LOW-PROFILE DYNAMIC WRIST ORTHOSIS

IS INSURANCE A BARRIER TO RECEIVING TREATMENT?

A Thesis Prospectus
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Bachelor of Science in Biomedical Engineering

By
Madisan Yates

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Technical Project Team Members
Kelsey Hannifin, Sophia Martinese

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.

Signed: ____________________ Date: 12/5/19

Approved: ____________________ Date: Dec. 6, 2019
Catherine D. Baritaud, STS Division, Department of Engineering and Society

Approved: ____________________ Date: 11/26/2019
William Guilford, Department of Biomedical Engineering

In the past, children with disabilities such as cerebral palsy, muscular dystrophy and hemiplegia were forced to wear bulky, rigid splints in an effort to help strengthen their wrist extensor muscles. These children chose not to continue the use of those devices because of the discomfort, look and usability of the device. Changing the design constraints to add ones such as low profile and dynamic movement will improve the usability of the wrist orthosis for children affected by motor impairments like cerebral palsy and muscular dystrophy. Low profile and dynamic mean that the material cannot be bulky and must allow for the movability of the wrist in many directions including flexion, extension, adduction and abduction.

The timetable shown in Figure 1 demonstrates what the team intends to accomplish by the end of January when returning from winter break. Each task is in order, as read down the first column and will be completed accordingly as shown in Figure 1. As the team moves forward with the design process, each task may take shorter or longer than laid out in the Gantt chart but looking ahead, the blue boxes in Figure 1 show the current time estimations for completion.

	11.04.19-11.11.19	11.11.19-11.18.19	11.18.19-11.25.19	12.02.19-12.09.19	01.13.19-01.20.20	01.20.20-01.27.20
Creating Design Combinations						
Selecting Two Solutions						
Prototyping						
Testing						
Iterations						
Clinical Trials						

Figure 1: Gantt Chart for Capstone Team: The Gantt chart represents a timeline through the beginning of next semester. Each column represents a different week in which the team will work on a different task for the remainder of the semester and into the following semester. The blue boxes represent time which will be spent working on each task (Yates, 2019).

The prospectus outlines orthotic and prosthetic device development through both technical and social lens. The technical portion focuses on the physical product development while the social portion focuses on the impact of insurance companies on the transferability of the product. The completion of the capstone project relies on team collaboration between Kelsey Hannifin and Sophia Martinese with advising from Professor William Guilford, of the Biomedical Engineering Department at the University of Virginia. The tightly coupled Science, Technology, and Society (STS) portion will analyze the barriers created by insurance companies that patients using orthotics and prosthetics face, using the actor network theory.

Children affected by motor impairments caused by cerebral palsy or muscular dystrophy, or acquired through injury such as stroke, can have weak wrist extensor muscles. It is often difficult for these children to control their limbs and with varying degrees of muscle tone, the wrist may already be put at a disadvantage in a relaxed state. The relaxed state makes it difficult for the child to perform simple tasks such as grabbing and lifting objects, which are vital for completing daily tasks including playing, writing, and eating.

On average, cerebral palsy affects 1 in every 323 children (CDC, 2018) while muscular dystrophy affects 1 in every 7,250 male children (CDC, 2019) in the US every year. Strokes affect 12 in every 100,000 children in the US every year (Philadelphia, 2014). In current therapy practices used to help treat these motor impairments, occupational therapists use one of two methods for treating weak wrist extensor muscles; one way is to use a static splint, which assists in biomechanical positioning and allows for optimal joint alignment and controlled movement for the patient (Lannin & Ada, 2011). In an Ireland study, occupational therapists preferred the use of static splinting for post-stroke patients due to the device's ability to reduce muscle spasticity and prevent soft tissue contracture while also improving overall range of motion (Adrienne & Manigandan, 2011). The other way is to simply use no splint and focus solely on strengthening the wrist extension abilities of the patient. A study compared the effect of static versus dynamic splinting on dexterity, pinch strength, and grip strength between children with and without cerebral palsy. Results indicated that static splinting or no splint at all did not improve any of the tests listed above for the patients. Dynamic splinting was the only form of treatment that improved the tests for the children with cerebral palsy (Burtner et al., 2008). Based on the results of these studies, a dynamic splint should strengthen the wrist extensor muscles to a point where the wrist raises optimally for the patients more than a static or no splint method.

CURRENT DYNAMIC SPLINT

As described by Chaillo et al. (2019), the capstone team from the 2018 year produced a prototype as a potential aid for patients with the motor impairments described above. Through identification of user needs, the team the final design of the velfoam sleeve seen in Figure 2, which consisted of compression fabric, Velcro, a plastic D-ring, an elastic strap, and a Benik Hand Splint with thumb support. The recognized design constraints were and still remain crucial for progression of the wrist splint: allowing dynamic movement and variable tension, durable, low-profile, supporting proper wrist and thumb positions, and customizable per each patient. The most important design constraint is pulling the patient's wrist up to the neutral position of 20°, which again is demonstrated in Figure 2.

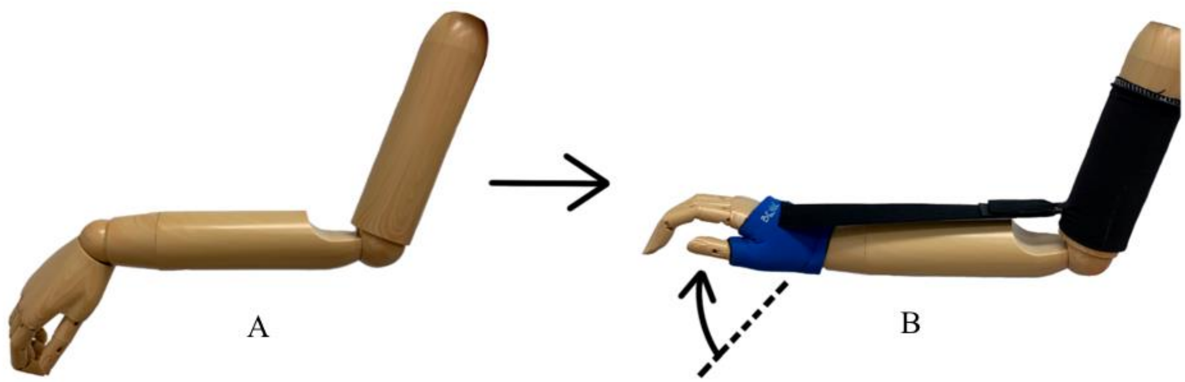

Figure 2: Existing Design for Low-Profile Dynamic Wrist Orthosis: Image A represents a wrist with weak extensor muscles, not wearing an orthotic device. Image B represents the same wrist wearing the existing low-profile dynamic wrist orthosis. The bottom arrow on Image B demonstrates the orthosis pulling the wrist up to the 20° neutral position (Adapted by Madisan Yates from K. Hannifin, 2019).

In order to experimentally determine the effectiveness of the design, the previous team created a protocol, which was approved by the Institutional Review Board. Therefore, the current team is tasked with carrying out the clinical trial, alongside any approved protocol modifications, to gather experimental data concerning the effectiveness of the device. The results will inform design changes for the finalized and optimized splint design. Working with consumers at every possible step of innovation will encourage production of a device that addresses and serves the most important needs of intended patients.

By testing pediatric patients in clinical trials, the results gained will assist in modifying the low-profile dynamic wrist orthosis. The overall support and dynamic movement, material, and aesthetic will be improved by these modifications. The outcomes are expected to help many pediatric patients with their overall functioning in everyday motions and tasks.

CONTINUING RESEARCH PLANS

Through Sue Berres, an occupational therapist at the University of Virginia hospital, the capstone team has access to the University Pediatric Occupational Therapy Center. The center gives the team a space for the clinical trial to take place in, as well as an area to craft each wrist orthosis when the time comes. Funding may be needed for materials in order to modify the existing model of the wrist orthosis. In order to change the model, materials such as elastic bands, wrist splints, and compression fabrics may need to be purchased at a later date.

While waiting for clinical trial patients, the capstone team will be moving forward with modifying the design through first, assessing and outlining the design constraints of the orthotic. The team will then complete a functional decomposition of the existing device to evaluate what other materials may be used to replace the current design components. A Pugh chart will be created to compare different design ideas once the functional decomposition is complete. Once new design ideas are fully evaluated for their effectivity, the capstone team will begin to construct the designs into physical models. Then the team will perform different tests on each model to evaluate which one is best and complete multiple iterations for the designs that demonstrate the most effectivity. The technical research gained from the capstone project will be written as a scientific article fully explaining the materials, results, discussion and the conclusion of the capstone team's project in its entirety.

IS INSURANCE A BARRIER TO RECEIVING TREATMENT?

As insurance companies become more and more involved in the healthcare industry, their impact on patient care is being assessed. Most insurance companies have a section within their policies stating what the covered benefits are for orthotics and prosthetics. Benefits may include anything from orthopedic shoes to multiple pairs of inserts a year (United Healthcare of California, 2019). Biddiss et al. (pg. 222, 2011) stated that "there is an absence of clear, consistent and central accountability mechanisms, which are vital in advancing the agenda for inclusive and more integrated services." With patients all over the world receiving different standards of care due to insurance companies treating everyone differently, it makes patient treatment difficult for the orthotists and prosthetists. To improve the overall healthcare system, more research should be done on insurance companies and their approval response rates of the orthotic and prosthetic devices.

MODELING OF THE INSURANCE COMPANIES

The actor network theory, represented in Figure 3, demonstrates the actants that play a role in the decisions and actions the actors take within the orthotic and prosthetic field. There are three actors in this network: patients, orthotists/prosthetists, and insurance companies. Each actor is impacted by different actants in the network: time, money, orthotic and prosthetic (O&P)

devices, and legislation. Legislation is an actant which impacts the insurance companies through the policies they have in place. Time is an actant which impacts the insurance companies through how long it takes them to approve the devices, orthotists and prosthetists through how long it takes them to make the devices, and patients through how long it takes them to receive the devices. Money is an actant which impacts the insurance companies through how much of the device the insurances will cover, orthotists and prosthetists through how much they charge the insurances for the devices, and patients through how much they spend on the devices after insurances have covered a portion. O&P devices are actants which impact the insurance companies through, depending on what the device is, them not approving the device, orthotists and prosthetists through them physically being in charge of making the devices, and patients through receiving the actual devices.

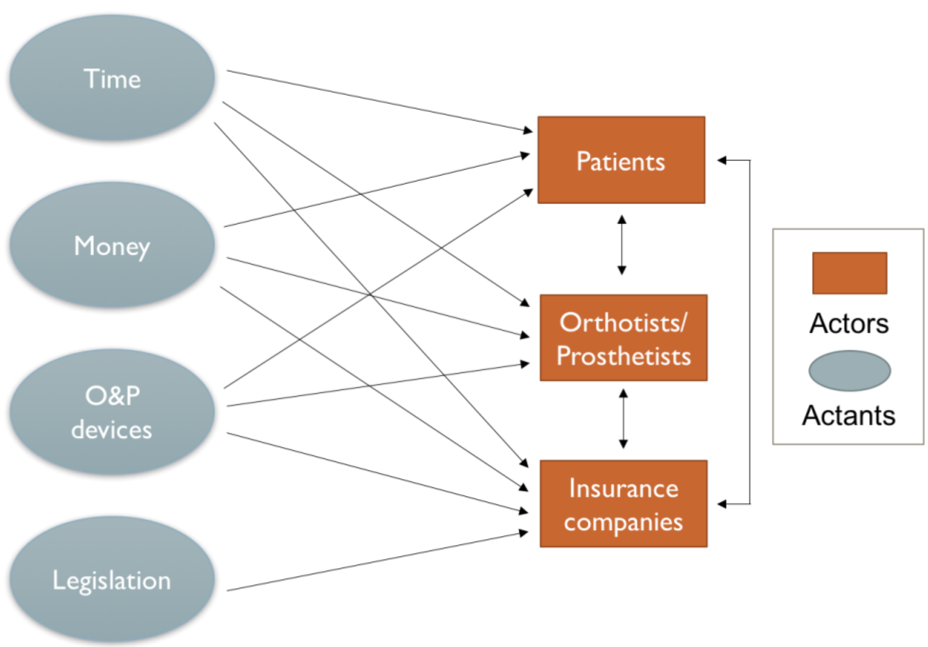

Figure 3: Actor Network Theory in the Context of O&P: The blue ovals represent actants within the network which impact the actions that the actors, represented by the orange rectangles, take in the orthotics and prosthetics field. (Adapted by Madisan Yates from Law and Callon, 2019).

Due to variations and inconsistencies in coverage for O&P devices, insurance companies vary in their response times and answers to O&P offices (Biddiss, McKeever, Lindsay, & Chau, 2011). In France, Sweden and the Netherlands, Simoens et al. (2008) found that based on varying rules for reimbursement, the patient would either have the O&P device paid for up front by insurance companies if approved or patients would have to ask for a reimbursement after the fact. Based on reimbursements and the model in Figure 3, patients would always be receiving their device but at what cost?

When patients come into an Orthotics and Prosthetics (O&P) office to be assessed for a device, normally a mold or cast is taken for the orthotist or prosthetist to make the device at a later date. In between the initial appointment and the appointment set for delivering the device, it may take a few days or up to a month for insurance to approve the device, depending on the patient's insurance company (M. Bryant, personal communication, October 28, 2019). Skaggs et al., (2007) found that children with preferred provider organizations (PPO) always had their devices approved faster than children with government-sponsored or health maintenance organizations. The government-sponsored insurance, even though they were found to approve all devices at a slower rate, approved ankle-foot orthoses (AFOs) much quicker than thoracic lumbar sacral orthoses (TLSOs). The TLSOs cost 4 times as much as the AFOs causing insurance companies, such as Medicare and Medicaid, to push off approving the devices. The actual procurement of the braces was faster for PPO children as well, most likely due to other factors such as socioeconomic status, time off of work and transportation barriers. In order to assess why specific insurance companies respond faster to their patients than others, research needs to be done into what the companies look for when approving devices for patients.

Further research into the insurance companies will hopefully lead to a better understanding of the relationships between the orthotists and prosthetists and the insurance companies. In order to address the problem of slow response rates all together, determining what can improve amongst the insurance companies may create the long term change needed within the healthcare field for years to come. Ideally, the research will shine a light onto what will prompt companies to work at a faster rate than they do currently, giving patients a better outcome with their O&P devices.

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