based on measurements of hand gripping diameter. Anthropometric measurements on hands of 60 participants were collected with a caliper. The results in the current study concluded the guidelines for handle design, including: (1) a definition of handle design was depended on the users' hand length and hand breadth, (2) different gender would affect the size of tool handle, (3) the handle length at least should be 100mm, (4) the cross-section handle of elliptical shape was better for gripping, and (5) the best ratio of handle cross-section with width and length should be 1:1.25. These findings can serve as references for tool handle design, and improve comfort for users.

1 Introduction

Correct tool design is important for preventing upper-extremity musculoskeletal disorders. Considering the ergonomics of a hand-tool, in addition to its main function, the most important part is the tool's handle. Tool handle design research has been previously limited to the determination of the diameters of cylindrical handles to increase performance and comfort for reducing the chances of CTD (i.e., blisters, inflamed skin, cramped muscles, etc.) [1-4]. Many studies have researched the topic of tool handle design to define the optimal size and shape of a tool handle. Most of the studies have focused on cylindrical [5-7] or elliptical [8-9] shapes of the handles to provide guidelines for determining the optimal diameters to increase finger-force comfort, exertion, and the contact area. According to the previous studies on the related designs of the ergonomic handle, a hand tool design principles are summarized as following:

- Handle diameter: a grip design should consider the hand action when holding the grip [10]. A handle with a diameter of 30 to 40mm is most suitable for a gun or electric tool [5]. Moreover, the handle suitable for both male and female was a cylindrical handle with a diameter of around 40cm [6]. Some studies suggested that the handle diameter should be in a range of 30 to 45 mm [7]. However, some studies argued that the diameter should be in a range of 25 to 50mm [6]. In addition, a suitable handle diameter should be 19.7% of the hand length [11]. The handle shape should be an elliptical shape with a width and length ratio of 1: 1.25 that can be used for the operation of push force and pull force [8].
- Handle length: the minimum handle length should be 100 to 125mm [12]. The palm width of 95% of workers is less than 100mm [7]. Moreover, the average of hand breadth for the males was 87mm, and that for the females was 78mm [13].

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2025/02/13- Helping Surgeons’ Hands: A Biomechanical Evaluation of Ergonomic Instruments

KSHIRIN ANAND - Feb 13, 2025, 7:38 PM CST

Title: Helping Surgeons’ Hands: A Biomechanical Evaluation of Ergonomic Instruments

Date: 02/13/2025

Content by: Rini

Present: None

Goals: Understand how instruments are evaluated from more of a biomechanics perspective and learn study design to apply to ours

Citation: J. G. Putnam, F. D. Kerkhof, K. N. Shah, A. W. Richards, and A. Ladd, “Helping Surgeons’ Hands: A Biomechanical Evaluation of Ergonomic Instruments,” The Journal of Hand Surgery, vol. 49, no. 9, p. 933.e1-933.e6, Sep. 2024, doi: 10.1016/j.jhsa.2022.12.006.

Content:

Impact of ergonomically designed surgical screwdriver handles on reducing required hand force and improving surgeon comfort - important to see study design

Methods

- Custom 3D-printed screwdriver handles were developed based on glove sizes (6-8).
- Ten participants (3 women, 7 men) tested three ergonomic handle sizes against a standard screwdriver.
- Measurements: **Thumb and index finger peak force, Contact area, User preference**
- Flexible force sensors measured force and contact area during screw insertion into a polyurethane block - probably can't use without breaking budget but can apply for the future

Findings

- Ergonomic handles for glove sizes 6 and 7 required significantly **less thumb force**compared to the standard screwdriver:
    - Size 6 ergonomic handle: 702 N vs. 1780 N (standard)
    - Size 7 ergonomic handle: 567 N vs. 1780 N (standard)
- Index finger force was also lower for all ergonomic handles.
- **80% of participants preferred** an ergonomic handle over the standard screwdriver.
- Handle size closest to glove size was preferred.
- **Larger handles improved torque application**, reducing thumb and finger strain.
- Women and those with smaller hands benefited the most from ergonomic designs.

Implications

- Ergonomic surgical instruments can improve efficiency, reduce fatigue, and minimize the risk of musculoskeletal injuries.
- 3D printing offers a cost-effective solution for custom surgical instruments without increasing inventory costs.
- Future designs should consider individual hand size rather than a "one size fits all" approach.

Conclusions/action items: Perhaps implement study design into our testing protocols.

KSHIRIN ANAND - Feb 13, 2025, 7:39 PM CST

SCIENTIFIC ARTICLE

Helping Surgeons' Hands: A Biomechanical Evaluation of Ergonomic Instruments

Jill G. Putnam, MD, Fam D. Kerkhof, PhD, Kalpit N. Shah, MD, Alexander W. Richards, BA, Amy Ladd, MD

Purpose "Ergonomic" is a common descriptor for a desk or computer workspace but is a term rarely used to describe a surgical instrument. Instead, surgeons spend many hours in inconvenient positions, often using instruments that are not ergonomic. Improving the ergonomics of surgical instruments may decrease the required force for simple tasks and allow for more efficient surgery.

Methods To evaluate the impact of ergonomic surgical instruments, the authors developed ergonomic screwdriver handles. The shape and size of these handles were engineered using previous dental studies and 3-dimensional modeling to create an ideal handle for specific glove sizes. Participants were recruited to test 3 different ergonomic handle sizes against a standard screwdriver while assessing digital peak force, digital contact area, and participant preference. Ten participants (3 women) with glove sizes ranging from 6 to 8 were evaluated.

Results Ergonomic screwdriver handles sized for glove sizes 6 and 7 required significantly less thumb peak force than the standard screwdriver for all participants (70.2 N for glove size 6 and 56.7 N for glove size 7 ergonomic screwdrivers, vs 178.0 N for "one size fits all" standard screwdriver). Participants consistently preferred screwdrivers that required lower thumb and index finger forces. All ergonomic handles required lower thumb and index finger force. Eighty percent of participants preferred a screwdriver modeled within 1 glove size of their own.

Conclusions Improved ergonomic handles require less force and are preferred by surgeons.

Clinical relevance The significant decrease in thumb peak force for glove sizes 6 and 7 suggests that there is room for ergonomic improvement in instruments, especially for surgeons with smaller hands. Manufacturing ergonomic screwdriver handles and using the evolving convenience of 3-dimensional printing may help to develop a more comfortable work environment for surgeons. *(J Hand Surg Am. 2024;49(9):932.e1-e6. Copyright © 2024 by the American Society for Surgery of the Hand. All rights reserved.)*

Key words Biomechanical, ergonomic, hand surgery, screwdriver.

Online Exclusive

MANY OCCUPATIONAL HAZARDS are unique to surgeons. For example, microsurgery involves repetitive motions and prolonged uncomfortable positions, including cervical spine hyperflexion, creating a risk of degenerative cervical conditions.[1,2] Repetitive pinching activities have been associated with an increased risk of carpal tunnel syndrome and osteoarthritis.[3–5] Unsurprisingly,

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2025/03/13-Design Meeting

KSHIRIN ANAND - Mar 13, 2025, 9:20 PM CDT

Title: Design Meeting

Date: 03/13/2025

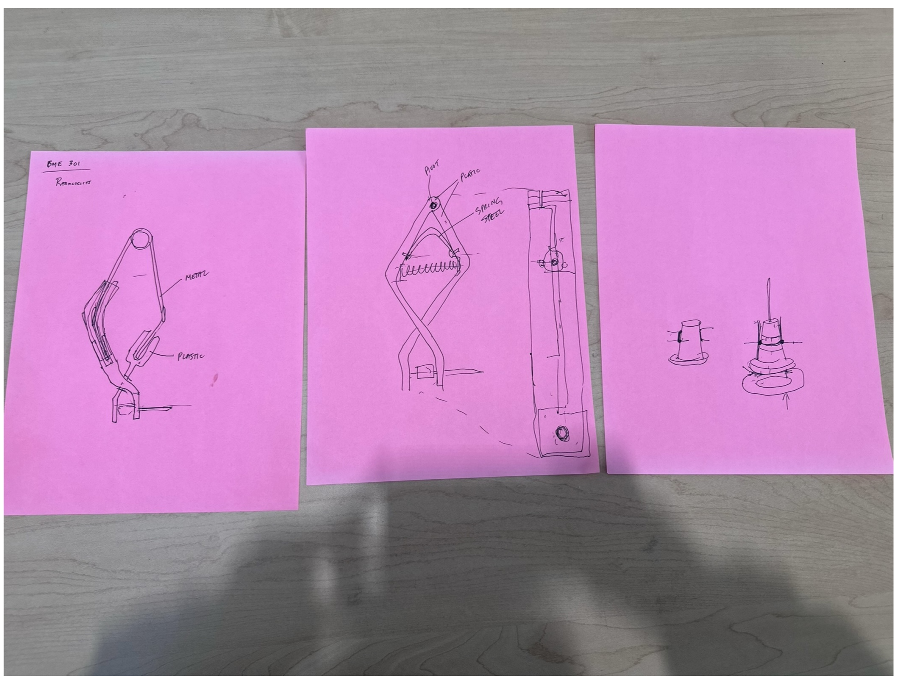
Content by: Rini

Present: Rini and Jesse (from TeamLabs)

Goals: To get experts opinion on the design, and ways to fabricate and model in CAD

Content: Notes from meeting

- Plastic can work at first, but relaxes over time
    - Will relax immediately when autoclaved for sterilization
- Modify design to incorporate metal spring at palm or fingers



- Needle Hub Mechanism shouldn't be molded to fit to account for tolerances with the needle hub
    - Adapting a 2 point attachment so needle doesn't rock
- Highlighted mechanisms within each design that could be difficult to CAD model (attachment and pivot points, needle brace, etc.)
    - Mentioned using 3D scanner at maker space to gather dimensions for needle hub

Conclusions/action items: Set up follow up meeting to help with CAD modeling chosen design

2025/02/13- Presentation tips lecture reveiw

KSHIRIN ANAND - Feb 13, 2025, 7:59 PM CST

Title: Presentation Tips

Date: 02/13/25

Content by: Rini and Gabi

Present: None

Goals: Review presentation tips

Slide Design:

- Layout: Align bullets consistently, use logical flow (not necessarily chronological).
- Content: Follow the 6x6 rule (6 words per line, 6 lines per slide). Avoid unnecessary images.
- Titles: Keep concise; avoid long titles or decorative borders.

Engagement:

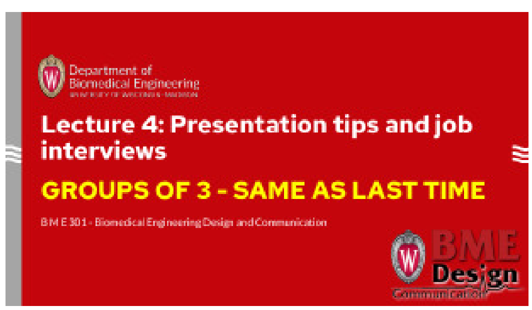
- Highlight project impact ("So what?").
- Maintain enthusiasm, eye contact, and avoid talking to the screen.
- Focus on key highlights (avoid deep technical dives).

Graphics:

- Use clear CAD images/sketches with labels/scale. Remove cluttered backgrounds.
- Results: Present graphs (not raw data), include statistics (averages ± deviations, ≥3 replicates).
- Common Errors to Avoid:
- Overly nested bullets (limit hierarchy).
- Raw data tables (use summarized graphs).
- Unlabeled or low-quality images.

Conclusions/action items: Implement in preliminary presentation

KSHIRIN ANAND - Feb 13, 2025, 8:00 PM CST



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BME_301_-_Lecture_4_-_Presentation_tips_and_job_interviews.pdf (950 kB)

2025/03/13-3D Scanning Directions

KSHIRIN ANAND - Mar 13, 2025, 9:39 PM CDT

Title: 3D Scanning Directions

Date: 03/13/2025

Content by: Rini

Present: Rini

Goals: Find out how to 3D Scan at the Makerspace

Link: https://making.engr.wisc.edu/equipment/3d-scanners/

Content:

3D Scanners at UW–Madison Design Innovation Lab

	Key Features & Specs	Software & Post-Processing	Access & Notes
Creaform Handyscan 700	• Professional-grade scanner with sub-millimeter resolution • Ideal for detailed, small to medium parts	• Uses Creaform VX Elements for mesh analysis (adding surfaces, lines, planes, points)	• VX Elements is available only on a few dedicated Makerspace laptops (check-out with shop manager approval) • May require powder spraying (provided) and target stickers for large objects
Creality RaptorX	• Wireless hybrid scanner • Combines blue laser and NIR technology • Scanning range: 5 mm to 4,000 mm • Suitable for capturing both fine details and large objects	• Inherent scanning software for capturing data (post-processing can be done in other mesh editors)	• Lightweight and portable, ideal for versatile applications
Structure Sensor (iPad-mounted)	• Integrated with an iPad • Portable and user-friendly	• Scanning software built into the iPad • Outputs .stl files that can be edited using Mesh Mixer (free)	• iPad is checked-out with the scanner • Mesh Mixer is installed on all CAE computers in the Makerspace
Einscan SP	• Stationary scanner for small to medium parts	• Uses Mesh Mixer for scanning and editing • .stl file output available via email	• Scanning software is installed on a nearby CAE computer (staff available for assistance) • Option to install on your own laptop
Creaform HandySCAN & Academia 50	• Similar to Handyscan 700 in capabilities • Available in an Academia version for educational use	• Uses VX Elements for both scanning and mesh editing • Alternate options available (e.g., DesignX)	• VX Elements is only accessible on Makerspace computers • For additional software options, consult with staff for more information

Conclusions/action items: Makerspace offers consultation and hands-on guidance for integrating 3D scanning data into your projects.

01/30/2025 Needle Holders to Reduce Staff Hand Exposure

Gabriela Cecon - Jan 31, 2025, 9:36 AM CST

Title: Needle Holders to Reduce Staff Hand Exposure

Date: 01/30/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To understand how needle holders may reduce staff hand exposure during computed tomography fluoroscopy (CTF) guided procedures.

Content:

- CT fluoroscopy, CT fluoro or CTF are in-room real-time CT imaging
  - Useful to guide interventional radiology procedures
  - Allows visualization of needle path small lesions and neighboring critical structures
- During the procedure, the needle advancement happens in the imaging/irradiation plane, so direct manipulation places the hand in the direct beam
  - In this case, the yearly occupational limit would be exceeded in <3 minutes
- Quick-check (QC) method: uses intermittent imaging to check needle position and needle advancement happens during beam-off
- Needle holders (NH): avoid direct manipulation of the needle during continuous viewing
- Some delicate needle holders have been developed but many authors prefer metallic sponge forceps or towel clamps
  - Widely available, lightweight, strong, easy to sterilize, and relatively low-cost
- Still, many professionals end up recurring to manual manipulation because of tactile feedback, grip, and bending
- Respiratory motion is a concern (e.g., lung biopsies)
- Hand monitoring was performed during two series of biopsies with comparable characteristics
  - 47 performed with only the quick-check method (QC) and occasional side-handle (SH) manipulation of the needle
  - 63 performed with needle holders
- Despite limitations, needle holders were shown to be efficient in reducing mean hand exposure during clinical procedures
  - The IR performs about 200 procedures a year
    - Without needle holders, the maximum allowable exposure limit (500mSv) would be reached after only 100 procedures
    - With needle holders, the total annual hand exposure would be below the regulatory limit

References:

[1] S. Sarmento *et al.*, “The use of needle holders in CTF guided biopsies as a dose reduction tool,” *Journal of Applied Clinical Medical Physics*, vol. 19, no. 1, pp. 250–258, Nov. 2017, doi: https://doi.org/10.1002/acm2.12234.

Conclusions/action items:

- Prepare questions for the client and set up an initial meeting
- Do more research on gaps with existing methods

02/04/2025 Neurological Complications of Dural Punctures

Gabriela Cecon - Feb 06, 2025, 11:28 PM CST

Title: Neurological Complications of Dural Punctures

Date: 02/04/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To gain a deeper understanding of the neurological risks and complications associated with lumbar and cervical dural punctures, aiming to incorporate features in our design that minimize them.

Citation:

[1] "Neurological complications of lumbar and cervical dural punctures with a focus on epidural injections - *Surgical Neurology International*," Surgical Neurology International, 2015. https://surgicalneurologyint.com/surgicalint-articles/neurological-complications-of-lumbar-and-cervical-dural-punctures-with-a-focus-on-epidural-injections/ (accessed Feb. 07, 2025).

[2] T. J. Amrhein, S. N. Parivash, L. Gray, and P. G. Kranz, "Incidence of Inadvertent Dural Puncture During CT Fluoroscopy–Guided Interlaminar Epidural Corticosteroid Injections in the Cervical Spine: An Analysis of 974 Cases," *American Journal of Roentgenology*, vol. 209, no. 3, pp. 656–661, Jun. 2017, doi: https://doi.org/10.2214/ajr.16.17738.

[1] D. Tran, King-Wei Hor, A. A. Kamani, V. A. Lessoway, and R. N. Rohling, "Instrumentation of the Loss-of-Resistance Technique for Epidural Needle Insertion," *IEEE Transactions on Biomedical Engineering*, vol. 56, no. 3, pp. 820–827, Mar. 2009, doi: https://doi.org/10.1109/tbme.2008.2011475.

Content:

Background: the client mentioned that spine injections are commonly performed for pain treatment but that there is a struggle since there are a lot of blood vessels close to the brain and if punctured, the patient can have a stroke.

- Lumbar and cervical dural punctures can occur as a result of a number of medical procedures, including epidural steroid injections (ESI) which are used for pain treatment [1]
- Potential punctures may be inadvertent or deliberate and they can cause neurological complications such as intracranial hypotension, subdural hematomas, cranial nerve palsies, and in cervical cases they become severe spinal cord injuries or strokes [1]
- The use of these procedures is widespread [1]
  - There are approximately 9 million epidural steroid injections in the US [1]
  - From 2000 to 2014, lumbar transforaminal ESI increased by 609% [1]
- Inadvertent dural puncture rate of 1.4% (14 out of 974 cases) [2]
- Challenges
  - Small target area in the cervical dorsal epidural space (1.5-4mm at C7), which requires precise control [2]
  - Midline gaps in ligamentum flavum which reduce the reliability of the loss-of-resistance technique [2]
    - Loss-of-resistance technique: a syringe is filled with air, saline, or anesthetic and attached to the needle and the operator applies pressure to identify resistance associated with denser tissues [3]
  - Injections are performed at all cervical levels (C1-C2 through C7-T1) so the device must be adaptable to different anatomical locations [2]

Design considerations:

- Need for a locking mechanism to secure the needle
- Some type of feedback system to avoid punctures
- The device must accommodate multiple hand positions

Conclusions/action items:

- Cervical needle injections present the risk for neurological complications which the device should minimize
- Further research must be done on standardized guidelines for such procedures
- Incorporate considerations into design ideas

02/04/2025 Needle Deflection and Tissue Deformation

Gabriela Cecon - Feb 06, 2025, 10:46 PM CST

Title: Needle Deflection and Tissue Deformation

Date: 02/04/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To evaluate possible ways of minimizing needle deflection and tissue deformation which cause displacement of the needle target during insertion and compromise the procedure.

Citation:

[1] N. Abolhassani, R. V. Patel, and F. Ayazi, “Minimization of needle deflection in robot-assisted percutaneous therapy,” *The International Journal of Medical Robotics and Computer Assisted Surgery*, vol. 3, no. 2, pp. 140–148, 2007, doi: https://doi.org/10.1002/rcs.136.

Content:

- Tissue deformation and needle deflection are the main complications in needle insertion procedures and significantly reduce the efficiency of treatment
- In percutaneous procedures, imaging is commonly used to assist with visualization but there are limitations to visual feedback along the insertion path such as lack of visual data in certain parts of the path or low resolution
- In this study, a model was described to estimate the amount of needle deflection during insertion without imaging feedback, and a trajectory-generation algorithm was proposed that allows for straight insertion of the needle with 2 degrees of freedom
- Deflection of flexible long needles is caused by the geometry of the needle tip and the mechanical properties of soft tissue
- Tissue deformation happens due to the mechanical properties of the tissue and frictional forces with the needle
    - Some suggestions to reduce that deformation are needle rotation and control of needle velocity based on force data
- To provide accurate needle insertion, it's valuable to calculate the magnitude of deflection orthogonal to the insertion direction and to compensate for it
- Bevelled-tip needles deflect toward the direction of the bevel and cause a curved path inside the tissue (figure 1)

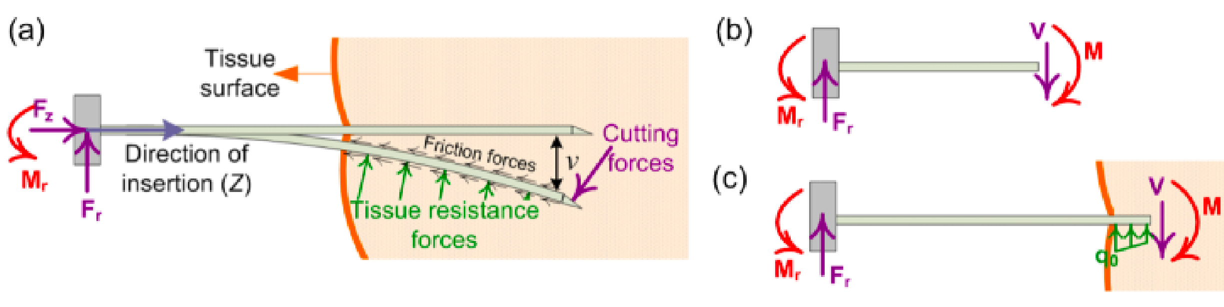


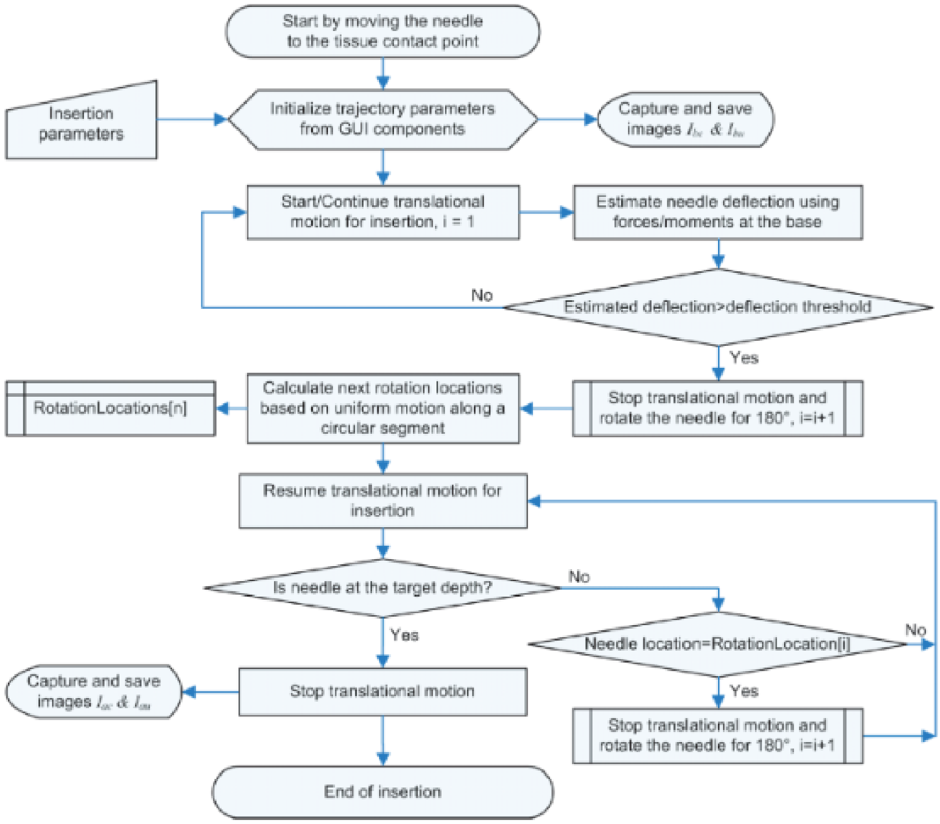
Figure 1: needle deflection in 2D. (a) Forces acting on the needle. (b) Shear force V and bending moment M at a cross-section just to the left of the tissue surface. (c) Shear force and bending moment at a cross-section just to the right of the tissue surface (inside the tissue)

- Trajectory generation: based on mathematical modeling, it was concluded that such needle deformation can be compensated by rotating the needle 180 degrees when deflection surpasses a pre-defined tolerance level
    - Whenever that movement is required, translational motion is stopped for the rotation to be performed
    - Depending on tissue type and depth of insertion, this may be necessary at several points along the trajectory
        - The following model estimates the amount of needle deflection at each time step:

$$v = \sum_{i=0}^{n} (3\Delta M_{r_i} L^2 - \Delta F_{r_i} L^3)/6EI$$

where n is the number of steps to reach a certain depth inside the tissue and □Mri and □Fri are changes in the amount of moment and force values between two consecutive steps

Flowchart of the trajectory-generation algorithm:



Conclusions/action items:

- Needle deflection is a major challenge in needle insertion procedures and should be considered in the design of the needle holder
- Further discussion with the group and brainstorming is ideal to evaluate ways of compensating for needle bending
- In-depth research must be done about the feasibility of incorporating a similar model to the device

02/05/2025 Soft Tissue Phantoms for Needle Insertion Testing

Gabriela Cecon - Feb 06, 2025, 11:26 PM CST

Title: Soft Tissue Phantoms for Needle Insertion Testing

Date: 02/05/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To compare different tissue phantom materials and determine their suitability for mimicking biological tissue.

Citation:

[1] A. Leibinger et al., “Soft Tissue Phantoms for Realistic Needle Insertion: A Comparative Study,” *Annals of Biomedical Engineering*, vol. 44, no. 8, pp. 2442–2452, Aug. 2016, doi: https://doi.org/10.1007/s10439-015-1523-0.

Content:

- A study was conducted to compare tissue phantom materials to real biological tissue, specifically porcine brain
- The comparison includes gelatin (commonly used) and a composite hydrogel (CH) developed at College Imperial London
- Testing was performed using fluoroscopy and imaging techniques to visualize internal behavior
- Indentation and compression tests were performed to test for stiffness

Findings:

- Gelatine has more elasticity but the CH better mimics the viscosity of real tissue
  - Gelatin doesn't capture the time-dependent relaxation of the tissue which occurs in real tissue
- Neither fully replicates real tissue so their use applies to different applications
- Both had similar insertion force profiles and resistance to insertion
- The CH had lower cutting resistance which means it was better for needle steering techniques
- Gelatine deforms more than CH
- There were limitations in both materials, so a matrix was developed (table 1):

Matching criterion	Gelatin	CH	MCH
Stiffness	✔	✔	✔
Relaxation		✔	✔
Inner friction	✔	n/a	
Fracture resistance		✔	
Transparency	Yes	No	Yes
Example application	Quasi-static scenarios e.g., surgical needle steering	Highest fidelity e.g., brain shift simulation[4]	Dynamic scenarios e.g., tool-tissue interaction experiments

Table 1: Summary table for the comparison of the phantom materials (MCH is a modified, transparent version of the composite hydrogel)

Conclusions/action items:

- The materials described in the study were efficient for phantom testing but have limitations which should be explored further
- More research on additional tissue phantom materials should be done
- Do research on the feasibility of those materials for phantom testing and look for other recommendations

01/30/2025 Assessment of Needle Guidance Devices

Gabriela Cecon - Jan 31, 2025, 9:43 AM CST

Title: Assessment of Needle Guidance Devices

Date: 01/30/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To evaluate needle guidance devices and how they reduce fluoroscopy time and hand operator hand dosage during procedures.

Content:

- Fluoroscopy time reduction:
    - Freehand procedures required a median of 50 seconds (range: 31–98 s) of fluoroscopy
    - Laser guidance alone or combined with needle holders reduced this time to ~30 seconds ($P < .02$)
    - Needle holders alone did not reduce fluoroscopy time
- Operator hand exposure:
    - Freehand procedures led to a median operator hand dose of 275 mSv
    - Laser guidance alone or combined with needle holders reduced this dose to less than 36 mSv ($P < .001$)
    - Needle holders alone did not significantly reduce exposure
- Procedure time:
    - Freehand procedures were the fastest (median 1.9 minutes)
    - Using laser guidance or needle holders slightly increased procedure time (~3 minutes), which is likely negligible in clinical practice

Gaps to discuss:

- Needle holders alone:
    - Still require frequent manual adjustment
    - Don't assist with visibility
    - Don't improve the number of corrections needed
- Overall, they helped with stability but not with needle target and placement

Reference:

[1] M. W. Kroes *et al.*, “Assessment of Needle Guidance Devices for Their Potential to Reduce Fluoroscopy Time and Operator Hand Dose during C-Arm Cone-Beam Computed Tomography–guided Needle Interventions,” *Journal of Vascular and Interventional Radiology*, vol. 24, no. 6, pp. 901–906, Jun. 2013, doi: https://doi.org/10.1016/j.jvir.2013.02.037.

Conclusions/action items:

- Discuss how the team can address the gaps that needle holders still present
- Do more research on visualization techniques

01/30/2025 Robotic Arm for CT Guided Procedures

Gabriela Cecon - Jan 30, 2025, 11:48 PM CST

Title: Robotic Arm for CT Guided Procedures

Date: 01/30/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To find strengths and weaknesses in this robotic arm device and how they relate to the scope of our project, as well as understand any proprietary information.

Content:

- Current gaps: existing robots for this application have limited dexterity, workspace, or accuracy
- This device promises a highly dexterous, low-profile robotic arm for CT-guided percutaneous needle biopsy
- Issues with manual procedures: radiologists need to be constantly moving the patient and adjusting the target
- The system is mounted to an active motion stage superior to the patient's head and teleoperated by a radiologist *(figure 1)*
- Allows for large working areas and many approach angles to targets
- The targeting error was lower than 1mm
- Even though it can be easily modified for different procedures, it is mostly designed for lung biopsies

Fig. 4: - Experimental setup for the robot with Optitrack system and marker for benchtop tests (green box), robot and controller (blue box), and simulation with input device (red box).

Figure 1: Experimental setup for the robot.

Reference:

[1] D. A. Schreiber, D. B. Shak, A. M. Norbash and M. C. Yip, "An Open-Source 7-Axis, Robotic Platform to Enable Dexterous Procedures within CT Scanners," 2019 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS), Macau, China, 2019, pp. 386-393, doi: 10.1109/IROS40897.2019.8968552.

[2] D. Schreiber et al., "CRANE: a 10 Degree-of-Freedom, Tele-surgical System for Dexterous Manipulation within Imaging Bores," 2022 International Conference on Robotics and Automation (ICRA), Philadelphia, PA, USA, 2022, pp. 5487-5494, doi: 10.1109/ICRA46639.2022.9811732. keywords: {Cranes;Target tracking;Minimally invasive surgery;Trajectory tracking;Computed tomography;Systems architecture;Medical services},

Conclusions/action items:

- Discuss the positive and negative points of this design
- Evaluate how we can incorporate robotics into our design
- Do research more in-depth about any proprietary information

01/30/2025 Zerobot - Remote-Controlled Needle Insertion

Gabriela Cecon - Jan 31, 2025, 12:12 AM CST

Title: Zerobot - Remote-Controlled Needle Insertion

Date: 01/30/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To understand the advantages and disadvantages of the Zerobot guidance system and its place in the competitive landscape.

Content:

- Physician exposure to radiation during the procedure is a major concern
- Commercially available robots for CT-guided have been developed
    - Many of them perform tasks like needle path planning, needle positioning, needle orientation, and needle insertion guidance, but they don't actually perform the needle insertion
    - Others that do perform needle insertion are yet to be commercialized and are only used in laboratories

Zerobot:

- Components:
    - A floor-mounted robot system with six degrees of freedom (DOF)
    - An operation interface that includes a portable controller, touch screen, operation PC, and a LAN connection to the robot
    - A needle holder designed to fit commercially available needles for different procedures
    - Force sensors at the robot's arm to provide real-time feedback
- Setup:
    - The robot is placed beside the CT table, aligned to the patient and the CT scanner
      The robot arm can rotate and be positioned on either side of the table
      The needle holder is attached, and the system is covered with a sterile drape
- Needle targeting can be manual or semi-automated (the software analyses the scans and calculates the alignment
- The physician controls the insertion via the touch screen or controller
- The needle orientation can be adjusted mid-procedure based on real-time imaging
- The robot has an ultra-fast insertion mode (500 mm/sec) for precision and reduced tissue displacement
- Advantages:
    - Eliminates radiation exposure to physicians
    - More precise and stable needle positioning
    - Less physical strain on the physician
    - Automates and standardizes the procedure, reducing error rates
    - Allows for remote control

Reference:

[1] T. Hiraki A * § *et al.*, "Zerobot ® : A Remote-controlled Robot for Needle Insertion in CT-guided Interventional Radiology Developed at Okayama University." Accessed: Jan. 31, 2025. [Online]. Available: https://ousar.lib.okayama-u.ac.jp/files/public/5/56370/20181214115849655803/72_6_539.pdf

Conclusions/action items:

- Conduct additional research on gaps and issues with the design
- Do research on patents associated with the device

03/12/2025 3D-Printing Plastics

Gabriela Cecon - Mar 13, 2025, 11:17 PM CDT

Title: 3D-Printing Plastics

Date: 03/12/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To compare different 3D-printing plastic filaments to be used as a soft material in the clamp jaws.

Link: https://bambulab.com/en/filament-guide

IEEE Citation:

[1] "Choose the right filament - 3D Filaments Guide for Bambu Lab Printers," *bambulab.com*. https://bambulab.com/en/filament-guide
[2] "Nylon 12 Powder SLS Powder For Strong, Functional Prototypes and End-Use Parts With high tensile strength, ductility, and environmental stability, Nylon 12 Powder is suitable for creating complex assemblies and durable parts with minimal water absorption. Nylon 12 Powder is specifically developed for use on the Fuse 1." Available: https://formlabs-media.formlabs.com/datasheets/2001447-TDS-ENUS-0.pdf

Content:

- Comparison of material properties for Bambu plastic filaments [1]
- Key considerations:
    - Biocompatibility
    - Flexibility
    - Durability (shelf life)
    - Sterilization resistance
- The Bambu printer at the UW-Madison Design Innovation Lab has a range of plastic filaments (table attached to this entry)
- TPU is the most flexible in the list
- Formlabs also prints nylon 12 powder filament
    - Somewhat flexible (flexural strength 66 MPa, flexural modulus 1600 MPa) [2] but less than TPU, whose bending strength and modulus are not even applicable due to the material being too flexible for a meaningful flexural modulus measurement

Conclusions/action items:

- TPU is the best material considering biocompatibility, flexibility, durability, and sterilization resistance
- Nylon 12 is also a good option when it comes to biocompatibility, durability, and sterilization resistance, however, it is less flexible
- Must consider how we will attach this portion to the rest of the design

Gabriela Cecon - Mar 13, 2025, 11:09 PM CDT

Download

Bambu_filament_guide.pdf (4.21 MB)

03/12/2025 Radiolucent Structural Materials

Gabriela Cecon - Mar 13, 2025, 11:49 PM CDT

Title: Radiolucent Structural Materials

Date: 03/12/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To explore radiolucent material options to build structural parts of the device such as screws.

Link: https://www.mddionline.com/materials/radiolucent-structural-materials-for-medical-applications

https://making.engr.wisc.edu/equipment/3d-printers/

IEEE Citation:

[1] “Radiolucent Structural Materials for Medical Applications,” *Mddionline.com*, 2023. https://www.mddionline.com/materials/radiolucent-structural-materials-for-medical-applications

[2] “3D Printers,” *Design Innovation Lab*, 2024. https://making.engr.wisc.edu/equipment/3d-printers/

Content:

- The device in general must be radiolucent and not interfere with the imaging path
    - All components, including potential screws, washers, pins, etc must be made of radiolucent material
        - Those structural and harder components must be fabricated of a material other than TPU for better functionality
            - Aluminum, stainless steel, and titanium are radiopaque and obstruct x-rays
            - For devices that are transparent to x-rays, thermoplastic and carbon-fiber composites provide properties that are competitive with traditional metals [2]
            - Typically, the material stiffness of plastics is much lower than that of metals
                - Flexural modulus is several hundred thousand pounds per square inch (psi) for many unreinforced thermoplastics; in contrast, the flexural modulus of aluminum is 10 million psi
            - Some newly developed composites have mechanical properties competitive with those of some metals, with flexural moduli as high as 8 to 17 million, and they're also lighter than traditional metals
                - Carbon has strength and stiffness properties that, in many cases, exceed those of metals
                    - However, it is brittle and often times difficult to fabricate in complex shapes
                    - Carbon fiber is also available for printing at the Makerspace [2]

Conclusions/action items:

- Perform more research on weather carbon fiber would be suitable for shapes like screws
- Consult with the Makerspace to get more information on the 3D-printing of the material

03/12/2025 Spring Clamp Holder

Gabriela Cecon - Mar 13, 2025, 10:59 PM CDT

Title: Spring Clamp Holder

Date: 03/12/2025

Content by: Gabriela Cecon

Present: N/A

Goals: To evaluate possible ways of implementing a spring clamp into the design to allow for a natural compression state.

Link:

https://snakeclamp.com/products/needle-nose-spring-clamp

https://www.rockler.com/rockler-needle-nose-spring-clamp

IEEE Citation:

[1] “Needle Nose Spring Clamp,” *Snakeclamp.com*, 2025. https://snakeclamp.com/products/needle-nose-spring-clamp (accessed Mar. 14, 2025).
[2] “Rockler Needle-Nose Spring Clamps,” *Rockler.com*, 2022. https://www.rockler.com/rockler-needle-nose-spring-clamp (accessed Mar. 14, 2025).

Content:

- Needle Nose Spring Clamp attachment [1]
    - Strong clamping force
    - Dual mounting holes for attaching either parallel or perpendicular to flexible gooseneck tube arms
    - Made of tough, lightweight fiber reinforced nylon

- Rockler Needle-Nose Spring Clamps [2]
    - Narrow clamping pads that fit into grooves and other tight spots
    - Great for repairs of small items, or for use in restricted spaces
    - The clamp geometry is specially designed so that opening the clamp is easy to accomplish with one hand

Conclusions/action items:

- Design concept is a good idea to maintain a natural compression state
- Present ideas to the team
- Continue research on materials for the different components (screw, washers, etc)

Preliminary Research on Needle Navigation and its applications

SOFIA YEATES-DELAHOZ - Feb 11, 2025, 9:42 AM CST

Title: Preliminary Research on Needle Navigation and its applications

Date: 1/30/25

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To conduct preliminary research on needle navigation and to learn more about its surgical applications.

Content:

Link to article: https://www-sciencedirect-com.ezproxy.library.wisc.edu/topics/computer-science/needle-insertion

Citation: Q. Huang, J. Zhou, and Z. Li, "Review of robot-assisted medical ultrasound imaging systems: Technology and clinical applications," *Neurocomputing*, vol. 559, p. 126790, Nov. 2023, doi: 10.1016/j.neucom.2023.126790.

- Needle guidance procedure is the insertion of a puncture needle into a designated location, and then the needle begins to work
- Advantages:
  - Less trauma
  - Less pain
  - Faster recovery compared to open surgery
- Disadvantages:
  - Smaller field of view
  - Requires additional image guidance such as laparoscopy, CT, MRI, US, and more
    - US has the advantages of real-time imagine, flexible deployment, metal compatibility, and no ionizing radiation, which is appropriate for guiding needle puncture
    - Freehand US guidance relies heavily on the surgeon's experience and makes it difficult to accurately locate the needle and demonstrate its position
- Robotic US-guided needle guidance systems have been proposed in a number of systems for biopsy, percutaneous radiofrequency ablation, brachytherapy, insertion, and more
- Tracking needles is important for robotic needle guidance systems because the echogenic properties of the needle make them poorly visible in US images.
- Visibility of the needle in the ultrasound image is affected by the needle size and insertion angle, which limits surgical planning under the guidance of visual servoing
- Other imaging modalities have been researched to compensate for the shortcomings of ultrasound
  - Some lesions that are not visible on US are visible on MRI, but MRI is not suitable for surgical guidance
  - Initial location of the lesion is known only by MRI and the biopsy can be done by the robot needle navigation guidance
  - Near-infrared (NIR) allows for a complete imaging of the veins on the body surface
  - Stereo NIR provided non-contact visualization of superficial vessels for identifying the target cannulation site.

Conclusions/action items: Take into account these advantages/disadvantages of needle navigation systems and use that to form questions for the client.

Preliminary Research on MRI and US Image-Guided navigation system using a needle manipulator

SOFIA YEATES-DELAHOZ - Feb 11, 2025, 9:42 AM CST

Title: Preliminary Research on MRI and US Image-Guided navigation system using a needle manipulator

Date: 1/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

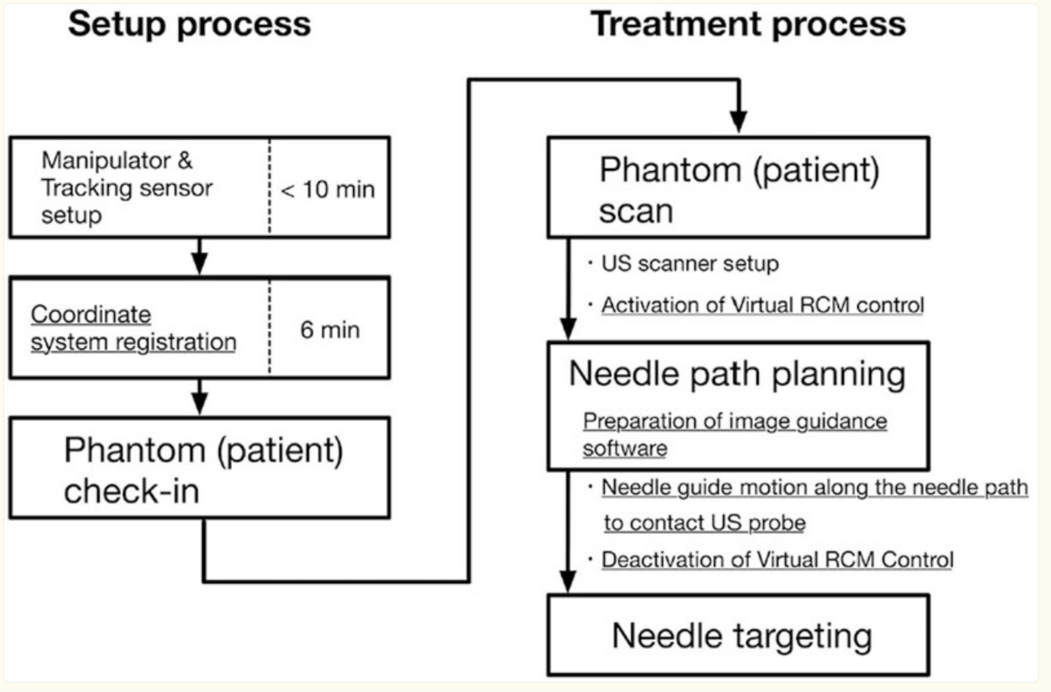
Goals: To conduct preliminary research on how needle navigation systems are used with MRI and US machines to see if that will be applicable to our project.

Content:

Link to article: https://pmc.ncbi.nlm.nih.gov/articles/PMC7067635/

Citation: A. Yamada, J. Tokuda, S. Naka, K. Murakami, T. Tani, and S. Morikawa, "Magnetic resonance and ultrasound image-guided navigation system using a needle manipulator," *Medical Physics*, vol. 47, no. 3, pp. 850–858, Mar. 2020, doi: 10.1002/mp.13958.

- Image guidance is crucial for percutaneous tumor ablations, which enables accurate needle-like applicator placement into target tumors while avoiding tissues that are sensitive to injury and/or correcting needle deflection
- Ultrasound is widely used for image guidance, MRI is preferable due to its superior soft tissue contrast
- Goal of this study was to enable the physician to interactively maneuver a needle under MRI guidance for percutaneous tumor ablation
    - In this study, needle placement occurs outside the MRI scanner under MRI-US fusion guidance combined with physical assistance provided by the needle manipulator
- The needle manipulator was a portable robotic arm comprising an end effector with passive gimbal and three-axis active linear base stage mounted on a four-wheel cart
- The range of motion for the linear base stage was driven by non-magnetic ultrasonic motors
- The needle manipulator allowed physicians to tilt the needle guide freely via the handgrip while the base stage automatically adjusted the needle guide position using virtual remote center of motion control in order to maintain the preset distance between the needle guide and target, and keep the needle directed at the target as shown elsewhere
- Image guidance software worked as an information hub for the entire system and provided the following features
    - Importing images from the MRI and US scanners
    - Position and orientation of markers from the tracking sensor
    - Device status from the robot console, visualizing them effectively with the procedure plan on the in-room monitors to navigate the procedure
- Needle placement accuracy: Targeting error over fifty trials was 1.6 +/- 0.6 mm with maximum and minimum errors of 3.1 and 0.6 mm.
- Maximum and minimum needle path angles from the vertical line were 27.2° and -26.1°
- This system leverages cooperative physician-device interaction to enable the physician to adjust needle guide angles directly in the scanner room
    - This input is more intuitive than control through a graphical user interface as the physician can maneuver the needle guide directly, without being distracted by needing to keep the needle aligned with the target
- A limitation of this study was that it was limited to phantoms.



Conclusions/action items: Discuss findings with the team and ask our client if any of these medical imaging devices will need to be used along with the needle navigator.

Preliminary Research on Needle Insertion System with Image Guidance and Deformation Simulation

SOFIA YEATES-DELAHOZ - Feb 11, 2025, 9:42 AM CST

Title: Preliminary Research on Needle Insertion System with Image Guidance and Deformation Simulation

Date: 1/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To conduct preliminary research on needle navigation and insertion systems in order to gain familiarity with the topic for the purposes of the project.

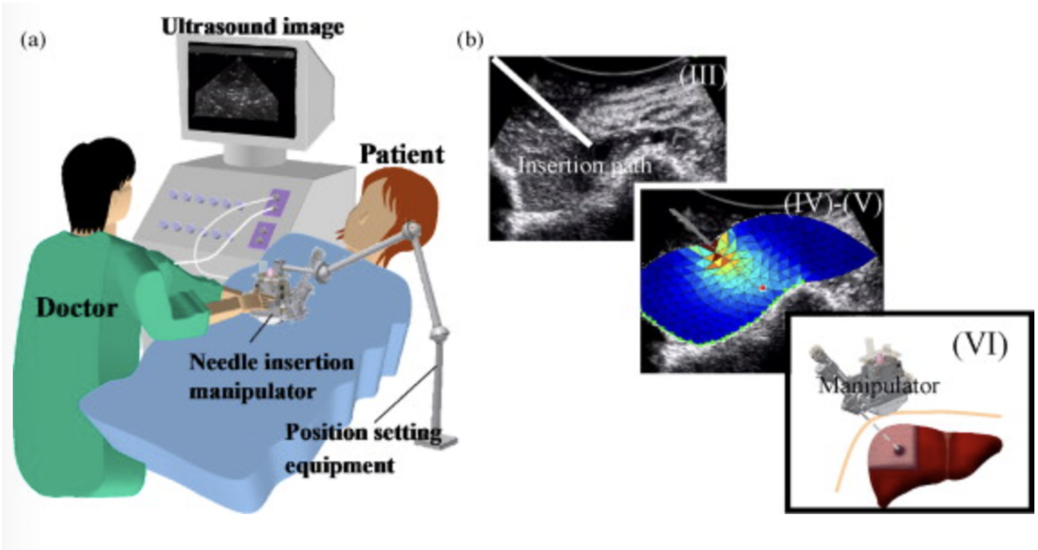
Content:

Link to article: https://www-sciencedirect-com.ezproxy.library.wisc.edu/science/article/pii/S0895611109001098?via%3Dihub

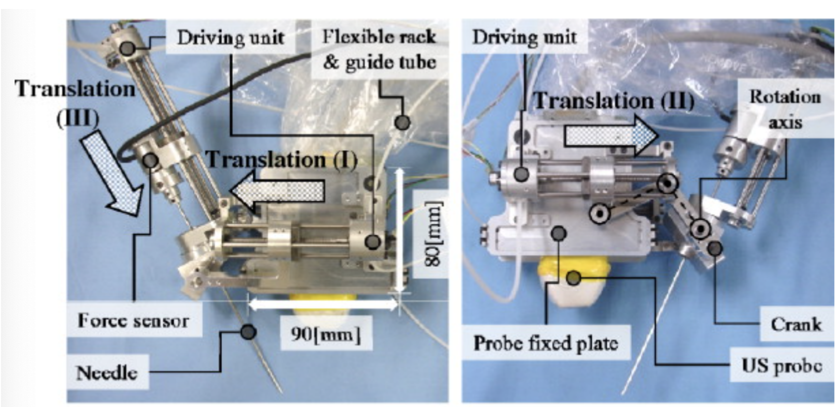
Citation: Y. Kobayashi *et al.*, “Development of an integrated needle insertion system with image guidance and deformation simulation,” *Computerized Medical Imaging and Graphics*, vol. 34, no. 1, pp. 9–18, Jan. 2010, doi: 10.1016/j.compmedimag.2009.08.008.

- Problems can arise when surgeons manually insert needles, including different treatment results and the possibility of a complicating disease resulting from needle insertion into large blood vessels, etc.
- The purpose for developing a needle insertion robot is to realize accurate needle insertion independent of surgeon skills
- There are some needle insertion robots that have been researched such as MRI-guided and ultrasound-guided needle insertion robots
- From this article, ultrasound equipment was used to guide the operation of the needle insertion
    - Ultrasound images are typically used in the needle insertion process because ultrasound equipment provides real-time imaging of internal organs and can be easily set up
    - Ultrasound is more widespread in use than CT and MRI equipment
- Needle insertion manipulator (the device from this study) must be compact so that it doesn’t interfere with the surgeon’s access to the patient during an operation
- The manipulator must also position the tip of the needle accurately
- Design: Ultrasound-guided needle insertion manipulator.
    - This design provides compactness and high-accuracy position and decreases registration error.
    - The process of treatment using the integrated needle insertion manipulator is:
        - The needle insertion manipulator is combined to the position setting equipment such as endoscope holding device. 3D position of the manipulator is flexibly changed and fixed at any position by the device.
        - The surgeon moves the ultrasound probe by hand and scans the target cancer. Surgeon sets the ultrasound probe with needle insertion manipulator at an adequate position to visualize the target cancer in the ultrasound image. In this process, the navigation system presents the position of ultrasound probe and tumor.
        - Needle insertion position and orientation are decided by the surgeon from the position of the target cancer displayed in the ultrasound images. In this process, the surgeon then uses the GUI (Graphical User Interface) to order the needle insertion path from the computer.
        - The position of the ultrasound probe with needle insertion manipulator is obtained using an optical 3D position measurement system. Then, the position is registered to the preoperative CT or MRI diagnostic image of the organ.
        - The physical organ model is developed based on the obtained images. Then, deformation of the organ during needle insertion is simulated. The surgeon optimizes the insertion path using the simulation results of deformation.

- The position of the needle is set at the insertion path determined by the manipulator. The needle is then inserted into the target cancer.



- Manipulator mechanism: Contains three degrees of freedom
  - Horizontal position: which decides the position of the manipulator horizontal direction in relation to the cross-section of the ultrasound image
  - Posture: Decides the needle insertion angle
  - Needle insertion: Decides needle insertion after the needle position and angle have been determined



(a) Translation side (b) Slide-crank side.

Conclusions/action items: Discuss the findings with the team and see what features of this device are optimal and applicable to the purposes of our project.

Preliminary Research on US-guided needle handling using a guidance positioning system in a phantom

SOFIA YEATES-DELAHOZ - Feb 11, 2025, 9:42 AM CST

Title: Preliminary Research on US-guided needle handling using a guidance positioning system in a phantom

Date: 1/30/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

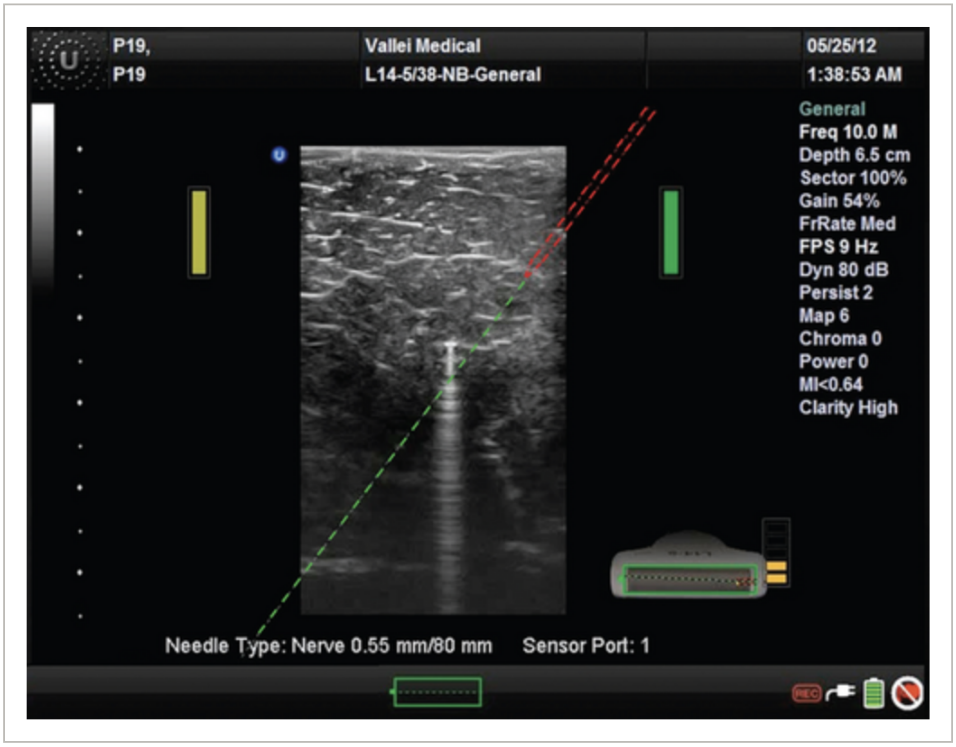
Goals: To learn more about the software behind the SonixGPS needle navigation system.

Content:

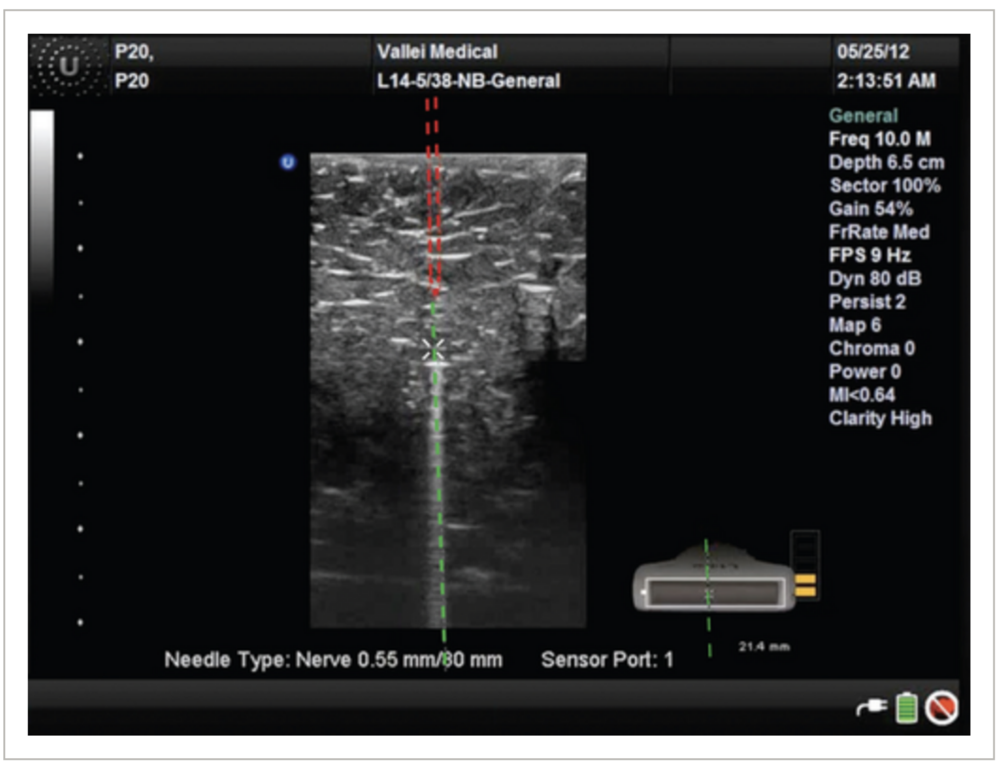
Link to article: https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/10.1111/anae.12461

Citation: L. K. P. Tielens, R. B. C. C. Damen, J. G. C. Lerou, G. -J. Scheffer, and J. Bruhn, “Ultrasound-guided needle handling using a guidance positioning system in a phantom,” *Anaesthesia*, vol. 69, no. 1, pp. 24–31, Jan. 2014, doi: 10.1111/anae.12461.

- The use of ultrasound-guided technique for peripheral nerve blocks is increasing and has been shown to be beneficial, but there are still many limitations
- This technique provides a view of the needle, target nerve, surrounding structures (such as blood vessels, lung, muscles, tendons, and bones) and the distribution of local anesthetic
- Shortcoming: Needle may frequently become invisible in less than very experienced hands
- Continuously viewing a moving needle requires a high level of skill, but is the key to the rapid, uneventful performance of a successful block
    - This is a significantly challenging skill to acquire as it requires a lot of practice to learn to align the needle and ultrasound beam precisely before and during insertion with the in-plane approach, as well as to assess the location of the needle tip with the out-of-plane approach
    - Steep insertion which targets a nerve at a deep level, further hinders obtaining a view of the needle
- Latest development is the needle guidance positioning system (GPS)
    - Needle GPS is a new application of medical navigation for regional anesthesia
    - This allows for the predicted trajectory and point of intersection to be continuously displayed on the screen, together with the US image.
- The study was to evaluate if the SonixGPS needle GPS can help physicians learn the skill required to advance the needle rapidly in the most direct way towards a target and to position the needle tip at the exact location, while keeping the needle visible at times.
- SonixGPS: needle GPS that is integrated into a standard ultrasound system
    - Can be used without or with navigation assistance
    - For the in-plane approach, orientation bars help guide the needle in the beam of the ultrasound
    - The footprint of the transducer and the relative position of the needle are shown at the bottom of the screen
    - After choosing an insertion point exactly in the middle of the transducer to get precise alignment, the predicted trajectory is shown as a green dotted line (in the image below)
    - With the needle in the right position and direction, the orientation bars turn green, the needle is seen straight under the transducer foot and the green dotted line hits the target
    - While advancing the needle into the tissue, the needle projection is shown as a red dotted line.



- For the out-of-plane approach, the transducer's footprint and the relative position of the needle are also shown.
    - After choosing an insertion point, the predicted trajectory is shown as a green dotted line and a white "X" marks the point where the needle tip will intersect the ultrasound beam.
    - The insertion angle and direction of the needle must be chosen so as to place the X exactly on the target.
    - When the needle tip intersects the beam, the white X turns green.
    - When the needle is advanced even deeper, the X turns white again, indicating that the needle shaft is seen instead of the needle tip.



- Results: Needle visibility was better while using the needle GPS
    - Better visibility of the needle was associated with a shorter execution time for both the US-only and the US aided by GPS technique
    - Better needle visibility was also associated with fewer needle repositionings for the US aided by GPS, but not for the US-only technique

Conclusions/action items: Discuss with the team and learn more about the SonixGPS design and evaluate it as a competing design.

Research on Phantom Tissues

SOFIA YEATES-DELAHOZ - Feb 14, 2025, 9:47 AM CST

Title: Research on Phantom Tissue - Brain Study

Date: 2/13/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To learn more about phantom tissue and how it can compare to human tissues.

Citation: A. Leibinger *et al.*, "Soft Tissue Phantoms for Realistic Needle Insertion: A Comparative Study," *Ann Biomed Eng*, vol. 44, no. 8, pp. 2442–2452, Aug. 2016, doi: 10.1007/s10439-015-1523-0.

Content:

Link to article: https://pmc.ncbi.nlm.nih.gov/articles/PMC4937066/pdf/10439_2015_Article_1523.pdf

Notes:

- Phantoms are common substitutes for soft tissues in biomechanical research and are usually tuned to match tissue properties using standard testing protocols at small strains
- The response due to complex tool-tissue interactions can differ depending on the phantom and no comprehensive comparative study has been published to date, which could aid researchers to select suitable materials
- In this study, gelatin and a composite hydrogel were matched for mechanical stiffness to porcine brain and the interactions during needle insertions within them were analyzed
- Many tissues have properties that vary between *in vivo* and *in vitro* conditions
    - Can be highly sensitive to factors such as post-mortem time, sample preparation, or mechanical history
- Soft tissue specimens are also cumbersome to fix and constrain which is why phantoms are commonly used
- Phantom materials should mimic the relevant properties of soft tissue closely in order to translate findings to medical procedures
    - Materials are usually selected based on typical mechanical characterization protocols, such as compression, tensile, indentation tests, or for best desired performance
- One of the most common soft tissue phantoms for modeling interactions is gelatin
    - They are stiff and are generally tuned by modifying the gelatin concentration which matches the properties of the soft tissue
    - Gelatin has a near linear elastic behavior, with lower rate dependency compared to soft tissue, which is generally highly viscous
- In this study, the materials used were as follows:
    - Composite hydrogel that contained phytagel (PHY), polyvinyl alcohol (PVA), and deionized water along with bovine gelatin powder
- Testing:
    - The needle insertions were performed using this mechanical testing system:
        - A straight needle was inserted from the top and exited through a hole in the bottom of the box for the different conditions

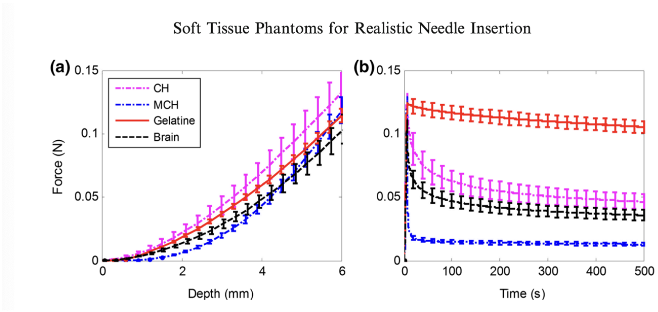


Figure 1: Results from compression and relaxation tests on porcine brain, gelatin, CH, and MCH.

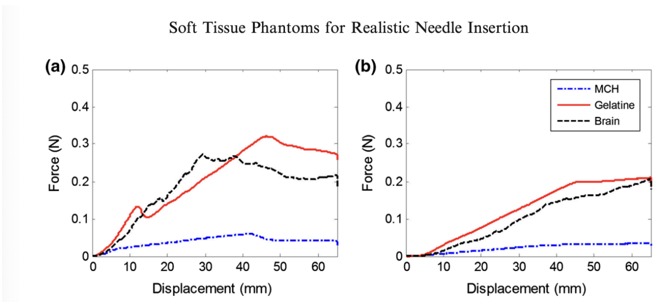


Figure 2: Mean forces of the needle for insertions and reinsertions into MCH, gelatin, and porcine brain.

- Takeaways from study:
  - Gelatin and composite hydrogels match different characteristics of tissue (in this case brain) during needle insertions but neither are a perfect substitute for mimicking its complete behavior
  - Selection of phantom materials should be informed by both the special material properties of the soft tissue reference and the complex needle-tissue interactions needing to be replace

Conclusions/action items: Start thinking about testing with phantoms so that in the future a testing protocol can be written. This can also help us in the case that our team chooses to go with Design #2 with the phantom tissue.

SOFIA YEATES-DELAHOZ - Feb 13, 2025, 11:35 PM CST


Soft Tissue Phantoms for Realistic Needle Insertion: A Comparative Study

INTRODUCTION

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10439_2015_Article_1523.pdf (2.51 MB)

Research on Lumbar and Cervical Epidural Steroid Injection Procedures

SOFIA YEATES-DELAHOZ - Feb 14, 2025, 9:48 AM CST

Title: Research on Lumbar and Cervical Epidural Steroid Injection Procedures

Date: 2/13/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To gain more familiarity with the background of these procedures in order to be able to present it in the presentation and in the report.

Citation:

[1] Cleveland Clinic, “Lumbar Epidural Steroid Injections: What It Is, Benefits, Risks & Side Effects,” *Cleveland Clinic*, Nov. 19, 2021. https://my.clevelandclinic.org/health/treatments/22091-lumbar-epidural-steroid-injection

[2] “Cervical Epidural Steroid Injections: What It Is, Benefits, Risks & Side Effects,” *Cleveland Clinic*. https://my.clevelandclinic.org/health/treatments/22293-cervical-epidural-steroid-injection

Content:

Links:

https://my.clevelandclinic.org/health/treatments/22293-cervical-epidural-steroid-injection

https://my.clevelandclinic.org/health/treatments/22091-lumbar-epidural-steroid-injection

Notes:

Lumbar Epidural Steroid Injection:

- Healthcare providers use lumbar epidural steroid injections (ESIs) as a pain relief option for certain causes of chronic low back pain.
- They inject an anti-inflammatory medication into the epidural space around your spinal nerves.
- Lumbar ESIs are most effective in providing pain relief from a herniated disk and spinal stenosis.
- A lumbar ESI is an injection an anti-inflammatory medication either a steroid or corticosteroid
- Main goal is to manage chronic pain caused by irritation and inflammation of the spinal nerve roots in your low back
    - This type of chronic pain is called radicular pain which can radiate down from your low back to hips, legs, and or fee

Cervical Epidural Steroid Injection:

- Helps manage spinal nerve roots in the neck (cervical region of the spine) due to certain conditions or injuries
- This type of chronic pain is called cervical radiculopathy, which can radiate down from the neck to the shoulders, arms, and or hands
- Provider injects a steroid or corticosteroid medication into the epidural space around the spinal cord in the neck
- The seven vertebrae in the cervical spine are named C1 through C7 from top to bottom
    - These vertebrae have several important roles including:
        - Protecting your brain stem
        - Protecting your spinal cord
        - Supporting the skull
        - Allowing you to move your head
- Herniated disks can frequently cause chronic pain as certain nerve roots of the spinal cord can become pinched or inflamed
- During a cervical epidural steroid injection procedure, provider injects the steroid into the epidural space
- Epidural space surrounds the spinal cord like a sleeve and contains the following tissues:

- Fat
- Dural sac
- Spinal nerves
- Blood vessels
- Connective tissue

- The steroid coats the irritated nerves that are causing the pain and work to reduce the swelling and pressure on the nerve
- The steroid allows the nerve time to heal
- Cortical epidural steroid injections most often lead to temporary pain relief, but some people do not experience pain relief from the injection
- Some conditions that can lead to being recommended for a cervical epidural steroid injection
  - Cervical herniated disk
  - Cervical degenerative disk disease
  - Cervical osteoarthritis
  - Cervical spine stenosis

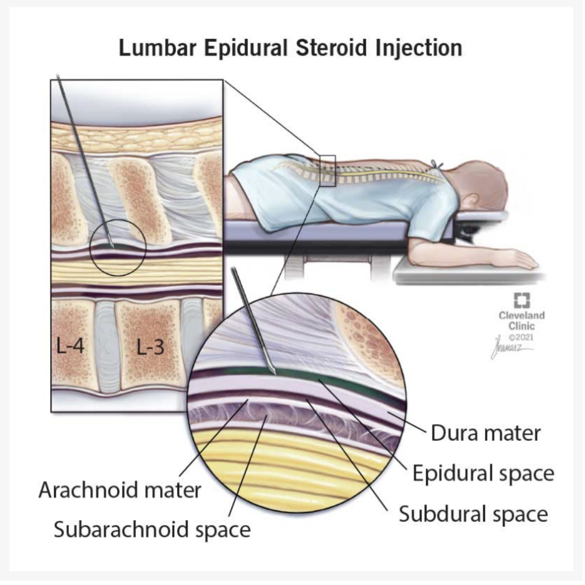

Figure 1: Fluoroscopic Guided Lumbar Epidural Steroid Injection

Conclusions/action items: Incorporate findings into the background sections of the preliminary presentation and report. Research ethics on this procedure and who is the targeted patient demographic.

Research on Risks and Long Term Effects of Needle Injections to the Spine

SOFIA YEATES-DELAHOZ - Feb 14, 2025, 9:48 AM CST

Title: Research on Risks and Long Term Effects of Needle Injections to the Spine

Date: 2/13/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To learn more about the risks associated with spine injections.

Citation:

[1] "Cervical Epidural Steroid Injections: What It Is, Benefits, Risks & Side Effects," *Cleveland Clinic*. https://my.clevelandclinic.org/health/treatments/22293-cervical-epidural-steroid-injection

[2] E. Eworuke *et al.*, "Risk of serious spinal adverse events associated with epidural corticosteroid injections in the Medicare population," *Reg Anesth Pain Med*, vol. 46, no. 3, pp. 203–209, Mar. 2021, doi: 10.1136/rapm-2020-101778.

Content:

https://my.clevelandclinic.org/health/treatments/22293-cervical-epidural-steroid-injection

Risks and Possible Complications of Cervical Epidural Steroid Injections:

- Although rare, risks and complications that apply to all types of ESI injections include:
  - Having low blood pressure
  - Experiencing a severe headache caused by spinal fluid leakage
  - Getting an infection from the epidural procedure
    - Epidural abscess, discitis, osteomyelitis, or meningitis
  - Having a negative reaction to the medication
  - Experiencing bleeding if a blood vessel is accidentally damaged during the injection, which can cause a hematoma or blood clot to form
  - Experiencing strokes to the spinal cord, brainstem, and/or cerebellum due to an accidental injection into a blood vessel
- Long-term side effects and risks:
  - Permanent neurologic deficit due to spinal cord or nerve root damage from the epidural injection
    - Can lead to conditions such as monoparesis and quadriplegia
  - Chronic pain due to spinal cord or nerve root damage from the epidural injection

Statistics on Risk for Injury from Needle Injections to the Spine:

- Overall, cervical/thoracic epidural spine injections were associated with a significantly higher risk of these events compared with lumbar/sacral ESIs
- Results from the study: Of the 11 probable cases, 5 received cervical/thoracic and six received lumbar/sacral injections
  - The rate of spinal adverse events was statistically higher for cervical/thoracic (29.4 per 1,000,000 patients) than lumbar/injections (5.1 per 1,000,000 patients

Table 3 Risk differences and score test p values for event rate (probable cases per 1 000 000 patients) comparisons

Event rate comparisons	Risk difference (CI)	P value
Cervical/thoracic versus lumbar/sacral	24.3 (6.7 to 63.8)	<0.001
Transforaminal versus non-transforaminal	-7.0 (–17.3 to 4.0)	0.16
Cervical/thoracic (transforaminal vs non-transforaminal)	70.7 (–3.8 to 311.6)	0.07
Lumbar/sacral (transforaminal vs non-transforaminal)	–8.8 (–19.1 to -1.1)	0.04

Table 1: Risk differences and score test p-values for event rate

Conclusions/action items: Include the risks of there being complications in the injection procedure in the background of the preliminary presentation and report.

SOFIA YEATES-DELAHOZ - Feb 14, 2025, 9:48 AM CST


Original research

Risk of serious spinal adverse events associated with epidural corticosteroid injections in the Medicare population

Efe Eworuke,[1] Leah Crisafi,[2] Jiemin Liao,[3] Sandia Akhtar,[2] Martha Van Clief,[1] Judith A Racoosin,[1] Michael Wernecke,[3] Thomas E MaCurdy,[4] Jeffrey A Kelman,[2] David J Graham[1]

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203.full.pdf (637 kB)

Research on Competing Designs of Needle Navigators - NAVIRFA

SOFIA YEATES-DELAHOZ - Jan 30, 2025, 11:20 PM CST

Title: Research on Competing Designs of Needle Navigators - NAVIRFA

Date: 1/28/25

Content by: Sofia Yeates-Delahoz

Present: N/A

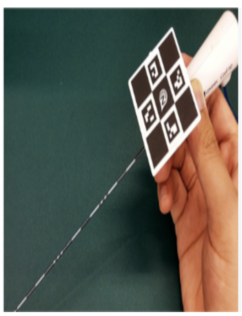
Goals: To learn more about needle navigators and what their functions are.

Content:

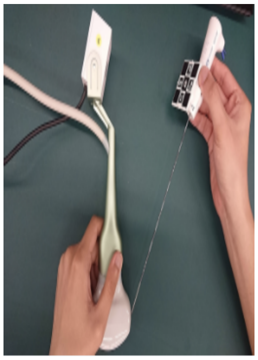
Link to article: https://navifus.com/navirfa-system/#:~:text=NAVIRFA%C2%AE%20is%20a%20%E2%80%9CGPS,ultrasound%20transducer%20in%20real%2Dtime.

Citation:

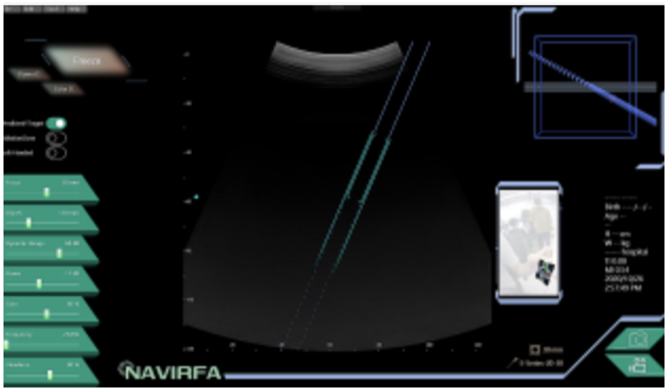
- NAVIRFA: Needle Tracking system that is designed to reduce complexity and improve accuracy in needle-based interventions for simpler, safer, and more-effective procedures
    - It is a “GPS for Needle” during ultrasonic interventional procedures, providing physicians with a precise and easy way for needle placement
    - NAVIRFA uses optical tracking technology to continually monitor the 3D position of the needle tip relative to the ultrasound transducer in real time
- Navirfa has demonstrated that it can improve surgical position
    - Tracking trajectory offers needle tip guide and a free puncture angle
    - The needle position is accurate
- Navirfa has also demonstrated that it can decrease complications during surgeries
    - Preservation of normal tissue nerve or vessel
    - Allows for shorter procedure times
- Navirfa optimizes surgical procedures by offering high training efficiency and is easy to set up
- NAVIRFA has a system configuration that consists of a tracking kit, a camera/optical sensor, and guidance software
    - Tracking kit: optical marker attached on needle instrument



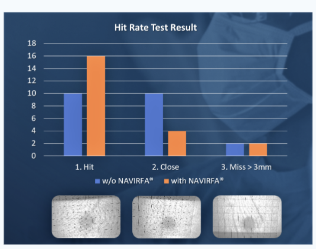
- Optical sensor: camera fix on the probe can recognize the marker

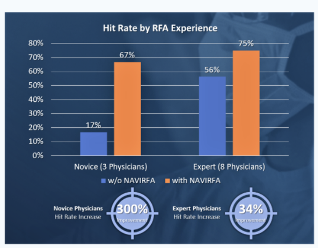


- Guidance software: position mapping to real-time ultrasound image



- Confidence Outcomes of this device: Usability Testing Report
    - Navirfa Needle Tracking System was tested by 11 physicians on the phantom and compared the accuracy between using an ultrasound alone and an ultrasound combined with Navirfa technology
        - Each user had 4 attempts, 2 times of each condition
    - Results:
        - High accuracy, error < 3.0 mm
        - Increased hit rate by 60%
        - Shorter procedure time





Conclusions/action items: Discuss with team if this competing design is applicable/related to our project and what features of it are favorable or not.

2/5/2025 - Standards Research - ISO 11608-1:2022

SOFIA YEATES-DELAHOZ - Feb 07, 2025, 10:37 AM CST

Title: Standards Research - ISO 11608-1:2022

Date: 2/5/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To conduct research on any standards that are potentially applicable to the device.

Citation: "ISO 11608-1:2022(en) Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems," *International Standards Organization*, 2022. https://www.iso.org/obp/ui/#iso:std:iso:11608:-1:ed-4:v1:en (accessed Feb. 05, 2025).

Content:

ISO 11608-1:2022 → Needle-based injection systems for medical use – Requirements and test methods

- This document covers needle-based injection systems intended for human use. It provides performance requirements and characteristics so that variations of design are not unnecessarily restricted.
- ISO 11608 series of documents deals with "hand held" or "on-body" delivery systems
- By hand held, users (patients or caregivers) control and stabilize the NIS at the injection site during administration of a discrete volume
- Delivery times for this type of NIS would therefore be limited to avoid instability and the potential for injection site trauma
- Design requirements related to system function are presented as to assist manufacturers during the design phase
  - These design requirements do not replace system testing of the components
- Materials to be used for the construction of these devices are not specified, as their selection will depend on the design, the intended use, and the process of manufacture used by individual manufacturers.
- Other standards referenced in ISO 11608 that could be applicable to this project
  - ISO 10993-1: *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
  - ISO 14971:2019: *Medical devices – Application of risk management to medical devices*
  - ISO 23908: *Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

ISO 11608 Series Road Map:

- This road map can be used to classify what standards are applicable to the device.

Figure 1 — ISO 11608 series road map

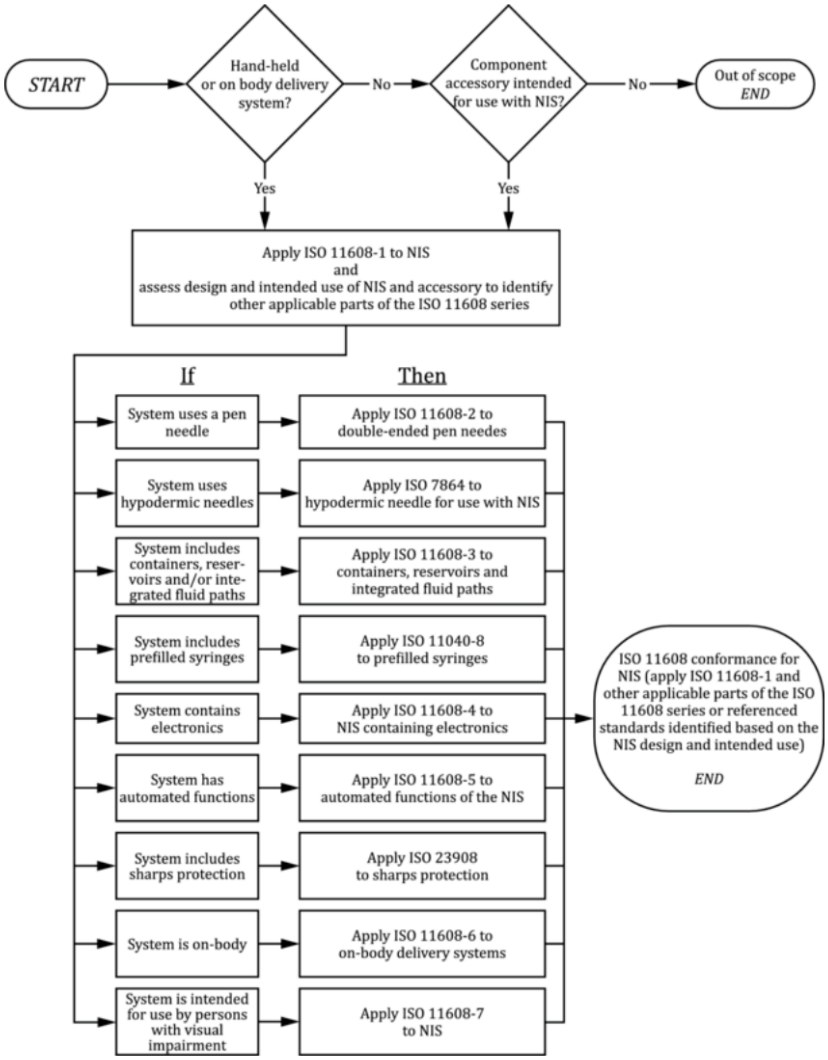


Figure 1: Road map of the ISO 11608 series that can be applied to different needle insertion systems.

Conclusions/action items: Conduct further research on standards that are applicable to testing on phantoms and also on hand-held needle device systems. Contact the UW library for access to the full ISO standard in order to be able to read all of it and see how it can potentially apply to the project. Incorporate the information learned into the *Standards and Specifications* section of the Product Design Specifications document.

2/5/2025 - Standards - FDA

SOFIA YEATES-DELAHOZ - Feb 07, 2025, 10:20 AM CST

Title: Standards - FDA

Date: 2/5/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To learn more about the regulatory control the FDA has over medical devices and how that applies to this project.

Citation:

"Classify Your Medical Device | FDA." Accessed: Feb. 06, 2025. [Online]. Available: https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

C. for D. and R. Health, "Overview of Device Regulation," FDA. Accessed: Feb. 06, 2025. [Online]. Available: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation

Content:

Overview of Device Regulation:

- Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III.
- The device classification regulation defines the regulatory requirements for a general device type.
- Most class I devices are exempt from Premarket Notification 510(k)
- Most Class II devices require Premarket Notification 510(k)
- Most Class III devices require Premarket Approval
- A description of device classification and a link to the product classification database is available here: https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
- The basic regulatory requirements that manufacturers of medical devices distributed in the U.S. must comply with are:
    - Establishment registration
    - Medical device listing
    - Premarket Notification 510(k), unless exempt, or Premarket Approval (PMA)
    - Investigational Device Exemption (IDE) for clinical studies
    - Quality System (QS) Regulation
    - Labeling Requirements
    - Medical Device Reporting (MDR)
- Premarket Notification 510(k) – 21 CFR Part 807 Subpart E: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k
    - If your device requires the submission of a Premarket Notification 510(k), one cannot commercially distribute the device until they receive approval from the FDA authorizing them to do so
    - A 510(k) must demonstrate that the device is substantially equivalent to one legally in commercial distribution in the United States
    - There is a list of Class II devices that are exempt from Premarket Notification 510(k) submission here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

Conclusions/action items: Incorporate these findings into the *Standards and Specifications* portion of the PDS document. Establish whether the device will be a Class II or Class III medical device.

2/5/2025 - Needle Holder Patent Research

SOFIA YEATES-DELAHOZ - Feb 07, 2025, 10:36 AM CST

Title: Needle Holder Patent Research

Date: 2/5/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To conduct research on patents of needle holder devices to see what the potential competition is.

Citation:

K. Brabrand, N. Bérard-Andersen, G. Fjeld Olsen, and V. Bakke, “Needle Holder Device,” Jan. 21, 2010 Accessed: Feb. 05, 2025. [Online]. Available: https://patentimages.storage.googleapis.com/6d/45/1f/0a495c1bfb0e9a/US20120022368A1.pdf

Content:

https://patentimages.storage.googleapis.com/6d/45/1f/0a495c1bfb0e9a/US20120022368A1.pdf

Patent Notes:

- This patent is for a needle holder for use in an image guided intervention procedure
- The needle holder includes a clip for holding a needle and a guide arrangement for supporting the clip and directing the needle at a desired angle relative to a patient’s body.
    - The clip includes a releasable connection such that the needle can be disengaged from the guide arrangement by a lateral movement of the clip and/or guide arrangement relative to the longitudinal axis of the needle.

Patent Background Info:

- Common interventional imaging methods include X-ray fluoroscopy, computed tomography (CT), ultrasound, and magnetic resonance imaging (MRI)
- Problem that patented device is trying to address: When starting an interventional procedure the needle is introduced a little into the patient from a selected entry point. To verify the correct position and direction a set of control images are taken. Due to the weight of the needle, especially the weight of the portion of the needle which is outside the body, gravity will deflect the needle from its intended path. This makes it difficult to ensure that the needle hits the intended target, which can be a very small area in the body.
- Examples of known needle holders can be found in: U.S. Pat. No. 4,883,053, U.S. Pat. No. 5,201,742 and WO 2004/021898
- This needle holder can be used with any conventional interventional imagine method, for example with CT guidance or fluoroscopic guidance
    - With fluoroscopic guidance x-rays are used to visualize the needle axis and direct it towards a lesion
    - To ensure that the needle holder can be accurately aligned with the target area during the use of x-ray imaging or other imaging techniques where the skin is not marked the needle holder may include markers.
        - Markers should be visible with the desired imaging method.
- Feature of the device: Each clip of the multiple clips is releasable and the use of a lateral movement relative to the needle to disengage the clip enables all the clips and hence the needle holder to be disengaged from the plurality of needles without movement of the needles.
- Another feature of the device: Since different interventional procedures require different sizes of needles, the clip of the present invention made with sufficient tolerance to accommodate a range of needle sizes.

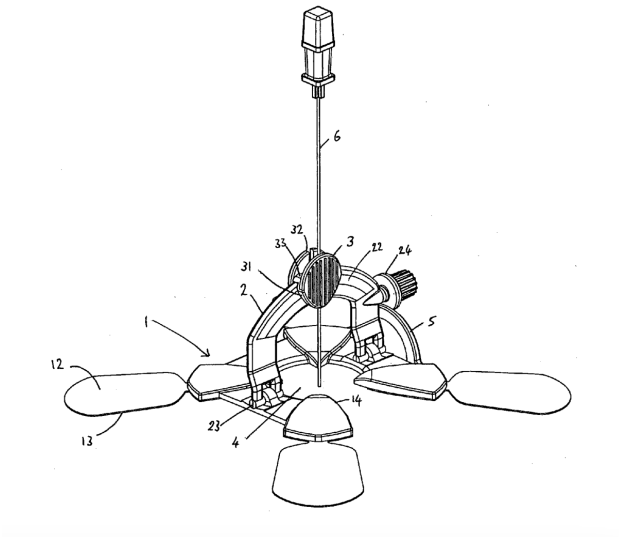
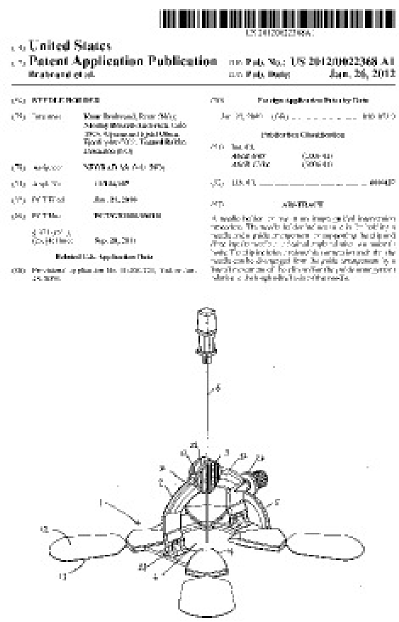


Figure 1: A sketch of the patented device.

Conclusions/action items: Add relevant information from research findings to the PDS. Conduct further research on the patents that were referenced in this document and see how they differ from this design.

SOFIA YEATES-DELAHOZ - Feb 11, 2025, 9:40 AM CST



United States
Patent Application Publication
Pub. No.: US 2012/0022368 A1
Pub. Date: Jan. 26, 2012

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US20120022368A1.pdf (1.32 MB)

2/5/2025 - Competition Research: Ultra-Pro II Device Research

SOFIA YEATES-DELAHOZ - Feb 11, 2025, 9:41 AM CST

Title: Ultra-Pro II Device Research

Date: 2/5/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To research devices on the market that provide potential competition to what our team intends to create.

Citation:

"Ultra-Pro II™ In-Plane Ultrasound Needle Guides-Multi-Angle | CIVCO." Accessed: Feb. 06, 2025. [Online]. Available: https://www.civco.com/products/ultrasound-needle-guides/ultra-pro-2-ultrasound-needle-guides-multi-angle/

Website link: https://www.civco.com/products/ultrasound-needle-guides/ultra-pro-2-ultrasound-needle-guides-multi-angle/

Content:

Device: Ultra-Pro II (In-Plane Ultrasound Needle Guides - Multi - Angle)

- CIVCO's needle guidance system utilizes a two-part system consisting of a custom reusable bracket and the disposable snap-on needle guide called Ultra-Pro II.
- Multi-angle brackets offer professionals different angles for instrument placement.
- The Ultra-Pro II needle guide incorporates flexibility and advanced features to increase productivity during US-guided procedures.
- The Ultra-Pro II guid features a large tab for improving quick-release function, allowing easy detachment of the needle from the transducer.
- The guide features a large funnel for instrument insertion and will accept a range of sizes including: 8.5FR, 14-23GA
- Brackets should be cleaned and disinfected between each use.
- Accurate needle path with on-screen guidance offers physicians real-time visualization ensuring patient safety throughout the procedure
- Reduces technique variability providing a shorter learning curve and reduced procedure time.
- This device is repeatable, easy-to-use, and has a "quick-release" feature for detachment of guide which provides physician flexibility during puncture procedures.
- Storage conditions:
  - Avoid storing product in areas of temperature extremes or in direct sunlight
  - Store in a cool, dry place
- Bracket is validated for a 5-year product life
- IFU for the device: https://www.civco.com/assets/ifus/04346212.pdf

Figure 1: Picture of the Ultra-Pro II device.

Conclusions/action items: Incorporate these findings into the PDS section and conduct further research on other potential devices on the market that are competition to the device our team intends to create.

3/13/2025 - TPU Material Research

SOFIA YEATES-DELAHOZ - Mar 14, 2025, 9:37 AM CDT

Title: TPU Material Research

Date: 3/13/2025

Content by: Sofia Yeates-Delahoz

Present: N/A

Goals: To learn more about TPU as a potential material for the flexible component of the device.

Link: https://www.hexpol.com/tpe/resources/tpe-academy/what-is-tpe/what-is-tpu/

https://omnexus.specialchem.com/selection-guide/thermoplastic-polyurethanes-tpu

IEEE Citation:

[1] “What is TPU | Thermoplastic Polyurethane Materials | HEXPOL TPE.” https://www.hexpol.com/tpe/resources/tpe-academy/what-is-tpe/what-is-tpu/

[2] Omnexus, “Thermoplastic Polyurethane (TPU) Material: Properties & Applications,” omnexus.specialchem.com, 2024. https://omnexus.specialchem.com/selection-guide/thermoplastic-polyurethanes-tpu

Content:

Thermoplastic Polyurethanes (TPE-U or TPU):

- Category of plastic created when a polyaddition reaction occurs between diisocyanate and one or more diols.
- Can be used as a soft engineering plastic or as a replacement for hard rubber.
- Typical TPU applications:
    - Castor wheels
    - Footwear
    - Sports equipment
    - Hose and tube
- Properties of TPU Materials:
    - High elongation and tensile strength
    - Excellent abrasion resistance
    - Low-temperature performance
    - Excellent mechanical properties, combined with a rubber-like elasticity
    - High transparency
    - Good oil and grease resistance

https://omnexus.specialchem.com/selection-guide/thermoplastic-polyurethanes-tpu

- TPU is the material of choice in applications where abrasion resistance is critical
    - Include technical parts

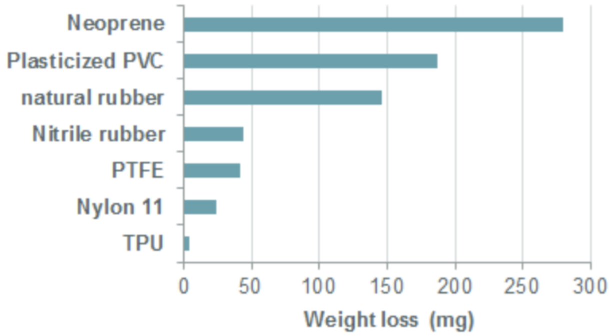

Figure 1: Abrasion resistance of materials is measured by the weight loss of a specimen in a standardized wear test. This figure depicts different materials and their abrasion resistance.

- Plasticizer-free TPU:
  - Hardness range of 55 to 80 Shore A
  - High-quality surface finish
  - Excellent adhesion to engineering plastics such as ABS and Nylon
  - Unequal scratch and abrasion resistance
- UV resistance
- Environmental filaments in TPU:
  - Environmental protection
  - TPU is abrasion resistant, other materials such as PVC crack over time
  - More elastic and lighter
  - In medical devices, it is accepted as a safe alternative to PVC
- Limitations of TPU:
  - Some grades of TPU have relatively short shelf life
  - Drying time is required before processing can begin
  - Not as cost-effective as other alternatives
  - Narrow temperature range for processing
  - Tendency to be hydrolyzed especially in case of polyester-based TPU

Conclusions/action items: Go to the Makerspace and ask about the feasibility of printing our design in TPU for the “soft material” element of the device which will hold the needle.

3/13/2025 - Bilateral Cervical Spine Injection Observation Notes

SOFIA YEATES-DELAHOZ - Mar 14, 2025, 12:20 PM CDT

Title: Bilateral Cervical Spine Injection Observation Notes

Date: 3/13/2025

Content by: Sofia Yeates-Delahoz

Present: Sofia Yeates-Delahoz

Goals: Provide notes from the observation of the bilateral cervical spine injection procedure.

Link: N/A

IEEE Citation: N/A

Content:

- The procedure was a bilateral cervical spine injection of a patient who had gotten a surgery and was feeling pain post-op. The patient reported a pain level of 6 before the injection procedure.
- After the procedure the patient
- The procedure was a bilateral cervical spine injection procedure so an injection occurred on both the left and right sides of the neck.
    - The doctor reported that during the bilateral spine injections or when performing the needle insertion on one side, using the non-dominant hand can be really tricky.
    - Some doctors try to use their dominant hand and position it over, but that can lead to more errors, so the doctors have to learn how to use their non-dominant hand to guide the needle.
        - Why our device will need to accommodate both hands (left and right) and provide sufficient stability for a physician's non-dominant hand.
- Once the needle is inserted into a certain point (need to figure out the length) it is much easier to guide the needle, since the needle is not at a length where it will bend.
- Dr. Ross provided me a hemostat (clamp) and a 25G x 2.00IN needle for the team to reference

Conclusions/action items:

Start working on the CAD model. Tell the team the observations from the procedure.

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

TAYLOR BRENDEMUEHL - Feb 14, 2025, 1:35 PM CST

Title:

Date:

Content by:

Present:

Goals:

Link:

IEEE Citation:

Content:

Conclusions/action items: