Standing Paraplegic Operating Room Device

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

Advisor: Amit Nimunkar, PhD

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

Biomedical Engineering, University of Wisconsin - Madison

Table of Contents

Abstract

Our client is a T12 paraplegic with no use of his limbs from the waist down. This has prevented him from continuing his work as an orthopedic surgeon. In order to return to orthopedic surgery, our client would need to be standing and capable of moving normally throughout the operating room. Therefore, the goal of this project is to design a device which can support our client in a standing position for around two hours and also quickly move him in all directions.

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, causing an injury to the T-12 vertebrae in his spine; the location of the T-12 vertebrae can be seen in Figure 1. An injury to this area of the spine caused our client to lose all voluntary control of movement in his lower limbs and trunk, removing our client's ability to stand and walk. Following this, our client is out of work, as during as lower extremity orthopedic operations, such as hip replacements, our client would be required to remain in the standing position. While looking for possible job opportunity, our client contacted Dr. David Jones at Berlin Memorial Hospital in Oshkosh, Wisconsin. The hospital staff expressed interest in our client but also expressed the need for an additional device that would allow for Dr. Cuppels to perform the movements of a standing surgeon. 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. The creation of such a device to support our client in the operation room will need to rival the physical movements of a standing surgeon as well as replicate a surgeon's presence, and take into consideration the physical limitations of T-12 paraplegia. That is, our device must be able to support our client in a non-obstructive way as well as have to potential to move quickly and dynamically along an operation table as necessary, while addressing our client's needs. Therefore, upon considerations of designs to create a stable base that will support our client in the standing position in the operating room, we will need to examine and develop not only stability mechanisms, but also movement mechanisms and user interfaces that will allow Dr. Cuppels to mimic the movements of a standing surgeon.

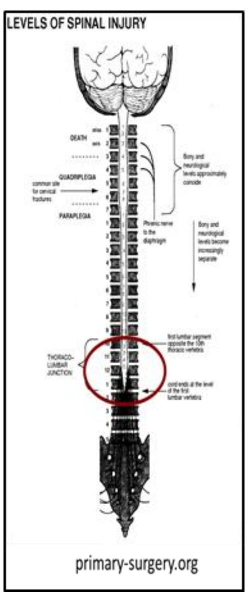


Figure 1: Human vertebral column illustrating levels of spinal cord injuries.

Background

A T-12 paraplegic refers to an individual that has sustained an injury to the T-12 vertebrae in the lower thoracic region of the spinal cord, in which voluntary nerves are either damaged or severed. Depending on the severity of trauma to the spinal nerves, an individual with a lower thoracic spinal injury may experience incomplete or complete paraplegia. Incomplete paraplegia refers to an individual that still experiences sensations and limited movement below the point of injury. Complete paraplegia refers to an individual that experiences a total loss of voluntary control and sensation below the point of injury. Our client can be classified as a complete T-12 paraplegic. This injury, however, does not compromise the use of Dr. Cuppels' hands, arms, abdominal muscles and trunk. Therefore, our client is still able to maintain a sitting balance in a wheel chair. The inability of our client to voluntarily move his legs causes a decrease in blood flow in his lower-extremities. To account for this, it is typically recommended that a T-12 paraplegic utilize electrodes to stimulate lower-leg muscle contractions to stimulate blood flow, or to massage the legs to prevent pooling of blood so that clots do not form. Therefore, In the development of our designs, this decreased blood circulation in our client's legs must be taken into consideration as a factor of patient safety.

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 our client to perform surgeries in the standing position we have the opportunity to greatly increase his ability to return to work. 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 OR 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 our client 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 his abilities.

Current Devices

Market Competitions

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 6^{th} century, there have been many fascinating improvements over the years (BBC). Today, there are motorized wheelchairs, standing wheelchairs, 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. 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 client'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 its 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." [2]

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 [3]

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 our client 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 our client's 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 our client's situation to our attention. Jan assured us that as long as our client 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 1.95 m tall and 1.52 m 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 to ensure balance while operating on patients. Our client will use the device while performing lower extremity surgeries. To perform such surgeries our client 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 client's 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 2. 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 45 lb (20.41 kg) 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.

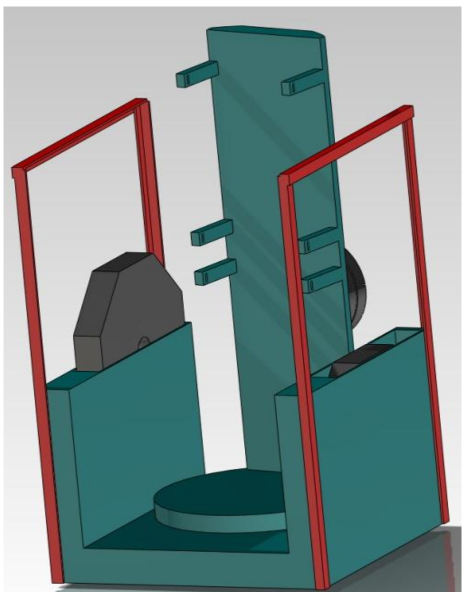


Figure 2, Removable Weight Design

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 3 ft by 3 ft (.91 m by .91 m) footprint on the floor of the operating room, and be just 56 inches (1.42m) in height. The client 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 #. While stabilizing himself with the parallel bars a nurse would secure the client's 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 the client's 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 the client 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 the client 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. A table summarizing the advantages and disadvantages of the Removable Weight design can be seen in Table 1.

Table 1. Advantages and disadvantages of the Removable Weight design.

Advantages of Removable Weight design	Disadvantages of Removable Weight design
Weights can be removed to allow for easy movement of the platform between surgeries	Stationary in one location
Small footprint within OR	Take a long time to move device if it needed to be moved during a surgery, because many of the weights would have to removed and then replaced after the main platform was in the desired location
Design can use a large safety factor, to make the device safer for the clients use	Possibly very heavy

Segway LeanSeat Design

One method of giving the client the ability to move dynamically within the operating room would encompass a Segway. The Segway LeanSeat design consists of a generation-one Segway, a LeanSeat, a steal box frame and four linear actuators, see Figure 3. The Segway forward and backward movement would be controlled by the client leaning his body. To roll forward the client would lean his upper body in a way to cause the Segway foot platform to tilt forward. The turning of the Segway platform would be controlled in the client's left hand grip, similar to a motorcycle throttle. Clockwise and counterclockwise turns would mimic the rotation of the left hand grip. The Segway would be capable of making quick movements and easily cleaned by rolling through a sterilizing solution. Unfortunately, because the Segway only has two points of contact, the client may not feel stable while in the movement phase.

Figure 3. Segway LeanSeat Design to enable dynamic movement within the operating room

A LeanSeat made by SegVator would be attached to the Segway for The client to sit on while in the operating room. The LeanSeat would place the client in a crouching position on the Segway in which he could perform standing surgeries. This would reduce the amount of force placed on the clients lower limbs. Furthermore, the group has consulted paraplegics who regularly use the LeanSeat for mobility and received positive feedback.

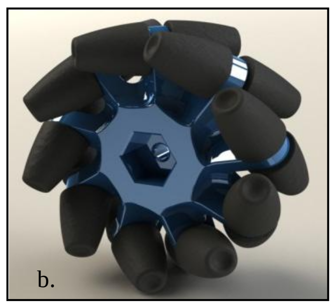
The Segway LeanSeat design also utilizes an extended steal box frame attached to the Segway footplate to support four linear actuators. The steal box frame would be approximately 16” wide by 36” long with linear actuators placed at each of the four corners. These linear actuators would extend for added stability when the Segway had been placed in the desired stationary position. To activate the fast electric linear actuators the client would flip a switch on the Segway handle. The linear actuators would keep the client stationary by providing a large moment keeping the Segway footplate from tilting. During the movement phase of the device, the linear actuators would be in the up position. While in the up position the linear actuators would only be a few inches off the ground to make it difficult for the client to drastically lean forward or backwards. This would help ensure the Segway would not move so quickly that the client may lose control.

Unfortunately, the group has determined a few drawbacks to the Segway LeanSeat design. The first drawback is the additional time within the OR needed while the device transitions between the stable and mobile phases. To transition between phases, the linear actuators will have to be turned on and off several times. A second drawback is the inability of the Segway LeanSeat device to translate left or right while facing the operating table, forcing the client to rotate the Segway before moving down the length of the table. Finally, modifying the Segway to use linear actuators for support arms is a completely novel design idea. The group was unable to find any papers or videos of similar previous Segway modification.

Thus the group may have difficulty obtaining knowledge and advice on developing the device. A table summarizing the advantages and disadvantages of the Segway Leanseat design can be seen in Table #.
Table #. Advantages and disadvantages of the Segway Leanseat design.

Advantages of Segway LeanSeat design	Disadvantages of Segway LeanSeat design
All components of design can be bought off the shelf	Client may feel unsafe while in motion on Segway
General public has a basic understanding of the Segway	Client cannot move laterally while facing the table
LeanSeat is specifically built to attach to Segway platform to assist paraplegics	Unwanted additional time is needed to activate the linear actuators whenever the client moves to a new position
Fabrication of the device would be relatively easy	Segway modification using linear actuators is a novel design

Final Design: Robotic Mecanum Wheel Platform



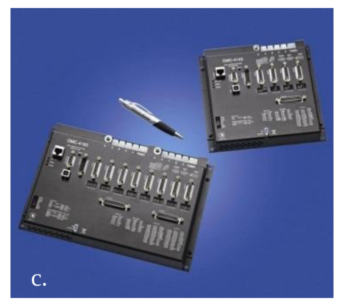


Figure 4. a) The Robotic Mecanum Wheel Platform. b) Omni-directional mecanum wheel. c) Galil 4-axis motion controller.

The Robotic Mecanum Wheel Platform (RMWP) is an electronically controlled platform mounted on four mecanum wheels and is driven by a 4-axis motion controller with motors (Figure 4.). The platform's movement is controlled by a joystick mounted on the support rails. It will have a desired speed of .25 m/s (slightly slower than walking speed) and will have a desired acceleration of .2 m/s^2 (it will reach top speed in approximately 1 second). By use of mecanum wheels this platform is omni-directional, meaning that it can move in any direction at any time. This includes translation perpendicular to the rolling direction of the wheels. The omni-directional nature of the mecanum wheels is due to the passive rollers tilted at a 45 degree angle mounted all around the wheel. These rollers change the direction of the movement vector by 45 degrees based on the direction of the rollers. Determining the direction of the entire four wheeled platform is based on adding the separate diagonal wheel vectors to form one large bot movement vector (Figure 5.).

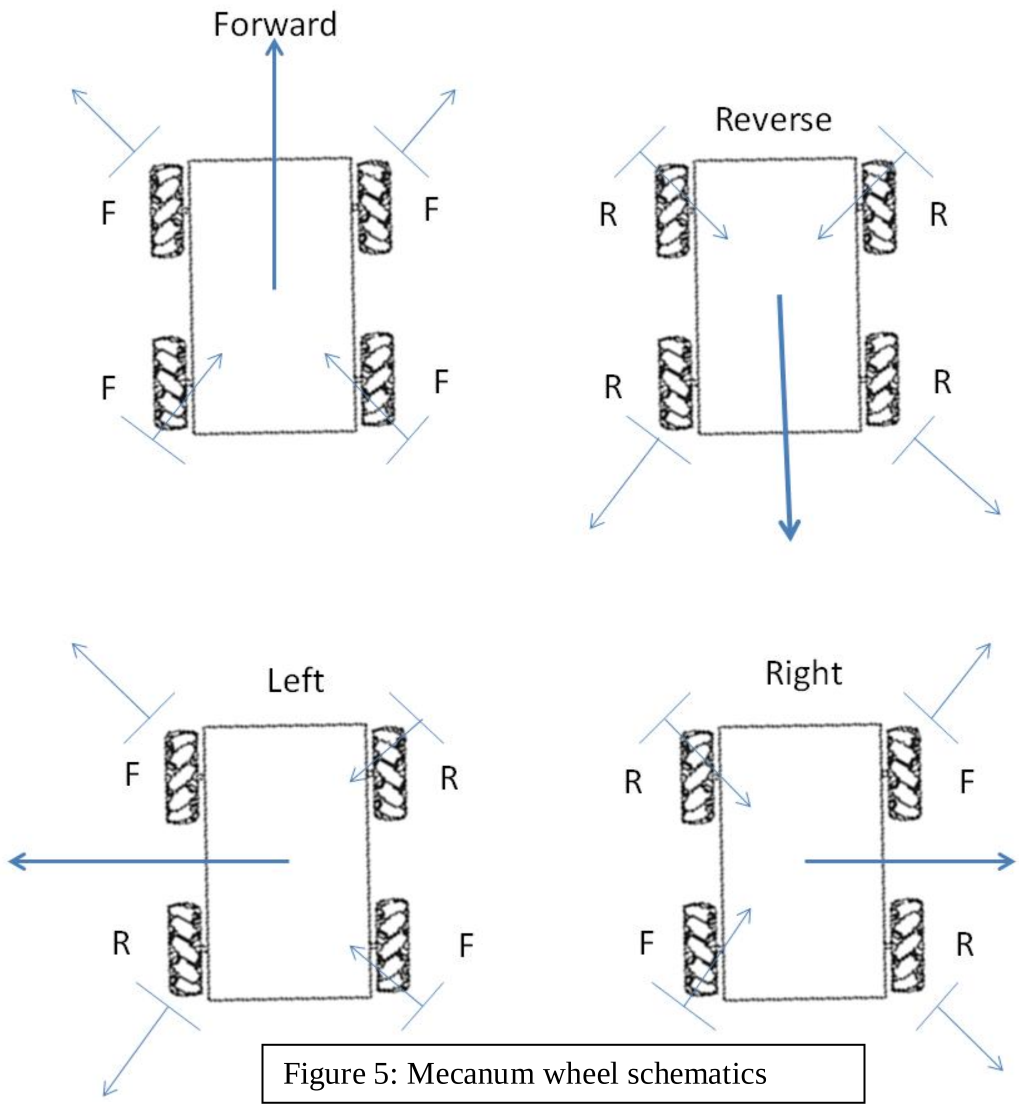
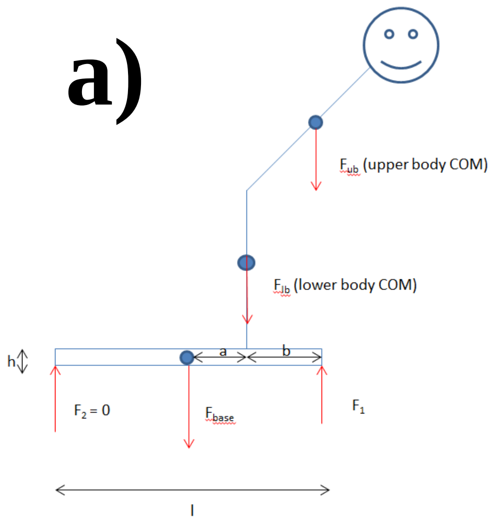


Figure 5: Mecanum wheel schematics

This platform is designed so that custom leg braces or a seating system could be mounted to the floor of the bot so that Dr. Cuppells could be secured in an upright position during surgery. Dr. Cuppels leg braces would be mounted approximately 6 inches from the front edge of the platform so that he will be able to be very close to the operating table. The base would have a low profile of approximately 2.5 feet by 3 feet and weigh approximately 250lbs. This will allow for a factor of safety of at least 2 to prevent tipping of the device (Figure6.). Calculations of the power it will take to move this device have been written in Figure 7.

a)



b)

```
close all
clear all


hleg = .9398; %m length of legs
hu = .889; %m length of upper body
theta = 0;
F1 = 0;
% F2 =
% Fb =
Fl = 0;
Fu = .65 * 823.2;
b = 0;   %meters
a = -b;


 for i = 1:100
        b = i*.01;

F2(i,:) = (a.*Fl - (hu.*cos(theta) - a).*Fu) ./(-b);
Fb(i,:) = F1 + F2(i,:)  - Fl - Fu;

% Fy = F1 + F2 - Fb - Fl - Fu = 0
% b*F2 + a*Fl - (hu*cos(theta) - a)*Fu = 0

F2(i,:) = 0.224808943 .* F2(i,:); %conversion back to lbs
Fb(i,:) = 0.224808943 .* Fb(i,:); % conversion back to lbs

 end

B = .01:.01:1;
B = B.* 3.28;

plot(B,Fb)
ylabel('Fb, lbs')
xlabel('B, ft')
```

c)

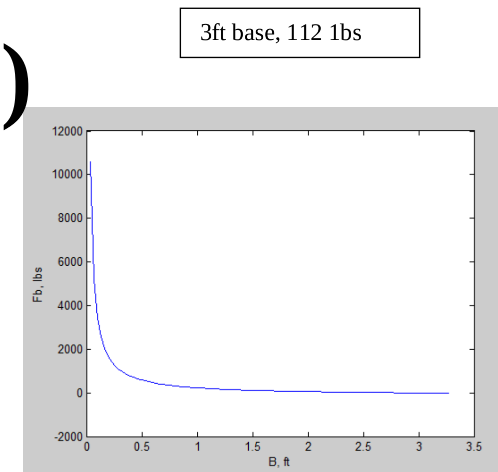
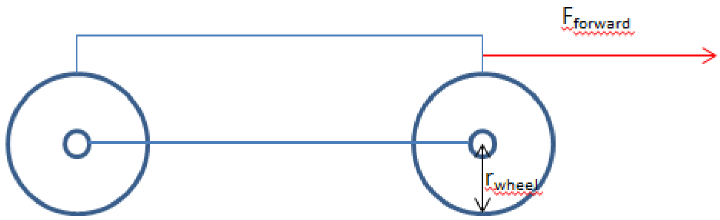


Figure 6. a) Free Body Diagram of surgeon mounted to base. b) Matlab code analyzing many different lengths and weights of base to analyze tipping. c) The graph shows that if the surgeon were mounted to the very front of the base leaning all the way forward and if the base were 3 feet long behind the surgeon, the base would only have to weigh approximately 112lbs to prevent tipping. The actual base will be made to around 250lbs to give an FS of >2.



$V_{desired} = 0.25 m/s = 2.46$ radians/second/wheel$_{r=4''}$
$a_{desired} = 0.2 m/s^2$
$m_{max} = 400$ lbs $= 181$ kg
$r_{wheel} = 4'' = .1016 m$

$C_{wheel} = 2*pi*r_{wheel} = .6364 m$
$F_{forward} = m_{max} * a_{desired} = 36.2 N$
$Torque_{per\ wheel} = (F_{forward} * r_{wheel})/4 = 3.677 Nm$
$Power_{per\ wheel} = V_{desired\ in\ rad/s} * Torque_{per\ wheel} = 2.26$ watts

Figure 7. Free body diagram of 2D four wheeled platform moving forward and power calculation showing that it will require 3.7 Nm of torque and 2.26 watts of power per wheel to accelerate the fully loaded 181 kg platform (with surgeon) at 0.2 m/s^2 up to a speed of 0.25m/s. These calculations will aid in selecting the correct motors to drive the wheels.

This design was chosen over the other design ideas because it is very stable while moving and while stationary and it also most closely replicates the movements of an actual surgeon during surgery by its omni-directional mecanum wheel drive. Humans by their nature are omni-directional, so it is very valuable to have design that is also omni-directional. This device will allow Dr. Cuppels to move backward and forward to move out of the way of x-ray machines or move closer to the table and allow him to precisely translate down the length of the table without turning. This device will allow Dr. Cuppels to move anywhere in the operating room without assistance, greatly reducing time spent in the OR. Reducing time spent in surgery is safer for the patient and more cost effective for the hospital. With the addition of custom $3000 leg braces, this design will come to a total of $8200, which is under our budget of $10,0 00 (Figure 8.).

Item Required	Estimated Cost
Custom Leg Braces	$3,000.00
Galil DMC-41x3 4-Axis Motion Controller with Drive	$2,200.00
Motors	$1,000.00
Steel	$800.00
4 Mecanum Wheels	$700.00
Rechargable Battery	$400.00
Joysick Control	$100.00
Total Cost	**$8,200.00**

Figure 8. Cost Analysis

Ethical Considerations

All engineers, especially biomedical engineers, must take into consideration the ethical aspects of their designs. The first fundamental canon in the NSPE Code of Ethics for Engineers is "Hold paramount the safety, health, and welfare of the public" [BM5]. If our device were to fail, it could lead to injury not only to our client, but his patients as well. Normally devices like ours would be regulated by the FDA to help ensure safety and reliability. Since the only regulation our device would need to meet is hospital approval, the burden of proving the safety of our devices is shifted more on to us. This makes it very important for us to take the necessary steps and precautions to produce a safe and reliable device. This will be done primarily through testing, but also by choosing high quality materials, being careful during building, and meeting OR standards. These steps will need to be taken regardless of whether or not the hospital approves our device without them. This is necessary to ensure the level of quality needed.

Quality of our device doesn't solely depend on preventing failure but also on its ability to enable our client to adequately perform surgery. It wouldn't be ethically sound for us to produce a device which would hinder our client's surgical skills. If our client isn't able to perform at a level comparable to before his accident, it may endanger his patients. In order to ensure this, our client will need to practice thoroughly with the device and possible be recertified using it. Only then will we satisfy the ethical requirements of an engineer.

Future Work

Funding

We estimate that our design would cost $8200, but we would like to have $10000 in funding. This extra money would give us leeway in case we need additional components or need to replace anything. Our client is unable to provide us with this funding himself. The Berlin Memorial Hospital staff previously stated that they may be able and willing to provide some funding. Berlin Memorial will be our first outlet to attempt to receive the funding required, and it will be one of the key points discussed in our upcoming meeting with the staff. Whether their funding would be a gift or considered part of our client's salary will also need to be discussed. Should the hospital be unable to provide all or any of the $10000, alternate sources need to be considered.

Another potential source of funding will be the University of Wisconsin. Organizations such as UW Foundation, WARF, and ASM provide funding to student groups with similar projects so it is possible that they would be able to provide funding to us. UW Foundation takes all donations to the University, but donors are able to choose what department or areas receive those donations. WARF typically funds technologies that would lead to startup companies. ASM provides funding to UW student organizations; we could create a student organization solely for this project. While UW has many opportunities for funding other sources must also be considered.

Another useful source for funding is the internet. Websites like kickstarter.com provide an outlet specifically for people to donate and fund all kinds of projects. While they are not designed specifically for this purpose, social media websites like Facebook, Twitter, and Reddit would also be good resources for spreading our goal and soliciting donations. People may be willing to donate because it is very easy to sympathize with our client's situation. If we pursue these routes, we would like to make a video specifically to tell our client's story and our project. This video will require very professional designs and descriptions, as well as assistance from our client. Hopefully exploring all of these options will provide us with enough funding to carry out our project and build our design.

References

1 Brain and Spinal Cord: T-9 to T-12
http://www.brainandspinalcord.org/spinal-cord-injury-types/t9-t10-t11-t12-spinal-injury/index.html%20

2 U.S. Food and Drug Administration (2011, October 15). Device Classification. Retrieved from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm

3 U.S. Food and Drug Administration (2011, October 15). Is This Product A Medical Device. Retrieved from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm

4 Ginsberg, S. H. (2011). Support for Medical Equipment (United States Patent). US 8,011,625 B2.

5 Fortner, G. D. (1990). Standing Lift and Support for Wheelchair User (United States Patent). 4,948,156.

6 NSPE (2011, December 13). NSPE Code of Ethics for Engineers. Retrieved from http://www.nspe.org/Ethics/CodeofEthics/index.html

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.