DESIGN OF AN E-TEXTILE SLEEVE FOR TRACKING KNEE REHABILITATION FOR OLDER ADULTS

A Thesis Presented to The Academic Faculty

by

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In Partial Fulfillment of the Requirements for the Degree Masters in the School of Industrial Design

Georgia Institute of Technology August 2013

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DESIGN OF AN E-TEXTILE SLEEVE FOR TRACKING KNEE REHABILITATION FOR OLDER ADULTS

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ACKNOWLEDGEMENTS

First and foremost, I would like to thank my wonderful family and friends for all their support throughout my life. Without them constantly pushing themselves to be the best, I would never have attempted to follow suit.

I would also like to thank my advisor Dr. Claudia B. Rebola for her guidance, Jim Budd and Clint Zeagler for their introduction and insight into wearable and interactive products, Dr. Vela for his encouragement, and Jim Schuster for fun, shared studio spaces. Furthermore, I would like to thank all those who strengthened the project, especially those at the local rehabilitation clinic, Brian Jones, Wendell Wilson, Jon Lau, and Scott Gilliland at Georgia Tech.

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LIST OF ABBREVIATIONS

СРМ	Continuous Passive Motion
ТКА	Total Knee Arthroplasty
TKR	Total Knee Replacement
РТ	Physical Therapist
ROM	Range of Motion
STEM	Science, Technology, Engineering, and Math

NOMENCLATURE

REHABILITATION SPECIFIC TERMS

Arthroplasty Arthroplasty literally translates to "total repair of the joint" (Wikipedia).

Manipulation A manipulation is a surgery performed to remove scar tissue from previous surgeries.

Flexion Flexion is a "position that is made possible by the joint angle decreasing" (Wikipedia).

Extension

Extension is a "movement of a joint that results in an increased angle between two bones or body surfaces at a joint" (Wikipedia).

TECHNOLOGY SPECIFIC TERMS

eTextiles

A subset of wearable computing that embeds the technology into the textiles.

SUMMARY

The occurrence of total knee replacements is increasing in the United States for persons over the age of 45 because they are inexpensive and a very effective method for treating degenerative joint diseases. Rehabilitation requires regular access to a wide variety of resources and personnel and, as the demand for post-operative, rehabilitative care increases, the ability to marginally relieve the healthcare system by offloading resources to the patient is necessary. Tools to enable tracking a patient's rehabilitative progress at home are an essential method to help unload the healthcare system. The purpose of this project is to design and develop a wearable home rehabilitation device for knee replacement. This thesis utilizes design ethnography tools such as expert interviews, rehabilitation observation, a participatory design workshop, iterative development, and an idea feedback study. Leveraging advancements in technology and the field of eTextiles, this study investigates the product feasibility and acceptance of discreet on-body sensors to provide a product that enables patients to better perform rehabilitation on their own, but also to allow for a feedback loop for physicians and therapists to view patient progress.

CHAPTER 1 INTRODUCTION

SIGNIFICANCE OF THE PROBLEM

Total knee replacements are becoming increasingly prevalent throughout the United States for persons aged 45 and older, as they are an inexpensive and effective method to treating degenerative joint diseases, such as Osteoarthritis, Rheumatoid Arthritis, and Post-Traumatic Arthritis. As total knee replacements become more frequent, the demand for post-operative, rehabilitative care increases. Unfortunately, rehabilitation requires regular access to a large variety of resources and personnel, such as isokinetic devices, physical therapists, and primary physicians. With the demographic shift towards a larger aging population, the ability to marginally relieve the healthcare system by offloading resources to the patient is necessary, and tools to enable tracking a patient's rehabilitative progress at home are a feasible method to help unload the healthcare system.

Advancements in technology have introduced electronics into wearable products, and within the past 20 years, have engendered the new field of smart textiles, or eTextiles (Bonfiglio, 2011; Seymour, 2008). eTextiles enable digital components and electronics to be embedded into the fabric, providing additional functionality to wearable products. eTextile research into the medical fields have focused on the monitoring of motor functions, patterns, ambient sensing, and the integration into orthotics, prostheses, and mobility assistive devices. However, few studies have been done to understand the wearability of technologies within the medical field and their feasibility as a consumable

product (Bonato, 2005; Patel, Park, Bonato, Chan, & Rodgers, 2012a). Furthermore, research has not approached the problem from a fully integrative perspective, encompassing not only the tracking of motor functions, but as an aid for the physical therapist.

GOALS OF THE STUDY

The goal of this study is to investigate how the use of eTextiles can promote better knee rehabilitation, particularly when the physical therapist is not present. Additionally, it will be assessing the wearability and social acceptability of lower-body technology. Using established ethnographic research methods, there are four major phases to this study.

This study intends to understand the interaction between various primary stakeholders, such as TKA patients and their doctors. Through expert interviews and the observation of the rehabilitation process, an examination of existing techniques utilized by physical therapists during knee rehabilitation will be analyzed with the intent to recognize how users interact with their existing rehabilitation products. Ultimately however, the purpose is to look for product opportunities in the current system.

Secondly, a Participatory Ideation Workshop will be conducted with users who have either performed, are currently attending, or intending to go through knee rehabilitation. The goal of this workshop is to understand the user's perception of rehabilitation and technology, establish design criteria, and develop potential directions for a final product.

Using the design criteria established during the workshop, the study will design and develop a physical therapy device using eTextile techniques and wearable

technologies. The roles that social acceptability, wearability, and fashion play are central factors to product adoption of wearable products. The objective is to develop a platform for which others can develop their own system.

Lastly, this study evaluates the wearability and social acceptability of the final product. The goal of this phase is to assess the design criteria developed throughout the study and establish the validity of the design platform.

CHAPTER 2 BACKGROUND

REHABILITATION

INTRODUCTION TO REHABILITATION

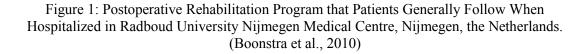
Total knee replacements (TKR), also known as Total Knee Arthroplasties (TKA), have become increasingly prevalent throughout the United States for persons over 65, having amplified by 161.5% among Medicare patients within the past 20 years and costing \$5 billion annually (Slover J, 2012). However, knee replacement is not limited to the geriatric population and the occurrence of partial knee replacements continues to rise for ages 45 through 65 (Henderson MD).

The influx of patients requesting TKR can be attributed to several reasons: the increase of indications for the surgery by medical professionals (Slover J, 2012), obesity (Slover J, 2012), to alleviate personal vulnerability and dependency on family (Toye, Barlow, Wright, & Lamb, 2006), and the rise in patients eligible for Medicare (Slover J, 2012). While preventive measures for TKR are highly encouraged by physicians, rehabilitation has become a commonly accepted practice because it is a reactive and restorative measure for persons undergoing surgery (Harnirattisai & Johnson, 2005; Hauer, Specht, Schuler, Bartsch, & Oster, 2002). After the surgery, inactivity causes muscles to atrophy by 4% to 6% per day (Sloves & Fox, 2010) and a variety of studies show how integral these rehabilitative methods are to the prevention of muscle deterioration and the build-up of scar tissue (Brander & Stulberg, 2006; Dias, Dias, & Ramos, 2003; Hauer et al., 2001; Hauer et al., 2002). As such, physical therapies for

TKR work best when initiated two to three days after the operation and typically continue for four to six weeks after the surgery (Boonstra, Schwering, De Waal Malefijt, & Verdonschot, 2010; Houglum, 2010). Typical in-patient rehabilitation programs are three to five days long and involve rehabilitation early after surgery (see Figure 1).

Postoperative Time	Rehabilitation Program During Hospital Stay
Day 0	Surgery
Day 1	Recovery in bed
Day 2	Flexion exercises sitting on a chair
Day 3	Flexion exercises are increased (Kinetec, ^a if necessary), and patient starts walking with crutches
Day 4	Increase of knee flexion angle and walking distance
Day 5	Discharge from hospital (90° of knee flexion)

^a Isokinetics Inc, PO Box 21 De Queen, AR 71832.



In conjunction to working with a physical therapist to prevent atrophy, patients are provided with daily activities to be performed in the home, such as knee extensions and hip abductions; however, it is up to the patient to perform said rehabilitative activities in the home.

Despite proper rehabilitation performance, however, studies show that the quality of life for patients over 60 quickly deteriorates the first two years after TKR surgery (Lavernia, Guzman, & Gachupin-Garcia, 1997). While predominantly being attributed to age, adherence to rehabilitation is known to be a large factor. Additionally, the American College of Sports Medicine and the American Heart Association recommend daily fitness regimens that emphasize both moderate intensity aerobic activity and muscle strengthening to increase flexibility and balance (Nelson et al., 2007). These are

particularly important to aging due to their ability to prevent and reverse physiological degradation, decrease risk factors for chronic diseases, lower one's chances for obesity, and reduce the risk of falling (Singh, 2000; Society, Society, Of, & On Falls Prevention, 2001).

REHABILITATION GOALS AND OBJECTIVES

Therapeutic exercise programs typically consist of three basic components: (1) flexibility and range of motion, (2) strength and muscle endurance, and (3) proprioception, coordination, and agility. While the ultimate goal is to leverage these components to fully recover and return to former activities, a combination of short- and long- term goals are set in order to appropriately progress through the program.

The main principles of rehabilitation are to (1) start therapy as soon as possible while avoiding aggravation to the injury, (2) ensure the patient will comply with the content of the program, (3) be responsive to the individual differences between clients, (4) follow the specific sequence of components described above, (5) provide a challenging program for the patient without overtaxing them, and (6) consider the total patient, ensuring that the whole body as a system is the focus of rehabilitation. Ultimately, the objectives are to prevent deconditioning while rehabilitating the injured part.

KEY STAKEHOLDERS

A variety of studies have delineated key stakeholders throughout the process of Total Knee Arthroplasty as (Bozic, 2009; Delnoij, Rademakers, & Groenewegen, 2010; Westby & Backman, 2010):

1. Individuals who have had a primary TKA

- 2. Allied health professionals, such as Physical Therapists, Occupational Therapists, Nurses, and Medical social workers / care coordinators
- 3. Physicians
- 4. Orthopaedic surgeons
- 5. Anesthesiologists
- 6. Dieticians

However, it is important to consider the role of each stakeholder and how integral they are to the rehabilitative process. Furthermore breaking down the stakeholders into primary, secondary, and tertiary levels of interaction with the patient showed the variety of people involved (see Figure 2).

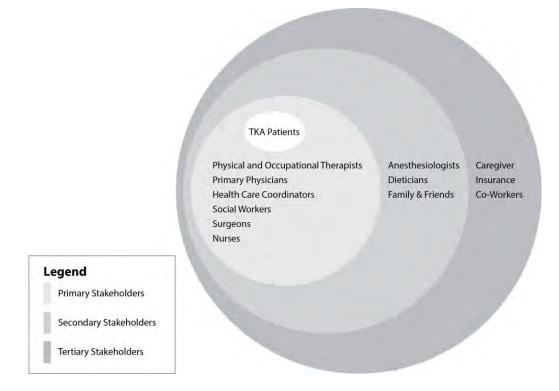
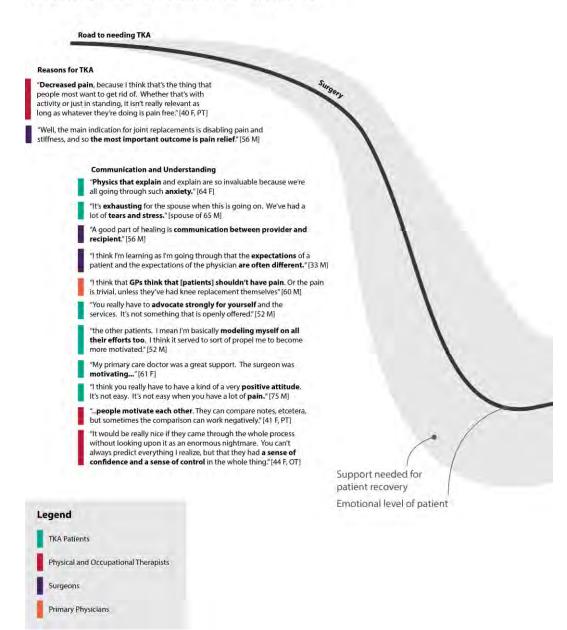


Figure 2: Total Knee Arthroplasty Rehabilitation Stakeholders and their Role with the Patient

Furthermore, Westby and Backman conducted ethnographic research throughout the US and Canada, to further understand the views and outcomes of patient and health professionals associated with TKA (Westby & Backman, 2010). Using focus groups to interview primary stakeholders, they categorized the information into themes to highlight deficiencies within the TKA rehabilitation. An initial User Journey Map from multiple stakeholder perspectives was re-created from their data and similar, yet more relevant themes for this study were created out of their data.

Figure 3 is divided in two halves for clarity, but it shows the pathway the patients and allied health professionals take when going through TKA. Following the thick line, the map depicts the emotional path the user undergoes and underlays the emotional support needed to be provided by stakeholders throughout. To give a description of the findings, patients undergo TKA to reduce the pain and stiffness in their knees, however, they do not have a full understanding of the whole process of rehabilitation. From the beginning, there is a lack of communication from healthcare professionals to their patients, and there is a lack of communication between health professionals, such as a patient's physician and physical therapist. Furthermore, Westby and Backman found that all stakeholders believe that there needs to be a better understanding of what the patient is going through and a better realization of what the patient's ultimate goals are. On the other hand, they found that motivation was a major theme throughout the whole process, and that depression and anxiety were a major hurdle, but motivation from health professionals was one thing all patients felt was adequate. Finally, one of their most important findings is that there is a lack of thorough rehabilitation for patients. Treatment cycles are too short and often rely on the patient exercising at home, when unfortunately home physical therapy devices are non-existent for those who are debilitated or unable to get transportation.

TKA Journey Map from Stakeholder Perspectives





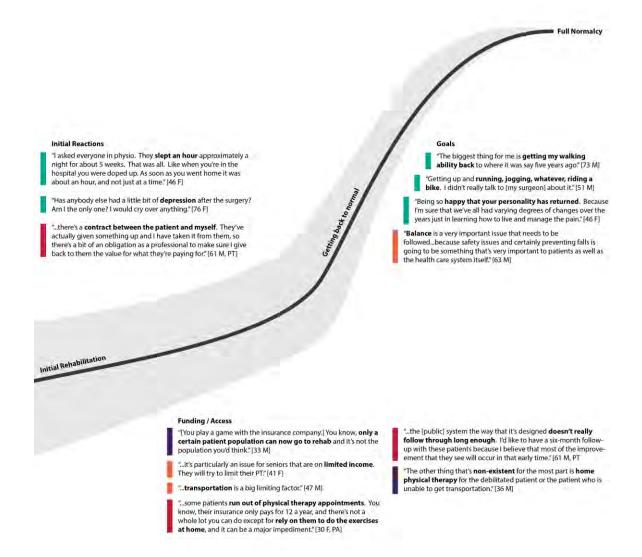


Figure 3b: User Journey through Rehabilitation for Total Knee Arthroplasty (right)

BENEFITS OF REHABILITATION

A variety of benefits exist for rehabilitation and for the continuance of those exercises throughout their daily routine, such as the ones delineated below. Regular exercises, such as stretching and strength training, can improve quality of life for older adults in a variety of ways (Hauer et al., 2001; Singh, 2000):

• Increased metabolic rate, with up to 7% higher resting metabolism and up to 15% greater daily calorie requirements after three months of regular exercise

- Decreased low back discomfort, with approximately 80% of patients reporting less or no pain after about three months of specific low-back strengthening exercise.
- Reduced arthritic pain, as indicated by subjective ratings of symptoms in strengthtrained adults who have arthritis.
- Increased bone mineral density that may prevent age-related bone loss and offer protection against osteoporosis.
- Enhanced glucose utilization that may reduce the risk of type II diabetes.
- Faster gastrointestinal transit that may reduce the risk of colon cancer and other motility disorders of the gastrointestinal system.
- Reduced resting blood pressure, including lower diastolic readings and lower systolic readings.
- Improved blood lipid profiles, including lower levels of LDL cholesterol and higher levels of HDL cholesterol.
- Improved post-coronary performance resulting from higher muscular functional capacity and lower cardiovascular stress from routine and unplanned physical activity.
- Enhanced self-confidence, as reported by previously sedentary men and women following two months of regular strength training.
- Relieved depression in older adults clinically diagnosed with mild to moderate depression.

ADHERENCE

Adherence to rehabilitation is known to be quite low, particularly in the home. A diversity of studies have been done to understand how to increase motivation. In particular, Reznick's (2002) research on motivation within geriatric rehabilitation

provides an instructive framework for the improvement of adherence. Her research uses the theory of self-efficacy as a method to provide educated interventions when motivation is low (Resnick, 2002). The theory of self-efficacy, derived from social cognitive theory, states that one's expectations of their ability to perform a task are directly correlated to their motivation to perform the task (Bandura, 1977, 1995; Bandura, 1986, 1997). The studies identify four "sources of efficacy information" integral to motivation as successful mastery experience, vicarious experience of seeing others perform tasks well, verbal persuasion, and physiological and affective states, such as pain (Resnick, 2002).

TECHNOLOGY

UBIQUITOUS AND WEARABLE COMPUTING

The age of computing can be divided into three generations: mainframe computing, personal computing, and ubiquitous computing (Abowd, 2012). These can be delineated by the number of computers per user, where mainframe computing describes one large computer to many users and the second, personal computing, as one computer per person (see Figure 4). The third term "ubiquitous computing", however, was coined in 1991 by Paul Weiser, the former director of the Computer Science Laboratory at XEROX Parc. In his influential article, Weiser depicted a world full of embedded sensing technologies to unobtrusively streamline and enhance life (Weiser, 1991). Although the concept was not new, he innovatively addressed the subject by integrating sensors into common objects, hence ubiquitous computing.

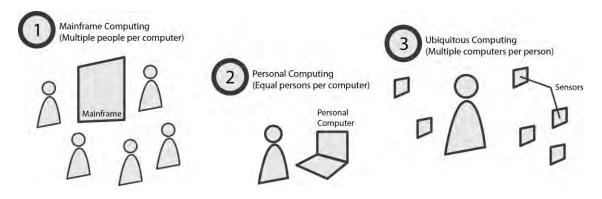


Figure 4: Three Stages of Computing

Shortly after Weiser's vision, the Wearable Computers Group was formed in MIT's Media Lab (Krumm, 2009). Wearable computing is an extension of Weiser's idea of incorporating computing into our everyday objects and activities. There is a difference, however, between ubiquitous computing and wearable computing, in that a wearable computer "is a computer that is subsumed into the personal space of the user, controlled by the user, and has both operational and interactional constancy;" for example it will always be on and will always be accessible (Mann, 1999).

Ed Thorp and Claude Shannon introduced the first wearable computer in 1966, as a cigarette-pack sized analog computer used to predict the outcome of roulette wheels. Using four buttons to indicate the speed of the wheel, the predicted results were transmitted by radio to an earpiece.

E-TEXTILES

A subsection of wearable computing is eTextiles. While wearable computing investigates how to make technology portable and uses on-body attachments of sensors, eTextiles emphasizes embedding electronic and computational technologies into the textiles themselves (Buechley, 2006). Rehmi Post and Maggie Orth were one of the first

to introduce fabric-based, capacitive and pressure sensors by embroidering conductive thread. Numerous researchers have expanded the field by applying electrical engineering principles to the field of eTextiles, to yield new methods for resistive sensors (Glazzard & Kettley, 2010; Yoshikai, Fukushima, Hayashi, & Inaba, 2009), capacitive matrices (Sergio, Manaresi, Tartagni, Guerrieri, & Canegallo, 2002), and educational outreach into Science, Technology, Engineering, and Math (STEM) (Buechley, 2006; Buechley & Eisenberg, 2008; Buechley, Eisenberg, Catchen, & Crockett, 2008; Satomi & Perner-Wilson, 2007).

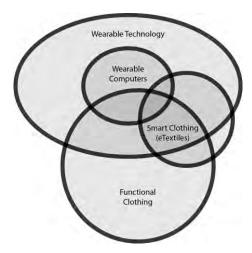


Figure 5: Relationships among Clothing Technologies (Dunne, Ashdown, & Smyth, 2005)

REHABILITATION AND TECHNOLOGY

REHABILITATION TECHNOLOGIES

Within the past 20 years, the medical industry has popularized sensing technologies as a feedback mechanism for physiology, motion, and mobility. In relation to tracking knee movement, a variety of methods have been used, but without full product success. As an example, Gibbs and Asada (2005) used an array of single conductive fibers around the knee and hip joints on a pair of spandex pants to detect expansion and contraction of said joints. While successfully detecting flexion, as the sensor warmed up, their results provided less accurate results each time the pants were worn. In the same realm of biofeedback devices, Munro et al (2008), developed a knee sleeve with a fabric sensor placed over the kneecap in order to track the degree of knee flexion for athletic training improvement. Functional testing however, showed that consistent feedback was not found due to sensor instability

Additionally, current research looks at more complicated methods to track movement, in which, bulky goniometers in stabilizer braces help track flexion and extension or use the Kinect to estimate angles based on bodily protuberances (see Figure 6). However, using new sensors on the body can provide more accurate data. While placing sensors on the body produces a lot of noise in the data collected, the closer a sensor is to the information being sensed, the easier it is for the information to be accurate. This accuracy is integral to biofeedback systems – users will not tolerate inaccuracy. Dr. Thad Starner, a notable expert within wearable computing, has a "twosecond rule" for devices. If a device consistently takes longer than two seconds to activate, users will ultimately stop using the device. The same can be translated to user information. If the information users receive is consistently inaccurate or inaccessible to them, they will find a more suitable device to meet their needs.



Figure 6: Existing research in knee sensing

INTEGRATION OF SENSORS INTO MARKET PRODUCTS

Existing technologies for exercise and rehabilitation can be broken into a few categories: locomotion rehabilitation, telerehabilitation, and minimally invasive physiological sensing. Products geared toward locomotion rehabilitation and telerehabilitation, such as the Lokomat and Virtual Rehabilitation, are extremely useful, however, they still require face time with trained medical staff. To enable rehabilitation in the home, the Continuous Passive Motion (CPM) machine is a well-known tool used by patients, however the benefits provided by the CPM are highly contentious and up for debate by physicians (Chen, Zimmerman, Soulen, & DeLisa, 2000; Pope, Corcoran, McCaul, & Howie, 1997; Ververeli et al., 1995). On the other hand, minimally invasive physiological sensing presents a promising method (Consolvo et al., 2008; Sung & Pentland, 2005).

Within the past 10 years, products have started to focus on minimally invasive physiological sensing. Qualitative analyses of a patient's activities try to understand the different types of activities performed by individuals and try to detect deviations in joint movement by using body-mounted sensors. Evidence for programs that promote living at home as long as possible focus on providing more reliable assessments of a patient's disabilities and help evaluate a treatment's effectiveness, as opposed to being developed for comfort and wearability over an extended period of time (Gibbs & Asada, 2005).

Successful biofeedback products on the market, such as the Nike fuel band, Polar heart rate monitors and the Jawbone Up, focus on very general biofeedback mechanisms. Within the past 5 years, research has driven biofeedback technologies towards their success as products through the use of machine learning and activity inference (Consolvo et al., 2008). Furthermore, Nike and Polar have coupled their devices with beneficial

motivational training programs where users can track their progress over time. For more information on existing technologies and products, see APPENDIX A for the review.



Figure 7: Competitive Analysis of Smart Devices

Figure 7 provides an analysis of existing products, comparing the type of activity they detect with the amount of analysis being performed on the sensor data. In the lower, left quadrant, Nike, Polar, Up, and the Fitbit predominantly use sensor data to detect basic activity, or activities with yes or no values, such as "Did a person take a step?" Their endeavors to move toward the distinction between activities, however, pull these products closer to the center of the graph. Within 2013, new products being shown at the International Consumer Electronics Show (CES) have featured biofeedback and healthcare-related devices that detect ranges of values, or activity states, such as temperature and blood pressure. These products, however, do not infer information based upon these states and therefore, they reside in the upper, left hand quadrant. On the other hand, Kinect and Leap are two products that leverage distance-states as a way to detect activities, but these products are location dependent and do not infer biofeedback, thus putting them in the lower right hand quadrant.

The highlight of Figure 7 is showcased in the upper right hand quadrant – the ideal market for human beings. Humans are state-based systems, meaning we send out a range of data, but technology is not yet at the point where the detection of all the states is easily possible. Additionally, as humans, we partake in a variety of activities. Using machine learning and activity inference, these human states and activities are rapidly becoming realized.

FASHION AND TECHNOLOGY

There are many aspects to consider when designing technological products, especially in the area of aesthetics and fashion. Sabine Seymour (2008) catalogs the work of designers integrating technology into fashion. Her intent is to show that "fashionable wearables have great expressive potential that is amplified through the use of technology." When the two fields come together to inform each other's iterative processes, new creative solutions emerge to push the boundaries of each field.(Papadopoulos, 2007) Furthermore, Seymour argues that the two provide an opportunity to enhance information and interactions between the user and their technologies.(Rheingold, 2000)

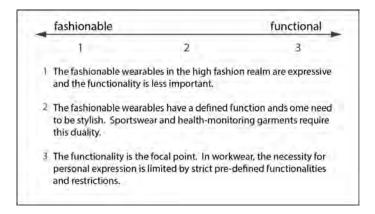


Figure 8: Fashionable Wearables Range in Levels of Expressiveness versus Functionality (Seymour, 2008)

Thecla Schiphorst (2013) further discussed the interconnectedness of aesthetics and technology. Studying technology in the lived and common spaces, her research focuses on the user experience, embodied interaction and somatic senses that technology can enhance.

The MIT Media Lab and Philips Research were among the original drivers of innovation for embedding technology into fashion. In 1995, Rehmi Post and Maggie Orth established the field with their Firefly Dress and Necklace (see Figure 9). Using layers of metallic organza to create connections between LEDs and the power source in the necklace, separate LEDs in the fabric would light up when a connection was made.



Figure 9: Firefly Dress and Necklace (Post, Orth, Russo, & Gershenfeld, 2000)

Others have helped advance the field as well. Francesca Rosella and Ryan Genz researched the incorporation of everyday functionality into fashionables in 2007. Their company, CuteCircuit, created the M-Dress, a dress that discreetly allowed the user to intuitively receive and make phones calls without having to carry a cell phone (see Figure 10).



Figure 10: Cute Circuit's M-Dress (Mobile Phone Dress) In 2006-2007, Kerri Wallace worked on responsive textiles, particularly wearable displays for performance and fitness monitoring (see Figure 11). As a result, touchscreen shirts are predicted to be realized within the next two to three years.



Figure 11: Kerri Wallace's Motion Response Sportswear

In 2005, Textronics (see Figure 12) ventured into wearable sensors developed for fitness and health monitoring. By pairing up with Polar, a market giant in health

monitoring systems for cyclists, they seamlessly integrated the components to provide more accessibility for Polar's user base.



Figure 12: Textronics' NuMetrex Sports Bra

In 2006, Leah Buechley introduced her research on the eTextiles Construction Kit, a tangible method to acquaint kids with computer science and technology, see figure 13. She furthered this research by pairing up with the companies Arduino and SparkFun Electronics to develop the commercial product, the Lilypad Arduino (see Figure 13).



Figure 13: Leah Buechley's eTextile Construction Kit (left) and Lilypad Arduino (right)

Lastly, Electric Foxy's Move concept came out for yoga, a balance- and formintensive field of exercise, in 2012 and tethered eTextiles to movement tracking to show areas of improvement in form (see Figure 14).



Figure 14: Electric Foxy's Move Shirt and Mobile Application

HEURISTICS IN WEARABLE TECHNOLOGY

A variety of articles have been published by notable experts within wearable technology, establishing the fundamental design considerations for wearability and social acceptability. There are different ways to explain the principles, (see Figure 15), but for the purpose of this study, these design considerations, or heuristics, can be categorized into three groups: Wearability, Social Acceptability, and Activity Cognition (McCann, Hurford, & Martin, 2005). The next sections describe these considerations in more detail.

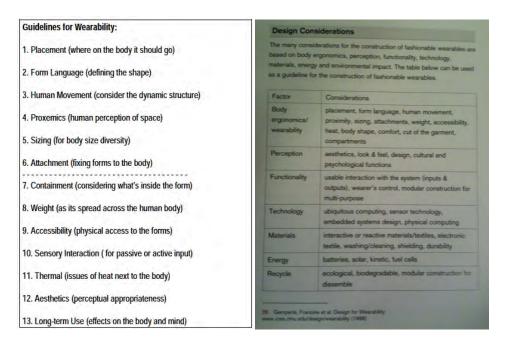


Figure 15: Guidelines for Wearability (Gemperle, Kasabach, Stivoric, Bauer, & Martin, 1998; Seymour, 2008)

WEARABILITY: DEMANDS OF THE BODY

Wearability is defined as the interaction between the human body and the object being worn. Wearability studies for wearable computing have pre-dominantly focused on the upper body (Bayati, del R Millán, & Chavarriaga, 2011; Bergmann, Chandaria, & McGregor; Bodine & Gemperle, 2003; Coyle, Morris, Lau, Diamond, & Moyna, 2009; Dunne et al., 2005; Gemperle et al., 1998; Knight, Baber, Schwirtz, & Bristow, 2002; Knight et al., 2006; Patel, Park, Bonato, Chan, & Rodgers, 2012b; Profita, 2011). However, this study focuses on the lower extremities. Additionally, awareness of human physiology and ergonomics are the foundation of designing a successful and wearable product.

Physical and perceived comforts are dependent upon a variety of factors. Placement, sizing, weight, bulk, stiffness, texture, pressure, constriction, technology containment, long-term use, attachment, thermal and moisture transport, human movement, flexibility, durability, and accessibility are all physical considerations for the human body. Throughout the study, these considerations are addressed.

Bell, et al tested the impact of perceived comfort on the cognitive performance of both soldiers and test-taking graduate students and found a positive correlation between comfort and performance.

Body placement

When looking for means of control, (see Figure 16) research shows that users prefer upper body placement (Bergmann et al.). Gemperle, et al (1998) have also provided suggested areas for component placement. Based on their research, locations such as the thigh and the calf are suitable areas for large sensor placement.

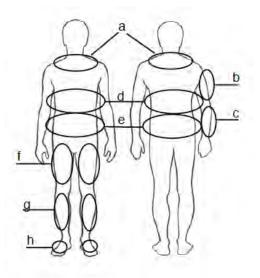


Figure 16: Body Placement Preferences (Gemperle et al., 1998)

Anthropometric Data

Anthropometric data for men and women is important when designing wearable technologies. Figure 17 shows collected data, such as ankle, knee, and hip circumferences and heights, fingertip height, and foot width. Furthermore, in order to understand dimensions of the human body for placing technologies. Figure 18 shows a study done to understand the knee flexion and extension in relation to arm reach.

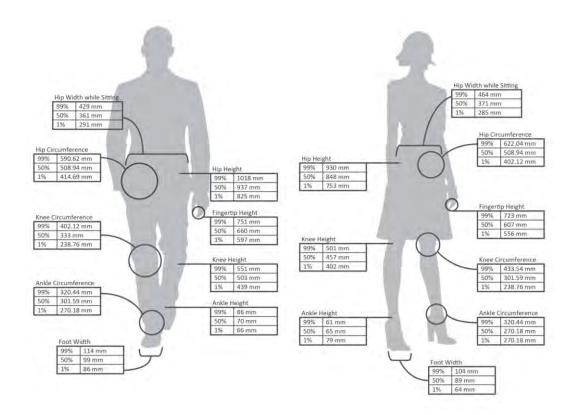


Figure 17: Lower Body Anthropometric Data for Males and Females in the 1, 5 and 99th Percentile



Figure 18: Knee Flexion to Extension in Relation to Reach

SOCIAL ACCEPTABILITY: DEMANDS OF THE CULTURE

There are different aspects that are integral to the social acceptability of a product. Acceptability is dependent upon a variety of different conditions, including context (Profita, 2011), cultural bias (Profita, 2011), age (Profita, 2011), gender (Profita, 2011), attitudes toward technology (Profita, 2011), form language (Norman, 2007), and aesthetics (Norman, 2007; Papadopoulos, 2007). The function of a product must outweigh any discomfort felt by the user. Studies in social acceptance have predominantly focused on gestural and mobile interactions (Profita, 2011).

Furthermore, wearability and social acceptance are completely subject to change over time and across cultures.

ACTIVITY COGNITION: DEMANDS OF THE ACTIVITY FOR END-USE

Cognition and psychophysical elements are also a consideration. Proxemics, or the human perception of space, and sensory interaction are the two defined by the experts. Dunne, Ashdown, and Smyth examine the flow of information within wearable products, such as cognitive ergonomics, context awareness, information flow, interfaces, and sensing the body.

CHAPTER 3

METHODOLOGY

STUDY PARAMETERS

This purpose of this study is to design and develop a wearable device to aid in home rehabilitation. More explicitly, the goal is to understand the potential role of eTextiles within rehabilitation. This research seeks to answer three questions:

- 1. How can embedded technologies and eTextiles promote better rehabilitation in patients who've recently had surgery for TKA?
- 2. What is the most acceptable method for embedding technology and eTextiles into rehabilitation?
- 3. How should electronic textiles look for best adoption of product?

This study was designed to have four major phases – Understand and Define, as a research phase, Ideation, or a phase for concept development, Build, as a prototyping phase, and Evaluation, a phase to feed back into future development (see Figure 19). Leveraging a literature review and a market analysis, this study will conduct expert interviews, observation and a participatory ideation workshop. Using the design criteria extracted from this research, ideation and building will ensue, of which the final products will be evaluated (see Figure 19).

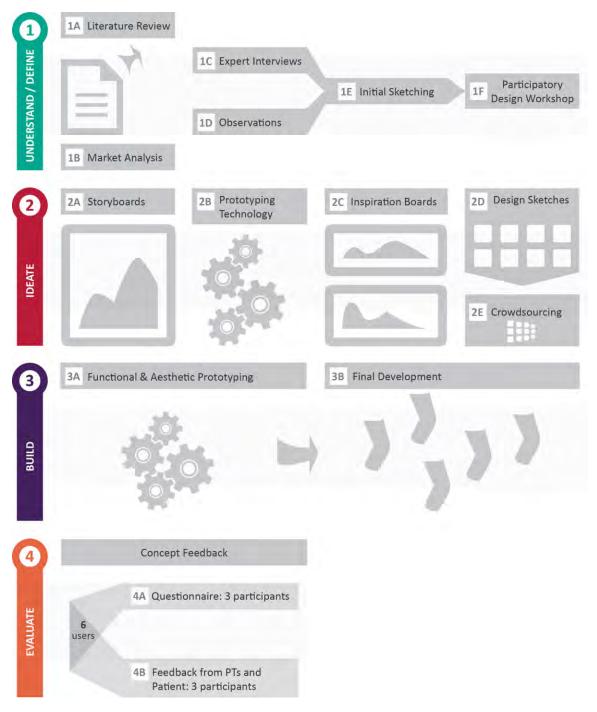


Figure 19: Methodology Map

POPULATION AND SAMPLING

The project used a within-subjects study method, with a total of 17 participants being used throughout. The observational phase, Phase 1D, of the study included 3 physical therapists and 2 patients, over the age of 18, currently undergoing knee rehabilitation. Using a Physical Therapist contact at a rehabilitation clinic in Atlanta, GA, snowball sampling was employed for the observational study. The Participatory Ideation Workshop, Phase 1F, included 6 participants over the age of 18, with experience with knee rehabilitation. Again, snowball sampling methods were used to recruit participants. Lastly, the Final Idea Feedback Session was broken into two segments, Phases 4A and 4B. The first segment utilized 3 persons of legal age using random recruitment techniques on Georgia Tech's campus. The second feedback session was conducted with 1 patient and 1 physical therapist from the prior observational session and 1 additional physical therapist from the same rehabilitation clinic used during the observational studies.

INCLUSION & EXCLUSION CRITERIA

Only persons of legal age of consent, 18 years of age and older, were eligible to participate. Additionally, physical therapists and participants with previous experience with knee rehabilitation were shown preference over participants without.

PHASE 1: UNDERSTAND AND DEFINE RESEARCH

The objective of the Understand Phase was to empathize with the target users. Good designs have a strong foundation built around knowing the needs of the user and, by engaging with users directly, researchers are able to uncover new insight into human behavior (d.School, 2013). The purpose of the Define Phase was to synthesize the findings from the Understand Phase and provide a design direction for the Ideation Phase.

PHASE 1A: LITERATURE REVIEW & PHASE 1B: MARKET ANALYSIS

Literature and market reviews are essential to understanding existing academic research and successful products out on the market. Literature reviews are intended to synthesize notable research conducted in the field, while market reviews analyze successful and unsuccessful products. The market analyses provided both a systematic review of the products and a value chart based upon key product features that define success.

PHASE 1C: EXPERT INTERVIEWS

First, semi-structured expert interviews were conducted with Physical Therapists, Applied Physiologists, and TKR patients. The goals of the interviews were to learn more about the process of rehabilitation, how it has changed throughout the years, and to understand what the stakeholders envisioned for the future. The interviews followed the format outlined by IDEO (2013), and highlighted 3 areas: open specific, go broad, and probe deep. By opening with easy, specific questions, this method quickly generates a rapport that allows researchers to ask about larger system-based questions, and eventually delve deeper into innovation challenges and potential concepts.

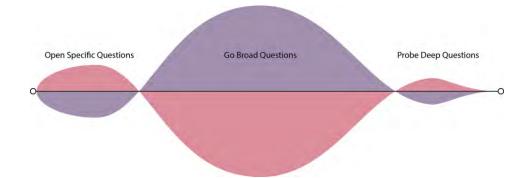


Figure 20: Interview Structure Outlined by IDEO

Not only is there a difference between what people say and what they do, but Carrillo (Carrillo, 2000) found that dialogues across different fields and, more importantly, within the same field, are more robust when engaged as a group, and shift the dialogues from assumption to reflection, and from individuals to the collective. This study also included ethnographic research methods such as observation and a participatory design workshop to engage the collective and reflect on their experiences.

PHASE 1D: OBSERVATION

Observational techniques, such as Shadowing and Directed Storytelling, were used in the study. Shadowing is a tool where the researcher shadows the users or stakeholders. This tool provides insight into a participant's activities and decision patterns, and is an exploratory research method conducted to gain a true sense of the user's actions, decision patterns, and routines. Directed storytelling is a method used to easily gather rich stories of lived experiences from participants. It is rooted in the social science method of narrative inquiry. Directed storytelling was leveraged for two reasons. The first was to trigger conversations between the researcher, the user, and their Physical Therapist for analysis and feedback on the overall rehabilitation process (Salvador & Howells, 1998; Sato & Salvador, 1999). Secondly, it was used to understand product and

service opportunities that were lacking or needing improvement (Brandt & Grunnet, 2000; Lafreniere, 1996; E. B. N. Sanders, 2000).

PHASE 1E: INITIAL SKETCHING

Using the information gathered, early concepts were sketched out in order to get an idea of potential directions for future work.

PHASE 1F: PARTICIPATORY IDEATION WORKSHOP

Participatory design is a rising research method for product development and human computer interaction. Its value stems from examining the "third space", or region of overlap between researchers and product end-users. By engaging both end-users and designers, this method blends their collective knowledge into new insights and plans for action (Muller, 2003). A variety of techniques to encourage the "third space" are available, such as workshops, and were utilized within this study.

Two well-known formats for these workshops are the Future Workshop (Bødker, Kensing, & Simonsen, 2004; Kensing & Madsen, 1992), where participants "critique the present, envision the future, and develop their ideas" as a group, and Sander's conceptual "say-do-make", where participants use "generative tools" to explore past experiences and what they envision for the future (E. N. Sanders, 2006; E. B. N. Sanders, 2000). Leveraging these two frameworks, this study used four tools to explore the present and future for a better rehabilitation product (see APPENDIX D).

). First, a "mind map" technique is a word association tool that was used both as a primer, to engage participants in the workshop, and used to understand how different stakeholders perceived the current state of rehabilitation by using central themes

identified from ethnographic research. Secondly, a creative matrix was used to promote divergent thinking. By juxtaposing categories related to stakeholders with categories related to possible, future solutions, a large number of ideas are created that are related to different product aspects. This creative matrix was coupled with a technique called the Kano Analysis, whereby the participants are asked to categorize the concepts and attributes as either a required, desired, exciting, neutral, or an anti-feature. The Kano Analysis was done to understand the positive and negative features of the future product. Lastly, the workshop ended with a design and build activity using physical materials as a way for participants to explore features that would enhance the rehabilitation experience using eTextiles.

PHASE 2: IDEATE

The goal of this phase was to generate a wide variety of concepts (d.School, 2013). The Ideation Phase for this study utilized an iterative approach. Leveraging tools such as image boards, trending, style boards, and competitive analyses, ideation from sketching through final prototypes were built.

PHASE 2A: STORYBOARDS

Storyboards were used to visually narrate scenarios for which a product will be used. The illustration of these narratives, allowed for researchers to build up empathy with their users and map out design solutions for them (Hanington & Martin, 2012).

PHASE 2B: PROTOTYPING TECHNOLOGY

A proof-of-concept prototype was leveraged to understand and ensure that the technology would work consistently.

PHASE 2C: INSPIRATION BOARDS

To develop the product further, inspiration boards, or image boards, were developed. Image boards are an image collection method used to visually communicate aesthetics, style, audience, context, etc. In this study, a collage method was used to define various aesthetic directions for the study (Hanington & Martin, 2012).

PHASE 2D: DESIGN SKETCHES

Sketches provided a visual inquiry into the aesthetic and functional possibilities for the final product direction.

PHASE 2E: CROWDSOURCING

Crowdsourcing is a technique leveraging a large group of people to complete a task provided by the researcher (Hanington & Martin, 2012). In this study, crowdsourcing was used to narrow down the thumbnail sketches conceptualized in Phase 2C and provide a direction for prototyping.

PHASE 3: BUILD

The aim of the Build Phase was to move from a more two-dimensional drawing phase to the physical realm where it is easier to "learn, solve disagreements, start conversations, fail quickly and cheaply, and manage the solution-building process" (d.School, 2013).

PHASE 3A: FUNCTIONAL & AESTHETIC PROTOTYPING

Prototyping allowed for the physical realization of a concept or idea. Further refinement of the previous exploration in Phase 2B was conducted, while an analysis of alternative methods for tracking rehabilitation in the home was also done.

PHASE 3B: FINAL DEVELOPMENT

A final direction for the project was established. Final development consisted of a male and female version of the product.

PHASE 4: EVALUATE

Evaluation is a great way to refine the design, make those designs better, and learn more about how the user would interact with the solution (d.School, 2013).

PHASE 4A: QUESTIONNAIRE

Feedback allowed for researchers to evaluate the social acceptability and the wearability of the product. In the first phase, a semi-structured interview and questionnaire was conducted to understand how the user's initial perception of the product changed over time. A questionnaire was used to determine the change in perception, as the user learned more about the product. Meanwhile, the participants provided feedback on how they would use it.

PHASE 4B: FEEDBACK FROM PHYSICAL THERAPISTS & PATIENTS

Additional feedback for further development was retrieved from physical therapists and patients used during the expert interviews and observations.

CHAPTER 4

RESULTS

This section explains the results of the expert interviews, the observations, the Participatory Ideation Workshop, and the Build and Evaluate Phases of the study. The next sections explain in detail the results of each method.

PHASE 1: UNDERSTAND & DEFINE

PHASE 1C: EXPERT INTERVIEWS

A total of 6 expert interviews were conducted to discover the sentiments that surrounded rehabilitation and potential opportunities that existed (see Figure 21). Major findings for the expert interviews were compiled with the observational analyses. See APPENDIX D for the transcripts.



Figure 21: Questions used during the Expert Interviews

Expert Interview 1

Dr. Mindy Millard-Stafford is an Applied Physiology Professor at the Georgia Institute of Technology. Dr. Millard-Stafford provided an overview of physical therapy before offering insightful directions for the project.

Resistance training and balance exercises are the two main parts of knee rehabilitation. The earlier you start rehabilitation after surgery, the better your range of motion will be afterwards. There are different types of knee rehabilitation devices, but the better ones provide feedback on your range of motion.

Isokinetic devices, such as the ones produced by Kin-Com and Cybex, are typically used during rehabilitation because they quantify and validate the amount of movement by testing knee motion and the forces. They also bend the knee to the degree specified by the physical therapist, therefore ensuring proper rehabilitation results.

Following, she provided a few areas for further research.

Compression stockings

Dr. Millard-Stafford suggested the integration of the sensors into compression hose. Older adults typically use compression hose because they are known to prevent blood clotting.

She also talked about the high instance of hip surgeries and potential areas of concern, such as the importance of hip and knee alignments. The possibility of integrating a means to detect ankle alignment in respect to the knee is important for the older generation because it ensures that other surgeries have been done properly.

Stimulation

Dr. Millard-Stafford suggested integrating a stimulation device to enhance physical therapy. It isn't just about the quantity, but also about the quality of rehabilitation. Stimulation provides better rehabilitation. She suggested stimulating the Vastis Medialis, the muscle next to the patella that helps control bending, might be beneficial.

Perceived vs. Actual rehabilitation

Dr. Millard-Stafford directed me to ask questions regarding whether the warmth provided in the knitted structure would provide a better-perceived rehabilitation experience, as opposed to the traditional one. She also postulated whether this allowed the user to do more movement, and how a device such as this would this affect the pain scale?

Expert Interview 2

Gretchen Schmaltz is a licensed physical therapist and the coordinator for the physical therapists at a local rehabilitation clinic. After providing a rundown of the facilities and the timeline of the process, Ms. Schmaltz talked about the importance of range of motion within therapy and patient accountability during rehabilitation. Physical therapists often know when patients do not perform their rehabilitation at home and often get frustrated when the patient does not perform it properly. When the patient gets to the facility, their range of motion is approximately 90 degrees and, typically, their goal is to get to 110 degrees. In the beginning of rehabilitation, they use the other knee as a baseline for the range of motion.

Expert Interviews 3 & 4

Interviews were also conducted with two additional physical therapists. They stated that the majority of patients are arthritic patients or ones who have pain, but Patella femoral syndrome is another big reason people have surgery. Furthermore, the two biggest problems people face after knee surgery are having to go back to the hospital for a manipulation or an infection. Rehabilitation is painful for many reasons, however, it's primarily painful because the scar runs right over where you're stretching. Initially after surgery, patients will receive a brace, but both patients and physical therapists discard them because they're not useful and because they limit the range of motion.

Potential opportunities for devices were discussed, such as vibratory feedback. They said it was probably more important to activate the Vastis Medialis instead of the muscle next to the knee. Because the brace limits range of motion, physical therapists are wary of anything that goes over the knee and suggest using two Velcro straps above and below the knee. They offer that using Velcro straps allows the technology to be passed from one patient to the next, while the Velcro can be disposed of. All three therapists confirmed that placement of the sensors is incredibly important and the accelerometers would have to dissect the leg in order to get a proper reading of the degree.

Expert Interviews 5 & 6

Interviews using directed storytelling techniques were also conducted with patients at the facility to better understand their experiences and their needs.

<u>Patient 1</u>

P1 had undergone surgery 4 months prior. P1 recently (1 month ago) had to have a manipulation done to the previous surgery because P1 accumulated an infection in the knee and it had to be remedied. The cause of this was due to failing to perform rehab after surgery. P1 said that it was scary to go through surgery and rehabilitation, and that it was easier to go through it the second time because P1 knew what to expect. During the rehab, P1 spoke about how hard it is to go through rehab, how P1 cheats at rehab when P1 is at home, and yet the physical therapists are really encouraging when going through it. "It's really painful, but they motivate you to push you further."

Patient 2

P2 had the surgery done on Dec. 31, 2012 and was hopefully in the last month of therapy. P2 had the other knee done 4 years prior and knew what to expect when going through it this time. Although P2 was impressed at how much better the technology had gotten. For the first knee replacement, P2 had gone to a class at the hospital that walked future patients through all the steps. The process for P2 was a stay in the hospital for 3 days after the surgery and then P2 went straight to the aforementioned rehabilitation clinic. After being there for a few weeks, P2 went home and a therapist came to see P2 2-3x a week for about 10-12 sessions. P2 said that the CPM machine was really beneficial, except that it left their knee very bruised afterwards.

When asked about what P2 thought the tool might use to motivate P2, P2 responded with "When you see you're making progress, that's motivation. It would be good, though, to know how far away you are from the end goal."

In terms of a user interface for patients, write everything down on a 5th grade level, not too simple, but simple enough. Use photos of exercises and provide information on what the different exercises will get you. ("This exercise would help me achieve three

degrees", "this exercise will make the hamstring stronger") The goal is to walk you through the exercises like a therapist would.

PHASE 1D: OBSERVATION

Observation was also conducted to see how patients and Physical Therapists interacted. Five individuals were recruited for this phase, 3 Physical Therapists and 2 patients. The study was conducted in two-hour blocks for each patient, where the patient underwent 1 hour to 1.5-hour physical therapy sessions. The major findings that came out of the observation were:

- 1. Rehab is slow. Not only is it an arduous process to go through, but the physical act of movement is slow.
- 2. Rehab is hard. Without the physical therapist present, users have a tendency to forego their rehab at home.
- 3. There is a disconnection between Health Professionals and Patients. Not only is there a lack of communication between them, but also there is a lack of tools and rehabilitation aids for patients.

ANALYSIS OF THE OBSERVATIONS AND INTERVIEWS

Different methods were utilized in order to conduct the analysis of observations and interviews. These included an AEIOU, an affinity map, and an ELITO analysis. The next sections explain in detail of each one of the methods and analysis.

<u>AEIOU</u>

AEIOU is a method of analysis that documents and codes information under a guiding classification systems of Activities, Environments, Interactions, Objects, and Users (AEIOU) (see Figure 22). The interrelated nature of the documentation forces the

researcher to observe situations through different lenses. The advantage of using AEIOU is that it allows for structured synthesis in the future, such as using the ELITO method. The AEIOU allowed for documentation of both process and tools, and ensured a more thorough Affinity Map.

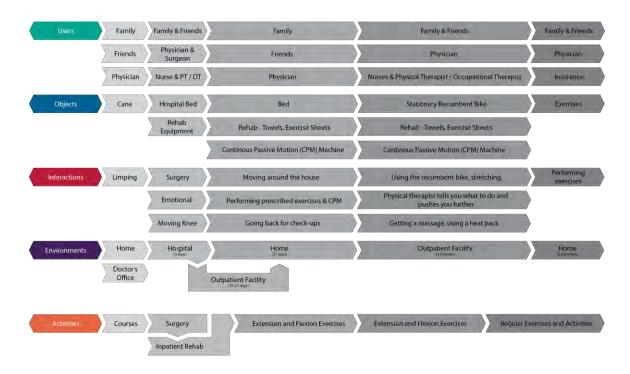


Figure 22: Observational Analysis: AEIOU

The AEIOU documented (see Figure 23):

- The experience that users undertake when going through rehabilitation and the timeline consisted of:
 - Patients are in the hospital for 3 days
 - If patients are healing well, they get to go home for 21 days and have a visiting physical therapist come in to help with rehabilitation. If the

patient is not healing properly, they go to an outpatient facility for 10 - 21 days, and then move home.

- After home rehabilitation, the patient has to go to an outpatient facility for 4-6 weeks, or until they achieve 90 degrees of bend.
- The stakeholders are involved in the process are:
 - Family and friends oversee the entire process
 - Physicians meet with the patient once a month
 - The physical therapists meets with users 2- 3 times a week during rehabilitation.
- Stretching and flexion / extension exercises performed during rehabilitation consist, but are not limited to:
 - o Biking
 - Stair climbing
 - Using towels and sheets to help stretch the joint.
- The patients are exposed to a colorful environment in order to help build morale.

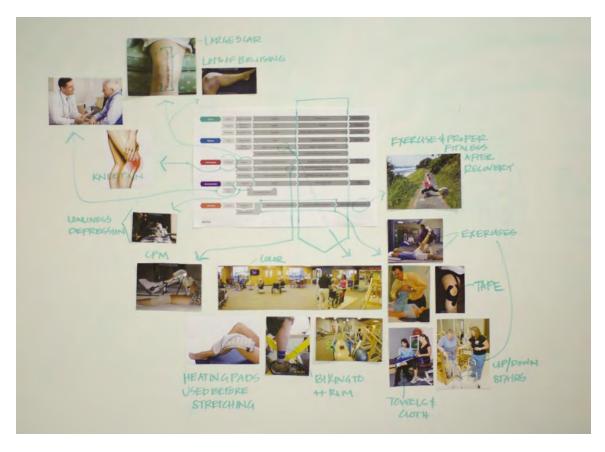


Figure 23: Observational Analysis: AEIOU Pictorial Analysis

Affinity Maps

Using Affinity Maps, two chief directions emerged from the observational studies. First, the Affinity Map was organized based upon consistent themes that arose during the observation. These themes can be found in Figure 24 and are:

- 1. Physical therapy is difficult to properly be performed at home, is typically neglected, and often leads to surgical manipulations or infection in the future.
- 2. The role of the Physical Therapist is both an educator and a motivator.
- 3. The various tools used in the rehabilitation center.

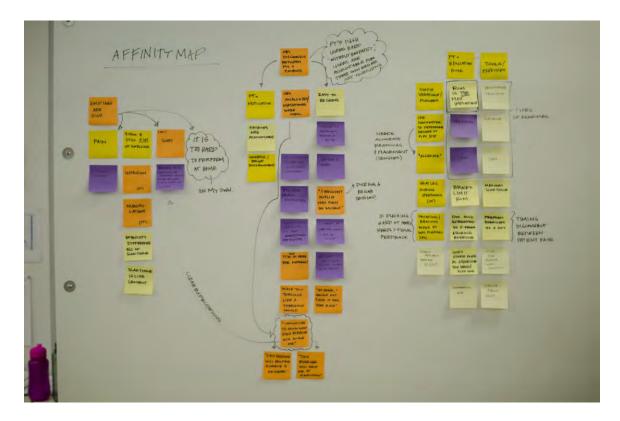


Figure 24: Observational Analysis: Existing research in knee sensing

Key observations using Figure 24 concluded that, despite understanding that they were being held fully accountable for their rehabilitation, the patients felt it was "too hard" to perform proper rehabilitation, which was performed 3 times daily for 15 to 30 minutes in the home and often led to regression in their rehabilitation at home. APPENDIX C provides a list of exercises to be performed in the home. Despite patient problems, physical therapists often responded in direct correlation to the amount of effort the patient wanted to put in - e.g. the more a patient pushed themselves, the more the physical therapist pushed the patient. Attitude about rehabilitation was very important.

The process of rehabilitation typically started with a heating pad being used during stretching. In order to make up for the regression, physical therapists would slowly build up the exercises during their sessions to push the patient to their limit, which often led to the patients closing their eyes throughout and bracing themselves while the physical therapist worked on their knee. Additionally, simple language, analogies, and metaphors were frequently used to encourage patients. A patient's progress was determined using a goniometer to measure the degree of flexion and extension of the knee. The placement of the goniometer was crucial to determining the angle, as it bisected the leg.

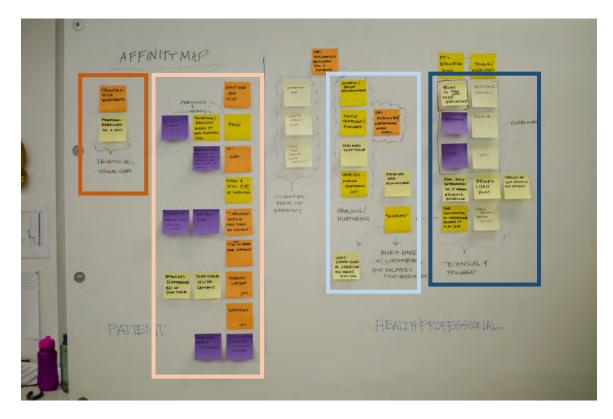


Figure 25: Observational Analysis: Patient / Physical Therapist Disconnection

Additionally, rehab is very emotional. The Affinity Map was re-arranged to show the disconnection between the technology-centric Physical Therapist and the emotioncentric patient. The darker orange (see Figure 25) corresponds to the amount of technology available for the patient to use in the home, while the dark blue outlines the technology provided at the rehabilitation clinic. Additionally, the light orange refers to the emotions that the patients consistently brought up during the rehabilitation session, while the light blue outlines the tools used by the physical therapists to mediate those emotions. Figure 25 clearly shows the difference in technology between patient and physical therapist and show how under-prepared physical therapists are to handle the patient emotionally and physically.

ELITO Analysis

To show clear connections between future design directions and observations, the ELITO method of analysis was utilized. By consolidating the key findings into a spreadsheet and organizing them by Observation, Judgments, Values, and Key Metaphors, concepts are developed in a linear fashion to those findings (see Figure 26).

Major concepts that emerged were to track both flexion and extension of the knee and the degree to which it was extended. Additionally, emotional support, feedback loops for pain management, and friendly patient competition would help promote adherence. Other features to consider were the integration of heat packs into the device.

Key Metaphor	Observation	Judgment	Value	Concept	URCULAR FEEDBACK
the second s				The second second second	PATIENT
Communication is	Disconnect between	Technical side is lost	Provide patient	Something on the knee that will	XXX
key	physical therapists and patients	from the patient's	tracking; provide feedback as to	provide feedback for	1 4 +
	and patients	perspective	whether they've	tech side	DT DT
			and the second se	tech side	PHTSICIAN PT
			reached a certain		R
Calm down	Emotions are high	What can be done to	degree	is there a way to	
Caim down	Emotions are high	manage these?	Managing these for motivation;	Is there a way to manage these	LUKED INTERGATE ALLANS
		manage theser	nurturing; tracking;	emotions and funnel	FOR PAIN TRACKING
			pain management;	them into their	/ FOR PAIN TRACKING
			overview of steps	rehab?	a brief of the the start of the
	It's really hard to	"I wouldn't inflict this		Visual feedback	
	perform rehab at	pain on myself"	, ceoback	mechanisms when	
	home	point on mysen		hit goal	
Keep it simple	Analogies and	Positive	Provide information	Use images when	
acch it simple	metaphors work	reinforcement	on what they're	necessary, and brief	
	really well; simple		going to get out of	descriptions	
	language		each exercise;		
	0.0		pictures of exercises;		
			give them		
	a constraint and	1	descriptions of what		
	BTHAND		will go on		
More accurate!	Goniometer usage is			Accelerometers; Flex	
Possibly	"accurate"	1.00.00	100	Sensors	
Provides for the	Heat leg during			Allow for a heat pack	
whole process	stretching			to be put in;	
				Leverage heat	
				generated by	
			1	electronics	
Real feedback	Squinting / bracing	Needs alternative		Audible feedback	
	while the PT was	feedback	1	when goal is hit; can	
	pushing leg	Call Mar Mar ann		turn it on / off	
ROM!		ROM is the most			
		important thing	1		
baseline		Uses other knee as a	T	Configure brace	
		baseline for		based off of other	
		bend/flex goal		leg's flex/ext	IL I - WITCHE
	Braces don't allow	Braces limit ROM; I	1	Don't have to pull on	HOW TO INTEGRATE
	for flexion	wonder if this is a	6	a brace	INTO OTHER DEVICES OR
		neurological thing?			WEARABLES?
	PTs push the	PTs are really		Maybe PTs can check	Contraction of the
	patients, but the	motivating		up on patients and	
	patients can't push			provide positive	FEEDER BALK TO
	themselves		11. 25.	feedback? Maybe it	FEEDS BACK TO
				pings PT when a	PATIENT
				patient is doing well?	
		1 - 1 - 1 - 1	1	And when they're	
		Destaura autoria a		not	
		Perform exercises 3x	1 · · · · · · · · · · · · · · · · · · ·	Daily wear	
	Managing of ticeurs	a day Scar tissue build-up		Add in something to	
	Massaging of tissue	leads to a	1	help massage tissue	
	1	manipulation		below knee	
	Patient pays for	How do we make this	Inexpensive for	Patient rents out	
	every new tool the	cost effective?	patient	tech	
	doctor prescribes	cost enectiver	patient	tech	
Helps with rebab	doctor prescribes	Stimulation of vastis		Use vibe motor to	
Helps with rehab	1	medialis		stimulate muscle	
	-	Compression		Use compression	
		stockings aid in		stockings	
		recovery		Stockings	
		recovery			

Figure 26: Observational Analysis: ELITO Analysis

PHASE 1E: INITIAL SKETCHING

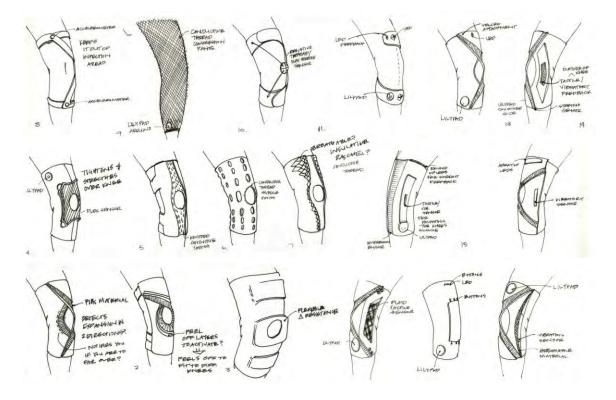


Figure 27: Preliminary Sketches

Preliminary sketches were created at the beginning of the project. Early sketches (see Figure 27) explored athletic variations of a knee sleeve using various technologies. Most sketches exposed the kneecap, using it as a point of reference for user placement. A few other concepts looked into integrating the sensors into common clothing, such as tights, while others looked at simple ways, such as multiple straps, to avoid the scar tissue in the area.

PHASE 1F: PARTICIPATORY IDEATION WORKSHOP

The goal of the participatory design workshop was to understand the needs of the users through the evaluation and design of a feedback device (see APPENDIX D). Six people familiar with rehabilitation were recruited for the participatory design workshop,

three females and three males, from a variety of different backgrounds. Table 1 showcases the demographics of the participants involved.

	Gender	Occupation	Age	Injury
1	М	Product Designer	>40	MCL Tear and Rehab, Both Knees
2	F	Architecture Student	<40	Broken Wrist, Rehab
3	F	Architecture Student	<40	ACL, MCL Patellar Tear and Rehab
4	F	Homemaker	>40	Knee Pain
5	М	Architect	>40	Knee, Ankle - Currently in Rehab
6	М	Senior Research Engineer	>40	MCL Injury, Rehab

Table 1: Workshop Participant Demographics

ANALYSIS OF PARTICIPATORY IDEATION WORKSHOP

Key findings from the workshop focused around invisibility and moving the product away from appearing as a technology product. Results from the mind map showed that people view rehabilitation as this arduous, uncomfortable, expensive, yet required process. In contrast, wearable products were supposed to be comfortable, light, and breathable, but they had to be careful as to not be itchy, heavy, or difficult to put on or take off. Moreover, technology was perceived as confusing, modern, bionic, advanced, complicated, and even expensive.

While the mind map was slightly abstract, the KANO analysis provided a clear set of features for the product. Users required features such as invisibility and reliability, while comfort and colors were considered desirable. Interestingly, audible feedback and reminders to perform rehabilitation were considered anti-features (see Table 2). Additionally, one thing in particular stood out in the KANO analysis. In section two, one participant wrote down habit-forming as a desired feature, yet two others ranked it as an anti-feature.

Required Features	Invisible, Reliable, Tracking, Customizable, and Easy to Use			
	Fits under Clothes, USB Capable, Tracking, Variety of Colors,			
Desired Features	Neutral Colors, Modern, and Not Geeky			
Exciter / Delighter	Comfortable, Washable, Have a Long Battery Life, and FUN			
Neutral Features	None			
	Noise, No Immediate Feedback and Tracking, and Reminders to			
Anti-Features	Perform Rehab			

Table 2: Product Ideation Workshop: KANO Analysis

During the design and build phase of the workshop, participants had a chance to propose new ideas. Most participants developed products that were hidden in everyday wearable products, such as belt loops, socks, jean seams, and kinesthetic tape. The participants additionally provided a wide range of technologies to be considered, such as multiple accelerometers, microwaves, sonar, IR, and stretch sensors.



Figure 28: Product Ideation Workshop: Mindmapping



Figure 29: Product Ideation Workshop: Kano Analysis



Figure 30: Product Ideation Workshop: Accelerometer-based System Designed by a Participant

PHASE 2: IDEATE

The Ideation phase generated over 100 concepts and narrowed the options down to 3 male and female directions.

PHASE 2A: STORYBOARDS

The storyboards introduced different product directions considered for further development. Looking at how users might interact with the system as a whole provided insight into features imperative for prototyping the technology.

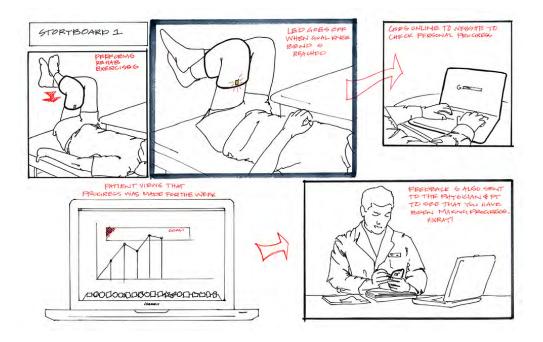


Figure 31: Storyboard 1: LED Feedback with Online Patient Tracking Storyboard 1 focused on having the users perform rehabilitation, tracking it

online, with the intent of having the physician or physical therapist review it later.

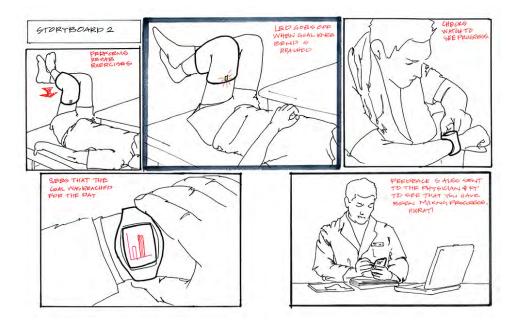


Figure 32: Storyboard 2: LED Feedback with Patient Tracking Watch

Storyboard 2 integrated user feedback into a watch. The idea was to incorporate the feedback mechanism into an item the user might wear normally.

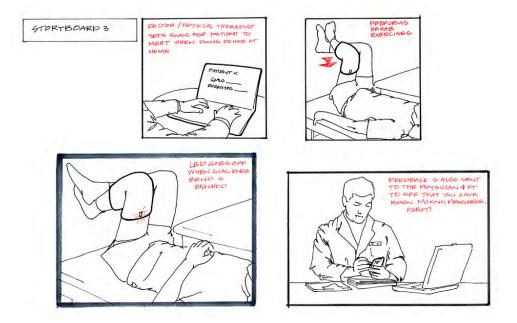


Figure 33: Storyboard 3: PT Input with LED Feedback for User

Storyboard 3 leveraged physical therapists to provide goals for patients to achieve. This shifted the tracking device from the user to the physical therapist.

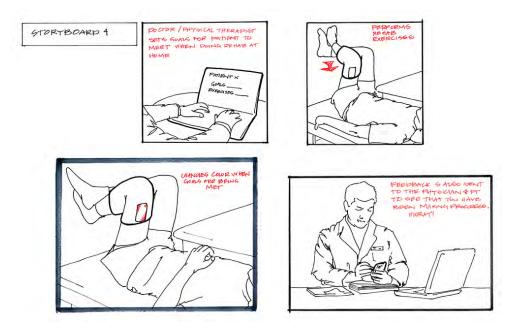


Figure 34: Storyboard 4 PT Input with Basic User Interface on Sleeve

Similarly, Storyboard 4 moves the goals to the physical therapist, but the user has a color-changing feedback interface.



Figure 35: Storyboard 4 PT Input with Complete User Interface on Sleeve

Storyboard 4 integrates a user interface into the brace so that the user can view the next exercise to be performed and see their progress.

PHASE 2B: PROTOTYPING TECHNOLOGY

Before further development, different methods for tracking flexion and extension were tested, such as knitted stretch sensors and accelerometers. However, as shown in Figure 36, there were a series of functions the device needed to perform.

Figure 36 shows the three methods that were explored to detect flexion and extension: accelerometers, stretch sensors, and conductive pleats. Early explorations were developed in conjunction with Georgia Tech courses. The first utilized two accelerometers on the outside of the leg, storing the information in a MicroSD card, and having the user upload their information to their computer. The second method attached the knitted stretch sensor to a neoprene knee brace, communicated the information via Bluetooth, and analyzed the data online. Lastly, the final method utilized conductive knife pleats on the back of the knee, and transmitted the information via Bluetooth, stored the information on a MicroSD card, and analyzed the data online.



Figure 36: Technology Processes for the Final Product

Method 1 – Dual Accelerometers

Research into the use of dual accelerometers was conducted in collaboration with Georgia Tech students in the Mobile and Ubiquitous Computing course taught by Professor Clint Zeagler, Dr. Gregory Abowd, and Dr. Thad Starner in the spring of 2013. The use of dual accelerometers was disregarded in this particular study due to the slow and spasmodic nature of rehabilitation, which produced false positives when collecting data from the Lilypad accelerometers. Further development is being continued by the project group.

Method 2 – Knitted Stretch Sensors

Knitted stretch sensors are not a new field, but instead of using conductive yarns, this method knitted conductive threads in with the wool yarn. This research was conducted during Wearable Product Design course project taught by Professor Clint Zeagler in the fall of 2012. As shown in Figure 37, the brace consisted of the knitted stretch sensor, the Lilypad Arduino, and the LED as a feedback mechanism for reaching a specific degree of bend. Figure 38 shows that as the knit stretches over the knee, the voltage decreases, allowing for detection of extension and flexion. Kirchhoff's Law (voltage = current * resistance) dictates that voltage and resistance are proportional, therefore as the resistance in the stretch sensor increases, so will the voltage.

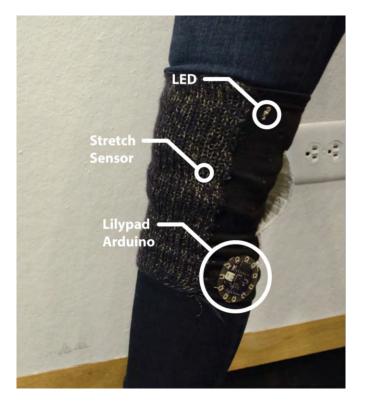


Figure 37: Prototype of the Knitted Stretch Sensor

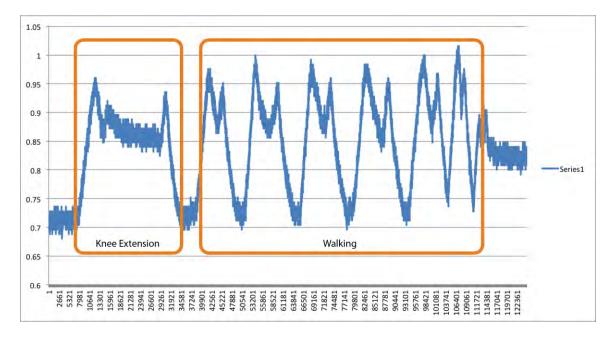


Figure 38: Voltage over Time

Additionally, further studies into felting (see Figure 39) and rib knits (see Figure 40) was conducted. What the research found during felting, was that the resistance correlated to the size of the piece, rather than reducing or increasing resistance after being washed.

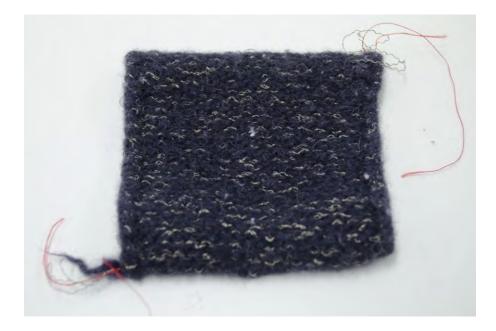


Figure 39: Felting the Conductive Knit



Figure 40: Ribbed Conductive Knit

Method 3 – Conductive Pleats

Design explorations into the use of conductive pleats were also performed. Conductive ink was screen printed onto the fabric and then the fabric was ironed and sewn into knife pleats on the back of the knee brace. As the knee bent, the conductive ink would touch and change the resistance, allowing for the detection of exercises. The research was disregarded because it did not perform as well as the knitted stretch sensor.

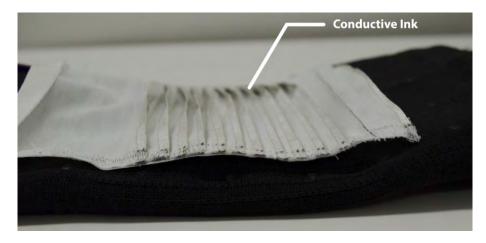


Figure 41: Screen Printed Conductive Knife Pleats

PHASE 2C: INSPIRATION BOARDS

As part of the Ideate Phase, inspiration boards were developed. A look into 26 different fashion houses and athletic industries provided insight and direction for development (see Figure 42 and Appendix E). Fashion shows debut semi-annually, during the Paris and New York Fashion Weeks. Fashion shows can typically be broken into Pre-Fall, Couture, Ready-to-Wear, Resort, and Menswear. These inspiration boards were created to understand the details and features that were considered fashionable in the industry, such as beaded edges, knitted textiles and clasps. Social acceptability separates between gender, so where possible, the boards separated the details between male and female trends. These inspiration boards studied spring and fall's 2013 Ready-to-Wear collections.



Figure 42: Example of Inspiration Boards, Diesel Fashion

DIESEL

Additionally, fall and spring colors established by Pantone were collected to

establish a baseline for future color choices (see Figure 43).

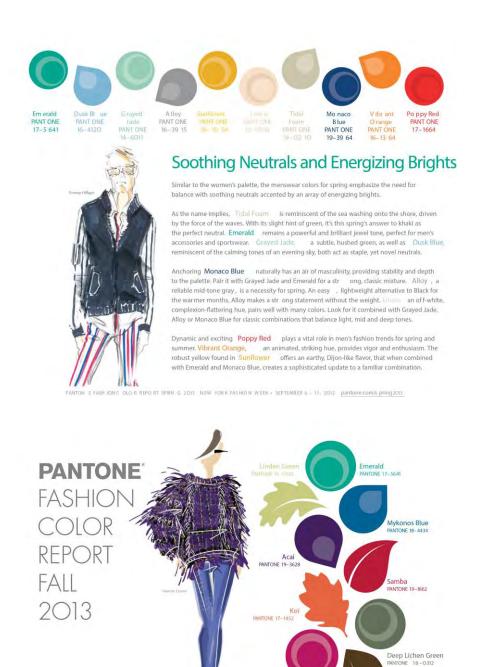


Figure 43: Men and Women's Pantone Colors

NEW YORK FA SHIO N WEEK + FEBRUARY 7 - 14, 2 013 pantone.com/f all 2013

Vivacious

Carafe PANTONE 19-1116

Turbulence

PHASE 2D: DESIGN SKETCHES

Sketches were developed based off of the inspiration boards. By working through the inspiration boards, details were collected and integrated into a wearable tracking device. The fashion sketches show what houses they were connected to. 120 sketches were created, 37 male and 83 female sketches. These sketches reflected styles such the romantic aesthetic put forth by Chanel and the street savvy chic Diesel and Tom Ford. Details familiar to each fashion house, such as buttons, clasps and layered materials were explored throughout this phase.

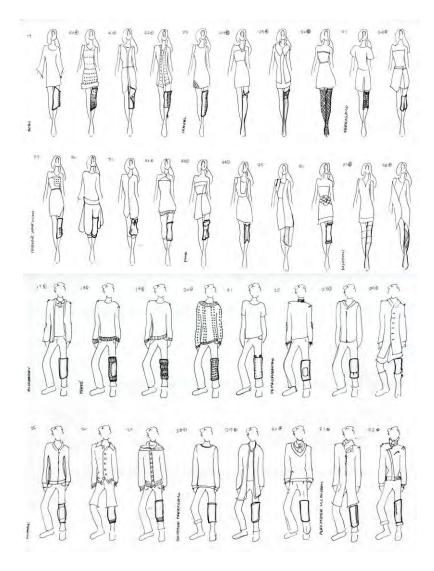


Figure 44: Design Sketches from Fashion Houses

PHASE 2E: CROWDSOURCING

Following the design sketches, there was a need to narrow the designs down for refinement. Crowdsourcing was leveraged to narrow down the 120 sketches created. The design sketches were posted in a high traffic area within Georgia Institute of Technology's Architecture Building with a note describing the purpose of the study and opportunities for participation. Students and professionals within the architecture building were used as design experts in this study. Post-It tags were provided for the students to tag their 3 favorite male and female choices. 101 female sketches and 59 male sketches were tagged, accounting for 160 total responses. If each person tagged 6 sketches each, this would allow for 26.4 participant responses, however, upon observation, the majority of people tagged 2 or 3 sketches each, which approximates to 53 responders.

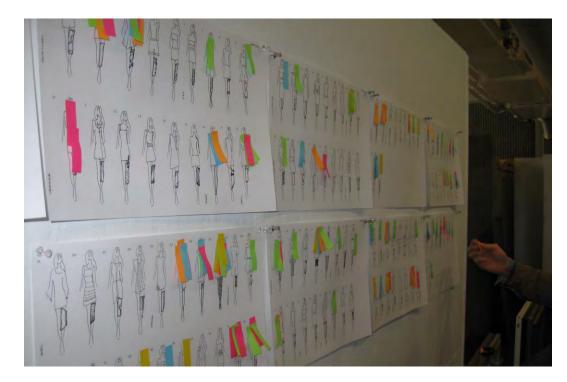


Figure 45: Crowdsourcing



Figure 46: Tagging the Sketches

<u>Analysis</u>

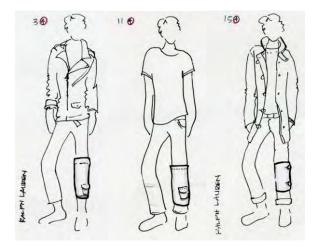


Figure 47: Top 3 Male Crowdsourced Choices

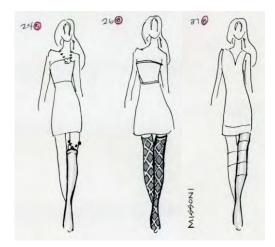


Figure 48: Top 3 Female Crowdsourced Choices

Crowdsourcing proved to be beneficial for narrowing the concepts down to several key design features. For female knee rehabilitation devices, participants found it more acceptable to integrate it into a product that covered the entire leg, such as leggings, pantyhose, and stockings. Female preferences were within the romantic and bohemian fashion houses of Chanel and Missoni (see Figure 48). On the other hand, male preferences showed an affinity for simple pieces similar to a knee brace, such as a lessconstricting knee brace with small pockets or a few buttons. Participants associated better with the male street style of Ralph Lauren and Diesel (see Figure 47).

PHASE 3: BUILD

PHASE 3A: FUNCTIONAL & AESTHETIC PROTOTYPING

After crowdsourcing the sketches, 4 prototype directions were developed. The prototypes incorporated feedback from the crowdsourcing and consolidated details for refinement. Talking to the Physical Therapists revealed two very important things for development:

- Physical Therapists will not support a knee brace device because it limits range of motion in the knee.
- The placement of sensors is incredibly important and changes the level of accuracy.

These two points influenced the design in several ways. First, the project looked at alternative ways to integrate the sensors since the physical therapists were opposed to a knee brace. Secondly, the project looked at how to maintain body / sensor orientation every time a user put the sleeve on. A variety of orientation strategies were considered, tilt sensors, accelerometers, etc., but it seemed easier to put the technology into a wearable device that forced the user to put it on the same way every time. Lastly, compression pants have a variety of benefits for recovery and the integration of the sensors into compression hose could be valuable (Born, Sperlich, & Holmberg, 2013). Inspiration for Detailing the Prototypes



Figure 49: Embroidery and English Smocking from AnthropologieTM



Figure 50: Inspiration from Vogue Patterns magazine



Figure 51: Knitted Patterns

While the initial inspiration boards were useful, the study looked into a variety of details, such as embroidery and English smocking, from Anthropologie and Vogue (see

Figure 49 and Figure 50). Additionally, dress and slouchy hat patterns were used to better understand the construction of those details (see Figure 51). The buttons also provided a method to easily integrate the sensor into everyday use.



Figure 52: Prototypes 1, 2, and 3

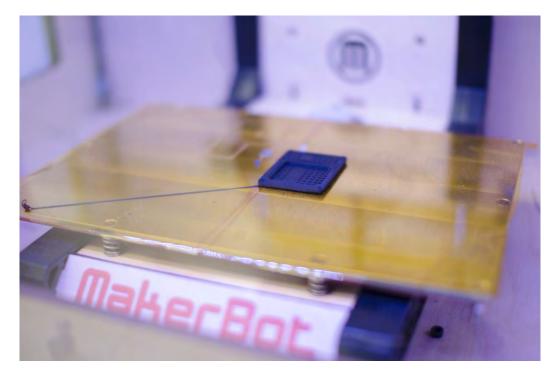


Figure 53: Prototype 4, Buttons to Encase the Arduino Components

Figure 52 showcases the prototypes developed. The first image showcases a knitted conductive swatch on a pair of stockings. This method appeared to be "tacked on", as opposed to fully integrated into the system. The second image integrated the sensor into an embroidered section. The third image was the initial exploration into a male version. The pattern did not provide a consistent method for each user, however.

Additionally, a swatch of different embroidery methods utilizing a variety of conductive threads was created for evaluation. Each pattern measured between 5.5" and 6" long. 'A' through 'D' utilized the feather stitch used in Figure 52 and used four different conductive threads with different resistances. 'E' and 'F' used the same conductive thread used in 'A' (see APPENDIX I), but 'E' used a flat embroidery stitch and 'F' used an open chain stitch.



Figure 54: Conductive Thread Embroidery Swatch

PHASE 3B: FINAL DEVELOPMENT

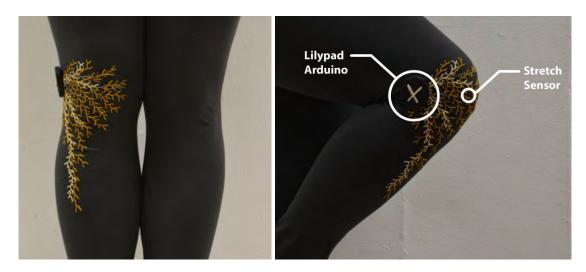


Figure 55: Female Final Prototype



Figure 56: Male Final Prototype

Ultimately, a technology platform for the sensor was developed. Using the change in resistance as a foundation for technology, a variety of methods and patterns can be used and provides customizability for the user. As long as the conductive thread runs over the kneecap, the change in resistance will occur.

The female pattern above evolved from the second prototype. There was a lot of visual information being provided and the goal was to scale it back. In an effort to do so,

the conductive thread follows the same pattern of the rest of the embroidery. The female version utilized an embroidery technique called a "feather stitch" to allow for stretching across the knee.

For the male version, more linear and geometric patterns were addressed. The male pattern took on this form due to its simplicity and utilized an open chain stitch that stretched across the knee.

PHASE 4: EVALUATE

Concept feedback was attained using two methods.

PHASE 4A: CONCEPT FEEDBACK

Table 3: Demographics

	Gender	Age	Occupation	Injury and Rehabilitation Experience
1	М	19	Student	None
2	F	22	Student	Ankle Wrapping, Shin Splints, Lower Back Stretches for Pain
3	М	30	PhD Student	Lower Back Pain

The first concept feedback was conducted at the Campus Recreation Center on Georgia Tech's campus. Three students were asked to inspect the device, put it on, and fill out a questionnaire. All the users knew how to appropriately put the device on, yet, except for knowing it was a pair of compression pants, none initially knew what the device did. Participant initial perceptions highlighted that the product was comfortable, unobtrusive and modern (see Figure 57). After filling out the questionnaire, the participants were informed as to what the device was and did. After learning about the function of the device, participant perceptions shifted to a rehabilitative device, but they still considered the device to be comfortable, while the technology remained invisible

(see Figure 58) – all of which were required features delineated during the Product

Ideation Workshop.



Figure 57: Top Three Words Describing the Product, Pre-Questionnaire



Figure 58: Top Three Words Describing the Product, Post-Questionnaire

Additional findings from the feedback sessions were that the device probably wouldn't be worn all day, however, they might wear it under their sweatpants. The participants were not concerned about having a technology device on their body and they would wear the device during rehab, especially if it tracked their movement because most found that it would help them perform better rehabilitation.

PHASE 4B: CONCEPT FEEDBACK

Additionally, feedback was requested from the physical therapists and patients from a local rehabilitation clinic.

Physical Therapist 1

PT1 was surprised by the prototype, expecting it to consist of a few straps. PT1 recommended integrating the product back into a sleeve, as long as it was a thin material and would stay up on the leg. PT1 suggested sewing the conductive thread in a circle to provide a point of reference for putting the device on.

When asked about using the conductive thread, PT1 didn't think a high level of accuracy could be attained due to differences in leg girth and length. Additionally, PT1 was concerned about detecting leg extensions and suggested sewing conductive thread on the back of the leg to detect the extension.

PT1 thought that the feedback could possibly be different between patients and physical therapist. While more accurate data for the patient would be optimal, it wouldn't, however, be bad if the patient were provided with ambiguous points of references for rehabilitation.

Patient 2

P2 liked the design and customization, but would have preferred if the product were a sleeve as opposed to a pair of compression pants. P2 stated that the pant leg is rolled up during rehabilitation, and it would be easy to just slide it on.

Physical Therapist 4

PT4 wanted the device to look more advanced – "the more advanced it looks, the better". PT4 recommended taking a look at Pro-Tec Athletics. PT4 also suggested trying to integrate the interface into a sleeve – "Patients don't want to look at a computer", but they do want the doctor to see their home rehabilitation.

PHASE 4C: TECHNOLOGY PERFORMANCE

Technology performance was studied to determine the validity of the final product. Embroidery methods A, for females, and F, for males, (see Figure 54) each used Silver-plated Nylon (see APPENDIX I for the data sheet), established the best resistance, and were used for final testing. The male and female versions showed a clear distinction between extension and flexion (see Figure 59 and Figure 60). The male version performed better, showing a larger gap between flexion and extension, between 2V and 4V, however there was a clear difference in the female version, between 3.5V and 4V.

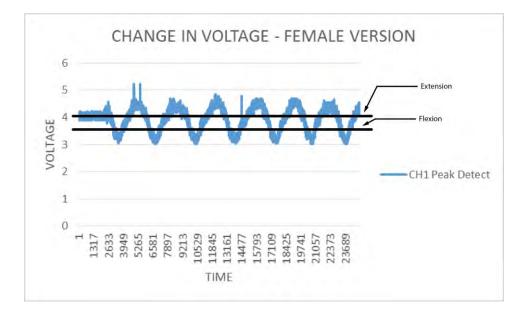


Figure 59: Change in Voltage - Female Version

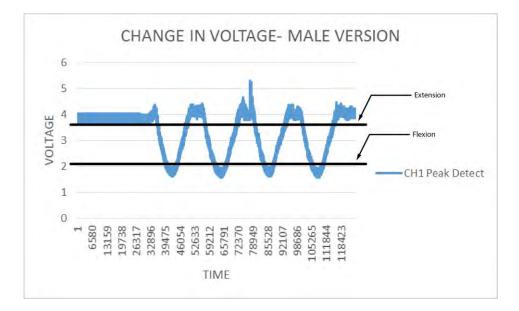


Figure 60: Change in Voltage – Male Version

Additionally, measurements were taken at 20 degree increments between 180 and 60 degrees, except for a 90 degree bend. The averages of each measurement were taken to provide a threshold for degree of bend (see

Figure **61** &

Figure 62). Again, the male version performed better, showing distinct gaps between 60,

80, 90, and 100 degree bends. The female version, however, shows clear distinctions

between degrees, but has a larger difference between the 80 and 90 degree movements.

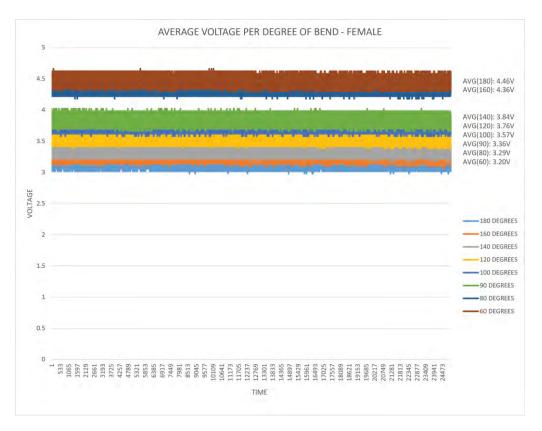


Figure 61: Average Voltage per Degree of Bend - Female Version

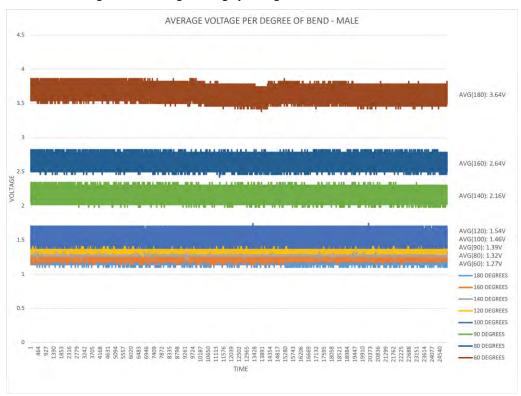


Figure 62: Average Voltage per Degree of Bend - Male Version

Furthermore, when measurements were taken every minute over a fifteen minute period, they remained consistent over time (see Figure 63 and Figure 64).

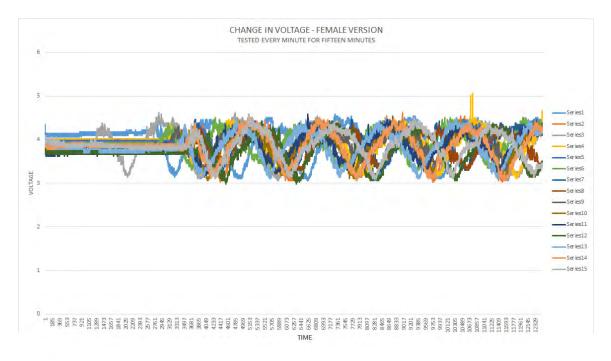


Figure 63: Change in Voltage – Female Version: Measurements were taken every minute for fifteen minutes

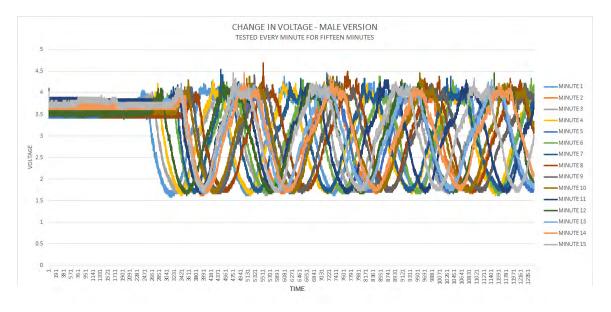


Figure 64: Change in Voltage – Male Version: Measurements were taken every minute for fifteen minutes

CHAPTER 5 DISCUSSION

LIMITATIONS OF THE STUDY

A major consideration for social acceptability and wearability are technology and fashion, however, these are subject to change over time and across cultures. Additionally, preferences change from person to person. The study tried to address the differences by establishing a technology platform to build the design off of, however, it is understood that these perceptions change.

Additionally, the study's observations, expert interviews, and feedback were all conducted at a single rehabilitation facility. Different facilities have different priorities and rehabilitation methods. The study tried to alleviate the bias in perspective by recruiting participants from outside the clinic for the Participatory Ideation Workshop. Ultimately, however, concept feedback for the advice was sought from the rehabilitation clinic and reintroduces their individual perspective. While this was the proper methodology for the project, the study recognizes that it would have been beneficial to include alternative rehabilitation clinics in the process.

On the flip side of this, the data was collected and analyzed by a single researcher. Multiple perspectives from research and industry were sought out to double check the integrity of the research, however, in doing so, the researcher understands how valuable additional perspectives are to the analysis of ethnographic research. Ideally, the integration of multiple perspectives throughout the process of observation and interviews would have been utilized to enhance the depth of research.

Furthermore, in the design of the device, important issues such as battery life, heat transfer, and security were thought of, but were not truly calculated for in the development of the product. The study focused more on understanding the social

acceptability and wearability of the device, and provided a good understanding of the technology. However, the expectation was that the technology would be able to scale down.

REFLECTION ON THE RESULTS

The data collected from the study was predominantly qualitative, yet the data was able to define a direction for future work. Expert Interviews and observations established the disconnection between health professionals and their patients and this study provided one method to help alleviate this.

The Product Ideation Workshop complemented and challenged the perspectives provided by the rehabilitation clinic. It provided great insight into what users truly wanted from a device, without the bias provided by the physical therapist. Interestingly, there was one thing that stood out from the workshop that needs reflection and that is the concept of habit-forming. One participant noted that a device that promoted habitforming was a desirable feature, yet two others noted that it would be an anti-feature. This feature can be construed in multiple ways. First, there is the performance of rehabilitation as a habit. Secondly, there is role of habitually performing rehabilitation properly. Lastly, using the device as a crutch or relying on the device to remind users to perform their rehabilitation can be considered habit. The first and the last options were considered anti-features, while participants encouraged the habitual performance of proper rehabilitation.

Moreover, the final feedback provided by the participants brought up a variety of issues. The most interesting was that a data model for the information provided to the user should be established. The information that physical therapists and users want to see might not be what the user necessarily needs. Physical therapists wanted their patients to have the most accurate data possible, however, the patient may respond better to more abstracted levels of rehabilitation feedback from their device.

SIGNIFICANCE

This study provides significant insight into the development of a socially acceptable and wearable knee rehabilitation device. Furthermore, it provides a solid basis for understanding user perceptions of what wearable technologies for knee rehabilitation should be.

Additionally, the Participatory Ideation Workshop provided novel and unique insight into hierarchal design criteria for a knee rehabilitation device.

FUTURE WORK

This study provides a wide variety of directions for future work. First, this study provided one way to design and develop a knee rehabilitation device. Other alternatives are encouraged, such as true sensor integration into textiles. Also, further development of this knee sleeve should be conducted. In particular, the integration of sensors into buttons and clasps are an area that could prove to be useful for successful integration into wearables. In addition, establishing more technical requirements for the technology platform needs to be delineated.

This research provides a basis for a longer, more comprehensive study into how the product would be used in situ over the course of a few months. A study, as such, would allow for researchers to understand how the tracking of rehabilitation in the home would influence the overall experience of rehabilitation and allow for more substantial data and insight into the user's experience.

Also, this study was the first part of a system of products designed to enable rehabilitation in the home. Development of a user interface for needs to be performed. Additionally, looking at various methods for the integration of user interface is important. Participants seemed to prefer methods that integrated the technology into the sleeve or other commonly used products during their experience, such as a watch or belt. Looking

into user interfaces that integrated themselves into the sleeve or into an application would prove to be beneficial.

Lastly, further research definitely requires that a data model for the user should be established. As discussed in the reflection of the results, research delving into what the most effective feedback method for patients looks like needs to be conducted. It is important to know what level of information users best would respond to, as the goal of home rehabilitation is to heal faster.

APPENDIX A

TECHNOLOGIES

CURRENT SENSING TECHNOLOGIES

A wide variety of sensing technologies are available, however sensors such as flex sensors, goniometer sensors, flexible stretch sensors, accelerometers, electromyography sensors and pressure sensors have proven beneficial within healthcare and rehabilitation.

The advantages of using flex sensors is that they allow you to determine the degree of which something is bent, however they don't allow for stretch in latitudinal or longitudinal directions.



Figure 65: Bending a flex sensor

Goniometer sensors are external sensors allowing for the detection of degrees of

freedom by determining the amount of light passing through a pair of optic fibers.



Figure 66: Examples of goniometer sensors

Stretch sensors change resistance when stretched, allowing you to measure when something is being stretched.



Figure 67: Stretch sensor

Accelerometers are extremely popular within ubiquitous computing and wearable computing. Accelerometers measure proper acceleration in all three directions, allowing for the ability to sense direction.



Figure 68: Example of an accelerometer

Electromyography sensors detect the electric activity produced by skeletal muscles. Their relevance as a sensor is due to the tracking of proper muscle activation during rehabilitation and encourage correct techniques.



Figure 69: Example of electromyography sensors

Pressure sensors are an alternative method for detecting muscle activation during rehabilitation.



Figure 70: Example of pressure sensors

EXISTING PRODUCTS

The Nike+ FuelBand device tracks daily activities, such as running and walking, with the ability to know your daily step count and calories burned. It helps track your progress and allows for you to sync with other Nike+ applications.



Figure 71: Nike+ FuelBand pairing with the iPhone

Polar heart rate monitors aid in fitness improvement by showing users what is needed to meet their goals.



Figure 72: Track your Polar metrics through your online profile

The Jawbone Up collects a variety of biometric data allowing for one to view sleeping patterns and daily activity on their computer or phone, however it only works on iOS and doesn't wirelessly sync to any devices.



Figure 73: The Jawbone Up connects through USB to track your patterns

The FitBit is an excellently designed smart pedometer that tracks distance traveled, steps taken, and calories burned throughout the day. It syncs wirelessly to your account, where you can add more information about your daily habits, such as diet or strength training. The sleek design allows it to fit easily into daily life.



Figure 74: The FitBit tracks everyday walking habits

APPENDIX B

IRB CONSENT FORMS

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY Georgia Institute of Technology

Project Title: eTextile Sleeve for Tracking Geriatric Knee Rehabilitation

Investigators: Dr. Claudia Rebola (PI) and Ceara Byrne (Student)

> Protocol and Consent Title: ConsentObservation01222013

You are being asked to be a volunteer in a research study.

Purpose:

The purpose of this study is to observe the processes and tools used during knee rehabilitation. We expect to enroll 6 people in this study.

Exclusion/Inclusion Criteria:

Participants 18 years of age or older who regularly attend knee rehabilitation are eligible to participate in this study.

Procedures:

If you decide to participate in this study, your part will involve a one hourlong observation session. We will discuss the study, and you may ask all the questions you have. After giving your consent, we may proceed with the session. The session is a one-on-one, face-to-face meeting where the researcher will shadow the Physical Therapist. With your consent, hand written notes, audio, and video recording will be used to record your responses. The total amount of time for the observation will be no more than 1 hour.

Risks or Discomforts:

There are no risks associated with this study. The evaluation does not address any sensitive/personal topics.

Page 1 of 3 Observational Consent Form February 2013

APPROVED Consert

Consent Form Approved by Georgia Tech IRB: March 12, 2013 - March 11, 2014

Benefits:

You are not likely to benefit in any way from joining this study. We hope that what we learn will help to improve rehabilitation in the future.

Compensation to You:

There is no compensation for participating in this study.

Confidentiality:

Your privacy will be protected to the extent allowed by law. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept in locked computers and only study staff will be allowed to look at them. Your name and any other fact that might point to you will not appear when results of this study are presented or published. No link will be maintained that could connect your identity with your responses. Videos will be accessible only to the research team and the video will be destroyed after data analysis is complete. To make sure that this research is being carried out in the proper way, the Georgia Institute of Technology IRB may review study records.

Costs to You:

There are no costs to you, other than your time, for being in this study.

Participant Rights:

 Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.

• You have the right to change your mind and leave the study at any time without giving any reason and without penalty.

• If you decide not to finish the study, you have the right to withdraw any data collected about you. We will destroy data not used.

• Any new information that may make you change your mind about being in this study will be given to you.

You will be given a copy of this consent form to keep.

You do not waive any of your legal rights by signing this consent form.

Page 2 of 3 Observational Consent Form February 2013 APPROVED Consent Form Approved

Consent Form Approved by Georgia Tech IRB: March 12, 2013 - March 11, 2014

Questions about the Study:

If you have any questions about the study, you may contact:

Claudia Rébola, Assistant Professor, School of Industrial Design, Georgia Institute of Technology, at (919) 389-2302 or <u>crw@gatech.edu</u>

Questions about Your Rights as a Research Participant:

If you have any questions about your rights as a research participant, you may contact:

> Ms. Melanie Clark, Georgia Institute of Technology Office of Research Compliance, at (404) 894-6942.

> Ms. Kelly Winn, Georgia Institute of Technology Office of Research Compliance, at (404) 385- 2175.

or

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

Participant Name (printed)

Participant Signature

Date

Signature of Person Obtaining Consent

Date

Page 3 of 3 Observational Consent Form February 2013 Consent Form Approved by Georgia Tech IRB: March 12, 2013 - March 11, 2014

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology

Project Title: eTextile Sleeve for Tracking Geriatric Knee Rehabilitation

Investigators: Dr. Claudia Rebola (PI) and Ceara Byrne (Student)

> Protocol and Consent Title: ConsentParticipatoryWorkshop01222013

You are being asked to be a volunteer in a participatory design workshop.

Purpose:

The purpose of this study is to design and evaluate post-surgery knee rehabilitation devices for geriatrics. We expect to enroll 6 people in this study.

Exclusion/Inclusion Criteria:

Participants 18 years of age or older related to post-surgery knee rehabilitation are eligible to participate in this study.

Procedures:

If you decide to participate in this study, your part will involve a one hourlong design workshop. We will discuss the study, and you may ask all the questions you have. After giving your consent, we may proceed with the session. This session is a group meeting where the researcher will lead you and the other participants in activities to generate concepts for an eTextile sleeve to aide in tracking rehabilitation. With your consent, hand written notes, audio, and video recording will be used to record your responses. The total amount of time for the observation will be no more than 1 hour.

Risks or Discomforts:

There are no risks associated with this study. The evaluation does not address any sensitive/personal topics.

Page 1 of 3 Participatory Des

atox Design Workshop Consent Form March 2013 Consent Form Approved by Georgia Tech IRB: March 12, 2013 - March 11, 2014

Benefits:

You are not likely to benefit in any way from joining this study. We hope that what we learn will help to improve rehabilitation in the future.

Compensation to You:

There is no compensation for participating in this study.

Confidentiality:

Your privacy will be protected to the extent allowed by law. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept in locked computers and only study staff will be allowed to look at them. Your name and any other fact that might point to you will not appear when results of this study are presented or published. No link will be maintained that could connect your identity with your responses. Videos will be accessible only to the research team and the video will be destroyed after data analysis is complete. To make sure that this research is being carried out in the proper way, the Georgia Institute of Technology IRB may review study records.

Costs to You:

There are no costs to you, other than your time, for being in this study.

Participant Rights:

 Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.

• You have the right to change your mind and leave the study at any time without giving any reason and without penalty.

• If you decide not to finish the study, you have the right to withdraw any data collected about you. We will destroy data not used.

• Any new information that may make you change your mind about being in this study will be given to you.

You will be given a copy of this consent form to keep.

You do not waive any of your legal rights by signing this consent form.

Page 2 of 3 Participatory Des

Participatory Design Workshop Consent Form March 2013

Consent Form Approved by Georgia Tech IRB: March 12, 2013 - March 11, 2014

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Participant Name (printed)

Participant Signature

Date

Signature of Person Obtaining Consent

Date

Page 3 of 3 Barticipatory Design Workshop Consent Form March 2013 Consent Form Approved by Georgia Tech IRB: March 12, 2013 - March 11, 2014

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology

Project Title: eTextile Sleeve for Tracking Knee Rehabilitation in Older Adults

> Investigators: Dr. Claudia Rebola (PI) and Ceara Byrne (Student)

> > Protocol and Consent Title: ConsentUsabilityStudy01222013

You are being asked to be a volunteer in a research study.

Purpose:

The purpose of this study is to evaluate a tool to aide in tracking knee rehabilitation over time. We expect to enroll 6 people in this study.

Exclusion/Inclusion Criteria:

Participants 18 years of age or older who regularly attend knee rehabilitation are eligible to participate in this study.

Procedures:

If you decide to participate in this study, your part will involve a one hourlong concept evaluation session. We will discuss the study, and you may ask all the questions you have. After giving your consent, we may proceed with the session. The session is a one-on-one, face-to-face meeting where the researcher will gain insight on your evaluations of a final prototype(s). With your consent, hand written notes, audio, and video recording will be used to record your responses. The total amount of time for the observation will be no more than 1 hour.

Risks or Discomforts:

There are no risks associated with this study. The evaluation does not address any sensitive/personal topics.

Page 1 of 3 Usability Consent Form April 2013 APPROVED Consent Form Approved I

Consent Form Approved by Georgia Tech IRB: March 12, 2013 - March 11, 2014

Benefits:

You are not likely to benefit in any way from joining this study. We hope that what we learn will help to improve rehabilitation in the future.

Compensation to You:

There is no compensation for participating in this study.

Confidentiality:

Your privacy will be protected to the extent allowed by law. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept in locked computers and only study staff will be allowed to look at them. Your name and any other fact that might point to you will not appear when results of this study are presented or published. No link will be maintained that could connect your identity with your responses. Videos will be accessible only to the research team and the video will be destroyed after data analysis is complete. To make sure that this research is being carried out in the proper way, the Georgia Institute of Technology IRB may review study records.

Costs to You:

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Participant Rights:

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Page 2 of 3 Usability Consent Form April 2013 APPROVED Consent Form

Consent Form Approved by Georgia Tech IRB: March 12, 2013 - March 11, 2014

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Participant Signature

Date

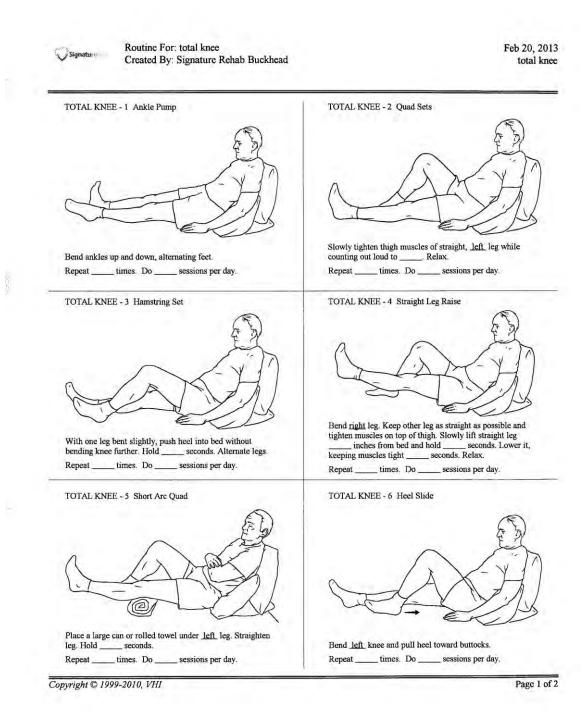
Signature of Person Obtaining Consent

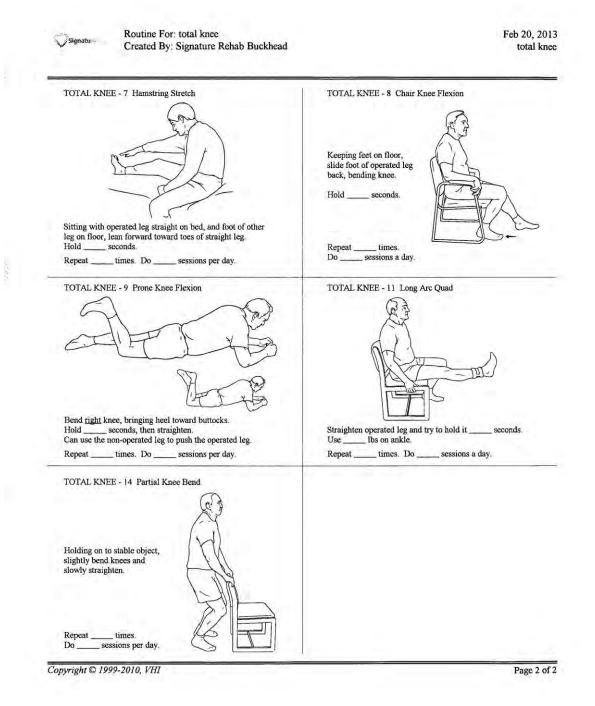
Date

Page 3 of 3 Usability Consent Form April 2013 Consent Form Approved by Georgia Tech IRB: March 12, 2013 - March 11, 2014

APPENDIX C

TKA RECOMMENDED REHABILITATION EXERCISES





APPENDIX D

EXPERT INTERVIEW TRANSCRIPTS

APPLIED PHYSIOLOGIST

Researcher: Hi, thank you for meeting with me.

Applied Physiologist: Of course. Tell me more about your project.

R: Well, it's a project I started working on last semester. The project was to develop a knee brace that helped track a rehab patient's progress over time. It's since been turned into my thesis and I've been writing the literature review. Now, I'm at a point where I'd like to go more in-depth in the project and learn more about rehabilitation from experts. Do you think you could talk about the rehab process?

AP: Sure, but I'm not too embedded in that process and I don't help patients go through rehab. I only know the physical movement of the body, but I've had my knee and hip replaced. Two very important parts of rehab are resistance training and balance. Basically, you're strengthening your knee so that you can balance on it and walk again. The earlier you start performing your rehab, the better because scar tissue builds up and prohibits the movement in the knee. Unloader braces are typically provided to the patients, to keep the leg straight, but they hurt and cause a little bruising. There are a lot of devices out on the market that can be used during rehabilitation, but not every rehab clinic has them. Devices like Continuous Passive Motion machines force you to do more movement, but we [in Applied Physiology] deal with Isokinetic Devices, such as Cybex and Kincom, where they determine the leg strength of the quadriceps and bend angle. I mean, you can use a goniometer, but these devices are accurate while your knee is moving. These are also devices you might be able to use during testing. Testing whether knee motion and forces change. Maybe perform a 2 week study on healthy people or younger people undergoing knee rehab. We have one here in the lab, I'll show you in a bit. So tell me more about the device.

R: Well, currently it's using a knitted stretch sensor, I wove conductive thread in with the wool yarn, attached it to a neoprene knee brace and tethered it to a computer to collect binary data so that, as you streth or bend your knee, it'll detect what you're doing.

AP: Does it have to be a knee brace? Can it extend down to your ankle? Because another thing to be cognizant of is the alignment of the ankle to the knee. After hip replacement, if the doctors don't align the hips properly, the knees will start to bow in the direction of the misalignment and cause other problems. [shows hips and knees]

R: That's definitely a possibility. Can you think of any other avenues of improvement or areas this brace could explore?

AP: Well, I read an article recently that talked about the benefits of compression hose. Once you reach a certain age, wearing compression hose comes highly recommended. It prevents blood clotting, especially at high altitudes, like when you fly. I'll find that article for you and send it to you. Could you integrate stim methods?

R: What are stim methods?

AP: Physical therapists will tap a muscle to help activate it. Sometimes you can get a person to extend a little further by tapping on the muscle. Would this be something that you might be able to integrate into the device? Could you stimulate the Vastis Medialis muscle for that last 15%. It might help with the quality of the movement, like if you go out for walks, your neural takes over. Which brings up perception of rehabilitation. Would people perceive that they're performing better rehabilitation because of the warmth of the knit? Would this allow them to do more movement or alter the pain scale? Would they think they're in less pain because their leg is warmer? You may want to look further into compression hose. Let me show you the lab and see if I can find that article.

R: Okay, this is great. Thank you so much.

[[end session]]

PHYSICAL THERAPIST & COORDINATOR

R: Good morning.

PT1: Good morning and welcome to our rehab clinic. Let me walk you through the facility. This is an outpatient rehab clinic, meaning we have this rehab area, but we also have rooms upstairs for people who've just had surgery and can't go home yet.

R: Can you tell me more about the process?

PT1: Sure. Hospitals typically keep patients for 2 or 3 days after the surgery. Patients start rehab as soon as possible so that they can increase their range of motion later on. Hospitals will have their own staff and a Physical Therapist will come and help them perform their rehab. When they're given permission to leave the hospital, they'll either go home, if they're doing well, or they'll come to an outpatient facility like ours. They'll typically stay at an outpatient facility for a few weeks, where they'll perform rehab 2-3 times a week, and then they'll head home. Once they're home, they'll continue to perform rehab by coming to the outpatient facility 2-3 times a week, while performing additional exercises at home. This will continue for 4-6 weeks, or until they reach their goals, in which case, they continue exercising for about 6-8 months on their own, until they fully heal.

R: How many people do you see at a time?

PT1: Right now, we have two people that are undergoing knee rehabilitation.

R: What are the age groups of people who pass through here?

PT1: We get a lot of different ages undergoing different types of rehabilitation. A lot are older patients, but you'll see younger people too.

R: What would you like to see for the future? For better results?

PT1: You see a lot of people not performing their rehabilitation at home. They think we don't see it, but you can always tell because they're not recovering as quickly as they should and they end up going back into surgery for manipulations or to fix infections.

R: What's a manipulation?

PT1: When you undergo surgery you develop a lot of scar tissue, especially when you're not properly doing your rehab. A manipulation has to be done to remove that scar tissue.

R: What are the goals set during rehabilitation?

PT1: When the patient gets to the facility, their range of motion is approximately 90 degrees and, typically, their goal is to get to 110 degrees. When the patient first gets to the facility, we use the other knee as a baseline for the range of motion. Let's talk to the patients and other therapists.

PHYSICAL THERAPIST 2

R: How does the process of rehabilitation change from person to person?

PT2: Goals change from person to person, but for the most part we provide the same exercises to everyone.

R: What's the age group you normally work with for knee replacement?

PT2: Mostly the older population.

R: Why do most patients have knee replacement?

PT2: The most common knee problem is patella femoral syndrome, but osteoarthritis and pain are also common.

R: Do you tap muscles to help activate them? Do you think that having a stim device to activate muscles would help?

PT2: It might help. You'd want to stimulate the Vastis Medialis.

PHYSICAL THERAPIST 3

PT3: So I've been listening to all the questions you've been asking and I've heard a lot about the device you're working on and there are a couple of things I'm really concerned about. First, I'm concerned about you using a knee brace because they limit a patient's range of motion. They prohibit stretching and bending. Additionally, they bruise the patient a lot so I typically have them throw the brace out as soon as they get them. I'd really like to see, like 2 straps, one above the knee and one below, maybe with a round pivot to hold the sensors. It doesn't have to be like that, but it just can't limit the range of motion.

R: Okay, well, what else do you think would benefit the device?

PT3: Maybe it can be reusable from patient to patient. Maybe you can throw away the Velcro straps and have the patient rent the sensors or something. This might help make it less expensive for the user.

R: Awesome, can you tell me more about the tools that people use in the home?

PT3: Well, there isn't much. You have a Continuous Passive Motion machine, but they're highly debated between physicians. Most won't even prescribe them because they do most of the work for the person instead of the patient doing their own work. Personally, I think they're good for the patient because at least it gets them bending and stretching their knee.

R: Why don't patients want to do their rehab?

PT3: It's really painful for them, probably one of the worst rehab experiences. The scar runs right over where you're bending and you're stretching that scar. Additionally, ethnicity plays a big role because African Americans develop scar tissue faster than any other ethnicity. The scar tissue is bad because it's like cement. It makes it difficult to move once it sets in.

PATIENT 1

R: Nice to meet you! What are you working on?

P1: Hi, I'm biking. Helps with extension and bending.

R: Great. So how long have you been here?

P1: I've been here for about four months, but I had to have a manipulation. It was great.

R: Why'd you have to have a manipulation?

P1: I wasn't doing my rehab right and then I had an infection.

R: Why was having a manipulation a good thing, then?

P1: Well the hardest part of this whole thing is the rehab. It's scary to go through surgery and the second time it was a lot easier because I knew what was happening.

R: How would you make the process better?

P1: I'd like to get more feedback on how I'm doing and I think seeing results would be a good motivation. Plus, the therapists provide a lot of encouragement.

PATIENT 2

Performed in conjunction with PT3.

R: Did you need to have a CPM machine?

P2: I was able to use one, but when I would use it, I would get bruises.

R: So how is your rehab going?

P2: It has been going really well.

R: Was it scary?

P2: No, I've had the other knee done before and I've taken classes to know what to expect. However, I wasn't expecting medicine to advance so quickly since my last knee replacement!

R: Why did you need to get both of them replaced?

P2: All my cartilage in my knees is gone. I played hard-court tennis competitively when I was younger and then I started doing aerobics when it first became popular. I've always been very active.

R: What's your process been like?

P2: Well, I was in the hospital for about 3 days. My family said that they could tell that there was a huge difference between the two surgeries just by the way I responded afterwards. I was out for 24 hours after the first surgery and I was awake a few hours after my second one. I told you it was amazing how technology had changed! After surgery, I came straight here [to the outpatient facility] because I couldn't stay with my sister this time. She's working and I was able to pay to stay here. After I did my initial rehab here, I went home and my sister checks up on me every so often. When I went home, a therapist would come 2 - 3 times a week for about 10 - 12/13 sessions. Now I come here.

R: What is it like doing rehab at home?

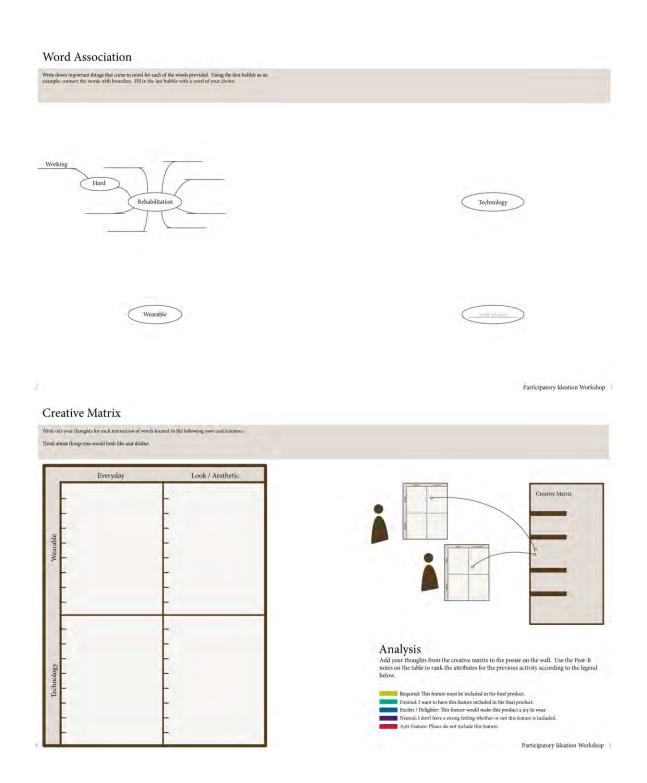
P2: At home, patients only go so far. At home I wouldn't push myself as far as the therapist would. I wouldn't inflict this pain on myself.

R: What do you think would make it better? What would motivate you to do it?

P2: I want to be able to see the progress. When you see that you're making progress, it's rewarding. I'd also like to see photos of the exercises I'm supposed to be doing and the benefits of each, such as "This exercise would help me achieve three degrees", or "This exercise will help me with stretching." As long as it would walk you through like a therapist would.

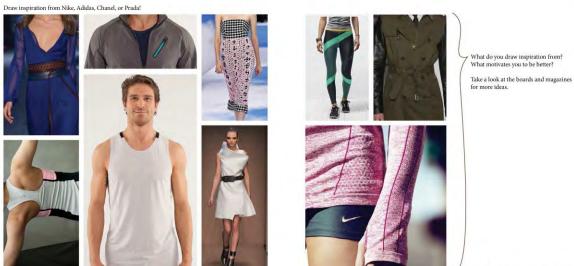
APPENDIX E

PRODUCT IDEATION WORKSHOP BOOKLET & RESPONSES

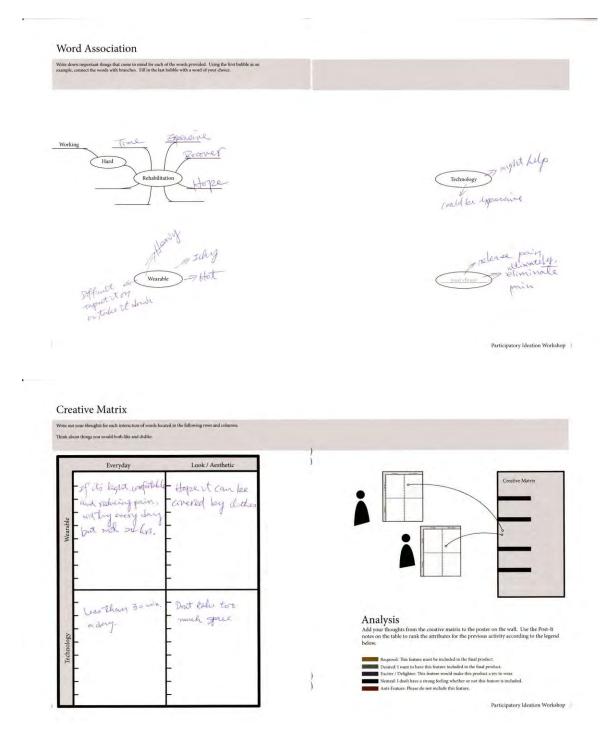


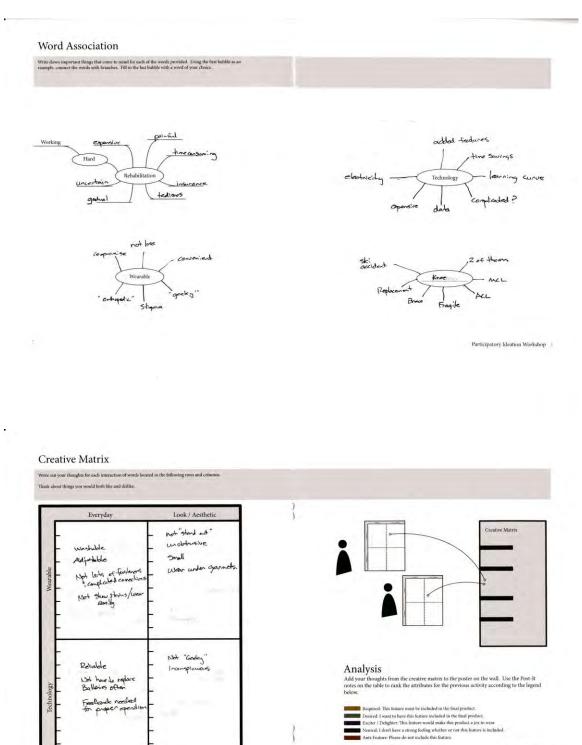
Creative Toolkits

Please pair up and use the tools and materials on the table to form your perfect wearable device. Use yourselves as models for the piece.

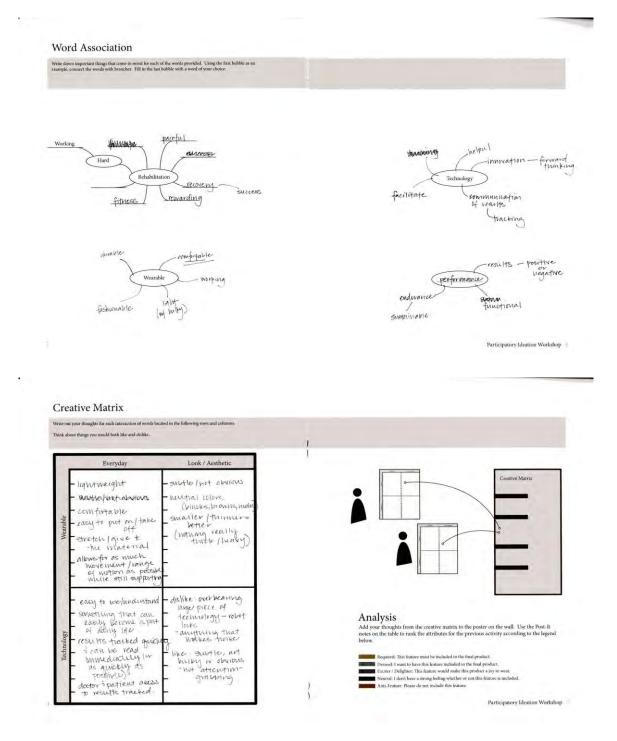


Participatory Ideation Workshop 7

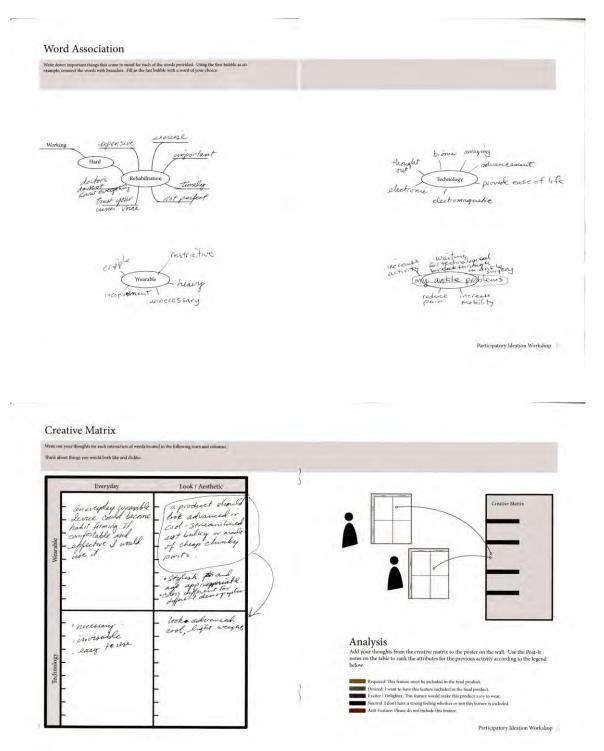


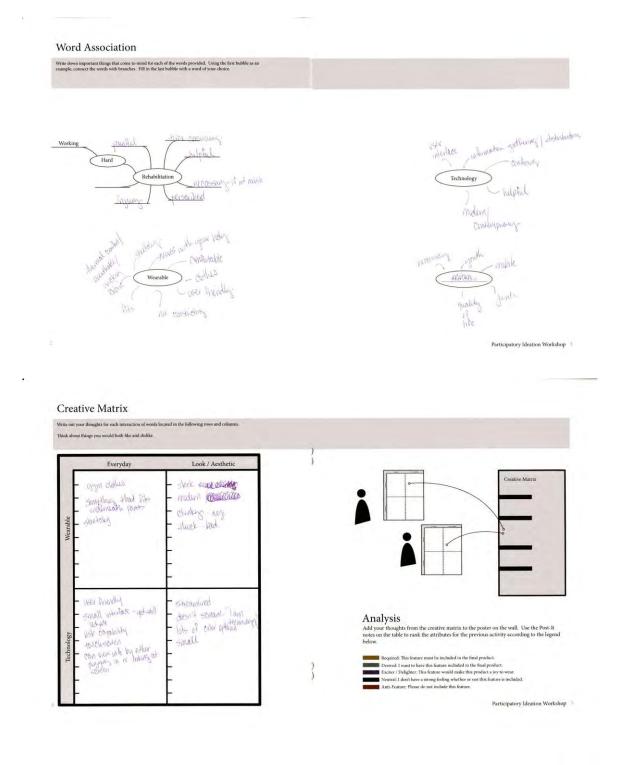


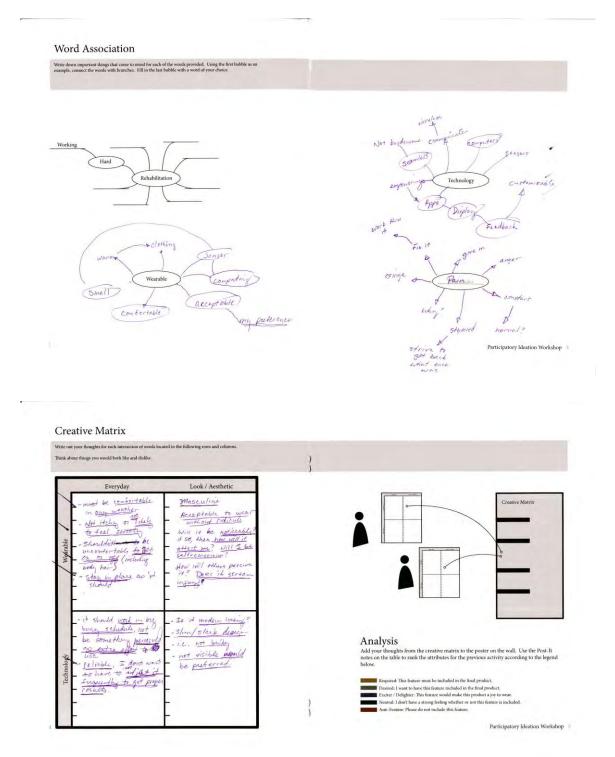
Participatory Ideation Workshop





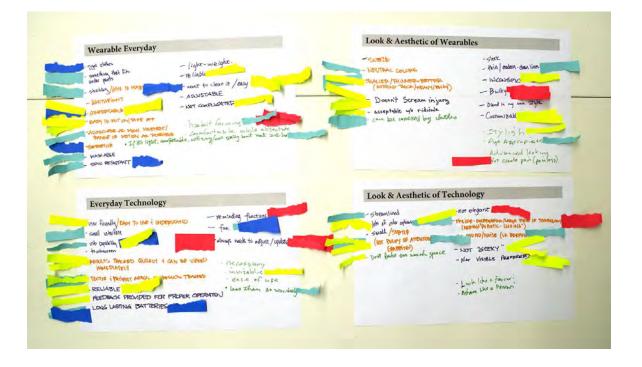








KANO ANALYSIS



APPENDIX F

INSPIRATION BOARDS

ALEXANDER MQUEEN



BCBGMAXAZRIA



BURBERRY



CHANEL



Dior





DKNY



DOLCE & GABBANA





Salvatore Ferragamo



Gianfranco FERRÉ



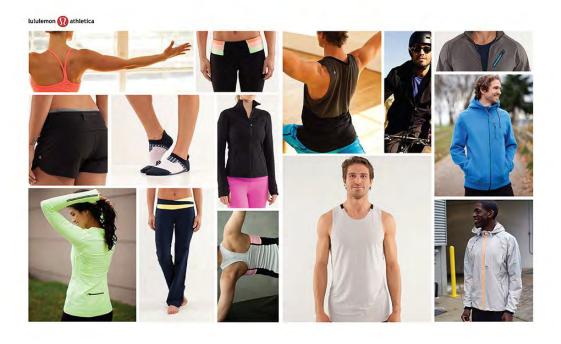
Guy Laroche





JILSANDER





MARC JACOBS

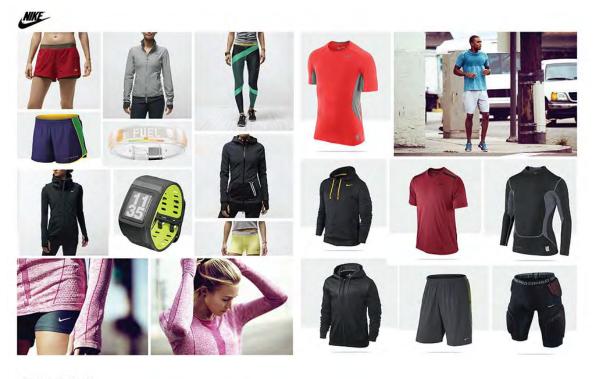


MICHAEL KORS



MISSONI





PRADA



RALPH 🖌 LAUREN



TOM FORD



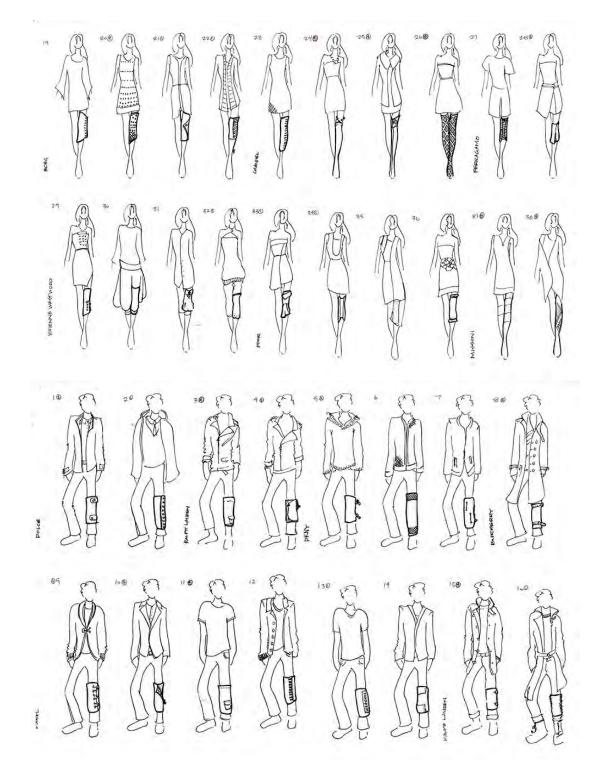


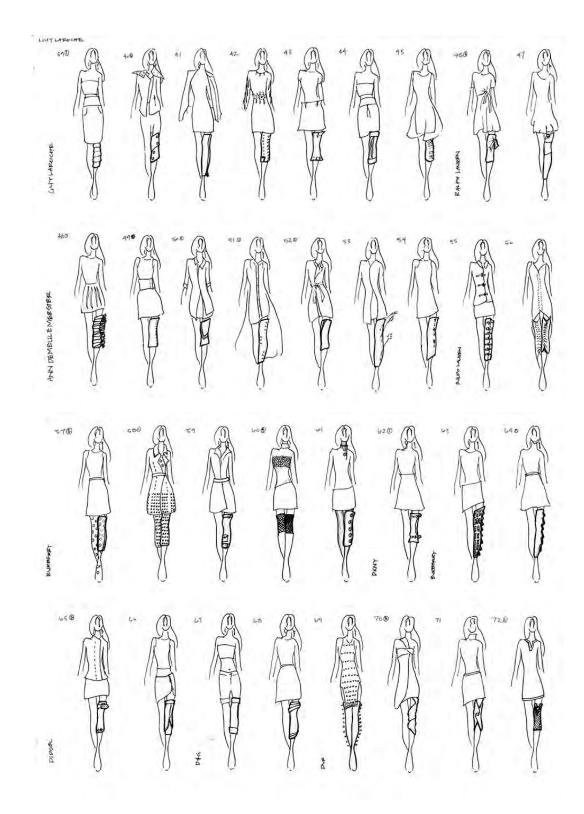
Vivienne Westwood

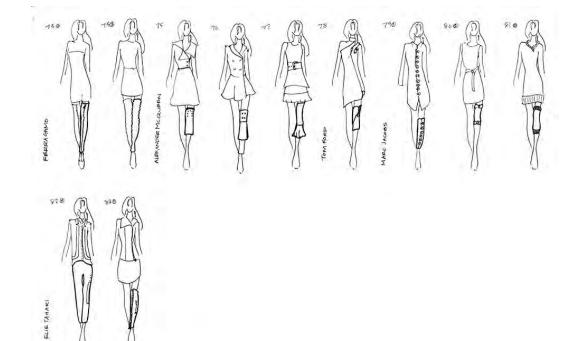


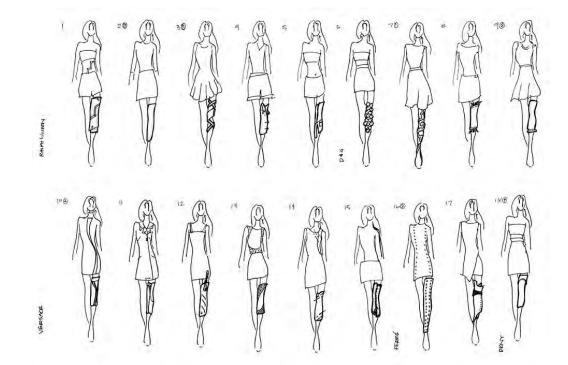
APPENDIX G

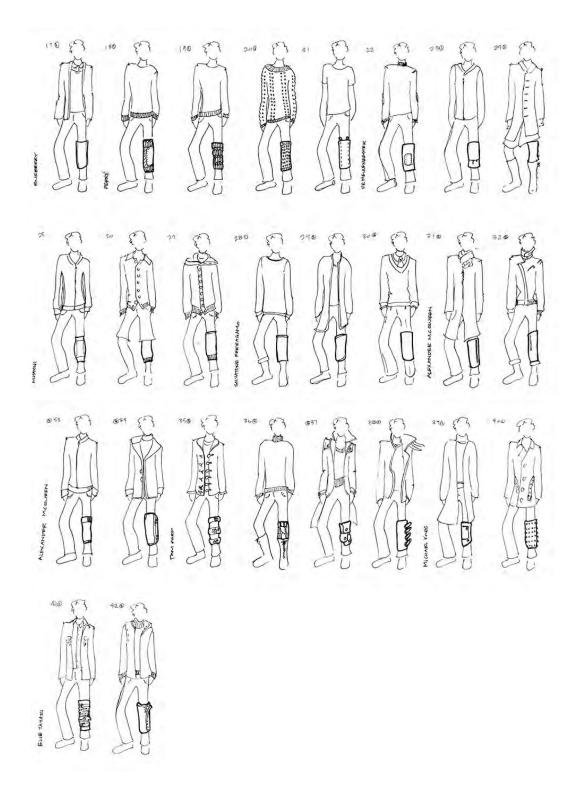
DESIGN SKETCHES











APPENDIX H

FINAL IDEA FEEDBACK QUESTIONNAIRES

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APPENDIX I

CONDUCTIVE THREAD DATA SHEETS



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