

The Knee Nook

Prepared for: Sarah Housman, Rehabilitation Institute of Chicago Prepared by:

> Carissa Black, Derek Liu, Henry Petrash, Greg Warga Section 9 Team 2 Professors Benjamin and Greenberg Engineering Design and Communication

March 10, 2007



Table of Contents

Executive Summary	1
Introduction	2
Design Concept	3
Background Research	5
Methods	5
Findings	6
Implications for Alternatives	8
Alternatives	9
Concepts	9
Tongue Clip	12
User Testing	13
Evaluation and Final Design Direction	15
Next Steps	16
References	18
Appendix A: Project Definition	19
Appendix B: Client Interview Questions	21
Appendix C: Client Interview Summary	22
Appendix D: User Observation Questions	23
Appendix E: User Observation Summary	24



Appendix F: Clustered Brainstorming List	26
Appendix G: User Testing Summary	27
Appendix H: User Testing Procedure	29
Appendix I: Design Review Summary	30
Appendix J: Bill of Materials	31



Table of Figures

Figure 1: How to Use the Knee Nook	3
Figure 2: Leg Straps	4
Figure 3: Neoprene Padding	4
Figure 4: Lever Shoe Horn Prototype	9
Figure 5: Knee Collar Prototype	10
Figure 6: Show Wedge Prototype	11
Figure 7: Tongue Clip Prototype	12



Executive Summary

Our goal in designing the Knee Nook was to create a portable device that allows a stroke survivor to easily don their AFO and shoe. Although the effects of a stroke vary, survivors often have limited use of one side of their body. The patient wears an Ankle Foot Orthosis (AFO) to prevent their weak foot from dragging and hindering ambulation. Because of the added bulk of an AFO, donning a shoe becomes difficult. The task is further complicated by the fact that the user can only effectively use one hand.

The Knee Nook allows stroke survivors with limited use of one side of their body to more easily don an AFO and shoe. Stroke survivors often place their weak foot on top of their strong knee, similar to the position of crossing one's legs, to allow them to easily reach their foot. To hold the user's leg in this position, we designed the Knee Nook. The Knee Nook is a hands free device that holds the user's leg in this position, which they often have trouble maintaining on their own. The device is placed on top of the user's strong knee and employs a neoprene pad to easily hold the weak leg over the strong knee.

In the process of designing the Knee Nook, we tested four mockups with a stroke survivor named Gelise at the Rehabilitation Institute of Chicago on February 9, 2007. The four mockups each took very different approaches at helping the user to don the shoe: an adjustable wedge base, a tongue clip, a knee nook, and a lever-assisted shoe horn.

The original Knee Nook design worked fairly effectively at the user testing session. The user was able to put the device on, and with hints and a few extra instructions, place her leg onto it, lock it into position, and use it to put her shoe on. The original Knee Nook's complexity and size were setbacks that needed to be addressed. However, the device's ability to assist the user in donning both the AFO and the shoe set it apart from our other mockups and made it a clear choice for our final design direction.

The changes that were made for the final prototype should solve all of the problems encountered during this testing session. The final prototype was subjected to intensive testing by all team members which uncovered areas for further work. The Knee Nook is still relatively big and making it more portable might be advantageous. It may not be intuitive that you can just slide the strap over your leg, and there may be straps that are easier to use.



Introduction

Our goal in designing the Knee Nook was to create a portable device that allows a stroke survivor to easily don their AFO and shoe. Although the effects of a stroke vary, survivors often have limited use of one side of their body. The patient wears an Ankle Foot Orthosis (AFO) to prevent their weak foot from dragging and hindering ambulation. Because of the added bulk of an AFO, donning a shoe becomes difficult. The task is further complicated by the fact that the user can only effectively use one hand.

While commercial products do exist to help stroke survivors don their shoe while wearing an AFO, they are only marginally effective and depend heavily on the user's skill and preferred technique of donning his or her shoe. For example, the heel cup from Sammons Preston, a rigid device that sits on the heel of a shoe, holds the shoe open to allow the user to more easily place their foot in the shoe, but often was too bulky and very difficult to remove when the foot had been fully inserted. Extra long shoe horns, another commonly used aid, were often difficult to maneuver given the user's limited use of one side of their body.

Stroke survivors are unique in that through physical therapy and learning new techniques to perform tasks, many can often regain enough functionality to return to an independent lifestyle. In designing the Knee Nook, our team strived to create a device that is easy to use, highly effective, and assisted most users in donning both their AFO and shoe. It was important to create a device that was hands-free once setup, given that the user had to perform all tasks with a single hand. Finally, our device had to be fully portable and simple to use, allowing the user to easily integrate it into an independent lifestyle.

This report details our design processes towards creating the Knee Nook and addresses how our design solves some of the problems faced by stroke survivors. We present our rationale in the device's features, and our analysis of different options through user testing. We believe that our design effectively addresses the current issues posed by stroke survivors, and therefore also recommend next steps should the Knee Nook be further researched for commercial production.

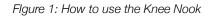


Design Concept

The Knee Nook allows stroke survivors with limited use of one side of their body to more easily don an Ankle Foot Orthosis and shoe. Stroke survivors often place their weak foot on top of their strong knee, similar to the position of crossing one's legs, to allow them to easily reach their foot. To hold the user's leg in this position, we designed the Knee Nook. The Knee Nook is a hands free device that holds the user's leg in this position, which they often have trouble maintaining on their own. The device is placed on top of the user's strong knee and employs a neoprene pad to easily hold the weak leg over the strong knee.

Using the Knee Nook is very simple (Figure 1). While sitting in a chair, the user slides the device over their strong leg into position above their knee, strapping the device using the tightening mechanism. Once secured, the user lifts their weak leg onto their strong knee. The Knee Nook then holds the user's foot in a position ideal for donning a shoe. For a complete list of requirements taken into consideration when designing the Knee Nook, see Appendix A.





The Knee Nook has two main parts: the neoprene pad and the straps. The device is fastened atop the strong knee using a strap that employ simple pulling clips for easy one hand adjustment. The neoprene pad serves as a means to keep the foot on top of the leg and distribute the gravitational force being applied to the leg. This allows the user to more easily reach their weak foot and also restricts the foot's motion, giving the user more control while donning their shoe. Specific features are detailed below.



Leg Strap

One durable leg strap made of 1" webbing tightens with the same technology used in backpacks for years (Figure 2). The product starts with 36 inches of durable, easily washable strap allowing each user to determine what size works best for them and simply cut off any excess. After a onetime adjustment there is no need to disconnect the straps, they easily slide up the leg, and can be tightened and loosened with an easy upward pull once in place. The reversibility of the device allows users to choose which side of their leg they wish to tighten the straps on, leading to easy accessibility for users with either left or right side hemiparesis.



The neoprene padding, keeping the leg in place and serving as a shock absorber, is much easier to clean than many regular types of foam (Figure 3). It also provides a great amount of comfort. The padding will not stick to clothing or leave behind any residue so users can be confident using it with even their nicest clothes. The thickness and design of the foam also allows it to be sewn, not glued, into place contributing to the Knee Nook's overall durability.

The Knee Nook is designed to be aesthetically pleasing and easily portable. The Knee Nook is constructed with economy in mind, and all parts are designed to function with minimal adjustment from the user. Therefore, the Knee Nook is designed to be highly



Figure 2: Leg Straps



Figure 3: Neoprene Padding

functional, while its ease of use and transport allows for seamless integration into the user's lifestyle.



Background Research

Methods

To learn more about foot drop and donning an AFO and shoe, we found information from the following sources:

Web Research:

The most useful information on foot drop and AFO design and operation was found on three websites sponsored by Massachusetts Institute of Technology, Scheck and Siress Orthotics and the Mayo Clinic. We found that the Scheck and Siress website was the best site for providing a basic background on the problems and processes of donning an AFO (For a complete list of web research see References section).

Client Meeting:

On January 9, 2007 team representatives met with Sarah Housman, a physical therapist from the Rehabilitation Institute of Chicago. Sarah's frequent interaction with stroke survivors and the AFO provided us with a basic understanding of the problem and identified the requirements of any proposed product (An outline of potential questions for the client can be found in Appendix B).

Ms. Housman stated that the end users of the product will be adult stroke survivors with no cognitive deficits. The design should be feasible to don in five minutes or less and cost under \$20. Further, the design should be aesthetically pleasing and be easy to transport (See Appendix C for further details).

User Observation:

On January 18, 2007 team representatives observed two AFO users, Kathy and Doritha, at the Rehabilitation Institute of Chicago. For a list of questions asked, please see Appendix D. The users were both asked to don their AFO and shoe using the traditional methods at RIC. The observation of these users provided information about alternative methods of donning the AFO and shoe (For complete details see Appendix E).



Findings

Physical Limitations

After surviving a stroke, people often experience a loss of muscle control, usually on one half of their body, making day to day activities a more difficult task (For more information on physical limitations in stroke survivors, see Appendix C).

Muscle Control:

Due to rigidness of the AFO and lack of muscle control, it is often hard for users to put their toes into the shoe without crushing the heel of their shoe as well as pushing in the tongue.

Leg Weakness:

Users experience difficulty resting their weak leg on the opposite knee as a result of leg weakness and smoothness of the AFO. They are unable to hold their legs up independently.

User Preferences

Upon interviewing and observing two stroke survivors at RIC, Doritha and Kathy, it became apparent that certain methods of donning shoes are preferred by the potential users (For more information on user preferences, refer to Appendix E).

Donning:

Users prefer donning the AFO and shoe in two consecutive steps as opposed to placing the AFO inside the shoe and donning them simultaneously. Doritha expressed the fact that putting the AFO inside the shoe first makes an already difficult task even harder. Although it may take longer for the user to don the AFO and shoe separately, it was made clear that the users much prefer the simplicity of donning them in two different steps. This must be kept in mind when designing shoe-donning prototypes.

Speed:

Both users, especially Doritha, expressed the fact that they are extremely frustrated with the amount of time that is required to don their AFO and shoe. Any device that would allow them to put on their shoes quickly would be accepted with open arms by the users, even if it lacked in other areas such as portability.



Comfort:

Both users, Doritha and Kathy, explained that they want a product that suits their needs without causing pain or discomfort. A user-friendly product is definitely preferred. Many products, like some of the shoe horns, do not provide comfort when donning the shoe.

Products

Through online research and user questioning, the team was able to discover some current products on the market that address the problem and what the users thought of the those products. The team also received user input on alternative approaches to the problem (For more information on current and alternative products, refer to References and Appendix E).

Shoe Horn:

There are many devices on the market that fit into the back of the heel of a shoe, allowing the user to slide their foot into the shoe with ease. The users interviewed already owned a special shoe horn recommended by their podiatrists and agreed that it makes the donning of their shoe easier. However, the difficulty was not totally alleviated in either user.

Heel Cup:

There are current products on the market that reduce the crushing of the heel of a shoe when donning a shoe while wearing an AFO. Although the heel cup is fairly effective, there are still issues with the tongue of the shoe flopping, as well as foot alignment when donning the shoe. This was confirmed in the user observation.

Larger Shoes:

Users report that having larger shoes helps, but only to a certain extent. Purchasing these shoes that are too big for their feet gave them extra room for the AFO, but the same problem of crushing the heel and displacing the tongue are still present. Another way of addressing the problem is required.

Velcro:

Currently, Velcro shoes are being used by some stroke survivors as opposed to traditional laced shoes. The users like the simplicity of Velcro over the use of shoe strings, but the long Velcro straps often get caught on their clothing. A suggested alternative is to limit the Velcro to the very ends of the straps. This would allow the user to reap the benefits of Velcro, without putting up with so many of its negative aspects.



Implications for Alternatives

Independent:

The main goal of the user is to be able not only to don their shoes within a short amount of time, but more importantly to accomplish this task without assistance from others. Both Doritha and Kathy would like to go on living their life as they did before having a stroke.

Cost Effective:

In the client interview, we learned that it is important for the product to be fairly inexpensive, with a price range between 5 and 15 US dollars. This makes the product available to a wide range of consumers. Any product that may cost less and accomplish the same task would be much preferred.

Portable:

The final product should be portable. A product that would accomplish the task at hand in addition to being compact enough to fit in the user's purse or small bag is ideal. Both the users and client established portability as a definite pro.

Safe:

The product must not cause pain to the user or put them in a situation in which pain may result. As a result of their condition, people who have survived strokes lack muscle control that may be necessary to prevent injury. This was stressed by both users as well as the client. Any materials used must be selected with this in mind.



Alternatives

Concepts

With the research on the problem at hand, the team came up with a few possible alternative solutions to donning the shoe while wearing an AFO. Through a process of group brainstorming, the results of which can be found in Appendix F, the team created four mockups.

Lever Shoe Horn

Rationale

Both users, Doritha and Kathy, had trouble putting their foot into the shoe without crushing the heel of the shoe. To compensate for this problem, their podiatrist recommended custom shoe horns. These shoe horns allow the user to put their foot into the shoe, but the users also experience difficulty pushing their foot so that it is completely in the shoe. We proposed a new device: a shoe horn with a lever (Figure 4). This device allows users to slide their foot into the shoe, and pull a lever, giving their foot an extra push completely into the shoe.

Description

The Lever Shoe Horn is used much like a regular shoe horn: users simply place it in the back of their shoe to aid in sliding their foot into the shoe. Users can actuate the handle on the Lever Shoe Horn to push the back of their foot if they encounter too much resistance. The device is constructed out of metal, with a rubber handle at the top so users can operate the device with comfort.

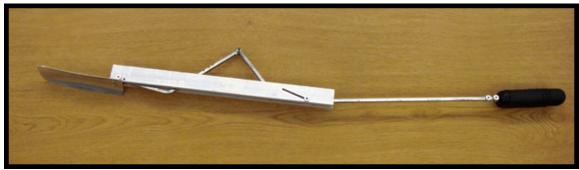


Figure 4: Lever Shoe Horn Prototype



Knee Nook

Rationale

Stroke survivors often place their weak leg on their strong knee, similar to a person crossing their legs, as a way to more easily reach their week foot. However, they experience difficulty holding their leg in this position. The Knee Nook is a device that holds the weak leg on top of the strong knee, and was proposed to the users and met with great excitement. Such a device would allow users to easily reach their foot, and thus more easily don their AFO and shoe.

Description

The Knee Nook (Figure 5) consists of three main parts: the body, the leg strap, and the pivoting support. Users strap the device on top of their strong knee, leaving the pivoting support hanging down. Users then swing their weak leg over the device, causing the pivoting support to rotate and lock into position when the leg is perched atop the strong knee. The prototype device was constructed out of wood and used Velcro for attachment straps. For added comfort and safety, a foam pad was attached below the body of the device to ensure that the user's knee was not subjected to great amounts of pressure.



Flgure 5: Knee Collar Prototype



Shoe Wedge

Rationale

Both had trouble getting their toes into the shoe during user testing because of the fixed angle of their foot and the difficulty of making their foot parallel to the ground. A ground-based shoe holder should angle the shoe upward, to compensate for this lack of ability to point the toes when putting on the shoe. This would compensate for the right angle of the AFO and allow users to don their shoe more easily.

Description

The design for the shoe wedge (Figure 6) is fairly simple. It consists of two metal pieces riveted to a hinge. The bottom of the larger piece of metal is covered with Dycem® non-stick material to prevent slippage between the ground and the apparatus. The top of the smaller piece is coated with a coarse material to prevent slippage between the shoe and the apparatus. Additionally, there is a Velcro strap attached to the smaller piece of metal to provide more stability for the shoe. An adjustable mechanism allows the wedge to be placed at the angle most comfortable for the users.



Figure 6: Shoe Wedge Prototype



Tongue Clip

Rationale

Users were faced with a recurring problem. As they put on their shoes, the AFO would push their tongue into the bottom of their shoe. This improper donning forced them to back their AFO out of the shoe, fix the tongue, and start the whole process over again. A proposed idea to address this problem is a tongue clip, in which the tongue of the shoe is held firmly in place at the front-top of the shoe. This ensures that the tongue will not slide and provides a large opening for the uses to don their shoe with ease.

Description

The Tongue Clip is a spring loaded device that fits over the top of a shoe. This provides the tension required for a clamplike apparatus that can fit over the shoe. On the inside of each slab is a high friction pad to prevent slippage of the clamp. A clip is attached on the large tube between the wood slabs, which users clip to the tongue of the shoe to hold it back.

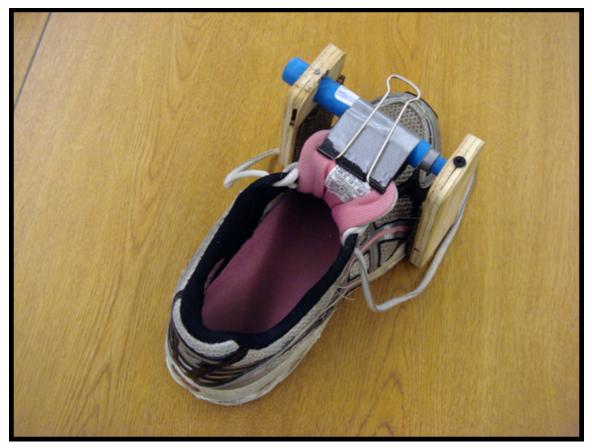


Figure 7: Tongue Clip Prototype



User Testing

Four mockups were tested with a stroke survivor named Gelise at the Rehabilitation Institute of Chicago on February 9, 2007. Although Gelise's ability to answer questions was affected by her aphasia, a possible user testing procedure can be found in Appendix H. Each mockup represented a different approach to donning the shoe: an adjustable wedge base, a tongue clip, a knee nook, and a lever-assisted shoe horn. The team's findings are summarized below (Refer to Appendix G for a complete outline).

Knee Nook

Findings

The plastic plate, meant to support the bottom of the leg, made attaching the straps extremely difficult and confusing. The Knee Nook's overall design was complicated and hard to use, but the client and user both agreed that the device's ability to hold the weak leg on the strong knee was helpful both in donning the shoe and the AFO.

Eliminate plastic plate

The plastic plate neither helped the user to don the device nor improved the functionality of the device. Future designs should not have such a plate.

Use only one strap

Having two straps provided no advantage, and made the device more difficult to put on. A better design would have only one strap.

Decrease size

The device's bulk made it awkward to handle, hard to use, and impractical. A greatly reduced size is preferred.

Eliminate Velcro

The Velcro adhered to the user's clothing. The client suggested a loop that would simply slide up the leg.



Tongue Clip

Findings

The Tongue Clip's spring-loaded method of attachment was difficult for the user to operate with one hand. Once attached, the device performed its intended function of keeping the tongue from slipping into the shoe.

Revise attachment method

The device should be easy to attach with only one hand. The client suggested something plier-like.

Change device geometry

If the device held the tongue higher, the opening would be larger, making it easier for the foot to completely enter the shoe.

Wedge

Findings

The user had no trouble understanding how the Wedge worked. However, the Wedge's straps compressed the shoe, and the user could not slide her foot all the way in.

Substitute walls for straps

The shoe should be attached in a manner that does not compress it. Use walls to hold the shoe in place instead.

Lever Shoe Horn

Findings

Because the user could only use one had, she was unable to hold the Lever Shoe Horn and guide her foot into her shoe at the same time.

Attach the shoe horn to the chair

An attachment to the chair would allow the user to hold the device in the necessary position.



Evaluation and Final Design Direction

In deciding on the final design direction, the team considered which device provided the most functionality.

First, two disadvantages were observed in the Lever Shoe Horn. There was no adequate way for the user to hold the device. The client also did not see hope in the approach as a whole, because the device limits critical space behind the shoe.

The Wedge and the Tongue Clip both marginally assisted the shoe donning process. However, neither design allowed the user to fully don her shoe. Also, the client pointed out that most users prefer to put on their shoe with their weak leg resting on their strong knee. These users would have no use for the Wedge.

The Knee Nook was the only mockup that assisted the user in fully donning both her AFO and shoe, and therefore made it the clear choice for our final design direction. For the device to be successful, however, many changes would need to be incorporated. Having a support underneath the leg and a second strap reduced the device's usability. The size and mechanics of the device were cumbersome and confusing to the user. However, the device's ability to hold the user's weak leg atop their strong leg was ideal.

The team's original idea was to construct a smaller, collapsable version of the Knee Nook. However, after an intensive design review (see Appendix I for summary), it was obvious that the Knee Nook needed to be completely redesigned. The new design would be ambidextrous, have no mechanisms, be easily adjustable, have no hard surfaces, slide onto the leg, and be highly portable.

A non slip ring was suggested as another way to hold the leg atop the knee. The team modified this idea to make it adjustable for different leg sizes by proposing a non-slip pad affixed with a strap. Of many attachment methods considered, backpack straps were found to be the most intuitive and familiar to the users. Since it was determined from user testing that only one strap was necessary, one inch webbing was used in conjunction with backpack-like attachment clips. A stuffed neoprene pad provides the necessary friction to hold the leg in place, while, similar to the original design, does not require the user to lift their leg overly high.

Thus, after deciding on the Knee Nook as the final design direction, the team redesigned the original mockup. The proposed design retains all the advantages of the original, while transforming the overly complicated and bulky design into one that is elegantly simple.



Next Steps

The original Knee Nook design worked fairly effectively at the user testing session. The user was able to put the device on, and with hints and a few extra instructions, place her leg into it, lock it into position, and use it to put her shoe on. The changes that were made for the final prototype should solve all of the problems encountered during this testing session. The final prototype was tested by each team member. This testing uncovered areas for further work.

To continue development of this design, we recommend further research in the following areas:

Size

The Knee Nook is still relatively big and making it more portable would be advantageous. Areas to investigate include:

Body

Can a smaller volume of foam be used without compromising comfort or stability?

Is there a way to design the device to make it even more compact?

Straps

Can smaller straps be while still allowing the user to feel secure?

G is there another, more compact, way to attach the pad to the knee?

would users feel comfortable using the pad without the straps?

Comfort

The strap adjusters and straps cause some discomfort when fully tightened. Areas to investigate include:

Body

Would it help for the shape to mimic the curve of the leg more?

 ${}_{\odot}$ Is there a different type of padding that could be used that would work more effectively?



Straps

Would padding under the strap adjuster reduce usability?

Ease of Operation

It may not be intuitive that you can just slide the strap over your leg, and the adjustable straps could still be easier to use.

Straps

Would positioning the strap adjusters in a different way make them easier to use?

Would putting instructions on the strap help users to know not to disconnect it?

©Could a different strap adjuster be easier to use?



References

Information on Foot Drop

James W. Pritchett, MD – Foot Drop. 29 Dec 2006. eMedicine. 17 Feb 2007 <<u>http://www.emedicine.com/orthoped/</u> topic389.htm>

Jerry Swansen, MD – Footdrop. 30 Sept. 2005. MayoClinic. 17 Feb 2007 <<u>http://www.mayoclinic.com/health/</u> footdrop/HQ00724>

Foot drop. 10 Jan 2007. Wikipedia. 16 Feb 2007 <<u>http://en.wikipedia.org/wiki/Foot_drop</u>>

Information on AFOs

Orthotics research. Editor unlisted. 10 January 2001. Massachusetts Institute of Technology. 17 Feb 2007 <<u>http://</u>web.mit.edu/jblaya/

Development of an Ankle-Foot Orthosis with Dorsiflexion Assist. Date unlisted. American Academy of Orthotists and Prosthetists. 15 Feb 2007 http://www.oandp.org/jpo/library/1999_02_024.asp

Effects of an AFO on ankle and knee biomechanics during walking. 08 May 2001. Dave Thompson, PT. 16 Feb 2007 <<u>http://moon.ouhsc.edu/dthompso/namics/leorthot.htm</u>>

Ankle-foot Orthosis. 25 Nov 2006. Wikipedia. 14 Feb 2007 < http://en.wikipedia.org/wiki/Ankle-foot_orthosis>

Information on Donning AFOs

Ankle-Foot Orthosis Patent Information. 12 June 2004. Free patents online. 15 Feb

2007 <<u>http://www.freepatentsonline.com/6827696.html</u>>

Floor reaction AFO. 27 Jan 2006. Scheck and Siress Advanced Orthotics and Prosthetics. 16 Feb 2007 <<u>http://</u>scheckandsiress.forbin.net/orthotic_care/AFO_Floor_Reaction.pdf>

Other Solutions to Foot Drop

WalkAide. 2006. Innovative Neurotronics. 15 Feb 2007 < http://walkaide.com/products/index.html>

Dorsi-Strap. 2007. X-Strap Systems. 16 Feb 2007 <<u>http://x-strap.com/dorsi-strap.htm</u>>



Appendix A: Project Definition

Project name: Shoe and AFO Donning ProjectClient: Sarah H.-- Physical therapist at the RICTeam Members: Carissa Black, Derek Liu, Henry Petrash, Greg Warga

Mission Statement

To create an inexpensive means of donning an AFO and shoe independently in fewer than five minutes.

Constraints

Must not change effectiveness of AFO use

Users and Stakeholders

Stroke Survivors

Anyone else who has trouble donning a shoe

REQUIREMENTS	SPECIFICATIONS
- Safety	- Does not require user to bend more than
User is able to maintain balance	35° to the left or right
User wont get hurt by product	- Has no sharp/hard edges
Product doesn't interfere with AFO operation	- Uses non-toxic Material
	- Makes no alterations to AFO itself
- Comfort	- Is used sitting down
User feels stable	- Is 2 inches high to keep weak leg from
	slipping off strong knee
- Convenient	- Is Smaller than 42 in ³
Product is easily portable	- Is Lighter than 4 lbs
Product can be used independently	- Can be used without assistance



- Ease of Operation	- Provides intuitive or simple and explicit
	understanding of use
	- Takes less than 5 minutes to don AFO
	and shoe
- Stroke Survivor Accommodation	- Accommodates all shoes sizes
Users of all sizes can use product	- Fits a 12 in diameter leg
-Maintenance	- Has no materials that collect particles
- Product is easy to keep clean	(ie., Velcro)



Appendix B: Client Interview Questions

Introductions

Questions About the Client

More about RIC

What is the individual's position within the company?

Questions About the Problem

Elaboration on the Problem (What is it and what makes this problem significant?)

Explain the process of donning an AFO.

What current methods are being used to don the shoe/AFO? What products do the users use? Which are preferred?

What about these methods is inadequate to the user's needs?

Questions About the Users

How limited is the motion of these stroke survivors? How much variation is there between these users?

Do the conditions necessary for the use of this product apply to certain demographics over others?

What activities do the users perform when wearing the AFO? How does the AFO limit these activities?

Are there any potential users of this device that would be willing to speak to us about the problem at hand? How might we contact them?

Who, other than the users, RIC and Northwestern, will interact with this design? For example, cleaning, manufacturing, and sales of the product.

Questions about the requirements, features, constraints, and other designs

Are there any special requirements for this design such as special features, size parameters, etc.?

What materials are currently being used in products already on the market? Which are preferred?

What considerations toward safety must be made when designing this product?

Questions about research

Are there any other experts that you would recommend who may help us regarding this project?

Would you suggest any other relevant means of research like books or websites on the subject?

Questions about follow up

Gather contact information

How frequently would you like to touch base regarding the project?



Appendix C: Client Interview Summary

Date: 1/10/2007

Location: Ford Design Center

Client: Sarah Housman

The team learned a number of important things during the first client meeting. We received practical advice on the functions and problems of the Ankle Foot Orthosis (AFO) device, as well as specifications to base our final design around.

Sarah Housman, our contact from the Rehabilitation Institute of Chicago (RIC), began her presentation by describing the common side effects of a stroke. Muscle weakness often occurs in the arm and leg of one side of the body, which results in either hemiplegia, which is complete loss of movement, or hemiparesis, partial loss of movement. She noted that while a patient may start out hemiplegic immediately following a stroke, he or she may progress to the hemiparetic stage with therapy. Specifically, Ms. Housman addressed stroke side effects in relation to the foot and ambulation; stroke survivors often experience foot drop because they cannot raise the ball of their foot off the ground. Furthermore, the knee may be weakened, possibly resulting in the knee buckling while walking. Another stroke side effect is abnormal muscle tone: either flaccidity (decreased muscle tone), or spasticity (increased tone).

Ms. Housman then described the AFO device. Made of rigid plastic, the AFO is a brace that extends from the ankle to the foot and prevents foot drop in the wearer. There are different variations of AFOs, including hinged or unhinged and cut or uncut.

We then discussed the problems of putting on a shoe while wearing an AFO. Often, a patient has to buy one shoe size larger to fit over the AFO. Even with a therapist putting the shoe on, it requires a considerable amount of force to put the shoe on. Ms. Housman noted that RIC custom makes an AFO for each patient, so the device fits snugly against his or her leg and foot. Specific difficulties that a stroke survivors may have are lifting the leg, bending the knee, bending the ankle, maintaining balance while putting on a shoe, keeping the shoe stationary, and pointing the toes. Further, since the AFO is constructed of rigid plastic, it often ends up crushing the back of the shoe when the user applies force.

The end users of the product will be adult stroke survivors with no cognitive deficits. The design should be feasible to don in 5 minutes or less and cost under \$20. Further, the design should be aesthetically pleasing and be easy to transport.

Thus, the team learned many important facts about AFOs and their users. We will further observe stroke survivors during a visit to the RIC.



Appendix D: User Observation Questions

Plan for Observation:

Request to watch stroke survivor don AFO and shoe Observe any accessories survivor uses Observe other impairments that potential users may have **Questions we want answered:** How do you currently put on your AFO and shoe? What about this method is inadequate to your needs? What products have you tried? Pros/Cons Have you ever thought of a product you wish existed? What kind of materials would be ideal? (cleaning, durability) What considerations toward safety must be made when designing this product? Is there anywhere that reviews products like this? Rank the following requirements for an AFO shoe device: Safety Cost Appearance

Ease of Use

Size/ Weight

What/Who has been most helpful with your recent adjustments?

What do you think about a knee nook? Shoe stabilizer? Do you have problems with the tongue of your shoe? Back of your shoe?



Appendix E: User Observation Summary

Team representatives visited the Rehabilitation Institute of Chicago on January 18, 2007. The client, Sarah Housman, introduced two of her patients as Kathy and Doritha.

Recommendations for Device Design

The tongue is often pushed into the shoe, so something to hold the shoe open would be very useful.

The fixed angle of their foot made it hard for the users to get their toes into the shoe. A ground-based shoe holder should angle the shoe upward to fix this.

The users had trouble keeping the AFO aligned, so a device that held the AFO while it was donned would be useful.

Doritha mentioned that AFOs should be designed like boots built for firemen. We could design an adapter that made AFOs more like a fireman's boots.

Some users wouldn't care about style, but most would. Changing the shoe would be undesirable.

According to the client and users, the most important aspect of a design is that it gives the user independence.

 \bigcirc Both patients agreed that a device to hold the weak leg onto the strong knee would be helpful.

User Difficulties

The users complained that Velcro straps always seem to get caught on clothes.

Doritha said that she couldn't put the AFO in the shoe first, because of a foot condition.

There aren't very many places that are good to grab onto on most shoes, which can make it difficult to pull back the heel.

Other than a special shoe horn from Doritha's podiatrist, the heel inserts previously designed by EDC students, and a similar shoe insert available commercially, the RIC has not found any other products to solve this problem.

When Doritha tries to put the shoe on, the strain causes spasms in her leg.

Doritha's shoe horn works very well with her gym shoes, but the large, weak heel of her boots made the shoe horn less effective.

Doritha's boots were three sizes too big, but she still had substantial difficulty putting them on.

Both patients, especially Doritha, (whose stroke was more recent than Kathy's) had trouble holding their weak leg onto the strong knee.



Solutions Currently Employed by Users

Whathy uses newer Velcro shoes to avoid having to use laces.

While she usually does not don her shoes this way, Kathy agreed to put the AFO in the shoe and don both on her leg, which worked very well.

Doritha has a special shoe horn that is wider and thinner than most, and works very well with her gym shoes.



Appendix F: Clustered Brainstorming List

Holding shoe steady:

19- Foot-sizer tool 25- Suction to floor 51-chair 9- Shoe blocks 21-Shoe-u 45- Shoe positions 19- Foot-sizer tool 23 Shoe bar 6- shoe shovel 18- Clamp shoe 5- rod with gripper 26- Shoe weight 29- Water-filled weight Holding shoe with sticky things: 22-Shoe putty 7-magnetic sole 10-Sticky floor 47-3m tape Holding shoe to chair: 46-Heel cup clips to chair 48-rubber band to chair leg 51-chair leg loops 27-Sit on string Expanding the shoe: 1-shoe horn 49-permanent shoe stabilizers 2-heel cup 16-Big foot 54-expanding ring 15?-Shoe opener

31-Push to deform shoe Adapting the AFO:

4-rod on AFO

11-Slick spray 62-Add slippery tape to AFO 55-add lead-in on AFO 8-AFO-n-sole 58-AFO pulls shoe into place 60-Super thin AFO

g List
Holding the tongue:
43-Magnetic tongue with elastic laces
13-Tongue clip
12-Elastic tongue ties
14-Tongue Spring
40-Pressure-activated tongue
Miscellaneous:
17-Knee Collar
24-Folding fin
50-shoe pedal
39-Slap-bracelet style tongue
34-Magnetic sock
56-carrying case
Changing the shoe:
36-Unfolding shoe
3-cut back of shoe
59-Heel folds out
52-accordion shoes
44-Shoe on AFO
53-pump to open shoe
59-Heel folds out
Wild Ideas:
32-Bob the Robot
38-Vacuum shoe
61-Rocket shoe
34-Magnetic sock
42-Wings
30-Shoe wings
37-Flap and magnet shoe
35-Uber-sock
41-Textile muscle



Appendix G: User Testing Summary

February 9, 2007

Rehabilitation Institute of Chicago

Name of Tester: Gelise

Approximate Age: 40

Time Since Stroke: Two weeks

Side with Weakness: Right

Severity of Weakness: Right hand unable to help with any process, right leg can be lifted about six inches off of the floor

Donning Routine: No routine developed yet since stroke occurred so recently

Other: Has aphasia so it's very difficult for her to communicate—some communication possible but responses to questions posed about mock-ups were extremely difficult to understand

	Cons	Pros
	User initially put devise on backwards	After we removed the plastic under-leg
	Locking device could easily get lost/drop on floor	support user said the straps were much easier to maneuver
	User had extreme difficulty putting plastic support under leg	Device worked to keep weak leg in place once it was all set up
	User had to un-strap herself from wheel chair	Lock kept L-support up and was fairly
	User had hard to attach both straps at same time	easy to release when process was over
	Straps were too bulky and about 8-10 in too long	Determined that devise would also aid in AFO donning
	Strap attachment interferes with the movement of the L- support	Devise allows user to don shoe
	User initially put shoe onto the L-support (not intuitive that device is for holding up the leg)	
	User had difficulty reaching weak leg to lift into place because the L-support was too long and the device was too bulky in general	
	Lock was difficult to put in place because it wasn't positioned on the outside of user's body	
	Velcro was getting stuck to the user's pants	
	The whole devise rotated forward when leg weight applied	
	L-support seemed to be causing leg discomfort	



Wedge	Straps to keep foot attached compressed shoe making it even more difficult to slide foot in	Devise made it easy for user to get foot about 2/3 of the way into the shoe
	Incline makes it harder (almost impossible) to put foot completely in shoe because of the added upward force necessary	Dycem bottom kept devise from sliding on the ground
	Device didn't allow user to successfully don shoe	Device was very intuitive user understood how it worked much better than te rest
Tongue Clip	User said that she didn't normally have too much trouble with the tongue of her shoe getting in the way	Devise actually held the tongue back and created a wider opening of the shoe
	Design makes it too difficult for users to attach by themselves with one hand	Client said that many potential users do have trouble with their tongue and that devise would be beneficial
	-needs to be attached in too	
	specific of an order	
	ie. clip tongue first then	
	left side then stretch to	
	right side and straighten	
	Device was not intuitive	
	-confusing that you can	
	only stretch from one	
	unmarked side	
	Device requires too much force and hand dexterity to attach	
Shoe Horn	Metal handle had to be held by neck/shoulder because the user needed their hand to maneuver foot into shoe	Appearance was very pleasing to the user
	her foot correctly	Knew exactly how it would be used
	The angles needed to put foot in shoe were impossible to achieve and testing was aborted	User pointed to devise when asked which one she had liked the most
	"Pulling" aspect of not even tested because it was obvious the device wouldn't work	



Appendix H: User Testing Procedure

Introduction

Demographic Information

Name

Gender

Age

Time since stroke

Side Affected

Severity of Stroke

Demonstrate how to use the mockups

Tasks

Don a shoe while wearing an AFO using:

Knee Collar

Initial reactions

Positives

Negatives

Wedge

Initial reactions

Positives

Negatives

Tongue Clip

Initial Reactions

Positives

Negatives

Lever Shoe Horn

Initial Reactions

Positives

Negatives

Thank them for participating



Appendix I: Design Review Summary

			Features to be	
		Features to Be	removed/	Additional
Reviewers Like PLASTIC	Reviewers Dislike SKI BOOT CLIP	Added None	modified Attachment method	Comments Look up cabinet
	ATTACHMENT		will be velcro-free	hinges for latch
CONSTRUCTION			webbing	ideas.
Lightweight and	Difficult to use with		Arm hinge will be a	Find a convenient
compact.	one hand.		torsion hinge	way to make the
				design
				ambidextrous.
FOLDING ARM	Hard to get straps			
	under leg.			
Increases portability				

Decisions Made After Design Review Suggestion/Criticism

Ski boot clip attachment method may be difficult

to use with one hand, and straps are difficult to

get under the leg. Find a convenient way to make the design ambidextrous.

Implementation

Use velcro-free webbing instead of ski boot clips

Have adjustments on both sides, although the user only needs them on one side



Bill of Materials				
All materials ava	All materials available from McMaster Carr (http://www.mcmaster.com)			
	DESCRIPTION	QUANTITY	PRICE	
Foam Sheet	Neoprene 8647K33	1 foot	\$6.65	
Strap	1 inch nylon webbing 3510T12	3 feet	\$1.35	
Strap Clip	1 inch no sew feed through clip	1	\$6.19/25	
Thread	Black Polyester Thread	6 feet	\$1.50/spool	

Appendix J: Bill of Materials