Stereotactic Radiosurgery Head Frame Holder

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Abstract

Stereotactic Radiosurgery is a precise method of delivering radiation therapy to a patient with a malformation in the brain. At the University of Wisconsin Madison hospital, a linear accelerator is used to focus beams of radiation onto the tumor to damage the DNA so that cells within the tumor are not able to further replicate and cause harm to the patient. To map the location of the tumor, the patient wears a head frame, known as a halo that is secured by tightening four precision screws into the patient's head. This procedure currently requires two medical personnel. Our team plans to fabricate a device that holds the halo while a single physician secures it into place. This device will mimic a height scale and will translate horizontally, vertically and rotate to adjust for any angle of recline. The mechanism will lock into place at the location where the physician will secure the halo. The halo will be attached to the device via clamps. This device will allow the halo to be safely attached to the patient in preparation for stereotactic radiosurgery.

Introduction

Stereotactic radiosurgery is a non-invasive procedure in which radiation must be precisely delivered to particular areas of the brain (Figure 1). During the procedure, a patient must wear a titanium head frame which is attached by four precision screws to their skull. Currently, our client uses a Velcro strap to stabilize the head frame while local anesthesia is administered and the screws are fastened. The main concern with this method is that it requires the attention of at least two medical personnel. Straightforward use and patient safety can be better handled with a rigid device that has locking joints. We propose a

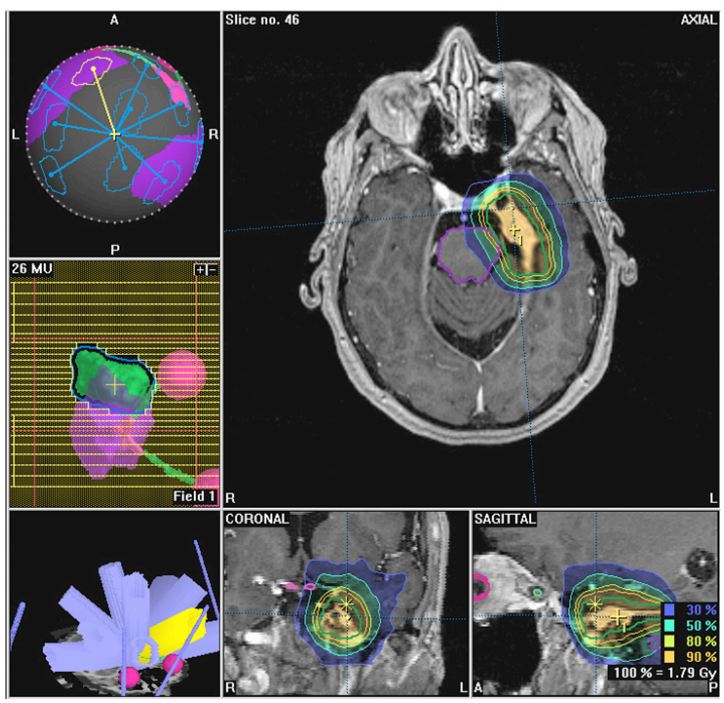

Figure 1: Brain scan as used to map the brain in stereotactic radiosurgery.
http://www.physics.ubc.ca/research/images/RadTherapy.jpg

universal device, capable of fitting any patient, which can be used in conjunction with a reclined wheelchair.

Background

Stereotactic Radiosurgery

Stereotactic radiosurgery is a non-invasive procedure primarily performed on patients with benign tumors, malignant tumors, or arteriovenous malformations. The objective of this procedure is to precisely deliver high doses of radiation to abnormalities without damaging surrounding brain tissue. The radiation does not destroy the tumor or malformation, but rather damages its DNA so that it can no longer reproduce. A period of months after the treatment, the abnormality shrinks and eventually ceases to exist. These procedures are generally given in a single session, as one dose of highly localized radiation is enough to damage the DNA of the malformation.

The procedure is a day long process for the patient and involves four phases. Initially, a titanium halo is attached by conical, t-bolt screws to the patients head. The patient is locally anesthetized while the four screws are drilled into the skull.

The next phase in the process is imaging. The patient undergoes a CT scan so that the location of the aberration relative to the head frame can be plotted. The third stage, computerized dose planning, involves the physicians devising a plan to attack the tumor using the patient’s past MRI scans and the CT scan that was taken in phase 2.

The fourth and final stage is radiation delivery. There are many machines that are capable of administering this type of radiation, but our client uses a linear particle accelerator, *Linac*. The patient is conscious and able to communicate with the oncologist during the entire procedure to alert the physician to any pain they may be feeling. Stereotactic radiosurgery and the use of the *Linac* is not a painful procedure, but at times may feel uncomfortable. This

Figure 2. Linear Accelerator used in Stereotactic Radiosurgery
http://www.peninsula.org/images/cancer_center/Trilogy%20Linear%20Accelerator2.jpg

procedure is performed 50 – 60 times each year in the UW Radiology Department.

Linear Accelerators

A linear accelerator is a machine capable of significantly increasing the velocity of subatomic particles by directing electrons, protons or other particles through a series of oscillating electric potentials (Figure 2). The process was invented by Rolf Widerøe in 1928[1]. The linear accelerators associated with radiosurgery allow accelerated particles to collide with heavy metal targets, causing them to release high-energy x-rays. The x-rays are then directed by a collimator into the head of the machine. The high-energy radiation eventually leaves the machine though the gantry, which is the part of the accelerator that can rotate. The patient lies in a fixed position, determined by lasers for accuracy, on a table surrounded by the gantry. The machine can direct concentrated doses of radiation within 0.25mm of its target[2].

Problem Statement

In patients who require concentrated radiation treatment to the brain, a major pre-surgery problem is attachment of the halo ring head frame. The head frame must be correctly positioned to provide a reference coordinate system for physicians later administering radiation. However, it currently takes two physicians to properly secure the head frame. Our goal is to design a device to hold the head frame in place independent of the patient head position. We propose a device into which the head frame can be docked without sustaining damage that can be lowered and locked into position around a patients head. This device will improve the precision of the head frame placement, and allow a single physician to secure the head frame.

Problem Overview

Our main focus for this project is to develop a safe, practical alternative for the current methods in use for head-frame placement. The method employed by UW Health for head frame attachment requires a minimum of two physicians and a Velcro system in order to hold the frame in place. However, this process is very time consuming and is open to multiple points of failure. That is, the attachment process is highly dependent upon multiple members of the staff, which

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[1] http://www.britannica.com/EBchecked/topic/643208/Rolf-Wideroe Encyclopedia Britannica.

[2] Comprehensive quality assurance for stereotactic radiosurgery treatments. R Ramaseshan *et al* 2003 *Phys. Med. Biol.* 48 N199-N205 doi: 10.1088/0031-9155/48/14/402

leaves substantial room for human error. Also, the Velcro system is unstable and is capable of detaching if not properly secured.

In light of these difficulties, we will concentrate on designing a device that will allow for only one person to attach the head frame in 5-10 minutes. This new device must focus on patient safety and stability as well as stability for the head frame itself.

Problem Motivation

The motivation behind this project is to provide doctors and patients with a less cumbersome experience for the placement of the head frame. This has both physical and mental side effects on the patient. In the physical sense, more support for the patient and a more stable head frame holder will equate to less discomfort through vibrations as the head frame is screwed in. This new stable frame will help prevent patient movement which may place uncomfortable torque at the contact sights. However, this does nothing to help quell the mental uneasiness of the patient being prepped for treatment. While a patient's mind is naturally anxious for the procedure, seeing a head frame being placed upon them with the use of such simple devices like Velcro as they are being prepped for brain radiation does not help to calm their nerves. Alternatively, if the patient sees a strong, stable device that is not overwhelming in its complexity, it may instill more confidence regarding the professionalism and seriousness of the procedure they are undergoing.

Design Constraints

This device will be used typically 50-60 times a year, and must be easy to use and easy to store. The head-frame holder must be stable, yet allow for a high degree of maneuverability, often in slight increments. The design must allow the head-frame to slide vertically 4-5 inches along a patient's head. It must also be able to accommodate a patient whose head is reclined, by having 45 degrees of angle freedom at the back of the holder. The design must also allow access to the four pins used to screw into the patient's head. If the patient is sedated, the head-frame holder must also support the patient in a way that keeps their airway open. No real weight or size issues were provided. The design must not be overly complicated, while giving an impression of professionalism to the patient.

Current Devices

The current process for head frame placement involves the use of a Velcro strap as well the combined efforts of two to three medical personnel. The system involves first placing a Velcro strap across the diameter of the head frame. Next, the head frame is secured to the Velcro strap threading the strap around the head frame and connecting to the inner portions of the strap. At this point, the head frame is then lowered upon the patient's head, guided by the staff members. The Velcro strap rests on the top of the patient's head while the head frame is being screwed into the patient's skull. This device is somewhat insecure and fails to provide any support for the patient as the patient is prepared for stereotactic radiosurgery. The strap does not allow positioning of the head frame independent of head position. The current device also fails to maximize the efficiency in its use of staff members involved in the head frame placement.

Competition

The only device currently on the market designed to assist in the head frame placement for stereotactic radiosurgery is the previously described Velcro system. We are unaware of any other device which promotes staff efficiency by requiring only one person to attach the head frame in a timely manner that also promotes patient safety and stability. The need for efficiency and stability in head frame placement is a critical objective for any device looking to improve this procedure.

Potential Designs

Articulating Dental Light Arm

Figure 3. Dental articulating operatory arm
http://www.beaverstatedental.com/

The first design our team came up with is an articulating dental operatory light arm (Figure 3).This mechanism mimics a light arm that is used in a dentist's office. There is normally either a light or an x-ray at the end of the dental arm that the dentist can easily maneuver and position above the patient. Instead of a light or x-ray at the end of the arm, there would be a clamp that would attach onto the halo. This design has five degrees of freedom which makes moving it to the correct location effortless for the physician. A major concern with this design alternative is that the joints are not rigid. While this makes the motion of the device smooth and simple, this may cause potential problems for the attachment of the halo. If the physician were to bump the arm while attaching the halo, the halo could be displaced and cause potential injury to the patient. This design is difficult to obtain. *R-tech Dental Equipment Services* donates used dental arms, but none are available at the current time.

Sliding Wall Track

The second design alternative is a sliding track set against or into the wall (Figure 4). It would be able to collapse next to the wall and would be minimally obtrusive when not in use. This design mimics a height scale in the doctor's office. The track moves vertically to adjust for differences in patient height and the halo slides horizontally along the track to adjust for patient head depth and shoulder angle. The track would also rotate along the vertical axis to account for the angle of recline of the patient in the wheel chair. This motion accounts for all of the directions that our client would like the doctor to adjust for while attaching the halo to the patient's head.

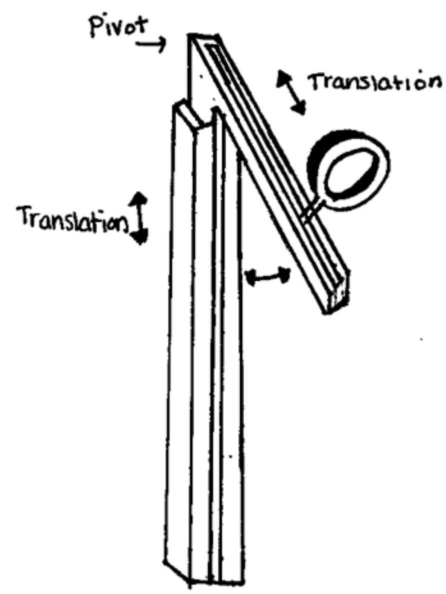

Figure 4. Sliding Wall Track

This design has only four degrees of freedom, but it locks in the exact location where the physician would like to attach the halo tension clamps at the end of translating segments.

The wall track also allows for any degree of recline, either most comfortable for the patient or most convenient for the physician. Although the patient can be reclined at any angle in the wheelchair

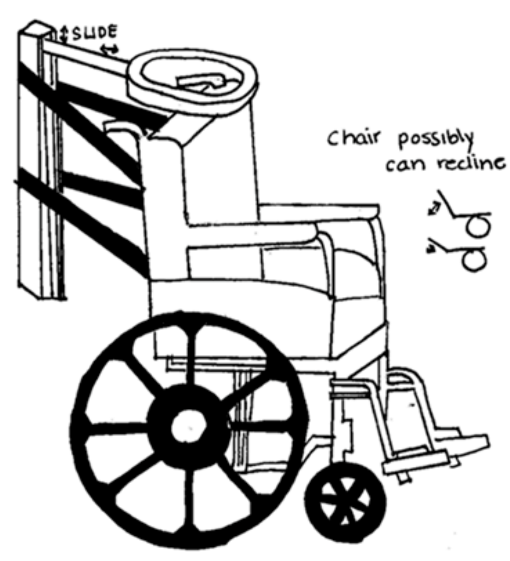

Figure 5. A-Frame Wheelchair attachment

while the halo is being secured, the patient cannot be sitting vertically upright. Our client would like the patient to be reclined at all times during the first phase of stereotactic radio surgery, and this design will allow for this patient position

A-Frame Wheelchair Attachment

The third design alternative is variation of the sliding wall track (Figure 5). This device also mimics a height scale in the doctor's office, but only accounts for vertical translation to adjust for height and horizontal translation to adjust for the placement of the patient and the head depth. An A-frame is attached to the back of the chair to allow for the deformation of the fabric in the back of the chair so that any patient can comfortably relax while the halo is secured. This design is large and bulky and would have to be attached and detached each time that the physician was to perform the first phase of the surgery. This would require storage of the mechanism.

A. Origin of Attachment	Mechanism	Cost (1-20)	Ease of Use (1-15)	Size (1-10)	Safety (1-25)	Ease of Construction (1-20)	Aesthetics (1-10)	Total (1-100)
Wall	Track	15	13	9	23	15	7	82
Free-Standing	Articulating Operatory Dental Light	4	15	9	17	20	10	75
Wheelchair	A-Frame with Track	12	10	7	23	7	3	62

B. Attachment to Halo								
Neodymium Magnets		18	7	4	12	n/a	10	51
Clamps		17	13	10	18	n/a	5	63
Screws-CCST		10	10	8	20	n/a	7	55

Table 1**a.** Design Matrix**. Origin of attachment**. A design matrix was created for all of the design alternatives and ranked in the categories above. The sliding wall track was the design that we thought was the safest for the patient, and the easiest to use for the physician. **1b. Attachment to Halo**The second section of the matrix is the attachment mechanism to the halo. The clamps were chosen for our device as they are the overall safest for the patient and easiest for the physican to use when attaching the halo.

Attachment of Head Frame

The head frame must be secured to the holder without incurring any damage to the head frame. In order to accomplish this, the head frame cannot be manipulated in any way. The device used to secure the head frame must therefore be easy to manipulate and remove. Several options were brainstormed to solve this problem. Table 1b summarizes the head frame attachment options.

Clamps

In this design, the physician attaching the head frame would simply have to insert the head frame in a dock on the head frame holder, and tighten a clamp over the dock to secure it in place. This alternative provides a simple, reliable way to secure the head frame without damaging it. Several options for clamp type exist, varying from bar clamps which are extremely adjustable for size, to spring clamps which require only one hand to operate.

Figure 6. Spring clamp
http://www.justclamps.com/spring_clamps.htm#615

Ultimately, since this procedure involves securing a head frame which is a standard size, the clamp which makes the most sense to incorporate in this design is a spring clamp (Figure 6), which a physician can easily position and operate with a single hand to a standard compression.

The only disadvantage to this design is patient perception. A standard spring clamp could appear to some patients as household or garage appliance. If this is the case, the clamps may appear out of place and seem inappropriately suited for clinical use. For this reason, a sleek clamp would need to be purchased.

Magnets

The head frame is composed of titanium, a magnetic material. For this reason, another viable alternative would be to incorporate small, neodymium magnets (Figure 7) into the head frame holder. In this way, the frame could be brought up to the holder, perhaps into a dock which holds the magnets, and held in place simply by magnetic force.

Figure 7. Neodymium magnet. Penny on left, magnet on right.
http://www.kjmagnetics.com/products.asp?cat=10

The advantages of this design include its ability to be operated with one hand, its standard positioning of the head frame in a standard position and location, and its size. This design does not require any external parts, which means that there is less bulk in the way when a physician is securing the head frame to the patient, and it makes the process of securing the head frame a simple single step.

The disadvantages to this design are that the design includes magnets. In a hospital setting, there are numerous materials that can be affected by magnetic fields. It is difficult to predict if the magnets in this design, though weak, would affect any of the surrounding devices or the head frame itself.

The strength of the magnets in this design is also a concern. The magnets must be strong enough to hold on the head frame, but they must be weak enough to remove the head frame without moving or jostling the patient's head in the process. This allows for a very narrow range of magnetic strength that would be difficult to determine and attain.

Screws

Although manipulating the head frame is not an option, the head frame already contains two holes for screw placement for when it docks into the linear accelerator for treatment. Since these holes already exist, they could be utilized to dock the head frame into the holder. In order to prevent damage to the threads or the holes, the screws used for placement on the head frame holder would need to be the same as those used for docking in the linear accelerator (Figure 8).

Figure 8. Conical t-bolt screws used to secure head frame.
http://www.radionics.com/products/stereotaxy/CRW_Catalog.pdf

The advantages to this design are that it utilizes pre-existing holes used for hardware that is designed to be used in conjunction with the head frame, which means the risk of damage to the head frame is very small.

The disadvantages to this design are that it would require two hands to operate, one to hold the head frame and one to tighten the screws. This would be time consuming. This design also involves very small pieces which are more likely to be dropped or misplaced during and after placement than the devices used in the other design alternatives.

Final Design

Ultimately, the Sliding Wall Arm was selected as the final design for the head frame holder (Figure 9). This will be used in conjunction with the spring clamp as the head frame attachment method.

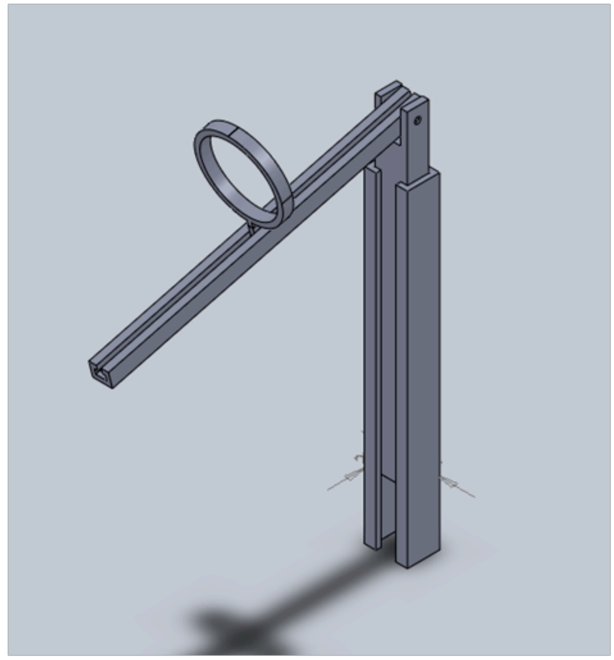

Figure 9. Final design selection: Sliding Wall Frame Holder

The sliding wall arm was selected by using the design matrix (Table 1a.) primarily for its ability to lock in place and its stationary and collapsible nature on the wall.

Not shown in this design is the head rest used to support the head and maintain its position. This will be external to the head frame holder design in order to maintain independence of the head frame position in relation to head position. The head rest will be attached directly to the wheelchair for patient comfort and stability. The head rest will be adjustable to allow for differing patient head and neck heights. The head rest will be small to allow for adequate room to position and adjust the head frame. The head rest will also include an adjustable attachment to support the chin and keep the airway open.

Future Work and Conclusions

After obtaining client feedback about each of our designs and the selection we made for final design, fabrication of the head frame holder and head rest will commence. The materials for fabrication will need to be decided and ordered. The material used will likely be PVC or aluminum. Each of these is light and easy to use during the fabrication process.

Depending on the level of complexity that is expected (depending on the material chosen), the design will be fabricated in the Engineering Centers Building shop or contracted out to the WIMR shop if it proves too complicated to fabricate by ourselves.

Testing of our design will begin with stability testing on a dummy. A dummy will be positioned in the same way as a patient having the head frame attached. This test will determine whether the positioning on the head frame holder is stationary and once locked in place. Following stationary positioning testing, the level of movement of the head frame due to perturbations such as accidental knocking of the holder will be assessed. The damage inflicted on the dummy due to these motions will be evaluated to determine patient safety in these situations.

Following positioning testing, time testing will take place. We will evaluate average people and physicians with and without training to determine the time it takes to position the head frame using our device and the time it takes to position the head frame using the old method of attachment. We will then compare the two times and determine if our device decreases the head frame positioning time.

Finally, physician surveys will be taken to determine their opinion of the head frame holder. We will use this feedback to determine if any changes need to be made to the head frame holder that would make it easier to use.

Appendix A – References

Comprehensive quality assurance for stereotactic radiosurgery treatments
R Ramaseshan *et al* 2003 *Phys. Med. Biol.* 48 N199-N205 doi: 10.1088/0031-9155/48/14/402

K&J Magnetics Inc. Jamison, PA. www.kjmagnetics.com

Peachtree Woodworking Supply Inc. Atlanta , GA. ©2001-2008. www.justclamps.com

Stereotaxy Product Catalog. http://www.radionics.com/products/stereotaxy/CRW_Catalog.pdf

Appendix B – Product Design Specifications

Function:

When a patient has a tumor or another type of abnormality, one way to reduce the size of the tumor is stereotactic radiosurgery. Stereotactic radiosurgery is a method of delivering radiation to a patient in an extremely precise manner using a linear accelerator. When the radiosurgery is performed, a halo "ring" is attached to the patients scalp at 4 screw-in attachment points. Our goal is to design a device which holds the halo independent of the patients head position and movements so that one physician can attach the head frame while the patient is sedated.

Client requirements:

- Must be able to move up and down the distance of a total head length.
- Must be able to move frontally and dorsally up to 1.5 in.
- Must be able to tilt minimally from the pivot point at the back.
- Cannot change the existing halo in any way. Can screw in to the existing holes in the head frame.
- Support to keep head and airway tilted to 45 degree angle.
- Must maintain easy access to head attachment points even when device is in place.
- Must have a head support in addition to the frame support.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: Must be used for 10-15 minutes in the morning for each procedure. Can be used 1-2 times a day, 50-60 times a year.

b. *Safety*: Must keep airway open and head stabilized. Must be support so that the head frame does not fall on the patient.

c. *Accuracy and Reliability*: Must move 1.5" in the forward and backward directions, and a whole head length up and down(measurement to be determined later).

d. *Life in Service*: Reusable, must be usable 50-60 times a year, ideally for multiple years.

e. *Shelf Life*: There are no degradable components to our design. Theoretically the device should have an indefinite shelf life when properly stored.

f. *Operating Environment*: The device will be operated in a hospital. It need not be sterile, but should be resistant to wear and dirt, and easy to clean.

g. *Ergonomics*: Should be easy to operate by one physician.

h. *Size*: Will only need one size, as it docks into a precisely standardized halo. Will also need to be attached to a standard wheelchair.

i. *Weight*: Weight is not an issue, should be able to be transported in and out of storage by 1-2 people.

j. *Materials*: Halo is made out of titanium, the material should be something that does not damage easily, and strong enough to support the weight of the head frame and human head without deforming.
k. *Aesthetics*, *Appearance, and Finish*: Aesthetically pleasing. Appearance isn't really an issue, it should be free of rough edges and sleek for safety.

2. Production Characteristics

a. *Quantity*: 1 deliverable.
b. *Target Product Cost*: Between $500-$1000, additional funding will be available if specialized materials need to be ordered.

3. Miscellaneous

a. *Standards and Specifications*: Must be approved for safety and function by the physicians utilizing the device.
b. *Customer/Patient related concerns*: Not applicable, device does not come in direct contact with patient.
d. *Competition*: There is currently no product on the market that secures the head frame while it is being attached.