Head Holder for MR-Guided Drug Delivery

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1. Abstract

Parkinson's disease (PD) is a degenerative brain disorder with no cure, which affects the elderly population. Convection Enhanced Delivery (CED) is a treatment strategy involving a direct infusion via catheter to a specific target area in the brain in order to overcome the blood brain barrier. CED is currently being researched as a potential treatment approach for Parkinson's disease in order to restore dopamine in brain tissue. The clients are currently exploring CED and applying real time MRI to the procedure in order to effectively monitor the infusion. High quality images require the use of the additional carotid coils, which get in the way of the current head immobilization device. Beagles and Rhesus Monkeys are used as in-vivo test subjects for the CED treatments. Since the desired antenna array rests against the testing subject's ears and temples, the current head holder used for similar drug delivery experiments cannot be used due to the ear bars. Thus, the client requires a head holder device that does not interfere with the contact that the MRI antenna array needs to make with the head of the testing subject. It is important that the head holder restricts the translational movement of the head to 1 millimeter or less, be entirely MRI compatible and compatible with the current experimental setup. The team has come up with three alternative designs, which meet the client's specifications: the Eye Bar design, the Band/Track design and the Fork Support design. The Eye Bar design is most similar to the current immobilization device used by the client but lacks ear-bars. The Band/Track design uses both band and blocks sliding along tracks to stabilize the head. The Fork Support design includes a system of forked HDPE plastic tubes, which rotate to immobilize the head. Based on the Design Matrix, the team has chosen the Band/Track design as the final design. This design meets the most challenging client requirement: meeting the 1mm translational movement error margin. Next, the team will discuss the final design with the client as well as a Veterinarian and order parts in order to fabricate the design. Finally, the prototype will be tested in SolidWorks and in-vivo by employing liquid capsules as a design accessory, within the blocks supporting the head, in order to track the movement of the head during the infusion procedures.

2. Introduction

2.1. Parkinson's Disease

Parkinson's disease is a chronic and degenerative brain disease. Often affecting men and women over the age of 50 years, PD is one of the most common central nervous system disorders of the elderly. It is estimated that 500,000 Americans are currently affected with PD and 50,000 more people are diagnosed each year. These numbers are expected to increase with the aging population [1].

Symptoms include tremors as well as difficulty with movement and coordination, which are a result of destruction of dopamine producing neurons. The lack of dopamine (neurotransmitter) causes improper cell messaging, which manifests in the loss of muscle function. Continual nerve destruction and subsequent reduction in dopamine results in progressive worsening of symptoms. The exact cause of the destruction is unknown. In addition, there are no blood or laboratory tests for a conclusive diagnosis, which makes the disease difficult to diagnose accurately [2].

Currently, there is no cure for Parkinson's disease. Treatment, usually medication based, focuses on reducing the symptoms and slowing disease progression [2]. The effectiveness of many systemic pharmaceutical treatments are further limited by lack of ability to cross the blood-brain barrier to reach the damaged neurons [3].

2.2. Convection Enhanced Drug Delivery (CED)

Parkinson's research has focused on techniques that allow more localized delivery of dopamine-restoring medications. Convection enhanced drug delivery (CED) is especially useful in overcoming the blood-brain barrier and reducing systemic toxicity [4]. A sketch of CED can be seen in Figure 1. The main components of CED are a catheter placed directly into the brain target and a continuous infusion of fluid. Using stereotaxic equipment and corresponding imaging methods, a surgeon directs the needle to a specific location in the brain with high accuracy. Once the needle is inserted, a continuous flow of infusate creates a pressure gradient, which forces the agents through the extracellular spaces via bulk flow. Theoretically, a homogenous distribution will be obtained [3]. CED also has applications to treat brain tumors [4].

Currently, CED is only used experimentally. Current difficulties include hardware malfunction, uneven volume distribution, and infusate reflux along the outside of the catheter. Therefore, further research and method refinement is needed for success in clinical translation [3].

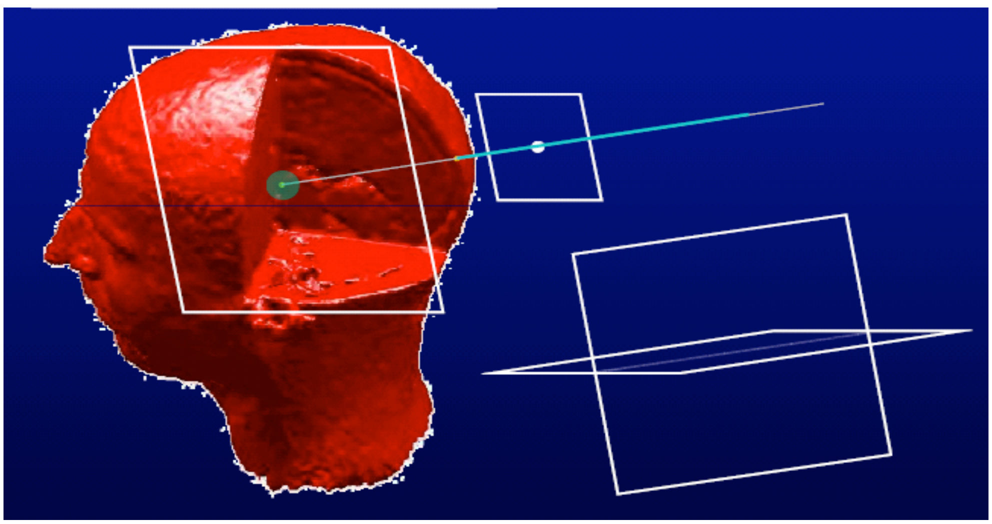

Figure 1: Sketch of CED [5].

2.3. Magnetic Resonance Imaging (MRI)

To monitor the progress of CED, researchers have turned to magnetic resonance imaging (MRI). A MRI marker is mixed with the medications in the infusate. Throughout the infusion procedure, the MRI is used to verify the position of the catheter and to track the volume distribution of the infusate. Dr. Wally Block, our client, is working on creating software that combines CED with real time magnetic resonance imaging (MRI). The software is then used to monitor needle alignment and insertion as well as drug delivery [5].

MRI is a non-invasive imaging procedure that is commonly used in a clinical setting. A standard MRI scanner and image can be seen in Figure 2. MRI uses high magnetic fields and basic spin physicals to create high contrast images of soft tissue [6].

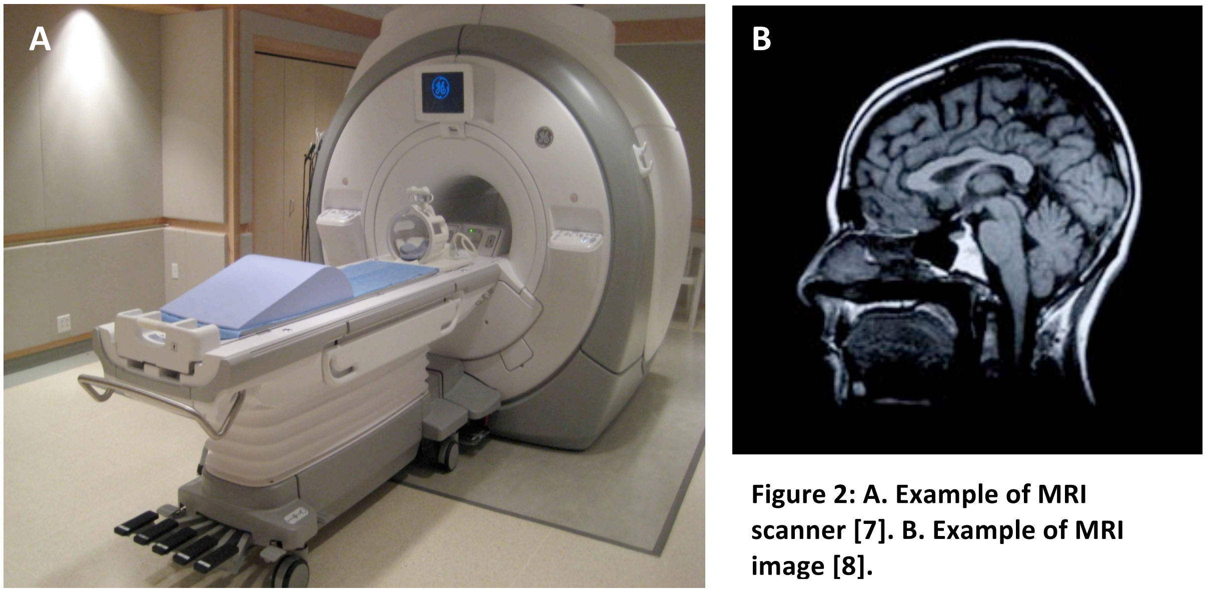

Figure 2: A. Example of MRI scanner [7]. B. Example of MRI image [8].

During an MRI scan, the subject lies on the table of the MRI scanner and is slid into the bore of the MRI to the middle of the magnetic field with accuracy of 1 millimeter. Underneath the plastic encasing, there are large superconducting magnets that create large magnetic fields that range from 0.5 to 3 Tesla (5,000 to 30,000 Gauss). In comparison, earth's magnetic field is approximately 0.5 Gauss [6]. When the patient is subjected to these high magnetic fields, the spins of the protons in the tissues align with the magnetic field [6].

Another component, the radiofrequency (RF) source, creates pulses of RF frequency. If the frequency of the RF pulse matches the angular frequency of the proton, the proton gains a photon of energy, which causes a change in the alignment of the proton's spin. Energy is released as the proton realigns with the main magnetic field and is recorded by the RF detector. Different types of tissues give different responses. Tissues that contain more water typically appear white in the images [9].

Additional non-superconducting magnets are used to create a gradient in the strength of the main magnetic field. Therefore, spatial distribution can be determined by using only a select frequency range of RF pulses. High resolution results from repeating the scanning process over small slices. The raw data is then subject to complex digital processing to create the final images [10].

2.4. Current Research Methods

The client currently uses Rhesus monkeys and Beagles as testing subjects for convection-enhanced drug delivery experiments, which require the use of a head holder to immobilize the head of the testing subject. An MRI interventions port is placed toward to the back of the skull and used to help guide the insertion of the catheter into the brain (Figure 3B). The client also uses a MRI antenna array to increase the signal to noise ratio of the MRI images (Figure 3A).

Figure 3: A. Photo of carotid coils. B. Photo of MRI Interventions port. Photos courtesy of Kevin Beene [11].

2.5.Current Head Holders

The head holder that our client currently uses is shown in Figure 4. It is designed so that the animal lies in a supine position (on its back). Bars are placed in the ears, at the top of the palate and at the zygomatic arches (below the eyes). This effectively prevents translational and rotational motion of the head. This head holder, however, is incompatible with the carotid coils. Therefore, our client requested a different head holder that is compatible with the carotid coils.

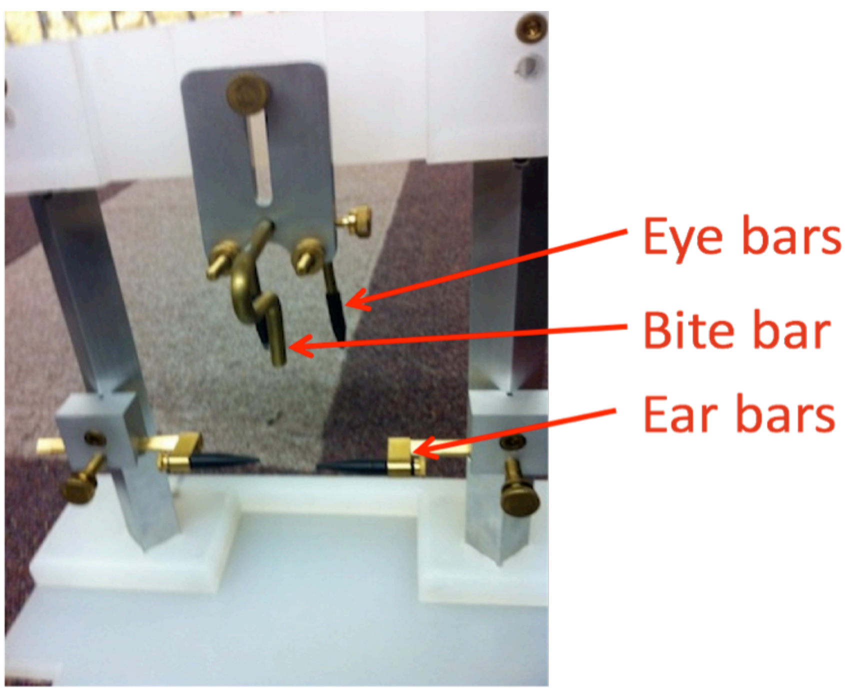

Figure 4: Photo of current head holder. Photo courtesy of Hope Marshall [12].

2.6. Animal Treatment Regulations

In order to engage in animal research, the investigator must submit an animal protocol. The protocol is a contract between the university and the investigator that describes the reason for the research, a detailed description of the research and euthanasia, and contains information about the species and number of animals. Pain management, monitoring procedures and endpoints are documented within the protocol to ensure that the least amount of stress is inflicted upon the animals. The Institutional Animal Care and Use Committee (IACUC) must approve all experimental protocols that involve the use of animals. The Graduate School ACUC oversees the Wisconsin National Primate Center [13].

Although it is unlikely that our head holder device will be used on live animals in the duration of this semester, the device must be designed with the animal in mind. Therefore, immobilization methods must cause minimal pain or stress to the animal.

3. Problem Statement

The client is working to create software that is able to display real-time imaging of convection-enhanced drug delivery through the use of an MRI machine. High quality images require the use of the additional coils. Since the desired antenna array rests against the testing subject's ears and temples, the current head holder used for similar drug delivery experiments cannot be used due to the ear bars. Thus, the client requires a head holder device that does not interfere with the contact that the MRI antenna array needs to make with the head of the testing subject.

4. Design Specifications

Since the head holder will be used for convection-enhanced drug delivery experiments, it is imperative that the head holder restricts the translational movement of the head to 1 millimeter or less. The device must be MRI-compatible, meaning it cannot contain any ferrous materials and it must fit within the MRI bore, which has a height and width of 34 centimeters and 60 centimeters, respectively. The head holder device must also be compatible with the experimental setup used by our client. Specifically, it must account for the use of the MRI antenna array, the MRI Interventions port, and the breathing tube. Lastly, given that the client works with both Rhesus monkeys and beagles, the device should allow for certain adjustments to be made depending on which testing subject is used so that the same degree of accuracy can be achieved despite the differing anatomies.

5. Designs

5.1. Design Alternative 1: Eye Bar Design

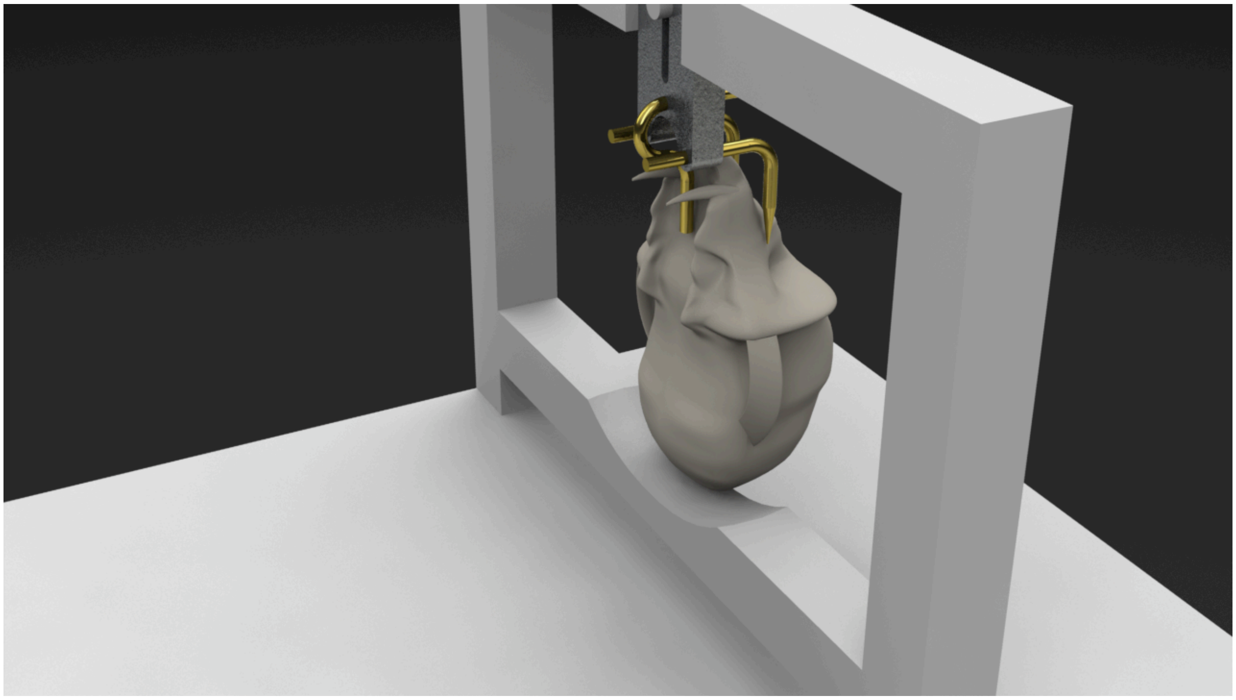

Figure 5: SolidWorks drawing of eye bar design [14].

The Eye Bar design is based on current stereotaxic device designs and uses current palate and eye bars, shown in Figure 5. These bars are made of brass and are held by an aluminum plate in order to be MRI compatible. The bars push down slightly into the eye sockets as well as up into the pallet, limiting translational movement of the head. The plate, as well as the bars can be adjusted using set screws, which allow for a variety of head sizes to be used with this device.

In order to replace the ear bars traditionally used in stereotaxic devices, the frame of this device is designed to cradle the head of the animal. A foam-like material will be placed on the headrest, which will conform around the back of the skull of the animal and hold it in place. This along with the pressure from the eye bars restricts skull movement in the y-axis.

The major disadvantage of the Eye Bar design is the difficulty of manufacturing the device. Although the device uses parts from current stereotaxic devices, a new frame will have to be built in order to hold these parts. The frame must be built out of aluminum in order to be small enough and still maintain the physical properties required. Compared to HDPE, aluminum is much harder to work with which increases manufacturing time and difficulty.

5.2. Design Alternative 2: Band/Track Design

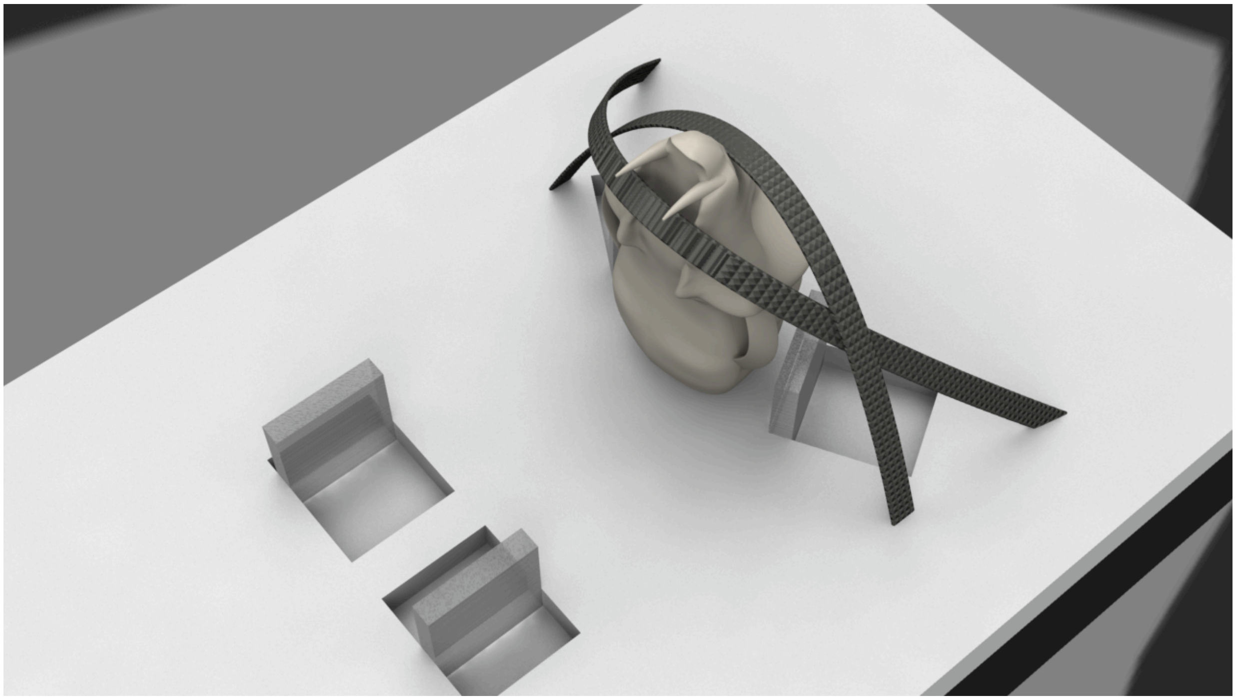

Figure 6: SolidWorks drawing of Band/Track design [14].

The Band/Track design, as seen in Figure 6, includes four high-density polyethylene (HDPE) blocks that slide back and forth along tracks built into the backboard supporting the Rhesus monkey or Beagle. Two blocks immobilize the head on the plane of the board by pushing against the head diagonally, shown in Figure 6, and the remaining two blocks push against the animal's neck at the jaw. The sliding mechanism for the blocks is still being investigated but will most likely be either a T-slot mechanism or a mechanism involving threading or gears.

In addition, the Band/Track design includes two adjustable crisscrossing elastic straps anchored to the backboard using plastic alligator clips (not shown) on either side of the head, as seen in Figure 6. These straps have been designed to immobilize the head in the y-direction represented by the plane perpendicular to the backboard. One strap will press against the animal's forehead while the other will press against the first molars behind the canines.

The Band/Track design will be easy to sterilize in between uses, as it is composed primarily of HDPE plastic. The straps will be made of silicone rubber, a strong yet easy to sterilize material.

One advantage of the Band/Track design is that it is highly adjustable and versatile. Since silicone rubber is an elastic polymer that would mold to the face shape of either animal, the Band/Track design would be effective in immobilizing the head of either the Rhesus monkey or the Beagle. In addition, the sliding mechanism built into in the backboard for the tracks would make the block placement adjustable to a fraction of a centimeter. The adjustability of the block placement in conjunction with the versatility of the bands holds the design to the 1 millimeter translational movement error standard specified by the client. The Band/Track design would be low cost, as well.

With respect to ergonomics, the Band/Track design would be advantageous since the HDPE blocks would slide easily and would be tightened into place using a simple screw mechanism. The bands would be easily adjusted, by clamping down the alligator clip, as well, which would make the head immobilization process relatively quick and straightforward for the surgeon.

The major disadvantage of the Band/Track design would be the durability of the silicone rubber bands. As the silicone rubber bands would be used multiple times, the tensile forces applied to the bands in conjunction with the sharp contact points against the animal's teeth as well as the points of contact with the alligator clips, would wear out the bands. A solution would be fabricating multiple silicone bands for the client so they could switch out the bands as they start to wear or snap.

5.3. Design Alternative 3: Fork Support Design

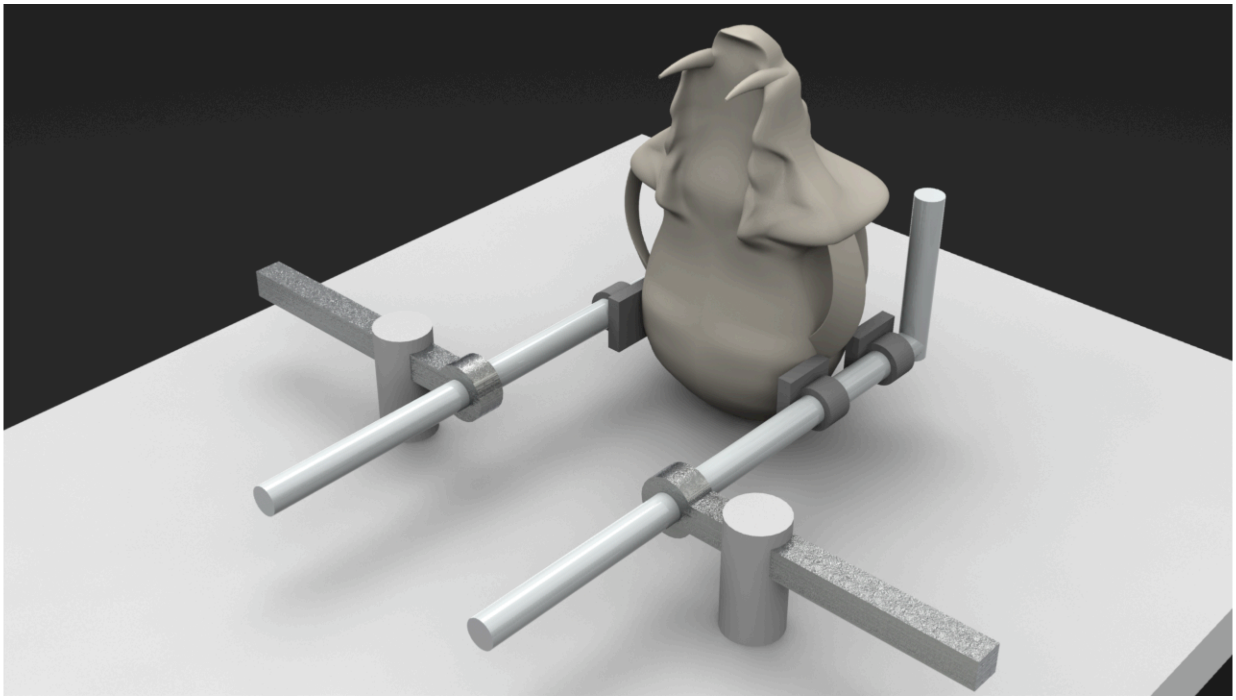

Figure 7: SolidWorks drawing of fork support design [14].

The fork support design is composed of two L-shaped bars that anchor near the neck. The bars slide along the long axis of the board and toward or away from the head to accommodate varying anatomies. The L-shaped bars are also designed to rotate medially and laterally with respect to the top of the head. These are used to cradle the base of the head without blocking the MRI Interventions port. In addition, two sliding blocks on each side support the head near the ears. The carotid coils will be placed over the blocks near the ears.

All components will be made of HDPE. Therefore, the device will be low cost and easy to sterilize between uses. In addition, the device will be durable enough to withstand multiple uses.

All moving parts will be secured using screw-lock mechanisms similar to the current head holder. This allows the bars to be adjusted to many positions along the long and short axes of the board. This also allows the bars to assume a large degree of rotational position to better cup the head. A thumb-screw mechanism can be used to make quick adjustments.

One disadvantage of the fork support design is it lacks direct stabilization in direction coming out of the board (the y-direction). The L-shaped bars only indirectly provide stabilization in the y-direction. Therefore, it is unclear at this time if the desired accuracy of less than 1 millimeter of immobilization will be easily achieved with this design. Another disadvantage of the fork support design is the difficulty in fabrication of the parts. However, the team could consult machinists in the student shop or use three-dimensional printing for custom parts in order to fabricate this design alternative effectively.

5.4.Design Accessories

5.4.1. Water Markers for MRI Alignment

In MRI-compatible devices, a common mark of reference is created with multiple liquid capsules placed within a device near the organ examined by the MRI machine. For example, in Figure 8, the liquid capsules placed within the ear-bars and eye-bars of the head immobilization device are circled in red. The liquid capsules can be seen in the MRI image and are commonly used as a reference point for surgeons in order to increase accuracy of measurements taken based on the MRI and facilitate procedures performed on the subject. Liquid capsules could be placed at external points of the device in contact with the Beagle or Rhesus monkey skull in any of the alternative designs. This would facilitate the CED surgery and research as well as aid in testing the head immobilization device for accuracy.

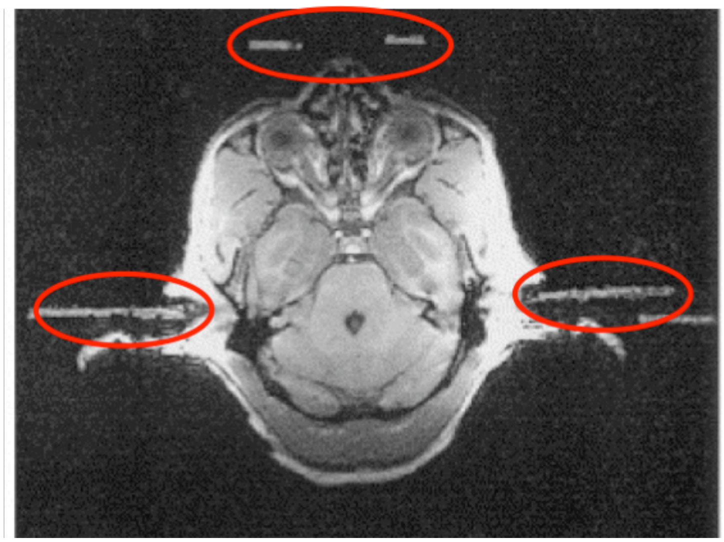

Figure 8: MRI with markers in ear bars and eye bars [15].

5.4.2. Head Elevation System

Currently, the CED infusion would be performed on the beagle or Rhesus monkey while the animal's head would lay flat inside the MRI machine. Since the entry point for the MRI interventions catheter is at the top of the head, the entry angle for the infusion could present a difficulty for the surgeon. In order to alleviate this problem, a head elevation system could be built into the backboard of the head immobilization device.

The head immobilization system would consist of an HDPE plastic sheet lying above the head placement area of the backboard. This sheet would be hinged onto the backboard, as shown in Figure 9 and cut at an angle of 30 degrees, the maximum elevation of the system. The HDPE headrest could then be elevated by the surgeon and maintained in place using a lawn-chair-like mechanism shown in the figure. The base of the backboard of the head placement area would extend 2 inches in width in order to add 2 columns (one for each side of the backboard) of slots for every 5 degrees of elevation up to 30 degrees. Plastic supports attached using a pin mechanism would slide into the slots, similar to a lawn chair, in order to stabilize the headrest of the system, thus immobilizing the board. This accessory will be presented as an option for the client and evaluated, changed, or implemented based on the client's suggestions.

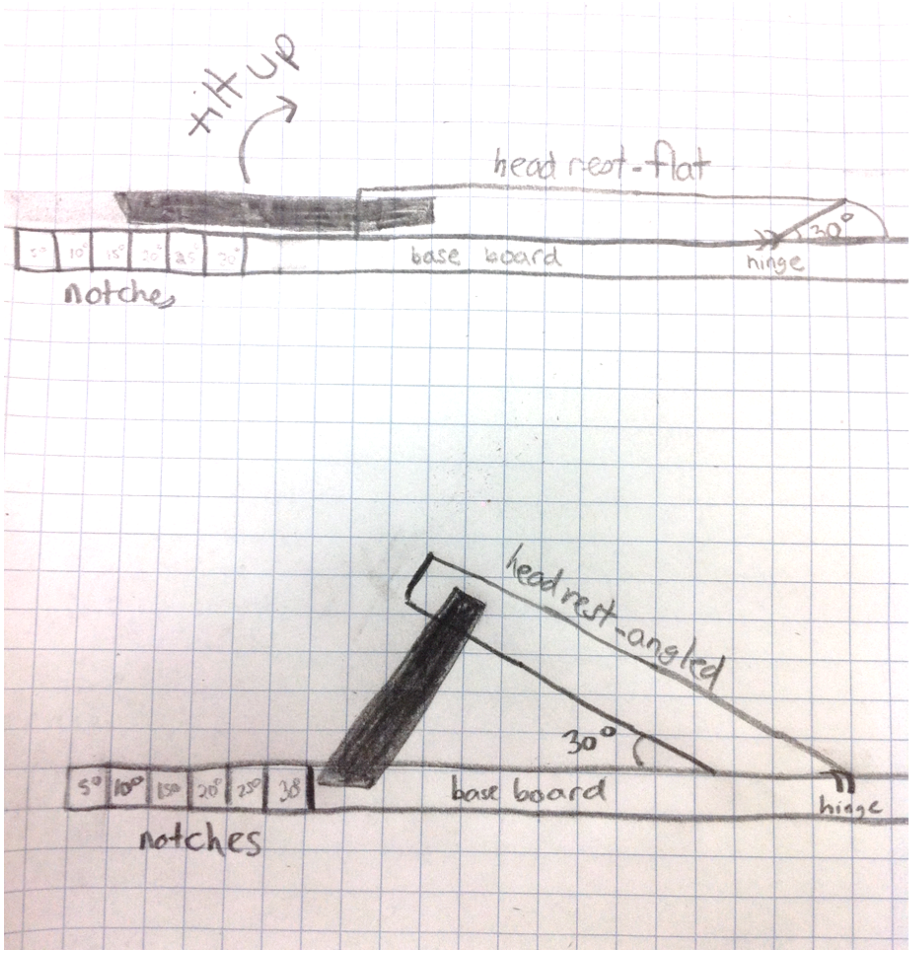

Figure 9: Sketch of head elevation system [16].

6. Design Matrix

Table 1: Design matrix used to compare three designs with weighted categories.

	Weight	Band/Track Design	Fork Support	Eye Bar Design
Cost	10%	10	8	8
Ease of Construction	15%	12	12	6
Ease of Use/Ergonomics	20%	20	16	16
Durability	25%	15	20	25
Margin of Error	30%	30	12	24
TOTAL	100%	87	68	79

The design matrix (Table 1) used to assess the three design alternatives was divided into the five categories of cost, ease of construction, ease of use, durability, and margin of error. Each of the designs was assigned a score of one to five, with five being the highest, for each category. Since each category has a unique weight based on their relative importance, the scores from each category were multiplied by their respective factors. The final scores for each design were reached by adding the scores of each individual category.

In the design matrix, cost was considered the least important category and given the smallest weight. Since the current head holder cost about $2,000 to manufacture, the team is confident that all of the design alternatives will be constructed at a mere fraction of the cost of the original head holder. The Band/Track design received the highest score in this category because the group believed that using the two straps to replace mechanical parts would make the Band/Track design the least expensive alternative.

In the ease of construction category, the Band/Track design and the Fork Support design scored identically. The Band/Track design will lead to a more complicated fabrication process due to the tracks that need to be built into the board. While the Fork Support design appears to be simpler than the Band/Track design, special care will have to be paid to the construction of the posts of this design to ensure that they remain stable and rigid. The Eye Bar design received the lowest ranking in the ease of construction category since it is based on the current head holder, which used brass for the eye bars and palate bar. Using brass as the raw material for the eye bars and palate bar of this design will surely lead to a more difficult manufacturing process. In the ease of use category, the Band/Track design received the maximum score due to the simplicity of the two straps versus other mechanical parts.

However, the Band/Track design alternative earned the lowest score in the durability category since the bands will likely need to be replaced due to normal wear over time. The Eye Bar design ranked the highest in this category due to the inherent strength and rigidity of the brass parts.

The last category, margin of error, was deemed the most important, and thus given the highest weight, due to the requirement that the device restrict translational movement of the head to 1mm or less. The Band/Track design received the maximum score in this category because the two straps in combination with the four tracks will ensure immobilization of the head in all directions. On the other hand, the Fork Support received the lowest score in this category due to its lack of explicit y-axis immobilization.

After summing the scores for each of the designs, the Band/Track design had the highest score, followed by the Eye Bar design with the second highest score, and then the Fork Support design with the lowest score of the three alternatives.

7. Final Design

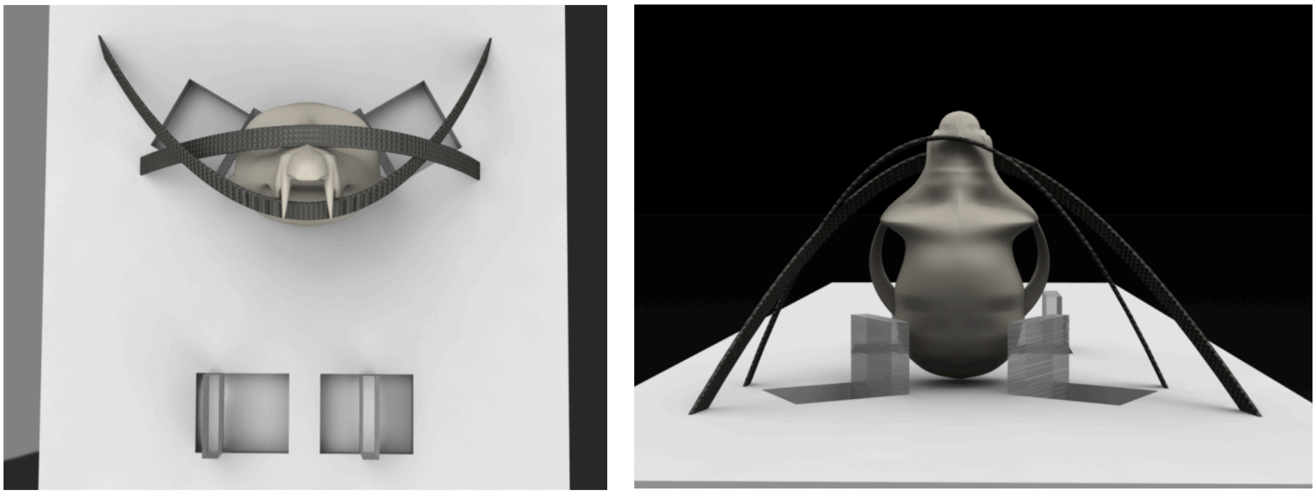

Figure 10: Different views of final design [14].

8. Future Work

8.1. Design Construction

Once the team has chosen an appropriate sliding mechanism for the device, a more detailed Solid Works model will be created. This model will help guide the construction of the device and could be used to 3D print some parts of the device. The model could also be used in preliminary testing to determine if the device will be able to handle the stresses of normal usage. Once the client has approved the model, construction of the device will begin.

8.2. Budget

In order to start constructing our designs, we need to purchase materials. Minimum expected costs are detailed in Table 2 below. Currently these are well within our budget of $1,000.

Table 2: Cost of design materials [17].

Material	Part #	Cost
½"x 2" x 48" HDPE Bar	8671K35	$10.76
½"x 12"x 24" HDPE Sheet	8619K472	$22.14
Sliding Mechanism		~$40
FDA-Compliant Silicone Rubber ¼"x 1"x 36"	8417K18	$15.39
Total		**$88.29**

8.3. Testing

After the device is built, it will be tested using the test subjects normally used in the CED procedure. The team will assess the devices ability to restrict subject displacement in all directions. Various subjects will also be used in order to confirm that the device is capable of functioning with subjects of varying head sizes/shapes.

8.4. Timeline

A timeline of the design process is shown in Table 3 below. The dates correspond to the Fridays that end the weeks for the progress reports. The highlighted boxes are the projected schedule that was created at the beginning of the semester. The "X's" represent events that occurred during that week.

Table 3: Projected Semester Schedule.

Task	Jan	Feb				March					April				May	
	27	3	10	17	24	2	9	16	23	30	6	13	20	27	4	11
Project R&D																
Background Research	X	X	X	X	X											
Design Brainstorm			X	X	X	X										
Final Design Selection						X	X									
Manufacturing																
Testing																
Deliverables																
Progress Reports	X	X	X	X	X	X	X									
PDS		X	X	X	X		X									
Midsemester Presentation					X	X	X									
Midsemester Paper						X	X									
Final Poster																
Final Paper																
Meetings																
Team	X	X	X	X	X	X	X									
Advisor	X	X		X	X	X										
Client		X				X	X									
Website																
Updates	X	X	X	X	X	X	X									

9. Acknowledgements

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- Wally Block (Client)
- Nikki Goecks (Collaborator)
- Ethan Brodsky (Collaborator)
- Chris Ross (Collaborator)
- Professor Yen (Advisor)

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11. Appendix

11.1. Product Design Specifications

Head Holder for MR-Guided Drug Delivery Testing (head_holder)
Product Design Specifications

Kim Maciolek (Team Leader), Gabe Bautista (Communicator),
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March 14, 2012

Function: Convection enhanced drug delivery (CED) monitored through real time MRI requires immobilization of the subject's head. Our client, Professor Wally Block, requests a head holder device that is compatible with his experimental setup for in vivo studies on beagles and rhesus monkeys. The head holder must not include ferrous materials or parts that will conflict with the MRI antenna array. Due to the high degree of accuracy required, the device must restrict translational movement to less than 1 mm.

Client Requirements:
Our client wants a head holder that:

- Is compatible with MRI and experimental setup
- Restricts translation motion to less than 1 mm
- Works with beagles and rhesus monkeys

Design Requirements:

1. **Physical and Operational characteristics**

   a. *Performance requirements:* The device should be reusable, easily sanitized, compatible with MRI, and prevent unnecessary damage to tissue.

   b. *Safety:* Device cannot harm animal, including inhibiting breathing or swallowing.

   c. *Accuracy and Reliability:* Immobilization should prevent translational movement from exceeding 1 mm.

   d. *Life of Service:* Device must be reusable and last 5 years.

   e. *Shelf Life:* Device should be stored at room temperature and atmospheric pressure.

   f. *Operating Environment:* Device will be exposed to high magnetic fields at room temperature.

   g. *Ergonomics:* Device must be easily used by one person including maneuvering and placement. Device must also conform to both species of subjects.

   h. *Size:* Device must fit within the MRI bore (60 cm across) with other experimental instruments (brain port and ear coils) for real time MRI infusions and animal monitoring.

   i. *Weight:* Maximum weight of device should be no more than 9 kg.

   j. *Materials:* Device should contain materials that are compatible with MRI. It should not contain ferrous materials. Materials must be easily sanitized. Materials must also be sufficiently rigid to withstand forces necessary for immobilization.

   k. *Aesthetics, Appearance, and Finish:* Finish should be conducive for gripping and have no ill effects on animals.

2. **Production Characteristics**

a. Quantity: At least one functional device is needed. Ideally, two functional devices will be made.

b. Target Product Cost: Total production cost should be less than $1,000.

3. **Miscellaneous**

a. Standards and Specifications: IRB/IACUC approval is needed to test on live animals.

b. Customer: Client is environmentally conscious and would prefer a reusable or semi-reusable device. A reusable device is also the most practical. Functionality, however, is main priority to the client.

c. Patient-related concerns: Device cannot be harmful to animal and therefore must immobilize head without harming the animal. Device will be sterilized between uses.

d. Competition: All other head holder devices are not compatible with experimental setup (ie use ear bars) or MRI. Current devices (although incompatible) cost approximately $2,000. A cheaper device is requested by the client.