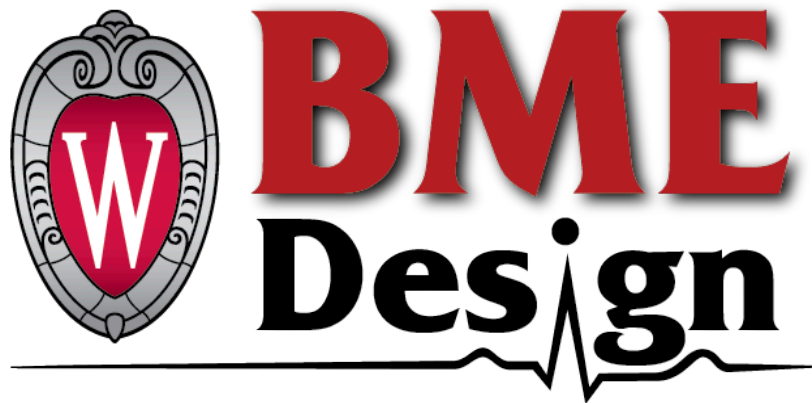




Hand Positioning Plate for Low-Dose Radiation Therapy (SteadyHand)

BME Design 200/300

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Abstract

Osteoarthritis is a widespread degenerative disease that affects millions of adults, causing significant joint pain and inflammation. Low-dose radiation therapy (LDRT) is a minimally invasive treatment option for osteoarthritis that uses low-dose X-ray radiation to reduce inflammation and relieve pain. However, current methods for positioning the hand during LDRT can require lengthy setup times, provide limited availability for consistent positioning, or cause patient discomfort. These limitations are particularly important because patients must maintain reproducible hand positioning across six treatment sessions. This project aims to develop a hand-positioning device for LDRT that improves setup efficiency, positioning reproducibility, and patient comfort. The proposed design uses a carbon fiber plate with indexed individual finger supports and padded wrist support to maintain consistent and comfortable hand placement. Low-density materials, including polyethylene terephthalate glycol (PETG) and polyurethane foam, were selected to minimize radiation beam attenuation while providing accurate structural support and comfort. The prototype will be evaluated based on three primary criteria: setup time, hand-positioning reproducibility, and radiation beam attenuation. Setup time will be measured through repeated trials, positioning accuracy will be evaluated by comparing placement across repeated setups, and beam attenuation will be compared with theoretical values. These results will determine whether the prototype meets the project's design requirements, including setup time of less than two minutes and hand-positioning within 2 - 3 mm. Ultimately, the device is intended to provide a more efficient, comfortable, and reproducible positioning method for patients receiving LDRT for osteoarthritis in their hands.

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Introduction

Motivation

Osteoarthritis is a widespread disease that affects millions worldwide, specifically 32.5 million adults as of October 2025 [1]. Its large-scale global impact makes therapies such as low-dose radiation therapy (LDRT) important to understand and improve upon. Low-dose radiation therapy is a new treatment for patients with osteoarthritis. It is characterized by X-ray radiation being delivered to the affected joints. This allows the patient to experience relief, as the degenerative nature of osteoarthritis is slowed [2]. LDRT is also important, as many other treatments for osteoarthritis consist of invasive procedures. [1]. These surgeries include smaller-scale procedures, such as Arthrodesis, where doctors will use various materials such as pins or rods to improve damage and inflammation caused by osteoarthritis. There also exists a larger-scale Total Joint Replacement, in which the entire joint is replaced by an implant that mimics the joint. While they do have their benefits, they often require long recovery times and periods of increased pain [3]. The less invasive nature of LDRT makes it a better and more realistic option for the many people affected by osteoarthritis.

Competing Product

As of recently, there are not many options for devices that help improve this therapy. Currently, there is a device that is on the market called the Dexalign Hand Positioner. While it currently does not have a patent, it is a useful device for LDRT. The setup involves a carbon fiber base plate consisting of two rotating aligners and holders for the thumbs in the middle. The alignment allows for easy replication and inclusivity, accommodating up to the 95th percentile of hand sizes [4]. The carbon fiber base plate is also close to the density of water, following current radiotherapy guidelines [4]. However, there are some downsides to it. The mechanics of the device force the 2nd and 5th digits together and the palm flat, making the procedure uncomfortable for the patient during radiation application. Indexing on it is also overcomplicated and could be simplified to make the device less overwhelming to look at and set up.



Figure 1: Dexalign Hand Positioner [4]

Current Device

The current device being utilized in the hospital consists of a cushion with a transparent plastic cover over the hand. The cover ensures the hand is stationary during the therapy, as well as ensuring replicability between treatment sessions. The cushion will also take the shape of the patient's hand for successive treatments to ensure consistency. The cushion provides the patient with ample comfort, but the design makes accuracy a little more challenging, as there is little indexing to go off of for adjustments.

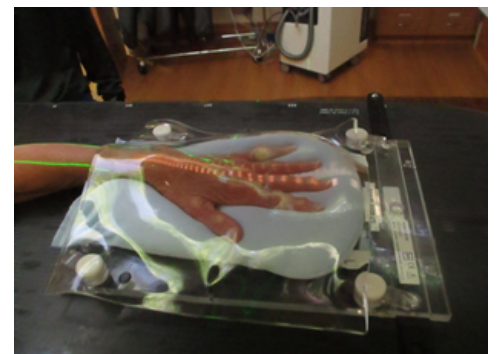


Figure 2: The current device used by the hospital

Problem Statement

Severe joint pain in the hands due to osteoarthritis and other inflammatory conditions is now frequently treated using low-dose radiation therapy. Current LDRT protocols require high setup reproducibility across 6 treatment sessions. Existing positioning systems, while effective, lead to further issues that need to be addressed. These downsides include significant discomfort for patients and complicated indexing that creates unnecessarily long setup times. The project aims to develop a hand-positioning device to be used in a clinical setting that minimizes setup time and patient discomfort while ensuring exact hand placement for each treatment session. The project must be replicable for use in other potential hospital settings as well.

Background

Low-Dose Radiation Therapy

Low-dose radiation therapy is a medical process used to help with osteoarthritis by aiming a small dose of radiation to help slow the inflammation. The X-rays attack the inflamed cells in the joints, which deflates them and relieves the patient's pain [5]. LDRT is an extremely safe method of radiation at only about 0.5 Gy per session, which is a very low dose compared to other radiation therapies [6]. A complete LDRT process consists of 6 sessions that take around 15 minutes each. However, the radiation beam is only active for 1 minute; the rest of the time is allocated to setting up the hand in the correct position. Additionally, the first session begins with a CT scan to map the inflammation and figure out where the radiation beam must be aimed.

Client Information

Dr. James Sohn works in the UW Department of Radiation Medicine at the University of Wisconsin School of Medicine and Public Health. His clinical interest is in dosimetry and experimental validation for boron neutron capture therapy and in benign diseases including osteoarthritis. Dr. Sohn's interest in osteoarthritis directly aligns with the project.

Design Specifications

The design must align with the requirements outlined by Dr. James Sohn to aid in low-dose radiation therapy. A therapist must be able to set up the device within 2 minutes and replicate the patient's hand position within 2 - 3 mm across multiple sessions. The product needs to be very easy to attach to the treatment couch and the indexing on the device must aid the clinician in treatment setup but cannot be overcomplicated. The device must be aimed to maximize patient comfort during the procedure. Based on the expected clinical patient population [7], the device must accommodate a patient hand-size range of 17.2-19.3 cm in hand length and 7.9-8.9 cm in hand width. There must be no pinching points or sharp edges. Cost, weight, and materials must be kept to a minimum to ensure that a physician has an easy time transporting the device and that the product can be easily reproduced across multiple clinics, while also being structurally stable. Since the product will be used in CT scans and low-dose radiation therapy, it must be durable enough to withstand repeated hand positioning setup and radiation exposure. It must be possible to remove the patient's hand in under 10 seconds,

if rapid removal is necessary. Given the device will be used in a hospital setting, it must withstand disinfection procedures without compromising its structural integrity.

Materials

In order for the therapy to be successful, the hand positioner must affect the beam as little as possible. If the photon beam passes through a high-density material, such as metal, the radiation scatters and the joints will be hit with a reduced dose [8]. This leads to less effective treatment. Additionally, the scattering could increase the dose on the skin and cause irritation. Therefore, the materials must have a similar density to that of water (1 g/cm^3) so that the photons are able to pass straight through undisturbed [8]. For the base plate of the hand positioner, the team decided that carbon fiber would be the best since it was found to cause attenuation up to roughly 15%, but it is typically around 2%-5%. Additionally, carbon fiber has a density of about 1.6 g/cm^3 , which is very close to the density of water [9]. Thus, it won't affect the success of the process too much and is a good, stable material to use.

The accessories of the final product will be constructed out of PLA or PETG 3D-printed material. Both of these filaments are made out of low-density polymers and consist of low atomic number elements, like C, N, and O. Since X-rays and Gamma rays attenuate exponentially based on mass density and increased atomic number, both PLA and PETG are very good at not creating beam attenuation; however, a thicker infill will lead to more disruption of the photon beam [10]. PETG is more well-suited to long-term device usage than PLA, since PLA will decrease in mechanical strength when it is exposed to radiation over a long period of time [11]. ABS is also a valid alternative to PLA and PETG that was recommended by the client.

Polyurethane foam will be used to line the finger sliders and cover the base of the wrist supports to provide comfort for the patient. It is a low-density material with a density and elemental composition similar to that of human tissue. Additionally, polyurethane has trapped air and gas inside the structure, which helps the photon beam pass through more easily [10]. This is a good material to use because polyurethane has little effect on the radiation beam and it is lightweight with good structural integrity.

Preliminary Designs

Battleship Design

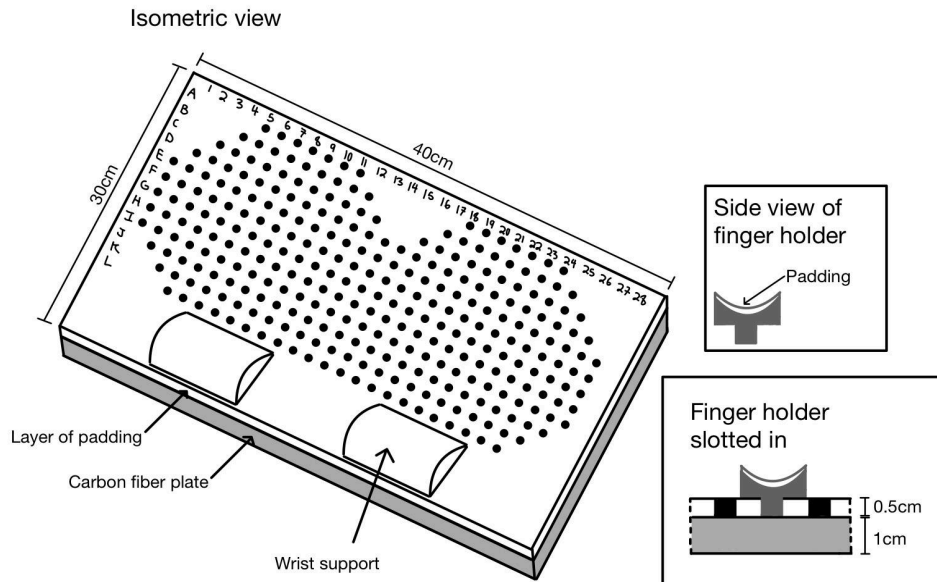


Figure 3. Isometric view of battleship design and enlarged view of finger holder slotted in.

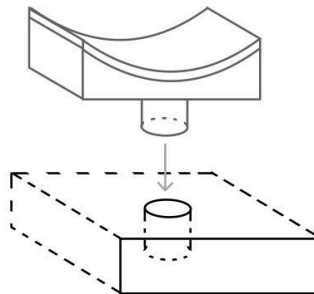


Figure 4. Isometric view of finger holder slotting in.

The Battleship Design consists of a 40 cm x 30 cm x 0.5 cm-thick soft tissue-like pad on top of a 1 cm-thick carbon fiber plate. The top 2/3 of the padding has 0.5 cm-radius holes spaced evenly 0.5 cm apart, into which finger holders are slotted. Each hand uses five finger holders, positioned uniquely for each patient to align with natural finger length and spread, and this positioning remains consistent across the initial CT scan and all six radiation treatment rounds. This enables the patient's fingers to be placed in the same position each round. In addition to the layer of padding on the base, two wrist supports on the edge and padding on each finger holder maximize patient comfort and prevent the fingers and wrist from slipping during the treatment.

Guidelines Design

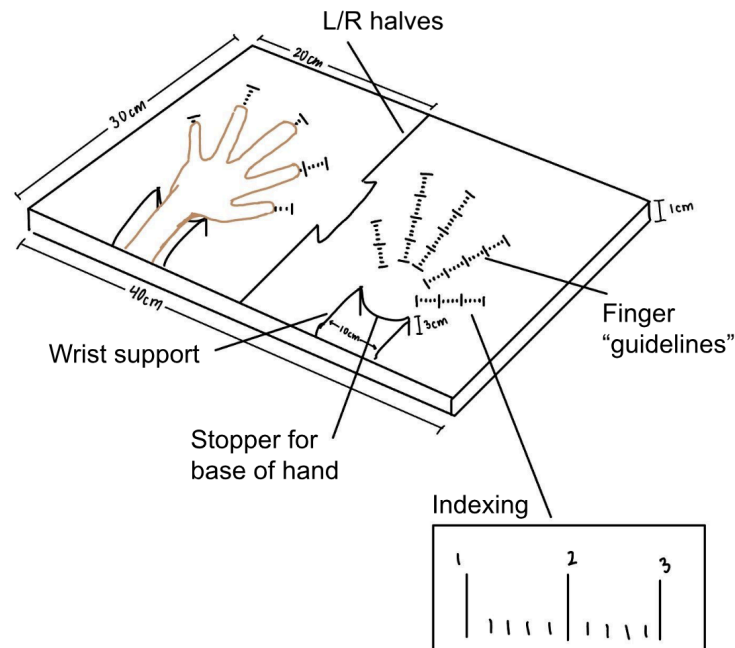


Figure 5. Isometric view of guidelines design.

A 40 cm x 30 cm x 1 cm carbon fiber plate split into two halves makes up the Guidelines Design. These halves allow for hands to be treated individually or, if simultaneous treatment is required, can be joined together. A wrist support contributes to patient comfort and acts as a stopper for the base of the hand to aid in positioning. Five indexed guidelines radiate outward from the palm position, and the patient's fingers are lined up with these lines. The indexing facilitates consistent finger placement across treatment rounds.

Sliders Design

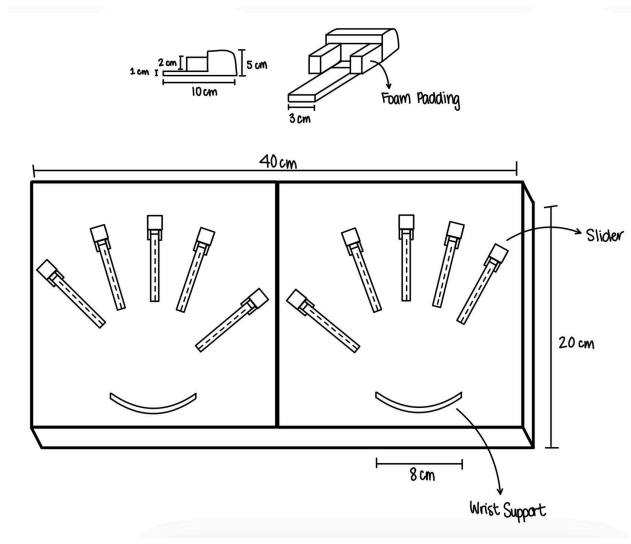


Figure 6. Top view of slider design and close-up of sliding mechanism.

The Slider Design is made of a 40 cm x 20 cm x 1 cm carbon fiber plate that is split in half, similar to the Guidelines Design, allowing for either individual or simultaneous radiation treatment of the hands. A foam wrist support contributes to patient comfort and aids in positioning and securing the hands. The tip of each finger is placed on a holder that runs on an indexed slider radiating outward from the center of the hand. These holders have padding to increase patient comfort, and they are lined up with the same index line each treatment round to accurately replicate the patient's hand position from the CT scan.

Preliminary Design Evaluation

Design Matrix

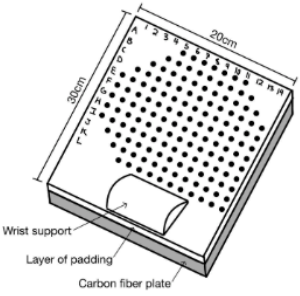
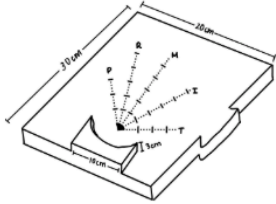
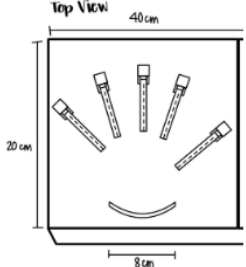
Design	Battleship Design		Guidelines Design		Slider Design	
						
Criteria (Weight)	Raw Score (X/5)	Weighted Score	Raw Score (X/5)	Weighted Score	Raw Score (X/5)	Weighted Score
Accuracy (25%)	5/5	25	2/5	10	5/5	25
Setup Time (20%)	3/5	12	5/5	20	4/5	16
Radiation dosage consistency (20%)	3/5	12	5/5	20	4/5	16
Patient Comfort (15%)	4/5	12	4/5	12	3/5	9
Ease of Fabrication (10%)	2/5	4	4/5	8	3/5	6
Simplicity (10%)	4/5	8	5/5	10	3/5	6
Total (100%)	73		80		78	

Table 1. Design Matrix

Matrix Category Explanations

Accuracy was weighted the highest at 25% because the hand-positioning device must replicate the exact initial hand position and orientation from the CT scan within $\pm 2-3$ mm for each subsequent treatment round [12]. This is crucial for maintaining consistent dosage and treatment area across sessions and minimizing normal tissue exposure [12]. The Battleship Design was rated 5/5 because the slotted finger holders hold the hand in the same position across treatment rounds. The Slider Design was also rated 5/5 because the wrist rest and sliding finger holders will keep each finger in the same line, while the indexing on the tracks enables the finger placement to be consistent.

Setup time and radiation dosage were both weighted second-highest at 20%. Patients' hands will likely be stiff and painful, so quick and easy placement is crucial to improve the existing positioning design—ideally about two minutes for one therapist. And, to maintain a consistent radiation dosage for effective and accurate treatment, the positioning device must be spatially predictable. The Guidelines Design was rated highest at 5/5 in both of these categories because the hand is placed against the wrist support and lined up with the indexed

finger guidelines without requiring adjustment of individual finger supports, and it features a smooth surface that ensures consistent attenuation across the field.

Patient comfort was assigned a 15% weight because, while secondary to clinical accuracy and dose delivery, maintaining patient comfort through a relaxed hand posture will improve the overall patient experience. The Guidelines Design was rated 4/5 because it allows the patient's hand to rest in a natural position without finger restriction and features wrist support. The Battleship Design also received a 4/5 because it features wrist supports and can accommodate many hand positions with movable pegs for custom placement.

Ease of fabrication was assigned a 10% weight as it did not significantly alter the design plan, but was an important consideration to make when determining which design was the forerunner. The designs were evaluated on whether they could be reasonably made given time constraints. The Guidelines Design has the most time-efficient and straightforward fabrication process. The design was given a 4/5 as the steps are linear and reliable. Simplicity was also assigned a 10% weight as it remained a guiding principle for the project. It was evaluated as an overall measure of setup complexity, as well as how straightforward the design was. The Guidelines Design provided the simplest solution that would still replicate hand positioning accurately, and was therefore rated 5/5.

Proposed Final Design

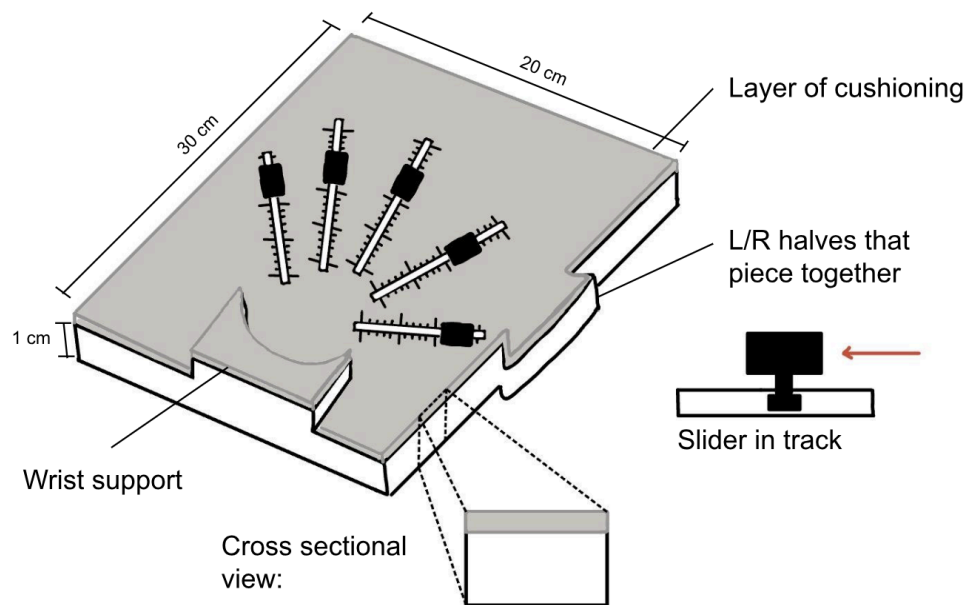


Figure 7. Proposed final design

The proposed final design integrates components from all three designs based on client feedback to create a prototype that maximizes accuracy and patient comfort while reducing setup time. It combines the wrist support and halved 40 cm x 30 cm x 1 cm carbon-fiber plate from the Guidelines Design with the indexed finger sliders from the Slider Design. The wrist support and carbon-fiber plate are covered in a 0.5 cm-thick

layer of cushioning, similar to the soft tissue-like pad in the Battleship Design. The indexed sliders and wrist support ensure that the fingers are held securely in place and the exact positioning is replicated across treatment rounds, while the split plate design allows the hands to be treated together or individually. Additionally, the layer of cushioning increases patient comfort.

Fabrication

Materials

PETG will be used for components of the project as its low density makes it compatible with LDRT. The material is resistant to moisture, chemicals, and heat, which allows it to be wiped down and remain unaffected by the treatment [13]. PETG is easily sanitized with typical hospital disinfectants and can therefore be used by a wide range of patients in a short amount of time, increasing treatment efficiency [14]. The material will allow for longevity throughout the device's life in service, as it does not degrade in the presence of radiation treatment.

Polyurethane was determined to be a suitable material due to its low atomic number, which allows radiation to pass through freely, ensuring that it will minimally alter the treatment efficiency [10]. Polyurethane is able to withstand total cumulative doses of 3 to 6 Gy of radiation, confirming that it will not degrade when used for LDRT, which is a dose of around 0.5Gy [15]. The material does not cause adverse skin reactions, making it a safe option for patients with sensitivities.

Carbon fiber will be used as the base plate for the hand-positioning device. The plate will be 1cm thick to ensure accurate attenuation. The material is strong enough to support the hand weight and the attached components that work to immobilize the hand. Carbon fiber has a low density—about 1.6g/cm^3 —making it comparable to the density of water, which allows for easier attenuation [9]. Carbon fiber allows a lightweight solution for a base plate, which improves mobility from the CT to the therapy room. The material is more radiotranslucent than other materials with the same purpose, permitting a more uniform dosage system for the patient [16].

ABS will be used for 3D printing, primarily for prototyping purposes.

Methods

The initial prototypes were constructed from cardboard and hot glue to determine viable solutions to overarching requirements; the designs will be refined through the CAD prototyping process. Aspects of the prototype—including wrist support, finger supports, and overall positioning plate—will be modeled in CAD software and 3D printed to test for comfort, indexing, and accuracy. The components will be ranked considering the criteria and put together to determine the best solution for all requirements. The prototypes will be constructed out of PETG as well as ABS to accurately represent the characteristics of the final product. The first 3D prototypes will be created with a sparser fill, which will be taken into consideration while determining design feasibility. The subsequent models will be 3D printed with denser material to replicate the properties of the desired product.

The final product will be constructed on top of a custom carbon fiber plate. The plate will be built to accommodate components like the wrist support as well as the finger indexing. The indexing may be machined onto the plate to ensure greater precision. The wrist supports as well as finger supports will be manufactured with PETG, and selected areas will be cushioned with polyurethane to provide a comfortable solution for patients.

Testing and Results

The hand-positioning device prototype will be tested on setup efficiency, position reproducibility, and radiological density for treatment planning.

Setup Time

The workflow and setup time evaluation will take place in a clinical mock-up room that will simulate the radiation therapy treatment room. Both the engineering team and a clinical staff member will be present. The procedure will involve securing the device to the treatment couch, placing a subject's hand into the device and immobilizing the hand, and taking note of the hand position using the device's indexing features. After a demonstration of how the device works, a clinician will perform ten trials of device setup, being timed during each trial, to measure the total time required to set up the device. Then a member of the engineering team will follow the same procedure ten times. The mean setup time and standard deviation will be calculated from these data to determine whether the device can be set up in under 2 minutes, on average. A t-test will be performed to find out if there is a significant difference ($p > 0.05$) between the setup time of an experienced user (the team member) and a first-time user (the clinician). This can reveal whether or not there is a learning curve when a user is introduced to the device.

Positioning Accuracy

To test hand-positioning accuracy, the team plans to simulate the real treatment process by setting up the hand in an initial position and then attempting to replicate the initial setup six consecutive times. To measure movement laterally, vertically, and rotationally, the team will use cameras mounted above and to the side of the device setup to provide an aerial and side view of the subject's hand. Images will be taken on both cameras after each trial, and a 1x1 mm grid will be overlaid on each post-setup image taken, which will be used to measure the difference in millimeters from the initial simulated CT scan setup. Hand movement will be recorded in three dimensions, with a ± 2 -3 mm tolerance in each direction. The coordinates of each trial will be compared against the initial setup, and a 95% confidence interval will be used to determine whether the true mean deviation in hand placement across trials falls within the acceptable range.

Beam Attenuation

Additionally, the team plans to measure the radiation beam attenuation caused by the prototype materials with the assistance of Dr. Sohn. Since accessories in the radiation path can alter the delivered dose, it is important to quantify beam attenuation so that patient dosage can be accurately calculated. Finding the

radiological properties of the device will involve scanning the 3D-printed prototype with a CT scanner to obtain its material in Hounsfield Unit (HU) values. The resulting CT dataset will be imported into the Treatment Planning System (TPS), where the prototype will be contoured and assigned a proper electron density. These experimental electron density values will be compared against literature values for the chosen materials using a percentage error calculation to verify whether the material attenuates the beam as expected.

Discussion

Statistical analysis of the collected data will determine if the prototype meets PDS requirements and clinical time constraints. A mean setup time of under two minutes would prove that the prototype is effective in reducing treatment setup time. A mean setup time of over two minutes would reveal some issue in design and would require refinement. If the t-statistic from engineering team member to clinician setup times is less than 0.05, it may be inferred that the device setup is intuitive and easy to learn. Whereas a t-statistic greater than 0.05 would mean the opposite.

If the average coordinate difference values from the hand positioning trials are within the 95% confidence interval (CI), it can be concluded that the prototype meets the ± 2 -3 mm tolerance in all dimensions. If the values fall outside the CI for any movement in x, y, z, or rotationally, the prototype positioning mechanism would need to be adjusted.

Finally, evaluating the HU values from the CT scan against theoretical material densities can validate whether the materials behave as expected in the radiation beam. A low percentage error between experimental and literature electron densities would show that the chosen material behaves predictably in the radiation field. Furthermore, giving electron density values to the TPS ensures that the radiation dose can be calculated accurately for the prototype, ensuring its clinical function.

Conclusions

The goal of this project is to develop a hand-positioning device for low-dose radiation therapy that improves setup time, hand positioning reproducibility, and patient comfort while minimizing interference with the radiation beam. Current positioning methods can either provide comfort during treatment with limited indexing or accurate treatment with overcomplicated indexing, but they both require lengthy setup times, which can decrease patient comfort. The proposed design addresses these limitations through the use of a carbon fiber base plate, indexed finger supports, and padded wrist supports. The prototype was designed to incorporate simple indexing, achieve a target setup time of less than two minutes, accommodate the expected range of patient hand sizes, and minimize radiation beam attenuation. Initial prototypes of this design were created using cardboard and hot glue to evaluate the viability of design ideas. The final prototype will feature finger and wrist supports made of PETG and will be fabricated through CAD software and 3D printed, while the custom carbon plate will be outsourced. Upcoming testing will test three main criteria: setup time, hand-positioning accuracy, and radiation beam attenuation. Repeated setup trials will determine whether the device can be consistently positioned within two-minute time limits with accurate hand positioning. Radiation beam attenuation will be tested and compared to theoretical values. Overall, the proposed design provides potential improvement over

existing hand positioning methods by combining rapid setup time, consistent hand positioning, and increased patient comfort in a single system. The results of this testing will determine whether the prototype meets the established design requirements and identify any modifications needed for further development. Future work will focus on fabricating the final prototype, completing the planned testing, and refining the design based on the results.

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Appendix

Product Design Specifications

Function/Problem Statement

Severe joint pain in the hands due to osteoarthritis and other inflammatory conditions is now frequently treated using low-dose radiation therapy (LDRT). Current LDRT protocols require high setup reproducibility across 6 treatment sessions. Existing positioning systems are overly complex, use complicated indexing systems, and compress digits 2-5 together. This causes significant discomfort for patients and creates unnecessarily long setup times. This project aims to develop a hand-positioning device to be used in a clinical setting that minimizes setup time and patient discomfort while ensuring exact hand placement for each treatment session.

Client requirements

- Consistent joint placement in the field within a tolerance of 2-3 mm.
- Maximize patient comfort with finger separation and a natural hand posture.
- One therapist can set up the device in about two minutes.
- Minimize the amount of material used to not interfere with the radiation beam.
- Cleanable with hospital disinfectants.
- Simple, repeatable attachment to the treatment couch.
- Fits left and right hands and most adult hand sizes.

Design requirements

1. Physical and Operational Characteristics

a. Performance requirements

- i. The device must maintain the patient's hand position during treatment and across all 6 sessions. It must maximize patient comfort and be set up by only one technician in ≤ 2 minutes.
- ii. Average hand sizes of patients 45 and older must be accommodated. This is defined by a length of 6.8-7.6 inches, a breadth of 3.1-3.5 inches, and a circumference of 7.0-8.6 inches [1].

- iii. The device must hold up under repeated CT scans and LDRT. It will be used 7 times for each patient (initial CT scan and 6 subsequent LDRT sessions). The radiation exposure time will be approximately one minute per session.
- iv. The device must withstand repetitive loading in hand positioning locations without bending or fracturing. The average weight of one hand is 400 g [2].
- v. It must be possible to fully disinfect the device according to clinical standards.
- b. **Safety**
 - i. The device is classified as a Class II medical device and must comply with all standards and specifications listed in section 3a.
 - ii. The device must not pinch patients' hands, restrict circulation, or cause excess pressure. It must not have sharp edges that could injure the patient.
 - iii. It must be possible to remove the patient's hand in under 10 seconds if rapid removal is necessary.
 - iv. The device must sit securely on the table or couch arm and completely immobilize the hands to ensure that radiation is accurately directed and normal tissue exposure is minimized [3].
 - v. The device must not alter radiation concentration unpredictably due to attenuation [4]. Radiation and X-ray exposure must not cause an adverse reaction between device material and the patient's skin.
- c. **Accuracy and Reliability**
 - i. The device must replicate the exact initial hand position and orientation from the CT scan within $\pm 2\text{-}3$ mm for each subsequent treatment round [3]. Setup time for each hand must be consistent across patients within one minute.
- d. **Life in Service**
 - i. The device must retain accuracy across 6 cleaning cycles per patient.
 - ii. The device must retain structure after repeated loading of the average weight of an adult human hand of 409.6g, 6 times per patient [5].
 - iii. The device must retain accuracy after use, ensuring replicable and comfortable hand positioning for the patients, without interference with radiation.
- e. **Shelf Life**
 - i. The device must be stored in relatively dry environments due to the tendency for 3D printing materials to soak up water from the air [6].

- ii. PLA has an average shelf life of 1-3 years, and PETG has an average shelf life of 5-10 years once both are exposed to air and printed. The product's shelf life will be close to this range as well to ensure accuracy and structural integrity [6].
- iii. The device must be stored at room temperature and without any direct sunlight. PLA specifically will weaken under UV contact, while PETG will be more UV-stable [6].

f. Operating Environment

- i. The hand-positioning device will be used in hospitals and clinics that perform low-dose radiation therapy (LDRT) for treatment of osteoarthritis in hand joints.
- ii. The device will be exposed to six radiation treatments of 0.5-1.0 Gy per treatment, for a total expected treatment dose of 3-6 Gy, without significant degradation or loss of structural integrity [7].
- iii. The device must maintain dimensional stability and positioning accuracy following exposure to the expected 3-6 Gy treatment dose.
- iv. The device must operate in a CT imaging environment with a temperature range of approximately 64-75°F (18-24°C) and relative humidity of 30-70% [8].
- v. The device must operate in a radiation-treatment room with a temperature range of approximately 68-75°F (20-25°C) and relative humidity of 40-60% [9]. The device must withstand repeated hospital sanitation and disinfection procedures without measurable degradation, warping, cracking, corrosion, or loss of functionality [7].
- vi. The device must remain structurally stable while being transported between the CT scanner and medical linear accelerator (LINAC) and will maintain the patient's hand position during transportation.

g. Ergonomics

- i. The device must accommodate 5th percentile female hand size through 95th percentile male hands [10].
- ii. The device must maintain the patient's prescribed hand position for the duration of the treatment session without requiring the patient to exert a continuous holding force [11].
- iii. Patient-contact surfaces must not produce a measurable pinching or excessive localized pressure.
- iv. A clinician must be able to position and secure the hand of the patient in ≤ 2 minutes.
- v. The device must maintain hand positioning within a maximum translational error of ± 2 -3 mm.

- vi. The clinician must be able to verify correct hand positioning using alignment features with a verification accuracy.
- vii. The materials of the device must not produce clinically significant interference with CT imaging or radiation delivery [12].

h. Size

- i. The device must not exceed a maximum footprint of 40cm x 40cm to remain within the available CT and radiation-treatment workspace.
- ii. The device must have the minimum practical thickness necessary to provide adequate structural stiffness and positioning accuracy.
- iii. It is important to have a uniform layer of known thickness that behaves similarly to water; this way the material in the beam can be accounted for.
- iv. The primary positioning plate must have a target thickness of 1 - 2 mm.
- v. The device must remain within the required radiation beam geometry and must not obstruct the treatment field or interfere with LINAC operation [12].
- vi. The device must minimize overall thickness and weight while maintaining the required structural stiffness and positioning accuracy.

i. Weight

- i. Low material and device weight must support ease of handling the product during low-dose radiation therapy set-up.
- ii. The product must be kept to a light weight to support storage and transportation of the device to other clinics.
- iii. Having a high-density material will affect the radiation beam, even under low doses, and will cause attenuation, which can lead to under-dosing the target area and cause unnecessary radiation exposure to healthy skin in the event of secondary electron scatter [13].

j. Materials

- i. The amount of material used for the device must be minimized to keep costs and weight to a minimum.
- ii. For the product's hand fixtures, PLA or PETG must be used to ensure the material does not affect the radiation beam. PLA and PETG do not degrade in their physical and mechanical properties when put under a high-dose radiation beam [14]. However, low-density foam is also a valid substitute [15].

- iii. The base plate that the hand will rest on must be made of a low-density carbon fiber or a radiation-transparent plastic material so as not to interfere with the radiation [13]. This is especially important since the radiation will come from above and below the device.
- iv. Absolutely no metals will be placed where the radiation beam hits, as this will be harmful to the patient [16].

k. Aesthetics, Appearance, and Finish

- i. Advanced indexing, such as the one on the Dexalign Hand Positioner, can be overly complicated. The product must avoid unnecessary features so that the set-up for low-dose radiation therapy does not take more time than is necessary [17].
- ii. The product must not have any sharp edges or components that could pinch the patient or the clinician setting up the device.
- iii. The density of the entire product must be similar to the density of water (1g/cm^3) so that the product doesn't cause harm to the patient through accidental beam attenuation [13].
- iv. The base plate of the SteadyHand product will be white or gray to maintain simplicity. It must also have a few black index marks to assist the physician in placing the patient's hand.

2. Production Characteristics

a. Quantity

- i. The design will consist of one base plate that will have all of the necessary components and indexing to hold the patient's hands comfortably and with recurring accuracy.
- ii. Only one device is necessary. However, documented instructions for the fabrication process must be provided to ensure accurate reproducibility by other clinics.

b. Target Product Cost

- i. The budget for the product will not exceed \$200. The budget will include costs for materials to produce the product as well as prototypes. There will be an additional \$50 budget available for 3D printing in the Wendt Design Innovation Lab.
- ii. The product will be cost-effective and reproducible for other clinics. The cost of the device will aim to be lower than the cost of current competitors.

3. Miscellaneous

a. Standards and Specifications

- i. SteadyHand will be classified as a Class II Medical Device Accessory under FDA 21 CFR 892.5050 [18]. Accessories that sit directly in a radiation beam path and come into

direct contact with human skin are considered moderate-risk devices that require certain standards to guarantee safe performance [19].

- ii. AAPM Task Group 176 provides guidelines for assessing the radiological safety of patient immobilization devices. Their findings validate that a 1 to 2mm carbon fiber base and printed PLA components maintain high radiolucency, preventing beam attenuation and unwanted skin dose disruptions during radiation therapy [13].
- iii. Since SteadyHand will come into direct contact with human skin, it must comply with ISO 10993-1, which deals with biocompatibility and skin contact, specifically cytotoxicity, irritation, and sensitization [20]. The nature of contact is with intact skin for a limited duration (< 24 hours). Devices that contact intact skin only and use low-risk materials no longer require biocompatibility test reports if a safe history of use is documented [21].
- iv. Since SteadyHand will be used in clinics, it must adhere to CDC / AAMI ST79 [22]. This standard mandates that all surfaces can withstand hospital-grade chemical disinfection without the material degrading. If PLA or other 3D-printed materials are used, layer lines must be sealed or post-processed to prevent pathogen entrapment.

b. Customer

- i. Clinicians and radiation therapists will be using the device to immobilize patients' hands during LDRT. The device must allow therapists to set up patients quickly and in the same position for every treatment. One therapist should be able to set up the device in about two minutes.
- ii. Patients are typically in their mid-forties or older. They all have painful hand joints from osteoarthritis or something similar, and awkward hand positions are hard to hold. SteadyHand must minimize patient discomfort by allowing a relaxed hand position. Digits 2-5 should not be compressed together, and the device should allow for space between the palm and base plate.

c. Patient-related concerns

- i. The product will be manufactured to ensure patient comfort and prevent irritation. The device will consider finger placement, adjustability, and natural hand positions to maximize patient experience.
- ii. The product will withstand typical hospital disinfectants to ensure sterility and minimize potential contaminants.

- iii. The device will not contain any metal parts or other materials that interrupt radiation flow or alter the consistency of the treatment.

d. Competition

- i. Dexalign Hand Positioner is the prominent solution used for patients undergoing low-dose radiation therapy. The device allows for consistent placement for each session for over 95% of hand sizes and types [8]. The hand positioning product aligns with radiation therapy requirements and advertises a rapid setup time for a seamless experience. Dexalign immobilizes both hands without enclosing the whole extremity.
- ii. Orfit Extremities System is another device used for patients undergoing low-dose radiation therapy. The device will allow patients to lie down or sit upright while immobilizing their hand using a thermoplastic mask. The device streamlines setup and ensures comfort with soft cushions [10].
- iii. Extremity Lock by CDR Systems provides a device to lock limbs in a fixed position for a prolonged period of time. The device uses imaging-compatible material to accurately reproduce ideal positions for low-dose radiation therapy [23]. In addition to LDRT, the product is used for CT scans, MRI's, and on-board imaging.

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