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TRANSITIONING A RESEARCH TOOL INTO A CONSUMER PRODUCT: THE WHEELCHAIR IN-SEAT ACTIVITY TRACKER

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ABSTRACT

Pressure ulcers remain a significant secondary complication for many wheelchair users, having significant adverse impacts on the health, function and independence of wheelchair users. Research suggests that both the magnitude and duration of loading on tissues can lead to tissue necrosis. This motivated research to measure the in-seat movement of wheelchair users as a means to characterize time of loading. During these research activities, the consistent finding was that persons were not adhering to their weight shift regimens as taught during rehabilitation. This served as motivation to develop a consumer product to inform users of their activities. The transition from a research tool to a consumer product is endowed with challenges. This paper describes the technology as well as the activities required to make this transition. Specific design challenges included attention to usability and device engagement and the need for near real-time data management and analysis to inform users of their in-seat movements.

Keywords: product development; pressure ulcer; wheelchair

INTRODUCTION

Pressure ulcers (PrUs) remain a critical problem for wheelchair users with negative consequences on nearly every aspects of their lives [1-3]. Individuals with PrUs experience reduced mobility, activity and participation [2-4], greater unemployment [5] and are at increased risk for future PrU development [6] and premature death [7] .

Based upon research into PrU etiology, clinical interventions include PrU prevention strategies that address both the magnitude and duration of loading. During seating evaluations of persons with SCI, pressure magnitude is managed by the selection of wheelchair cushions and other postural supports [8, 9]. Wheelchair users who are at-risk for pressure ulcers are taught a weight-shifting regimen as a component of promoting tissue health. Weight-shifts consist of leans to off-load the buttocks at regular time intervals [8-12].

Unfortunately, researchers have consistently concluded that wheelchair users perform many fewer pressure reliefs than they are taught [13-17]. Many researchers and clinicians have suggested that providing feedback will increase awareness and lead to behaviors that could reduce PrU risk [8, 18-21].

This project seeks to design a commercially-viable system to inform wheelchair users about their weight-shifting activity as a means to promote healthy behaviors and prevent pressure ulcers. Termed the WiSAT (Wheelchair In-seat Activity Tracker), this technology is based upon technology used within a research project that monitored in-seat activity of wheelchair users [17, 22]. Such a product can empower wheelchair users with knowledge about their behaviors associated with PrU prevention. It also can provide necessary information for clinicians to individualize prevention strategies and researchers who study PU occurrence. While leveraging the experience garnered during research, the development of a consumer-based device is endowed with many challenges. This paper will detail the myriad R&D activities required to transition a research tool into a consumer product.

1.0 WiSAT Description

As a research tool, the WiSAT was designed a) to be housed completely within the wheelchair cushion cover, b) to not impact any user activity, and c) to not be engaged in any manner by the wheelchair user. The system stored all data for post-processing and was deployed for 2 week intervals.

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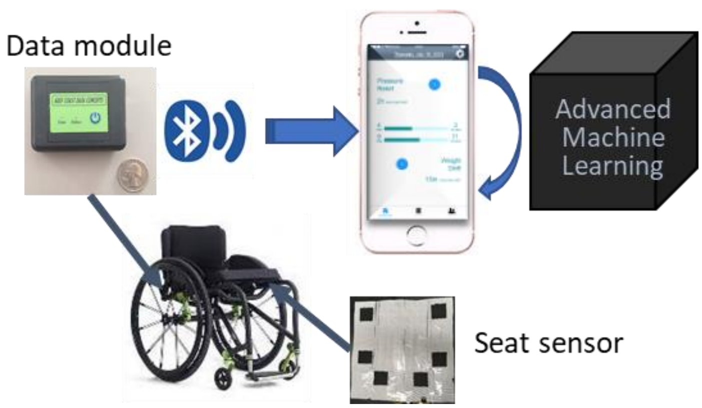
In distinction, the consumer WiSAT must interact with the user and provide information about the users' in-seat movements. The consumer WiSAT consists of 3 subsystems:
1) Hardware
- Seat sensor placed underneath the wheelchair cushion to measure the in-seat movements
- Data acquisition & communication module to collect sensor parameters and transmit them to the mobile phone via Bluetooth Low Energy.
2) Classification algorithms use Machine Learning to classify in-seat activity into weight-shifts and in-seat movements based upon the force inputs from the seat sensor.
3) Mobile phone app receives the raw sensor data from the hardware module and processes data into weight-shifts and in-seat movements for the user. Also monitors hardware status and leads user through initialization process needed to configure the machine learning algorithms

Figure 1. Schematic of the WiSAT's subsystems and operation



2.0 Transitioning from a research tool to consumer product

Transitioning to a consumer product necessitates foci on new functionality. Most importantly, re-design was needed from a device that is not to be engaged, managed or touched by a research subject to a device that must be fully engaged and managed by the user. A synopsis of the differences is depicted in Table 1.

Achieving this transition required different design methodology and identification of new design specifications. The project adopted Agile Development and human-centered design activities to achieve the new design objectives.

One important consideration during this transition was: deciding what tasks should be performed within an academic setting versus contracted out. In this case, the research team was unified in their belief that the use of experienced industry contractors would better position the WiSAT for commercial production. As a result, we established contracts for the mobile phone app, hardware module, and seat sensor. Only algorithm development remained as an internal development project.

Table 1. Differences between research and consumer requirements.

	Research	Consumer
App	Does not exist	Accept raw signals from hardware; classify into weight shifts & in-seat movement parameters; manage initialization; monitor hardware; display user-interface
Algorithm	Researcher-led initialization; reports activity using post processing	Near real-time processing, simple user setup to inform machine learning
Hardware	Stores data for 2 weeks; hand-assembled seat sensor	Uses inductive charging, Bluetooth communication; production-quality seat sensor; stores data for 6 months or more

Hardware

Seat sensor: The research seat sensors were manually fabricated using off-the-shelf FSR sensors. The wide variability in force-voltage responses required each sensor to be calibrated individually. The consumer product required a higher level of quality control and reliability. Tekscan was contracted to fabricate a new seat sensor using its production techniques. This resulted in a more robust sensor with greater consistency across individual products.

Data acquisition module: The research unit was designed to collect and store data for 2 weeks after which the data was manually retrieved and processed. The consumer product required extensive re-design to enable the module to transmit data to a mobile device and to facilitate the user's management of the overall hardware operation.

R&D activities

The seat sensor was redesigned to incorporate Tekscan's production capabilities and to insure compatibility with different combinations of cushions and wheelchairs. Because the seat sensor is placed underneath the cushion, force measurement can be impacted by the cushion-wheelchair seat interface. This required extensive empirical testing of many cushion-wheelchair combinations using wheelchair users.

Several hardware and firmware changes were made to the data acquisition module. The form factor of the module was reduced by incorporating a smaller battery designed to last 3 days and by optimizing components of the printed circuit board. This objective was defined because the WiSAT will be placed within the wheelchair cushion cover along with the seat sensor.

Bluetooth Low Energy communication was added to transmit the data to the mobile app. This required us to define an application program interface (API) to facilitate communication between the logger module and the mobile phone app. Within the module firmware, we adjusted the way that data is stored in the file system to accommodate our API and to allow for an increased file storage capacity (target of 6 months of data or more). An inductive charging circuit was added to allow the users to charge the module without removing it from the cushion cover. Each iteration underwent bench-testing to insure operation and to identify bugs and errors.

Classification algorithms: Within the research device, algorithms were individualized using elaborate 'truth' data collected by the researcher and subject during set-up. For each participant, a separate classifier was built during post-processing of the data, which is not feasible for a consumer product. Instead, the consumer product requires users to run through an initialization set-up to inform machine learning algorithms that are robust across users. This required the design of a simple set-up process that leads the users through forward and side leans, as well as the design of more robust algorithms capable of near real time classification of in-seat movements with messier data. The algorithms needed to accommodate differences in users, cushions and wheelchair configurations in near real time.

R&D activities

The redesigned algorithms required extensive testing beginning with short term-controlled testing and segueing to lesser controller real-world data. Data collection included three phases: 1) controlled, scripted activity in a laboratory environment, 2) real-world simulations, and 3) real-world wheelchair use. Controlled scripted activities included a 15-minute sequence of movements (i.e., leans, reaches, postural shifts) that are performed on multiple cushions. Real-world simulations included 90-minute data sets that were scripted to ensure enough true-positive and true-negative data was collected while including more typical sitting durations. Finally, real world testing involved sending the user home with the equipment for more extended use. In combination, these evaluations allowed us to capture the idiosyncrasies and nuances of each configuration and combination of user and equipment.

Mobile phone app: The research device did not inform users of their activities; the research objective was to document activities without impacting them. So, to develop the consumer product, a mobile phone app had to be designed to communicate with the data acquisition module and provide users with feedback about their in-seat activity. Two types of feedback are programmed into the app: passive and active. Passive notifications require the user to access the app and review their in-seat activity relative to user-defined goals. Active notifications will push a message to users when activity goals are not achieved over 2-3 hour durations throughout the day. The app also includes capability for users to review historical data over using weekly or monthly timeframes

R&D activities

Mobile phone app development utilized an Agile Development process to develop the software and deployment of a Human-Centered Design activity to design the user interface. The process commenced with the development of an extensive mapping of its functional requirements. This document defined the variables and data requirements, including data storage, calculations and inter-communications. This document was provided to the software developer and was iterated frequently. The Agile development process included short weekly meetings with the developer to cover progress and address design issues.

During these meetings, the data requirements were translated into a database schema, and prototype user-interface (UI) screens were used to communicate the app design decisions to the developer. Due to our Agile development methodology, we were afforded the flexibility to incorporate user feedback into our UI even after development had already begun. Additionally, Agile allowed the mobile app, algorithm and hardware development to occur in parallel; mobile app development was adjusted to address the changing demands of the other subsystems.

While this appears to be labor-intensive, focused 30-minute meetings were definitely worthwhile. One caveat must be acknowledged: to insure these meetings were short and focused, someone must attend to defining the agenda and sending meeting notes.

The entire UI also needed to be designed and evaluated. These included home and detailed screens of all the in-seat parameters that reported in-seat activities for a day, week and month. Each parameter is reported relative to a user-defined goal. WiSAT management screens covered initialization procedures, hardware monitoring and information about tissue health and weight shifts. Examples of the day and week weight shift notifications screens are depicted in Figure 2.

A two-step user-centered design process was used to insure the mobile phone app was usable and provided meaningful information. Design of the UI included multiple user engagements and re-designs. Initially a web-based survey was used to gather feedback about multiple screen designs. Features of the top-rated designs were incorporated into two potential screen designs which were evaluated using a face-to-face usability evaluation to assess effectiveness and satisfaction. Screens were rendered using app prototyping software and subjects were led through specific tasks to evaluate the UI. This process was repeated twice to create the final UI designs.

This design assessment followed the philosophy that design is reflected as a series of compromises, UI screen prototypes were not judged in a dichotomous manner with the goal of selecting the 'best', rather each was evaluated on its strengths and weaknesses. Design iteration was embodied by design changes that attempted to maximize the strengths and minimize the weaknesses of the designs.

A second usability evaluation consisted of system-level evaluation. This required functional prototypes of all three subsystems, so occurred after extensive development. The WiSAT was deployed on users' wheelchairs for 2 weeks. Users had to fully manage the system and were instructed to monitor in-seat activity via the app. So, subjects needed to charge the unit, insure Bluetooth connectivity was maintained, and monitor their in-seat activity. TestFairy software was incorporated into the app to monitor usage. TestFairy collects screen navigation and records bugs and errors. This systems-level testing was used to fix usability problems and bugs.

3.0 Current and future efforts

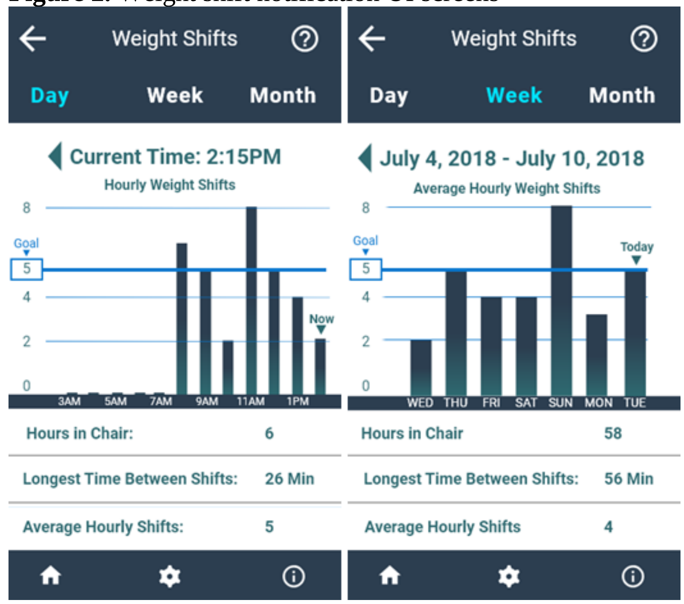
The ultimate success of this project will be determined by whether the WiSAT is made available to wheelchair users as a consumer-product. Two key activities are underway to achieve this goal: technology transfer and a pre-clinical trial.

WiSAT technology has been included in a utility patent application as a means to establish value and provide commercialization assurance for potential partners. The key claims revolve around an unobtrusive system with the ability to measure in-seat movements using a seat sensor placed underneath the wheelchair cushion. This requires both an anthropometrically designed sensor and robust machine learning algorithms.

Other activities involve engaging companies that 1) offer products for wheelchair users or 2) have expertise in small embedded systems and who may want to enter the wheeled mobility space. This is not typically a skill of faculty members and reflects a significant barrier to technology transfer. While the university's Industry Engagement office states an intention to engage companies, all engagement to date has been initiated and managed by the investigators.

In addition, to better define the value of the WiSAT, an evaluation trial is planned. The objective of this trial is to determine whether *WiSAT can influence the weight-shifting behavior of wheelchair users*. Wheelchair users will be provided with a WiSAT for use over 4 ½ months. Baseline activity will be collected with the app in a quiescent mode so that WiSAT acts as a data logger. Then, passive and active notifications will be activated so the users can engage all the WiSAT features. Inherent to this trial is the need to produce many WiSAT systems for evaluation, to engage clinical partners, and then design and deploy a relevant and meaningful trial. We decided that, as inventors, we should not administer an evaluation trial. Inventors are biased. Rather the University of Pittsburgh and the Hines VA Medical Center have been engaged to do so. Credit is due to the sponsors of this project to allow an independent evaluation because it incurs more costs than an internally-administered evaluation.

Figure 2. Weight shift notification UI screens



4.0 Conclusion

Research activities are a useful means to investigate the need and use of user-centered devices that can impact health and wellness. However, the requirements of research-centric systems are vastly different from that of a consumer-based product. If research indicates a value in developing a consumer product, many R&D activities are required to make the transition. Most research studies emphasize control to optimize internal validity. The use of a consumer product is embodied by the lack of control. Simply put, users must operate and manage the products themselves. With respect to the WiSAT, extensive R&D was required for all three subsystems, necessitating multiple technology development and user testing activities. The result was a more robust system that has the design and functionality of a consumer product to monitor and inform wheelchair users about their weight-shift behavior.

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