Standing Paraplegic Operating Room Device

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Clients: Dr. David Jones, MD and Dr. Garrett Cuppels, MD

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Abstract

Our client is a T12 paraplegic and former orthopedic surgeon. In order to goal of returning to orthopedic surgery, our client needs a device that will allow him to be in a standing position throughout surgeries that he wouldn't be able to do sitting down. This device will also need to allow for movements required by these surgeries. The goal of this project is to create a device that can achieve these requirements while being safe, cost efficient, and meeting any and all regulations. The first two months of this project have been spent gathering background information, defining the problem, and outlining the specifications needed. From there initial work into developing a mechanism for the stability of this device has been started but not completed, as well as researching the regulations. The rest of the semester will be spent finalizing the stability mechanism, then moving on piece-by-piece until a prototype is made.

Introduction

Our client, Dr. Garret Cuppels, is an orthopedic surgeon who specializes in both lower and upper extremity surgeries. However, 18 months ago Dr. Cuppels sustained a serious injury to his spine following an accidental fall. The fall was from a third story balcony and Dr. Cuppels injured the T12 vertebrae in his spine; the location of the T12 vertebrae can be seen in Figure 1. An injury to this area of the spine caused Dr. Cuppels to lose all voluntary control of movement in his lower limbs and trunk, removing our client's ability to stand and walk. Dr. Cuppels quickly found himself out of work as lower extremity operations, such as hip replacements, require the surgeon to remain in the standing position. Following the accident, Dr. Cuppels underwent therapy and used devices such as standing wheelchairs, but due to insurance issues our client was unable to have continued access to therapy and rehabilitation services and now uses a standard sitting wheelchair as his primary mode of transportation. Despite of his injury, Dr. Cuppels retains in him a strong desire to return back to work.

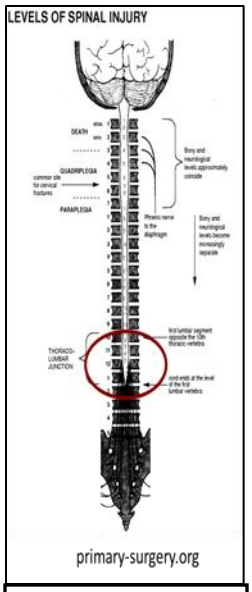

Figure 1: Human vertebral column illustrating levels of spinal cord injuries.

While looking for possible job opportunity, Dr. Cuppels contacted Dr. David Jones at Berlin Memorial Hospital in Oshkosh, Wisconsin. Even considering Dr. Cuppels' condition, the hospital staff was still interested and flew him out to the hospital to meet. However, it is uneconomical for them to hire an orthopedic surgeon who can only perform upper extremity surgeries such as shoulder surgeries. Again, due to his condition, our client may find himself unable to practice surgery even though his hands and his mind are fully capable of performing surgeries. As such, the basic premise of this project is to develop a device that will allow our client to perform lower extremity surgeries in the standing position. To give Garret this ability will make him much more marketable and will have a direct impact in helping our client to regain a position within the operating room. To make such a device will require careful consideration of our client's requirements in addition to hospital, insurance, and FDA regulations.

Motivation

This project has the unique ability to directly make a difference in an individual's life. By successfully constructing a device that will allow Dr. Cuppels to perform surgeries in the standing position we have

the opportunity to greatly increase Garret's ability to return to work. Additionally, the construction of a standing paraplegic O.R. device will affect not only Garret, but has to potential to touch many more lives. Such a device will serve as an example to all those individuals affected by disabilities that they are not defined by their conditions; that with determination everybody has the ability to lead a meaningful and productive life.

Client Requirements

The primary condition specified by our client is that our device must allow for him to perform surgeries within the operating room. The device must prove to be very safe and stable. Additionally, the device must have a minimum foot print within the O.R. so as to not obstruct surgeries. Since the device is in the hospital setting, it must comply with hospital, insurance, and FDA regulations, which will be examined further in a later section. The device must be easily cleanable and portable between surgery rooms. It must be able to rotate clockwise and counterclockwise, allow for vertical, horizontal, and transverse translation and provide Dr. Cuppels with the ability to lean over patients. Finally, our device must instill confidence in our client's patients; a device that is aesthetically pleasing and will provide Garret's patients greater assurance in Garret's abilities.

Current Devices

Figure 2 (Left): Motorized wheelchair.
http://www.1800wheelchair.com/pwr/product-reviews/Power-Wheelchairs/Outdoor-Indoor-Use/Pride-Mobility/p/306-Pride-Jazzy-1121-Motorized-Wheelchair.html

Figure 3(Right): Standing wheelchair.
http://www.christopherreeve.org/site/c.mtKZKgMWKwG/b.4453477/k.3D3E/Wheelchairs_Seating_Positioning.htm

There are many products currently in production that assist individuals with paraplegia. The most common or frequently used item is the wheelchair. Although the wheelchair has been around since the 6th century, there have been many fascinating improvements over the years (BBC). Today, there are motorized wheelchairs (Figure 2), standing wheelchairs (Figure 3), and even commercial products that help transport non-handicapped people (e.g. Segways). These products could be useful for our client in everyday use; however, a more specific design will need to be developed for his use in the operating room. The main goal of our research on current devices focuses on the mechanism that allows

paraplegics to function in a standing position. We will be using a variation of the apparatus showcased in figure 3. Furthermore, there are devices known as *standing frames* that may be most useful to this particular project. Standing frames are currently used by patients who benefit from the freedom of standing. They do not have wheels for transportation, but rather remain stationary. Our device needs to incorporate this and serve a crucial functional role as well.

Regulations

Before consideration of design options and ideas, it is necessary to obtain a thorough understanding of the rules and regulations that govern this type of device. As one might imagine, guidelines in the healthcare field are strict. There are many layers of accountability that a device, its makers, and its users must face. First, and foremost the device must be safe for any patient in the operating room. Second, the device must insure Dr. Cuppel's own safety while he is performing the surgery. And thirdly, the device cannot inhibit or restrict the movement, function, or communication of any other person or machine in the operating room. There are three entities that help to insure that these parameters are met: (1) the United States Food and Drug Administration (FDA), (2) the insurance companies that protect the hospitals and surgeons, and (3) the hospital itself, in our case Berlin Memorial Hospital in Berlin, Wisconsin.

FDA

The first regulatory body that is a concern for us is the Food and Drug Administration. The FDA regulates what is considered a medical device, which by their definition is:
"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." (U.S. FDA)

Our device would likely fall under this definition as it could be seen as a way or mitigating our client's paralysis as well affecting the structure and function of his body. In order to determine the regulations, the next step would be classification. The classifications are as follows:

1. Class I General Controls
    - With Exemptions
    - Without Exemptions
2. Class II General Controls and Special Controls
    - With Exemptions
    - Without Exemptions
3. Class III General Controls and Premarket Approval (U.S. FDA)

Looking at similar devices, it is likely that our device would end up Class I if it is purely mechanical and Class II if it includes electronics. However, exact classification would be impossible without a final design. The likely outcome would be needing to submit a 510(k) for premarket approval as well as PMA approvals. Requiring clinical trials could be another possibility, as well as none of the previously mentioned regulations and only registration of the device.

After talking with Michael Courtney who is in charge of the FDA's Orthopedic Spine, Orthopedic Joint and Physical Medicine Rehabilitation Branch, it was determined that since we would be making an individual device that wouldn't be commercially sold that the FDA wouldn't not regulate our device in any way. This allows us much more freedom in our design, and allows us to avoid a lengthy process which would require many a resource. However, it is still important for our design to follow the standards that the FDA has put in place for medical devices. These standards, thing such as using certain materials and accounting for a certain degree of safety, will help ensure that the device is safe, reliable, and functional. It will also help instill confidence in Garrett as well as his patients which is very important as well.

Insurance

Insurance company compliance is necessary because without coverage it would be difficult for a surgeon to practice. Surgeons need malpractice insurance for protection in case something goes wrong during surgery. This issue is pertinent to our project, because our device directly affects Dr. Cuppels ability to perform a surgery. Jan Pankratz, an assigned risk consultant of the liability insurance company MMIC was able to shed some light on this area of concern. Moreover, MMIC is the company that insures Dr. David Jones, the surgeon who brought Dr. Cuppels situation to our attention. Jan assured us that as long as Garrett is competent, privileged by the hospital to practice, does not have a history of malpractice, or drug abuse he would be covered by their firm. Additionally, Jan said that the insurance company is not concerned with FDA approval of devices like ours (Pankratz).

Hospital

Though our group plans to visit Berlin Memorial to get a more realistic idea of the space constraints in the OR, we have spoken with the head of the OR at Berlin Memorial, Kathy Roehl. Ms. Roehl provided us with a basic idea of the regulations on our device set by the hospital. The device must fit through the doors of the OR, which are 1.95m tall and 1.52m wide; the device must not be permanently attached the floor of the OR; and the device must be cleanable with Virex spray, a powerful disinfectant. Ms. Roehl also indicated that any device place in the OR must be FDA approved. As we have already spoken to the FDA and found that they are not set up to regulate devices like this, we must receive a commitment from Berlin Memorial to allow a non-FDA approved device in the OR (Courtney).

Stability Design Alternatives

The design alternatives discussed in this manuscript focus on developing a stability mechanism for our client, Dr. Garrett Cuppels, to ensure balance while operating on patients. Dr. Cuppels will use the device while performing lower extremity surgeries. To perform such surgeries Dr. Cuppels will need to make large movements, such as rotating a newly replaced hip about its joint axes by lifting and revolving the leg, without fear of losing balance. Each of the stability design alternative utilizes a different approach to stabilize Dr. Cuppels' center of mass while performing large movements. The first stability

design idea was the removable weight design, second was concealed base design, and last was the bed-insert design.

Removable Weight Design

The removable weight design uses additional weight to lower the client's center of mass and ensure stability. A SolidWorks drawing of the design can be seen in figure 4. The design contains slots on either side of the standing platform, and also a compartment under the platform where additional weight can be placed. Each side slot and bottom compartment was designed to hold a 20.41 kg (45 lb) free weight. The rear of the device also has a location to which additional weight could be added to offset the client's forward movements. Furthermore, the bulk of the device would be constructed out of 1 ¼" aluminum angle iron to add strength and weight.

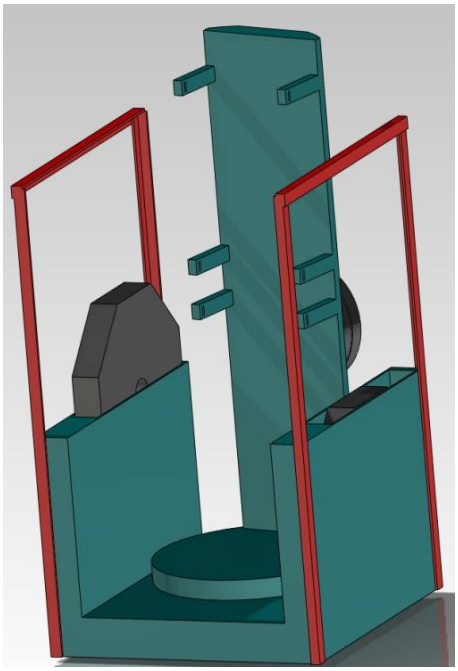

Figure 4: Removable Weight Design.

A small overall footprint of the stability design is desirable to enable nurses and other hospital staff to move easily around the operating room. The removable weight design would have a .91m x .91m (3ft x 3ft) footprint on the floor of the operating room, and be just 1.42m (56in.) in height.
Dr. Garret Cuppels would use the red parallel bars shown in red to position himself within the device. He would then place his feet on the circular standing platform with his back against the flat upright portion of the design, see figure 4. While stabilizing himself with the parallel bars a nurse would secure Dr. Cuppels upper and lower knee using straps and the mounts on the device. By securing both the upper and lower knee the knee would be forced into the locked position. Finally, a strap would be placed around Dr. Cuppels waist to secure his hips to the device. The client has control of his trunk and from the suggested locked position he would be able to make movements above and around the operating table safely.

After securing Dr. Cuppels to the standing platform, he would be able to rotate clockwise/counterclockwise and also move forward and backwards by use of a gear and track setup. The specific gear and track setup has not been finalized because the team has not determined if the device will include electronics or be purely mechanical. Electronics may enable Dr. Cuppels to make more precise and easier movements, but may induce unwanted electronic signal noise within the OR. On the other hand, a strictly mechanical system may become cumbersome to use and bulky within the design. Another advantage of using a weight removal system in the operating room is the ability to disassemble and transfer the device quickly and efficiently. Only one staff member would be required to move the device. Most likely Dr. Cuppels will be working in multiple ORs, so an easily movable device is crucial.

Concealed Base Design

The concealed base device is a stability mechanism for the greater OR paraplegic standing mechanism. This design relies on a wide base over heavy weights to stabilize the client during surgery. This wide base is in the shape of a U so that it will fit around the center support of a common operating table as well as under the operating table. Having the structural support under the operating table will serve to stabilize the client without getting in the way of other nurses and surgeons. Protruding out from this U-shaped base will be a stage for the client to stand on (it is assumed that leg braces will be mounted on this stage). The stage will have two rails for the client to hold onto during surgery. This stage will be able to translate in the X and Y directions (left right/forward back) and will be able to rotate in the clockwise and counterclockwise directions. It has not been decided whether this device will be completely mechanical to allow for easy maintenance, assembly and cleaning or if it will be electromechanical, which would allow for the client to move the stage with more ease and precision during operations.

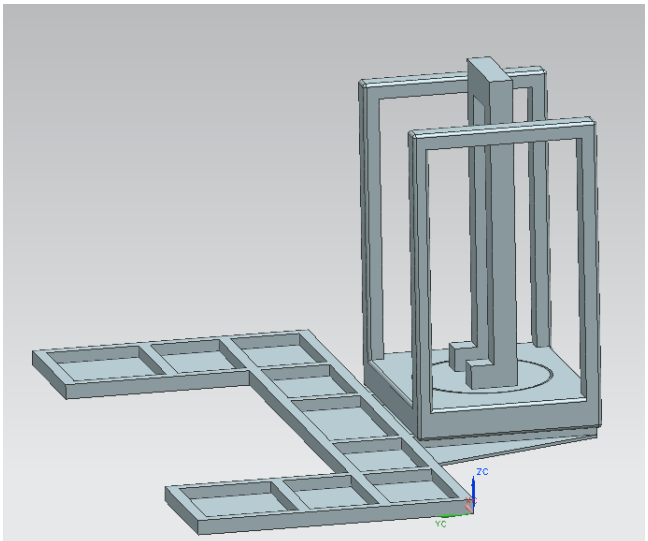

Figure 5: Concealed base design. SolidWorks design by Michael Konrath

Bed-insert Design

The bed insert design, shown in Figure 6 was designed to be purely mechanical, and to have as small a presence in the O.R. as possible. It utilizes two key features to do so. The first of which is a flat piece that is inserted underneath the mattress of the O.R. bed. This piece is what provides the majority of the support necessary to keep our client in a standing position, by relying on the weight of the patient and mattress. This force should be enough to prevent our client from tipping in any direction. By coating this piece in a high friction material such as rubber, any sliding should also be prevented. This piece would connect to the rest of the design via a simple screw and bolt and an

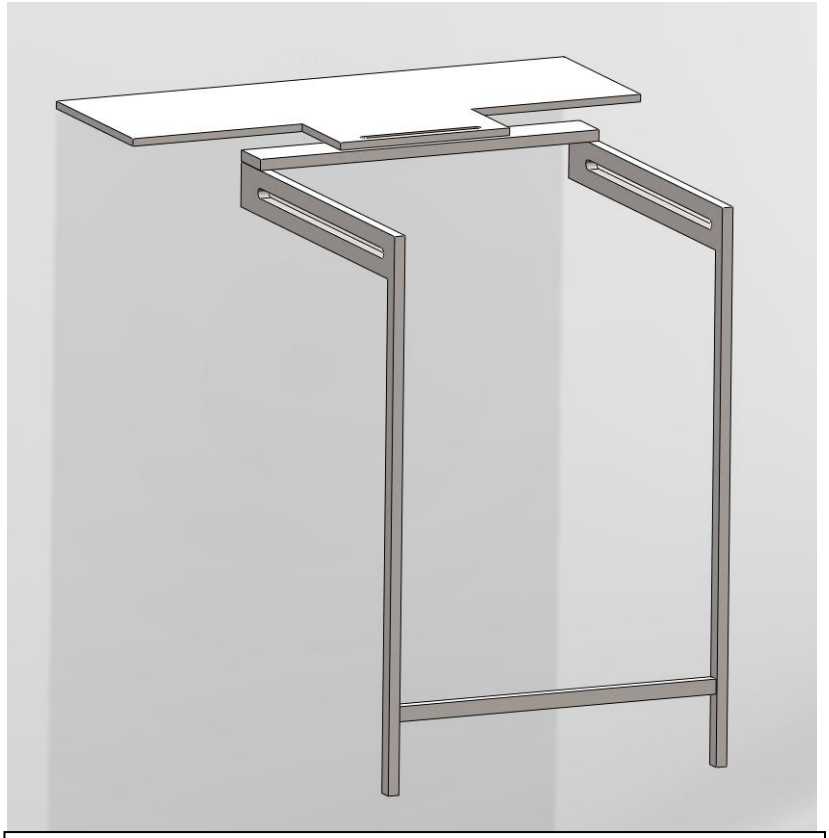

Figure 6: Bed Insert Design. The wide and flat part seen in the top of the picture is inserted under the mattress of the O.R. bed to support the device. A harness is attached to the slots in the top of the legs to support our client. SolidWorks design by Blake Marzella.

adjustable slot. The slot would allow you to adjust the horizontal position and angle of the rest of the device, allowing for a wider range our client would be able to reach. Of course this adjustment would take time and assistance from the rest of the staff to make, and could not be done on the fly (at least without further modifications). The idea for this feature came from a patent for a transducer stand (US patent 8,011,625) which uses a similar flat piece that fits underneath the mattress to provide support and stability. The device detailed in the patent uses this technique in order to maintain a constant height between the transducer and the bed. Unfortunately, this constant height is not a desired quality for our device, and in its current state, would prevent vertical movement of either our client or the bed.

The second key feature is slots in the legs which allow for the attachment of a harness which would be fastened around our client's waist. This would keep our client both connected to the device and, with the addition of knee braces to keep his legs straight, in an upright stance. The harness would be attached with rings which would be able to slide along the slots in the legs. This would allow for forward and backward movement. Notches would likely be needed to prevent unwanted sliding. The harness could lead to circulation problems in the legs, which is already a concern for paraplegics. Sitting in a wheelchair most of the day already limits circulation to the lower extremities, so we would want to avoid this in our device. Using leg braces to lock the knees and relying on some stability from the straightened legs would relieve some of the pressure from the harness. The sliding harness was also inspired by a patent for a similar device. US patent 4,948,156 is for a device which connects to a standard wheelchair. The device consists of curved bars that a harness can slide along, a handlebar, and pads to lock the knees. This allows for a paraplegic to pull themselves into a standing position as long as they are wearing the harness, which is also worn in the sitting position. Our design replaces the wheelchair with the bed insert and the curved bars with straight slots.
The mechanics of the device have not yet been worked out. The dimensions will need to be updated once more precise measurements are obtained. Materials will also need to be determined after accounting for safety, cost, weight, and any appropriate regulations. Until then, the exact size of the device and therefore the amount of space it would take up in the O.R. is indeterminate. Determining the weight of the patient required to support the device is also undetermined, and lightweight patients such as children may prove difficult. Also, until the exact dimensions and therefore forces are determined it is difficult to predict the extent to which the harness would cut-off circulation. Until we are able to watch orthopedic surgeries in order to get a better understanding of whether or not the bed insert will be permissible. If the bed needs to be adjusted throughout surgery, or the mattress is too small to fit a large enough insert, relying on the bed for support may be out of the question.

Future Work

Contact must be made with Berlin Memorial Hospital to get a commitment that the hospital will allow a device without FDA approval into the OR, as it is impossible to get FDA regulation on an individual devices (Courtney). The group must also then visit Berlin Memorial Hospital to research the physical constraints that will be set on the device before we choose a final design. The design team must then continue to develop stability mechanisms and choose a final design. Once a stability mechanism is decided the group must research paraplegic leg braces and methods of actuating the device. This should complete our research on the major elements of the design and should allow the group to decide on a final design. Once these tasks are complete a prototype must be made for the end of the semester.

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Appendix

PDS

Standing Paraplegic O.R. Device

Updated: October 11, 2011

Justin Cacciatore, Michael Konrath, James Madsen, Blake Marzella, Bret Olson

Advisor: Amit Nimunkar

Function/Problem Statement:

To design and construct a device that will enable our client, a T-12 paraplegic, to perform standing orthopedic surgeries in the O.R. for up to three hours. The device should allow the client to cover a range of motions including: clockwise and counterclockwise rotation, as well as vertical and horizontal translation. It must be stable, serviceable, compact, cleanable, portable, safe, comfortable, affordable, and comply with hospital standards. Our intention is to design and construct a device for our client over the timeline of two semesters.

Client Requirements:

- Must allow for standing O.R. procedures

- Be able to rotate clockwise and counterclockwise
- Must support vertical and horizontal translation
- Stable, compact, portable, cleanable, safe, comfortable, affordable
- Comply with hospital standards
- Be in use for up to 3 hours
- Support client build of 6'1'' 215 lbs, safety factor of 2
- Device must leave small footprint in O.R
- Less than $10,000
- Materials capable of being autoclaved
- 10 years of device use
- Make of simple, easily fixed parts
- Easily disassembled – easier portability, cleanability

Design Requirements:

Our final constructed device will be designed and constructed for intended used by our client within a hospital O.R. setting. As such, all appropriate hospital standards as well as the functional standards of the device must be considered.

1. Physical and Operational Characteristics

A. Performance Requirements:

- Support a 6'1'' individual weighing 215 lbs in a standing position for up to three hours

- Able to support clockwise and counterclockwise rotation, and vertical and horizontal translation.

B. Safety

- Must not harm the client during periods of use lasting up to 3 hours

- Pose no risk to contamination of O.R. environment – easily cleanable and stable

C. Reliability

- Able to withstand a service life of 10 years

- Be composed of materials that can take consistent cleaning (possibly in an autoclave)

- Made out of easily serviceable parts

- Disassembles easily for cleaning

D. Life of Service

- Consistent use within O.R. hospital setting for 10 years.

- Must be easily cleanable for O.R. setting

- Portable device within minimum footprint

E. Operating Environment

- Must comply with hospital and O.R. standards

F. Ergonomics

- Device must be comfortable for client during periods of extended use

- Small footprint so as to not interrupt the environment/work space of others in the O.R.

G. Size

- Small footprint in the O.R. as to not be obstructive

H. Weight

- As minimum a weight as possible for easier portability

J. Materials

- Common materials and components that could be easily serviceable incase of breakdown

- Materials that are easily to clean up to O.R. standards

- Possible consideration of autoclavable materials

- Easily disassembled parts

K. Aesthetics, Appearance, Finish:

- Minimum O.R. footprint

- Device that instills confidence in potential patients of our client

2. Production Characteristics:

A. Quantity: 1 Deliverable

B. Target Product Cost: Less than $10,000

3. Miscellaneous

A. Standards and Specifications

- We must adhere to O.R. and hospital standards for use.

B. Customer/Patent Related Concerns

- None identified through current research

C. Competition

- While there are standing wheel chair devices on the market, none of these devices specifically relate to our client's needs. That is, a device that can be used within an O.R. setting. As such, competition, through the current research, is not a primary concern.