OPTIMIZATION OF A LOW-PROFILE DYNAMIC WRIST ORTHOSIS FOR MOTOR-IMPAIRED CHILDREN

AN ACTOR-NETWORK APPROACH FOR REDUCING ABANDONMENT OF PRESCRIBED ASSISTIVE TECHNOLOGY

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Assistive technology devices, as defined by the US Technology-Related Assistance for Individuals With Disabilities Act of 1988, are “any item, piece of equipment, or product system, whether acquired commercially or off the shelf, modified, or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities” (p. 1046). Some assistive technology device users are identified as having varying levels of motor impairment, which makes controlling limbs difficult or even impossible. Unfortunately, children are not excluded from living with such disabilities and disorders, which can include cerebral palsy, muscular dystrophy, and stroke aftermath, and may require the help these devices promise. The established idea that function can be recovered through central nervous system adaptation, or neuroplasticity, has an influential role in how medical care providers approach intervention for those affected (Sharma et al., 2013). Orthotics, which include splints, are a type of non-invasive assistive device for encouraging neuroplasticity or providing functional aid for stabilized or worsening conditions. Splints are medical equipment used for immobilizing parts of the body and provide protection and support. Thus, some children require splints for motor impairments. The technical project concerns experimental evaluation of and modifications for an existing dynamic and low-profile wrist splint designed for these children. Furthermore, the technical project will also encompass the creation of an alternative design that best represents the work of the current team.

Despite the abundance of available prescribed assistive technology, such as orthotics, there is a recognized issue of users, or patients, abandoning assistive devices. The Science, Technology, and Society (STS) paper will examine reported reasons for disuse of these items and identify which reasons could be diminished due to proposed changes in the environment and the circumstances under which the technology is prescribed. The topic of the STS portion is

loosely coupled to the technical project. Orthotic splints are a form of assistive technology, as orthotics aid mobility and functionality. The STS section will instead refer to a broader range of prescribed assistive technology, which includes categories such as Aids for Daily Living, mobility aids, prosthetics and orthotics, and seating/positioning aids (Cook & Krue, 2010, p. 2). The foundation of the relationship involves the assessment of shortcomings surrounding the acceptance of an assistive device, which is a form of technology with which the technical team will be challenged during optimization.

The technical project personnel consist of two other undergraduate students, Sophia Martinese and Madisan Yates, and the advisor William H. Guilford, Department of Biomedical Engineering, University of Virginia. Due to the slow nature of the established patient recruitment protocol, the team and advisor identified a reliable primary project focus. Instead of waiting for incoming subjects for gathering experimental data and performing user-based modifications, the team is shifting toward entirely redesigning the splint, as indicated by the Gantt chart in Figure 1 below.

	Nov. 4th-11th	Nov. 11th-18th	Nov. 18th-25th	Dec. 2nd-9th	Jan. 13th-20th	Jan. 20th-27th
Creating possible solutions						
Identifying best solutions						
Prototyping						
Testing						
Redesigning						

Figure 1: Technical Gantt Chart: The steps in the engineering design process are not fully subjected to the above dates, but the chart provides an initial tentative timeline. Clinical trials presently have no deadline, as subject criteria create a slow recruitment process (Created by Hannifin, 2019).

PROVIDING PATIENT PROGRESS THROUGH ORTHOSES

Children with motor impairments are affected by weak wrist extensor muscles and their flexor muscles may also experience a higher degree of muscle tone, or tension, which both

position the wrist downward in the relaxed state. In this state, wrist flexor muscles are shortened and are at a biomechanically unfavorable position for producing force. This increases the difficulty encountered when gripping and lifting objects, both of which are employed within daily tasks of life, including eating, writing, dressing, and playing. These issues can arise from brain injuries or congenital conditions, notably cerebral palsy; according to the Centers for Disease Control and Prevention (2018), acquired or congenital cerebral palsy is the most prevalent pediatric motor disability. Pediatric patients with motor disabilities can be seen by occupational therapists, who focus on accomplishment of daily activities through development of fine motor skills. Splinting is common within the practice of occupational therapy (OT) for improving hand function and is intended to prevent contractures, increase range of motion, and decrease spasticity (Adrienne et al., 2011).

Currently available splinting options generally surround static splints. In the case of children with a degree of increased tone in the wrist flexor muscles, occupational therapists may have patients practice a multitude of activities while using a static wrist splint. These functional hand splints allow for biomechanically favorable positioning of the hand but restrict the natural wrist movement necessary for fine-tuned hand movements (Jackman et al., 2014). In addition, Burtner et al. (2008) tested upper-extremity splinting methods in spastic hemiplegic children and electromyography data suggested that long-term static splinting may lead to muscle atrophy as a result of disuse (p. 41). Due to the aforementioned limitations, a therapist may instead choose to work on strengthening wrist extensors without implementation of a splint. Prior art and dynamic approaches exist for providing muscle movement. For example, Dynasplint Systems, Inc. provides pediatric splints for restoring range of motion in the wrist and combating joint stiffness but only provide an adjustable, prolonged stretch in the chosen wrist position and do not allow

for constant mobility or finger freedom (https://www.dynasplint.com/product/pediatric-wrist-extension-splint/). Arnold and Janson (2017) also outlined the method for creating a range-of-motion 'dinosaur' splint for patients with limited range in wrist extension and flexion, but the device does not promote muscular strengthening through movement and is quite bulky. In addition, prior art concerns dynamic finger splints that are not low-profile and do not allow for supported wrist mobility (U.S. Patent No. 7601130B2, 2009). Thus, it is clear that a different design is more suitable for providing pediatric patients with a low-profile device for extensor strengthening during daily activities.

One of the aims of the technical project is to evaluate the efficacy of a previous dynamic splint design as a potential solution for aiding affected children by providing biomechanical support while allowing movement. A capstone team from the previous year designed a custom low-profile dynamic wrist splint, a process outlined by Chaillo et al. (2019). Their final design consisted of a commercially available Benik Hand Splint, elastic, a compression sleeve, Velcro, and a D-ring. This design is believed to fulfill the design constraints identified by the previous team and the occupational therapist on the study. As shown in Figure 2, the existing design mechanics lift a weighted hand from the dropped resting state. In this position, flexor muscles within the forearm are now at the optimal length required for producing force, allowing the child to accomplish tasks with more ease and reduced time. The past capstone team also created an Institutional Review Board-approved protocol (HSR #:

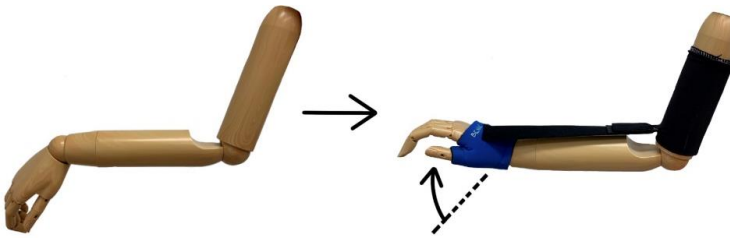

Figure 2: Existing Design for Low-Profile Dynamic Wrist Splint: This design moves the affected wrist to a neutral position through the use of a Benik hand splint and an elastic strap connecting to the compression sleeve on the upper arm (Created by Hannifin, 2019).

21291) for a clinical study (Chaillo et al., 2019, p. 4). The experimental protocol results are expected to provide user-based perceptions and information regarding effectiveness of the existing design. This feedback can affect the team's current design approach.

The subject recruitment process is less timely than anticipated so it is likely that very few subjects will be participating in the clinical trial. Therefore, the team is returning to the beginning of the process to create a new splint design while conducting any possible clinical trials as they arise. This involves analysis of the importance of the current design constraints and possible identification of different constraints. The parts of the existing design have undergone functional decomposition. Through this process, the team can identify combinations of parts for new designs, compare these to the baseline design established through Pugh analysis, and then proceed with the device design chosen. Additionally, the team will estimate the torque applied at the wrist by the ideal design and use an Instron machine to mechanically test material options to determine yield strength and fatigue. Resulting prototypes will also be tested to find the applied forces on the body. The results will provide information concerning what the device is predicted to do and what it actually does when worn. Resources required by the team will include the occupational therapy clinic at the University of Virginia Children's Hospital and any lab equipment needed for materials testing. Funding will be required for gathering materials for prototyping and testing iterations. The technical research will be presented in the form of a scientific journal article.

Ultimately, the desired outcome of the project is a re-design of the proposed splint, a device for patients with similar mobility conditions, that properly positions the hand for activities and training extensor muscles. Through commitment to vital design constraints, re-evaluation of the existing design, and collection of quantitative data concerning the splint functionality, the final

design will ideally be suitable for reducing some of the many difficulties faced by children learning to grow and function with their impairment.

WHAT'S MISSING FROM PATIENT NETWORKS?

The World Health Organization (2018) estimates that 1 billion people, roughly 14% of the global population, are in need of assistive devices. Despite the aid the devices promise to individuals who have access to them, there exists a prominent occurrence of abandonment of assistive technology (AT). Survey data from Phillips and Zhao (1993) established that 29.3% of devices for 227 disabled adults were abandoned, and some of the categorical reasons for abandonment involved device performance, ease of acquisition, and changes in the user's needs (p. 41). A literature study provides that a wealth of relationships exist between prescribed device compliance and certain factors, specifically ones related to the client, medical issues and changes, and device qualities, assessment, and training (Wielandt & Strong, 2000, p. 68-73). A 2000 survey of 155 AT recipients indicates that "consumer involvement [is significantly] related to assistive technology continuance/discontinuance" (Riemer-reiss and Wacker, p. 48).

Insight into the scope of the reasons for AT disuse requires understanding of how someone can receive such a device. The generalized diffusion a prescribed AT device can be visualized through the handoff model (Carlson, 2013). As shown below in Figure 3 on page 7, multiple people are involved in the diffusion of this technology from an idea, indicated by Star A, to the useful product, Star C or D, in the patient's ownership. Each handoff is represented by an arrow. Here, a researcher passes along their idea to a designer through persuasion by their research and evidence backing a difficulty caused by a condition. After taking on the idea and developing a design, the designer must convince manufacturing companies to produce their design, Star B. What comes from the manufacturer, Star C, is the marketed product, which may differ slightly

from the designer's original plans if manufacturing constraints are identified. The healthcare provider seen by the patient either modifies the marketed product, creating Star D, or decides the device is suitable 'as-is', a decision imparted before the last handoff. The provider is likely a specialist the patient is referred to by their physician. The specialist needs the education and insight necessary to identify which available product is best for the patient. In addition, the specialist needs training for performing any modifications to the product, such as selection and creation of different programs for hearing aids, or adding cushioning support or grip material inside or outside a foot orthosis. Finally, the patient, an end user, now receives a device, either Star C or D, that is believed to be the best option for them.

Legend:
A = artifact idea
B = artifact design
C = manufactured artifact
D = modified artifact

Figure 3: Handoff Model Representation of Prescribed Assistive Technology: Each separate person or entity involved in this process, represented by a differently-colored rectangle, procures a version of the artifact, as indicated by the stars. Each player receives the artifact version through a handoff, represented by the arrows (Adapted by Hannifin from Carlson, 2019).

In this situation, the patient holds autonomy over the product and decides on their own if they will use it and for how long. When such devices are decidedly left untouched, any possible health benefits are lost and the economical investments of the user, any associated insurance coverage, and funding for research and design are wasted. Additionally, abandonment may be "seen as a failure for the team, as well as having a potentially negative impact on the healthcare team-patient relationship" (Verza et al., 2006, p. 89).

Due to identified reasons for AT abandonment, suggestions call for reevaluation and structuring within the communication between the user and prescriber; one such observation notes that users find value in being involved in the selection process and receiving instructions for device use, so consumer collaboration and support services are recommended to be in place (Phillips & Zhao, 1993). The psychology of assistive technology devices are additional obstacles that impede acceptance and adoption. Verza et al. report that part of the reason for disuse within the first year may be due to what these devices represent. The initial adoption of AT may validate their complication, affect self-image, and lower the level of perceived independence (2006, p. 92). Patients may also believe that they do not actually need the device or ditch the artifact due to social embarrassment and lowered self-confidence (Wielandt & Strong, 2000). Notable factors relate to the perceived benefit of the device and non-agreement between the user and prescriber. Interestingly, these factors are reflected in the paradigm of medication non-adherence. Medication is prescribed in an environment and fashion akin to AT, but historical lack of adherence has sparked discussion concerning the possible effect of medication communication technologies (Hurtado-de-Mendoza et al., 2015).

The STS paper will indicate the need for more accountability on either side of the last handoff through transforming the model into the scope of a small-scale actor network. It is apparent that some form of an actor, which can be human or non-human based on Law and Callon's Actor Network Theory (ANT) (1982), is necessary for decreasing assistive technology disuse. This missing part of the network, as indicated by the top right box in Figure 4 below, will transform the level of agency and responsibility between human actors but must not strip away values held by direct or indirect users. The human actors and their one or two-way relationships are represented by the blue circles and arrows respectively. Non-human actants are represented

by the green rectangles. The missing actant's effect will be under investigation to replace and understand the links and relationships indicated by the question marks.

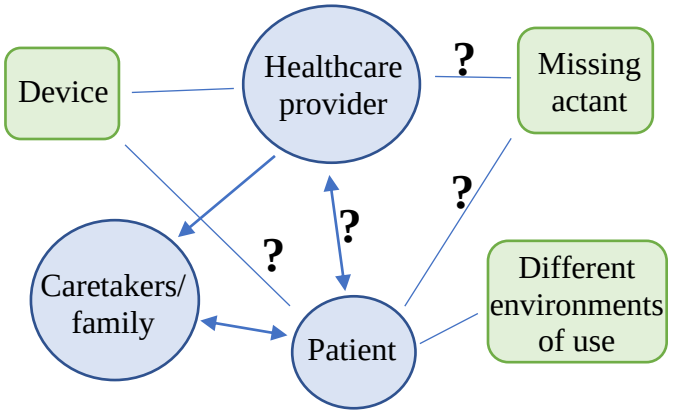

Figure 4: Prescribed Assistive Technology Actor Network with Variable Actant: The introduction of a non-human actant has the potential to impact the essential provider-patient relationship and the technology use, but the changes are unknown, as represented by the question marks (Created by Hannifin, 2019).

As with the medication technologies mentioned above, there is a concern over intrusiveness and power manipulation upon implementation of an artifact perceived as a control mechanism (Hurtado-de-Mendoza et al., 2015). The paper is intended to identify actant options, whether in the realm of insurance policies, AT device programs, or the provider-patient interaction, and discuss how levels of agency, communication, and technology use are altered due to the actant's presence. This will require insight into published policy, organizational and clinical recommendations, as well as consideration of human values and core ethics within the healthcare system. In addition, the STS portion could benefit from interviews with healthcare providers who match patients with assistive devices, as they potentially have methods aimed for increasing this form of adherence.

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