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 metastasize. 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 human set of arms and will translate horizontally, vertically and rotate to adjust for any angle of recline. The mechanism will stabilize at the location where the physician secures the halo. The halo will be attached to the device via clamps. This device will allow the halo to be safely attached to a 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. A simpler method of attachment, while maintaining patient safety, can be delivered with a rigid device that has locking joints. We propose a universal device, capable of fitting any patient, which can be used in conjunction with a reclined wheelchair.

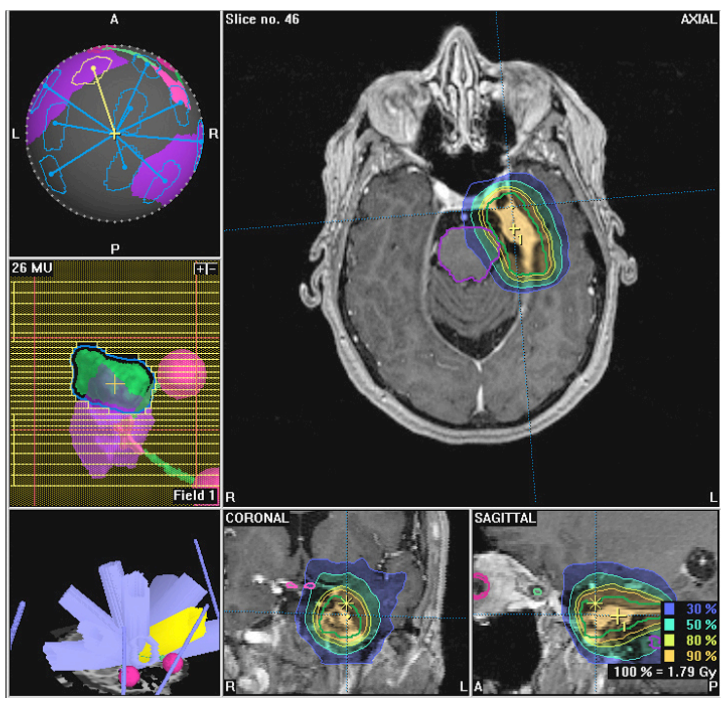

Figure 1: Brain scan as used to map the brain in stereotactic radiosurgery.
http://www.physics.ubc.ca/research/images/RadTherapy.jpg

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 recedes. These procedures are generally given in a single session, as one dose of highly localized radiation is normally 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 four conical, t-bolt screws to the patients head. The patient is locally anesthetized while the 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.

In the third stage, computerized dose planning, a team of physicians devise a plan to attack the tumor using the patient's past MRI scans and the CT scan that was taken in phase two.

The fourth and final stage is radiation delivery. There are many machines that are capable of administering this type of radiation, including a linear particle accelerator, gamma knife, or proton beam. The patient is conscious and able to communicate with the oncologist during the entire procedure to alert the physician to any pain they may experience. Stereotactic radiosurgery and the use of the *Linac* machine is not a painful procedure, but at times may feel uncomfortable. This procedure is performed 50 – 60 times each year in the UW Radiology Department.

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

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 precision, on a table surrounded by the gantry. In this manner, 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 one physician and one resident assistant 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 stabilized into position around a patients head even in the presence of significant force. This device will improve the precision of the head frame placement, and allow a single physician to secure the head frame in a decreased or comparable time to the current method.

Problem Overview:

Our primary focus for this project is to develop a device that will allow one staff member to efficiently and effectively attach the head frame. The current method employed by the UW Hospital for the head frame attachment requires a minimum of two people. One member of the

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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

staff is required to securely hold and position the head frame with the aid of a Velcro strap while a physician actually attaches the head frame to the patient. The attachment process is slow and cumbersome and fails to maximize an efficient use of time. This is primarily due to the fact that there are two staff members involved who have to work together in a confined region around a patient who typically cannot move. For example, because the screw slots on the halo are located equidistant from each other along the circumference of the halo, each time the physician needs to move to a different screw to continue the attachment process, the staff member holding the halo consequently has to move each time as well and stabilize the head frame from that new position. Another difficulty arises from the fact that the head frame is primarily supported by a human and thus is not completely stable and secure. As the physician is screwing the head frame into the patient's head, he or she needs to make sure that the head frame is as stable as possible in order for the head frame to be in the correct position in relation to the patient's head. In light of these difficulties, we have focused on designing a device that will allow for only one person to effectively attach the head frame.

Project Motivation:

The driving force behind the development of our device was to design a head frame holder that would allow just the physician to attach the head frame efficiently and effectively for patients that are either sitting or reclined. We have designed our device with the intention of decreasing or maintaining the time currently required to attach the head frame. We have also focused on designing our device so that it will allow significantly more support, security, reliability, and duplicability than a staff member simply holding the head frame could offer. While our main motivation is to develop a more efficient procedure for the staff, a secondary motivation comes from creating an attachment process that is a fast and simple, thus not adding any more stress to an already nervous patient.

Design Constraints:

Stereotactic radiosurgery is generally performed 50-60 times a year at the UW Hospital and as such, our device must be easy to use, store and transport. The device holding the head frame must be highly maneuverable and be able to securely hold the head frame in any position the staff may desire. The design must allow the head frame to slide vertically 4-5 inches along a patient's head. And it must be able to accommodate for a patient who is reclined by having at least 45 degrees of angle freedom at the back of the holder. This allows the head frame to be placed perpendicular to the reclined patient's shoulders. The design cannot obstruct access to the four pins that are used to attach the head frame to the patient in case the patient needs to be removed quickly in the event of a medical emergency. Most significantly, the device must allow one person to efficiently attach the head frame.

Current Frame Holder

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 protocol first places 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 of the 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 requires only one person to attach the head frame, can be completed in a timely manner, and also provides patient support. 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

We first describe an articulating dental operatory light arm (Figure 3). This mechanism mimics a light arm that is used in

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

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, we would place a clamp that attaches the halo. This design has five degrees of freedom, which makes moving it to the correct location effortless for the technician. 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, locking the frame holder into place would be difficult. 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. *Theisen Dental* liquidates 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 design provides all degrees of freedom required by our client while attaching the halo to the patient’s head.

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.

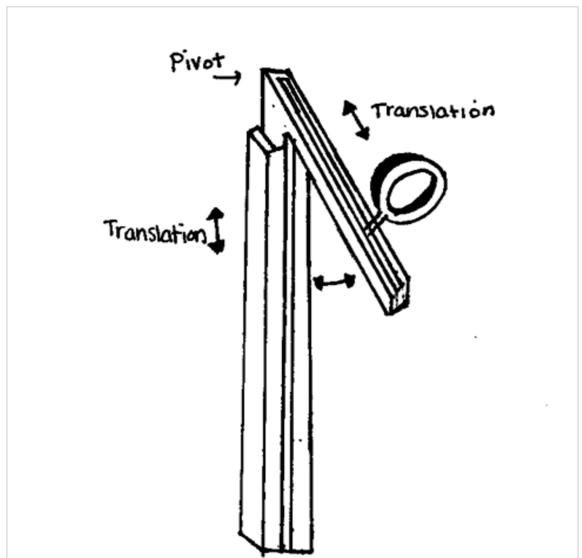

Figure 4. Sliding Wall Track

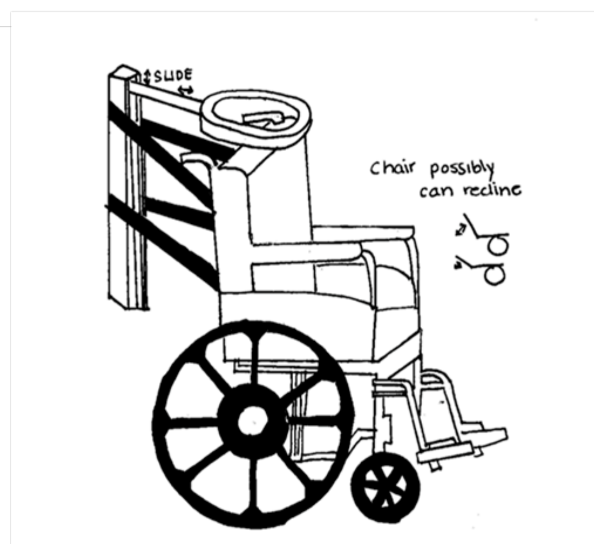

Figure 5. A-Frame Wheelchair attachment

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 while the halo is being secured, the patient cannot be sitting vertically upright. However, 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 mechanism storage.

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 are discussed in the following section.

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 clamps 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, streamlined clamp may be desirable.

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 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 the stray magnetic fields produced. 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 equipment.

The strength of the magnets in this design is also a concern. The magnets must be strong enough to hold onto 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. 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

After discussing our initial design choices with our client, an alternative final design was pursued. Our client did not like the sliding wall track design due to the limited range of motion that would be possible behind the patient. After some discussion, it was decided that we would pursue the dental arm design instead.

Figure 9 – Final Design

Our device uses the articulating dental operatory light arm to maneuver the head frame to the correct position (Figure 9). The dental arm and the attached base allow five degrees of freedom. The base can translate freely in the xy-plane allowing the multiple halos to be attached within a short amount of time. The dental arm can also translate vertically up to 68.58cm. This property accounts for the varying heights of patients who come through the hospital needing stereotactic radiosurgery. The dental arm rotates 360° around the z-axis to allow for the arm to be maneuvered wherever the physician needs to attach the dental arm. The device also has a pitch of greater than 90°. A pitch of 45° allows the patient to potentially be reclined in the wheel chair while the head frame is attached. The halo can be attached at an angle the same way that it can be attached while the patient is sitting vertically in the wheelchair. The device our team fabricated effectively secures the halo while a single physician attaches it to the patient's skull.

The base was fabricated with high density fiber board, which is a light and supportive material. The dental arm is set into a polyvinyl chloride (PVC) pipe that is stabilized inside by a wooden dowel. The PVC pipe is also supported on three sides by wooden supports that help to counterbalance the weight of the dental arm. The weight of the dental arm is also counterbalanced with bricks laid down on the base of the device.

The dental arm has two handles that allow for the physician to correctly position the head frame for stereotactic radiosurgery. Two spacing bars drop down from each handle to allow for the patients head to fit above the halo. The bars are attached to the dental arm via hinges that allow for the two spacers to rotate in. The bars are attached to each other with a spring that also allows for the elastic recoil of the spacers to further secure the halo into place. At the base of the spacing bars, two semi circular plates are attached with L-brackets to allow a resting space for the halo, so that it is secure even if nothing else is there to secure the halo. Finally, when the halo is placed on the semi-circular plates, it will be clamped down with two ***spring*** clamps to secure the halo while the physician screws the precision screws into the patient's head. Our device assures the security of the halo while a single physician is attaching it to a patient's head.

Testing

Translation testing

Initial tests were performed on the head frame holder to assess how efficiently it can be moved from room to room if multiple procedures are being performed in a day. Rolling on the wheels attached to the base moved the device. It was timed as it was translated a standard distance of 2.9718 meters. From the time and distance, an average speed was determined for each trial. The data for these trails are summarized below in Table 1.

Table 1: Translation testing

Trial Number	Distance (m)	Time (seconds)	Speed (m/s)	Average Speed(m/s)
1	2.9718	8.01	0.3710	0.4220
2	2.9718	7.0	0.4245	0.4220
3	2.9718	6.3	0.4717	0.4220

Three trials in total were performed and averaged to give an average translating speed of 0.42m/s. This value is about 1/3 of average walking speed for an adult[3]. In the future, more trials could be performed to give a result that would be statistically more precise.

Positioning Testing

To ensure that the head frame holder can be positioned around a patient and remain stationary throughout the procedure, positioning testing was performed using a mock head frame and a dummy. These trials were qualitative and were used to assess relative motions at various head frame positions. The head frame remained stable when positioned at any height in the z-direction. The frame was stable when rotated up to a pitch of 45°, which satisfies the client's requirements. The dental arm and its stand can be translated in the x-y plane without changing the stability of the device. The only stability issues that were encountered during positioning were the slight vibrations that were present when the tightening of the screws was simulated. This can easily be remedied by affixing an additional piece of hardware to each hinge at the point of attachment which will prevent much of the movement generated by tightening the screws into the skull.

Physician Testing on Patients

The next phase of testing for our project involves bringing the device to the hospital to allow physicians to perform the head frame placement procedure with the head frame holder device in the presence of additional staff in the event of a problem. If any problems with the device occur, the procedure can be performed as it is currently without the head frame holder, and issues with the head frame holder will be addressed. Physician feedback will determine what changes can and need to be made to increase the device's stability or ease of use for the physician.

[3] http://wiki.answers.com/Q/What_is_the_average_speed_of_human_walking

Future Work

Head Rest

Before the device may be used on reclined patients who have been sedated, a headrest must be fabricated to prevent the patients' heads from falling backwards during the procedure. This device will either be a simple neck brace, or a headrest that is affixed to the back of the wheelchair that slides into place at the base of the patient's neck. Both alternatives will be easy to fabricate and position, and should not interfere with head frame placement.

Incorporation

After the headrest has been fabricated and additional testing has been performed with the help of the physicians performing the procedure, the head frame holder will be incorporated into the Stereotactic Radiosurgery procedure at the UW-Madison Hospital. It is our client's goal to see this happen within the next month so that as many patients as possible may benefit from additional sedation during the head frame placement portion of the procedure. If the head frame holder proves to be a successful addition to the procedure at the UW-Madison hospital, it can be duplicated and used in other hospitals as well.

Summary of Ethical Considerations

Although the main concern of this project was not patient safety, there are still ethical issues involved. The most prominent ethical issues arose from trying to integrate our device into the current hospital procedure. The device will need to be tested by physicians on phantoms in mock procedures before it can be used on actual patients. The phantoms used for this testing should accurately represent a human head. The phantom should include a soft outer layer that resembles skin and muscle and a harder inner layer that corresponds to the bone tissue. After undergoing multiple trials using the phantom, we would be ethically confident that the head frame holder could be used on patients.

During the initial trials on humans there should be multiple staff members present in the event that our device fails. This would prevent patient injury and allow for a quick change to the previous procedure. The patient and medical personnel of the first stereotactic radiosurgery performed with our device should be required to complete a Human Subject Protection Training Program in accordance with UW-Madison standards. Ethically, we believe that the patients should be informed of their options and should be given a choice on whether they would like to use our device or not. For the maximum safety and efficient use, the individual using our device should be trained by using a phantom and have sufficient knowledge of the limitations of our head frame holder.

Our device will eventually be replacing a resident physician that is now required to hold the head frame with his/her hands. We understand that by replacing a human, we lose the ability of the holder to foresee and react to unique circumstances. However, we believe that with the design of our device and a trained physician, the loss of human perception would be compensated for by the additional stability and security our head frame holder offers.

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

Management Planning

Time Management:

Task	**Estimated Hours**
Brainstorming	8
Material purchase (including travel)	4
Mock head frame construction	6
Head frame holder construction	8
Base construction	10
Painting	1
Papers/posters	4
Total	**41**

Cost Management:

Item	Quantity	Price	Item Total
MDF (Wood for base)	1	8.31	8.31
PVC pipe	1	2.94	2.94
PVC sheeting	3	3.97	11.91
Hinges	1	2.47	2.47
Wheels	4	3.98	15.92
Clamps	2	5.97	11.94
Screws	1	4.97	4.97
L-brackets(small)	1	2.98	2.98
Screws	1	0.98	0.98
Spray Paint	1	5.27	5.27
Wood(supports)	1	1.97	1.97
Spring	1	1.52	1.52
Weights	7	0.39	2.73
		Subtotal	73.91
		Tax	4.07
		Subtotal	77.98
Dental arm	1	75.00	75.00
		Total	**152.98**

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.