Robotic Hand Orthosis Providing Grasp Assistance for Patients with Brachial Plexus Injuries

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Project Summary/Abstract

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The brachial plexus is a network of nerves that transfers signals originating in the cervical spinal cord to the shoulder, arm, hand, and fingers. These nerves provide motor function and sensation to those structures. Traumatic injury to the brachial plexus in adults can result in paralysis of the upper limb in varying degrees of severity. Surgical intervention can restore motion and control to the shoulder, upper arm, and lower arm through muscle and nerve grafts. However, hand mobility and control is difficult to restore, resulting in severe disability and decrease in quality of life for patients with impaired functionality following such an injury. Robotic exoskeleton technology can be utilized to provide an assistive device that provides significant improvement in the mobility and dexterity of a paralyzed hand.

The *overall objective* of this research is to design, fabricate, integrate, and test a lightweight and portable robotic hand orthosis intended to restore hand functionality through fully controllable individual finger actuation. This objective is based on the *hypothesis* that use of such a robotic hand orthosis will result in significant improvement of hand ability for adults with brachial plexus injury, as evaluated through the Southampton Hand Assessment Procedure (SHAP).

To achieve this, *several novel design aspects* are incorporated. The use of miniature linear actuators and lightweight materials allows for the motors and sensors to all mount atop the dorsum of the hand, and eliminate the need for bulky external actuation units. In addition, the actuators have inbuilt force sensing capabilities to provide feedback on the force being applied to each individual finger, even before contact is made with a grasped object. Furthermore, wrist flexion/extension is powered, resulting in a more realistic grasping paradigm than is commonly found in robotic orthoses. Moreover, an intuitive control system will be designed in order to fully capitalize on the controllability of each finger, allowing for varied grasp geometries and motions.

A summary of the specific aims of this study are:

1. Design and prototype the robotic hand orthosis with the goal of creating a uniquely dexterous, lightweight and portable device. In addition, the control methodologies required to exploit the full capabilities of the orthosis will be designed. This will result in the development of an experimental research platform to determine the viability of the design and hypothesis.

2. Perform a feasibility trial of the robotic orthosis device by providing it to a small cohort of adult patients suffering from paralysis due to a brachial plexus injury. The patients will be assessed via the SHAP, and their respective scores both with and without the orthosis will be evaluated to determine their level of improvement in dexterity and function.

Project Narrative

The proposed research, the development of an innovative robotic hand orthosis with intelligent grasping control, is relevant to public health as it will restore a large measure of functionality to the paralyzed hand of a person who has suffered a brachial plexus injury. The proposed orthosis will utilize novel technology that will result in a device that is compact, portable, dexterous, and intuitively controllable while overcoming the disadvantages of previously developed orthoses that rendered them difficult to use. The restoration of functionality to ones hands will significantly improve their quality of life as well as their ability to again participate in the workforce and complete dexterous activities in their daily lives.

Facilities and Other Resources

Virginia Tech

1. Robotics and Mechatronics Lab (RML)

The PI's lab is a well-established and rapidly expanding 3,500 square foot research center on Virginia Tech's main Blacksburg campus located on the ground level of Randolph Hall at 460 Old Turner Street. The lab is divided into four major areas/rooms, including student workspace, a prototype integration area, a workshop with fabrication facilities and storage, and a conference room. In terms of current ongoing work, the laboratory currently houses several haptic glove prototype systems, a Novit Falcon haptic interface, Geomatic Touch haptic devices, several cable and rod-driven continuum robotic test platforms, several serpentine tail prototypes (universal-spatial robotic tail, roll-revolute-revolute robotic tail, discrete modular tail), a fully integrated hybrid mobile robot, , several docking mechanisms for modular and reconfigurable robotics, a prototype spatial tracking system, an RC helicopter instrumented for ship air wake measurement, and two mobile robot hexapods instrumented for either teleoperation or vision-based autonomous operation.

Experimental data analysis, computer-aided design (CAD), and code synthesis are performed on a variety of laptops and desktops/workstations in the lab. Experimental code is written in Simulink, LabView, C/C++, Python, and VisualStudio. Data analysis is performed using Matlab, Excel, and Python. CAD models are built in Solidworks and then validated through ADAMS, ANSYS, and Abaqus simulation software. In addition, the lab possesses a multitude of microprocessors and single board computers from manufacturers such as Teensy, Arduino, Raspberry Pi, O-Droid, and Tegra in order to quickly design and synthesize mechatronic prototypes.

RML currently hosts 12 graduate students, including six full-time Doctoral students and six full-time Masters students. The number of graduate students is expected to grow to 16 in Fall 2018, with the addition of four more full-time Doctoral students. The PI also has access to additional full-time electrical and software support engineers and several undergraduate and local high-school students that participate in research activities inside the lab throughout the year.

2. Department of Mechanical Engineering Machine Shop

RML is located on the same floor at the Mechanical Engineering Department's Machine Shop. The shop contains a variety of equipment for general and specialized machining, including computer numerical control (CNC) lathes, CNC milling machines, drill presses, a laser cutter, and 3D printers. The machine shop staff is available to assist in manufacturing at no direct cost other than materials. The machine shop will be used for manufacturing experimental hardware for the prototype work (as needed), and is fully available for the research project.

3. Terrestrial Robotics Engineering and Controls (TREC) Lab

In addition to his own laboratory space, the PI also has access to Virginia Tech's TREC lab. TREC features a fully equipped in-house machine shop. Equipment includes a 3-axis Hurco Vertical Machining Center, 3-axis Tormach 1100 personal CNC machine and Baleigh digital lathe. It also features a personal laser cutter, band saw, and drill press, as well as a fully furnished electronics maintenance area.

4. Department of Mechanical Engineering CAD Lab

This lab provides high-performance computing for interactive CAD/CAM/CAE education and research utilizing a suite of high performance workstations. Pertinent software includes ANSYS, AutoCAD, all Autodesk software offerings, CATIA, FLUENT, LabView, NX, Pro/Engineer, SolidWorks, and many other industry standard CAD software.

5. The Frith Design Laboratory (Frith Lab)

The Frith Lab is a space designed to support the retention and development of young engineers through hands-on learning, peer mentoring, and authentic problem-solving. Part collaboration and innovation space, part fabrication and prototyping space, and part learning laboratory, the Frith Lab enables engineering students to learn by dissecting, designing, making, and analyzing engineering products. The lab features over $150,000 worth of equipment that any student working on this research grant can use once they have completed the safety training required for a machine. It features a Tensile/Compression Materials Testing machine, 3-D printers, laser engraver, CNC router, and drill press, along with various hand tools available for checkout. The tools can be used for projects assigned in engineering classes but students are encouraged to come and use the lab for their own research work as well.

6. Research Centers

The PI is a Core Faculty Member of the Virginia Center for Autonomous Systems (VaCAS) and an Affiliate Faculty Member for Virginia Tech Center for Bio-Inspired Science and Technology (BIST). These centers provide a forum for discussing ongoing research projects with faculty peers and interested students to obtain feedback and suggestions about the ongoing research work.

7. Administrative Support

Virginia Tech has research coordinators to assist with paper work and other administrative functions for administering grants. Their offices have high speed copy machines that are networked to the PCs in the labs and a fax machine. Two full-time department staff assists us with our computing needs. Other support staff includes university IT offices, and a designated departmental staff member to assist the PI with purchasing and other administrative functions.

8. Library

The PI has electronic and physical access to Virginia Tech's University Library system. Virginia Tech provides its faculty and students access to a wide cross-section of high-quality journals and conference proceedings, allowing the PI and his team to stay current on state-of-the-art advances during the award. Any book or paper to which the PI and his team do not have access may be easily ordered through the Interlibrary Loan service and digitally or physically delivered.

Carilion Clinic Institute of Orthopaedics and Neurosciences

1. Carilion Clinic

Carilion Clinic is a not-for-profit, integrated healthcare organization composed of seven hospitals that range in size from a 25-bed critical access hospital to a 737-bed academic medical center, including a Level 1 trauma designation, three Life-Guard helicopters and representation from all major specialties and sub-specialties of medicine. In addition, Carilion includes Jefferson College of Health Sciences, an accredited institution providing allied health education to nurses, physician assistants, respiratory and occupational therapists and emergency services personnel at the Associates, Baccalaureate and Masters levels. Lastly, Carilion partners with Virginia Tech for the Virginia Tech Carilion School of Medicine and Research Institute.

The clinic approach, represented by other notable delivery systems including the Cleveland and Lahey Clinics, embodies an integrated approach to providing patient-centered healthcare. Since announcing the model, the number of physicians employed with Carilion has jumped from 419 to 681, with the total number of advanced care providers currently sitting at nearly 1,000 employees. System-wide, Carilion consists of more than 240 individual practices throughout southwest Virginia offering a wide spectrum of care, including urgent care, home health, retail pharmacies and wellness centers.

Carilion is headquartered in Roanoke, VA and its flagship hospital, Carilion Roanoke Memorial Hospital (CRMH), is one of the largest in the state of Virginia. As the region's only Level 1 Trauma Center, it acts as a regional resource that has provided access to comprehensive trauma services since 1983. CRMH is also home to Carilion Children's, a full service, 92-bed "hospital within a hospital" that provides medical care to neonatal, pediatric and adolescent patients. System-wide, Carilion serves nearly one million patients across western Virginia and parts of West Virginia and North Carolina.

2. Carilion Clinic Institute for Orthopaedics and Neurosciences

The Carilion Clinic Institute for Orthopaedics and Neurosciences brings specialists in orthopaedics together with those in neurosurgery, physical medicine and rehabilitation, pain management, physical, occupational therapy, and imaging with 500-700 patients seen daily. The 116,000 square foot facility possesses 125 patient exam rooms, 9 procedure rooms, 6 conference rooms, and 7 diagnostic imaging rooms. The 250 person staff and 83 healthcare providers, including 37 orthopedic surgeons and 8 neurosurgeons, excel in all forms of treatment, ranging from medications and therapy to surgical and non-surgical procedures. Specialties within the orthopaedic program include Hand & Upper Extremity, Foot and Ankle/Podiatry, Orthopaedic Spine, Orthopaedic Trauma, Sports Medicine, Concussion Management, Joint Replacement, Neurosurgery, Physical Medicine and Rehabilitation, Pain Management, and Pediatric Orthopaedics. Therapy services offer both physical and occupational therapy housed in dedicated rehabilitation space, with certified hand therapists available for same day appointments.

Leadership Team Organization

As a mechanical engineering and electrical and computer engineering professor whose expertise is mechatronics design, control system design, and robotics, Prof. Ben-Tzvi will guide the design process of the proposed robotic hand exoskeleton orthosis. Monthly in-person meetings during the design phase of the project at Carilion Institute for Orthopaedics and Neuroscience in Roanoke will allow the design team to receive expert advice and input from Dr. Bravo, as well as from occupation/physical therapists familiar with brachial plexus injuries. Dr. Bravo will be in charge of the design and execution of the pilot study during the trial phase, with weekly in-person meetings between the two teams commencing once the project has progressed to that stage. Both teams will work together to conduct the trials for the study itself that will be conducted. Throughout the duration of the project, weekly teleconferences will be held when there are no in-person meetings scheduled in order to keep all members of the project up to date. With Dr. Bravo based at the Virginia Tech Carilion School of Medicine as well as ION in Roanoke, VA and Professor Ben-Tzvi at Virginia Tech in Blacksburg, VA, the two teams are separated by only a 45 minute drive.

Specific Aims

The brachial plexus is a network of nerves that transfers signals which provide motor function and sensation to the shoulder, arm, hand, and fingers. The network originates in the cervical spinal cord (neck) and extends to the shoulder, arm, hand and fingers. While injuries to this region may occur in newborns during birth, they can be successfully repaired via surgical intervention; however, when caused by trauma in adults, injury to the brachial plexus can result in paralysis of the shoulder, arm, and hand with varying degrees of severity. In such cases, surgical options have had success restoring shoulder and arm function, but less so in returning sensation and mobility to the hand [1].

Robotic exoskeletons, gloves, and orthosis have been active research subjects for many years [2]; however, structural and operational hurdles make them impractical for wide spread use by patients. Current systems, whether rigid exoskeletons or pneumatic/cable actuated soft systems, often require large external actuation systems, and may not properly track natural finger flexion if not perfectly aligned. Both features result in a device that is neither portable nor comfortable. Moreover, prior designs are often controlled via electromyography (EMG) sensors attached to the injured arm, or by sensing finger motions of the injured hand and magnifying them. However, due to the full arm and hand paralysis faced by patients suffering from brachial plexus injury, this is not always a feasible control method.

Our *long-term objective* is to develop an intuitively controlled robotic orthotic solution designed to restore a measure of grasping ability and hand functionality in daily activities to greatly improve quality of life for patients with various levels of hand paralysis and loss of sensation due to brachial plexus injury. Our previous work on exoskeletons and robotic gloves [3]–[17] as well as our partnership with the expert surgeons and occupational hand therapists at the Carilion Clinic Institute for Orthopaedics and Neurosciences, puts us in an excellent position to provide such a solution. The *goal of the present application* is to design and integrate a prototype robotic hand orthosis and perform a pilot test involving a small number of patients with brachial plexus injuries to study the design's feasibility.

The *hypothesis* behind this proposal is that a portable, lightweight, compact robotic hand orthosis can significantly increase the injured hand's functionality, as measured by the patients' ability to perform in an accepted and standardized testing protocol. This hypothesis will be tested by completing the following specific aims:

Aim 1: Design and prototype a robotic hand orthosis that provides grasp assistance for patients suffering from hand paralysis due to brachial plexus injuries

This aim does not necessitate a hypothesis, as it is directed towards the development of the robotic hand orthosis. The orthosis will be designed to assist patients in daily grasping motions, while being lightweight and portable enough to be comfortably worn throughout the day. In addition to delivering a device that will be used to determine the feasibility of the research, a unique and novel method for controlling the orthosis will be developed to provide a greater degree of control for the robotic hand orthosis. The prototyping stage will be conducted in concert with Dr. Bravo as well as with input from patients with this type of injury.

Aim 2: Perform a pilot study on a small group of patients with hand paralysis due to brachial plexus injury

Hypothesis: Adult patients suffering from paralysis caused by a brachial plexus injury will report an increase in hand functionality in daily activities performed while wearing the robotic hand orthosis as compared to their ability to perform these activities without the orthosis.

This will be measured by requesting the patients to perform a combination of activities as laid out in the Southampton Hand Assessment Procedure [18]. In this assessment, the subject performs a series of abstract tasks as well as activities of daily living (ADLs), which are timed by the participant and recorded by the assessor. The times are normalized and classified by grip configuration. The *expected outcome* of this aim is that while wearing the orthosis, the wearer will be able to perform the tasks significantly faster ($\alpha = 0.05$).

In addition, qualitative data regarding fit, control functionality, and device performance will be collected from the patients following the trials and incorporated into the design. This will provide further optimization of the orthosis in order to deliver the highest possible level of assistance.

Significance

Injuries to the brachial plexus, the cervical confluence of the nerves that control the arm, can result in partial or complete unilateral paralysis**.** In traumatic adult cases, the cause is often a severe impact (such as a motor vehicle accident), or a sudden extreme out and upward jerks to the arm. One study reported such an injury was identified in 1% of multi-trauma victims, and in nearly 5% of motorcycle and snowmobile accidents [19]. Brachial plexus nerves can be injured at the root level of the cervical spine (preganglionic injuries) or distal to dorsal root ganglion (postganglionic injuries). The root avulsion injuries require early surgical treatment, whereas postganglionic injuries have greater potential for clinical recovery so surgery is often delayed. Therefore, there is a balance between a wait-and-see approach and early surgical intervention. If the patient's nerves fail to regenerate and the surgery is delayed long enough, the resulting paralysis is difficult to treat due to the permanence of nerve injuries, causing significant impairment for the injured [20].

The Disability of the Arm, Shoulder, and Hand (DASH) score is used to rate the ability of an injured person to perform everyday activities [21]. A score of 100 is complete disability, while 0 is no disability. Prior to surgery, the responses of adult patients with a brachial plexus injury in one study reported a mean DASH score of 52, representing a severe disability [22]. However, the study found that one-third of patients reported no noticeable improvement following surgery, and a large percentage of patients were unable to return to work. The surgeries utilize neurolysis, nerve grafts, and neurotization in order to heal, replace, or regenerate the limb's nerve function [23]. Unfortunately, due to the hand's complexity, restoring hand function is largely unsuccessful, even though rough motion can be restored to the rest of the arm. Improving hand function for these patients can thus provide a significant improvement in their capacity to perform daily actions, ability to work, and their overall quality of life.

Prior attempts to provide increased hand mobility and grip strength for brachial plexus injury patients range from a simple on-arm pinch grip orthosis to a "bionic" prosthesis. The pinch grip orthosis utilized a linear actuator to actuate a thumb brace, allowing the patient to use the affected hand for basic gripping actions [24]. The orthosis was controlled myoelectrically through the placement of diodes embedded in the orthosis in contact with the patient's forearm. For the bionic prosthesis, the injured hand was partially or fully amputated and replaced with a prosthetic hand [25]. A free muscle was then implanted into the forearm along with a selective nerve transfer to allow for control of that muscle. Electromyographic (EMG) feedback from the muscle is used to control the prosthesis after an extended rehabilitation and training period. While promising, this method requires major surgery, including amputation, and the attendant possible complications as well as a very long rehab and training process. In the proposed research, the use of a lightweight, compact robotic orthosis has the potential to greatly increase the hand's usability without requiring extensive surgery or training. Recent work in soft and rigid robotic hand exoskeletons, gloves, and orthoses has largely targeted wheelchair bound patients. This allows the units to be large and require sizeable external compressors, batteries, motors and/or air cylinders that can be transported on the chair. Requiring someone to transport such a large base unit is not desirable for ambulatory patients.

Work on such an orthosis targeting patients with brachial plexus injury would leverage the PI's extensive history building and testing robotic exoskeletons, gloves, and orthoses for a myriad of applications, from haptic control [13]–[15] to rehabilitation [5], [10], [16], [17] to virtual reality interaction [3], [4], [11], with a selection of these projects shown in Figure 1. In Figure 1(a), the SAFER glove is shown grasping different objects. This robotic glove used a novel cable routing system to drive the rigid frame, without the need for an external battery and actuation units. While possessing onboard

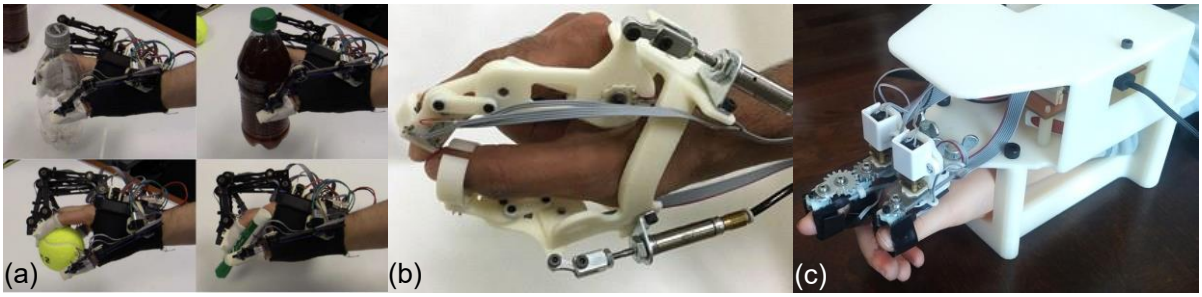

Figure 1. Related Prior Research: (a) SAFER glove demonstrating different grasps [16], (b) Two-finger pneumatic exoskeleton [6], (c) Cerebral palsy diagnostic device for children

actuation, computation, position sensing and force sensing, the frame was too large and bulky for practical daily use. A pneumatic two-finger robotic orthosis prototype is shown in Figure 1(b) [6]. The design utilizes pneumatic actuators and a lightweight 3D printed design to provide extremely fast actuation of the digits. The pneumatic actuators also provide a high degree of controllability, but require both an air compressor and a pneumatic cylinder, hindering its portability. The device shown in Figure 1(c) is intended to assist doctors in the diagnosis of cerebral palsy in children through a reflex assessment. Unlike the previous two systems, this was designed to be table-mounted with miniaturized finger mechanisms in order for them to be suitably small for use by children in the age group of 1-5 years. The hand pictured with the system belongs to a 5-year-old child. Our experience with miniature and precision mechanisms lends itself well to this project.

The proposed research aims to develop and integrate a compact, portable robotic hand orthosis that utilizes series elastic actuators to provide self-sensing force measurement, a compact form factor, and a high level of dexterity and grasping force controllability. The orthosis will have the potential to greatly improve the manual grasping dexterity of patients suffering from brachial plexus injuries.

Innovation

The proposed robotic hand orthosis has significant potential to restore hand functionality in a population underrepresented in prior robotic glove and exoskeleton studies due to the localized yet complete nature of their nerve damage and the wide variability in resulting impairment. Our research aims to remedy the shortcomings in previous strategies to create a lightweight and portable robotic hand orthosis. It is our belief that the proposed orthosis is innovative due to its combination of portability and dexterity, enabled by novel actuation and control methodologies developed by our team. While the approach is exploratory, the orthosis has the potential to return grasp functionality and dexterity to patients suffering from an injury that often results in significant levels of disability. Integration of an intuitively controllable, lightweight and portable robotic hand orthosis would lead to significant improvements in quality of life and ability to re-enter the workforce following a serious traumatic injury. In addition to the minimal form factor of the orthosis, the finger mechanisms ensure natural bending utilizing side-mounted linkages, a novel rigid orthosis solution based on an extensive literature review.

Furthermore, the orthosis will be operated through a small set of verbal commands that correlate with an equally small set of archetypal grasp groups defined by their interaction with similar object geometries. These groups encompass the 33 common grasps defined in [26]. Upon receiving the command for one of these groups, i.e. “Cylinder”, the system will begin to flex the fingers through a progression of the grasps in that group, each targeted at grasping sequentially smaller objects. The temporal patterns and naturalistic motion paths are characterized by grasp mappings via Principal Component Analysis (PCA) [7]. Once the regression model determines the orthosis has reached a defined degree of similarity with a grasp, the motion will stop. When the grasp is to be released, the user simply says “Open” and the orthosis will release the commanded grasp.

Finally, the addition of wrist flexion/extension actuation in tandem with grasping motions will enable natural and comfortable action. The robotic hand orthosis is designed to restore the majority of pinch and grasping functionality to both fully and partially paralyzed hands. While outside the purview of the proposed study, the orthosis may also be used as a combination rehabilitation-biofeedback device during recovery from surgical treatment while waiting for nerves to regenerate. The orthosis would keep joints supple, avoiding contractures, and provide biofeedback of the extremities, which could potentially enhance recovery post-surgery. This functionality will be explored in future studies.

Approach

Aim 1: Design and prototype a robotic hand orthosis that provides grasp assistance for patients suffering from hand paralysis due to brachial plexus injuries

Overall Strategy: The objective is to produce a lightweight, portable, intuitively controllable, and compact rigid orthosis to increase the manual dexterity of adult patients whose hands are paralyzed due to nerve damage. This will help improve the quality of life for patients with brachial plexus injury, as surgical options are limited for adult patients. Our team’s previous expertise in designing, prototyping and integrating of robotic exoskeleton gloves in addition to the medical expertise from the clinical team members will be leveraged to create an orthosis to provide maximal assistance to the patients.

Preliminary Studies: Current robotic exoskeletons, gloves, and orthosis technologies are thoroughly

described in review literature [2], [27], [28]. Upon a meta-review, it can be seen that such devices are often too large for everyday use, require significant exterior actuation units, and utilize user control systems that either amplify existing hand motions or incorporate EMG inputs. Generally, when building robotic exoskeletons and orthoses, researchers follow one of two design methodologies. In the first case, a rigid exoskeleton is used to apply forces at the locations where the tendons of the hand normally apply forces, resulting in a large and protuberant rigid outer frame, or, as in the case of the Rutgers glove, a rigid structure mounted on the palm of the hand [29], [30]. The CyberGrasp® [31] and the Festo ExoHand [32] are both state-of-the-art commercial exo-gloves that, while providing impressive levels of dexterity, have large and bulky profiles that preclude their use day-to-day.

An alternative approach is the application of soft robotics principles for gloves and orthoses. However, many of these innovative designs are still rather thick due to the need for inflatable segments to induce bending and require compressors and air storage cylinders to operate [33], [34], which hinders the user's mobility. The pneumatic inflatable actuators also have difficulty approximating natural flexion. Alternatively, exoskeleton gloves that utilize routed cables for actuation are another approach for robotic gloves [35], [36]. However, tendon-driven gloves may require uncomfortable pre-tensioning, experience significant efficiency losses due to cable friction, and require bulky actuation units often worn on the waist/backpack. In addition, the cables are generally fixed at points on the glove by sewing them into the fabric, which introduces undesired and uncomfortable shear forces on the finger and may cause slippage/twisting of the fabric, which disrupts proper force application and reduces repeatability.

User control is another important aspect of robotic orthoses. Devices such as the Exo-glove [36] detect wrist motion and treat that as a signal to initiate finger actuation, while the NASA/GM RoboGlove [37] uses the small force changes induced when the user's fingers contact the glove surface as a signal to apply force in a certain direction. For those with brachial plexus injury, the hand may be fully paralyzed and the wrist motion can be impaired or non-functional as well. This limitation precludes such control approaches. Other prostheses and glove systems utilize EMG inputs; however, fine muscle control of the injured arm can be challenging or impossible with this type of injury [38], [39].

The proposed orthosis is intended to provide natural bending and repeatability as a rigid exoskeleton, while retaining a minimal form factor. Research on the typical grasping actions of the human hand were utilized to guide the design of the linkage mechanism [40]–[42]. In addition, the orthosis emphasizes design compactness and motion efficiency [43].

Research Design: The key aspect of this aim is to optimize the design of the robotic hand orthosis and integrate a robust working prototype. The design concept is shown in Figure 2. For rapid prototyping purposes, the current design is shown using 3D printed polymer. The orthosis is designed to minimize the number of actuators while optimizing the ability to approximate tip, three jaw chuck, and lateral pinches [44] as well as cylindrical, spherical, and hook grips [45].

The compact size and high level of control possible with this system are enabled by our novel actuator design. Two proof-of-concept actuators developed in the PI's lab are shown in Figure 3(a) which utilize a series elastic actuator (SEA) for indirect force measurement [46]. The use of SEA allows for indirect measurement of force applied directly from the actuators without utilizing contact sensors at the fingertips. Our new actuator design, seen in Figures 3(b) and 3(c), is comprised of the same key components as the proof-of-concept, yet will be at least 30% smaller than the original by incorporating a magnetic encoder and compact drive components. Furthermore, the actuator is an order of magnitude faster, allowing the user to fully traverse the joint space in approximately 0.4 seconds. The actuator is non-backdrivable due to high gear ratio of the gearbox. Therefore, when the

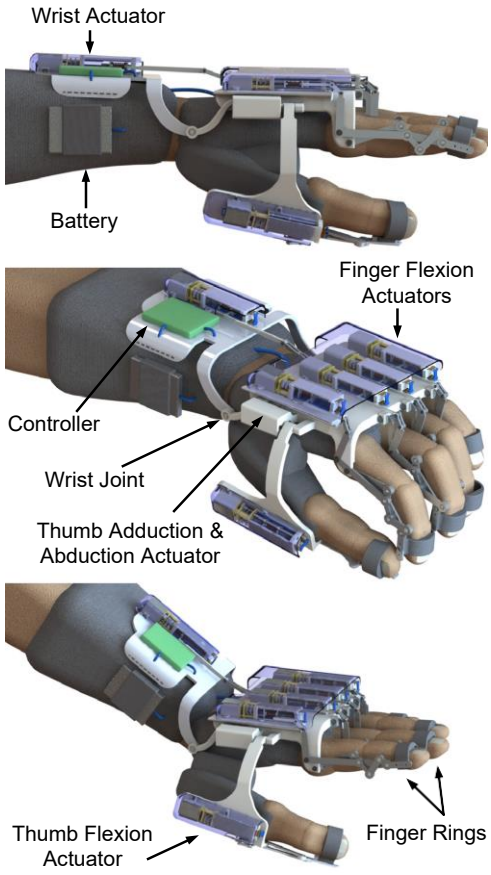

Figure 2. Proposed Robotic Hand Orthosis Design

fingers go to a set position, they will remain in that position even after forces in the opposite direction are applied. This helps to reduce power consumption due to motor operation. Furthermore, the springs in the actuator provide compliant distribution of the grasping forces applied, thereby assisting in gripping non-uniform objects and maintaining the desired grip force.

The links of each articulated mechanism driving individual fingers using the SEA are kinematically coupled in that there is one motor for three degrees of freedom (DOF) per finger corresponding to flexion/extension. Each actuator will drive the corresponding finger's flexion through the mechanism. The articulated mechanism itself is composed of two four bar linkages connected in series and is detailed in previous works done by the lab [6], [8]. The finger linkages have extremely thin profiles (~2 mm), which allow for a comfortable fit between the fingers. While finger adduction/abduction is not actively controlled with this prototype, fingers are held slightly apart at fixed angles by the linkages. These angles are adjustable and can be set to the most comfortable position for each user. Thumb abduction/adduction will be driven by a rotary motor fixed to the main hand plate, and thumb flexion will be driven by an actuator of the same style as those for the fingers, mounted on the back of the thumb's base on a small plate driven by the rotary motor. When a human grasps, the wrist extends in a coupled motion, with studies finding the minimum optimum angle of wrist extension to be 25° [47]. The orthosis is designed to possess this wrist extension/flexion capability, utilizing a similar link mechanism as that of the fingers to provide symmetric 30° extension/flexion. The actuators each have sufficient force output to prescribe a fingertip force exceeding 40 N, the average 180° distal pad press force per finger found in one study [48], and allowing for a thumb-index pad pinch exceeding 60 N, the largest average pinch force reported across several studies [42], [47], [48].

Throughout the design process, the design engineers will meet with Dr. Bravo, therapists, and patients with brachial plexus injury to ensure stakeholder input is leveraged in the design. Drawing upon the PI's experience from previous working prototypes built in the lab, the driving components and the battery packs for the orthosis are chosen such that the system can function for a day without recharging. The orthosis has six motors, each with a nominal draw of 0.1 A and stall current draw of 0.35 A. The ARM Cortex-M4 microcontroller, along with the associated electronics, has a max draw of 150 mA during operation. With a battery of 7.4 V and 2500 mAh the device can run continuously for two hours under full load. The battery is small, at 10x5x2.5cm in dimension and almost 100 g. The SEA and the non-back drivable nature of the transmission system allows the orthosis to maintain its grip force without actively drawing current, therefore, along with the intermittent frequency at which objects are grasped, the device can be expected to last one full day without recharging.

The proposed orthosis is intended to weigh around 250 g without the battery source. The resulting total mass thus approaches 350 g, enabling long term use with minimal fatigue. Additional ergonomic factors were also considered in the design. One such is the novel finger linkage design, allowing for misalignments between the axes of rotation of the mechanism and those of the finger joints [6], [11]. Additionally, the linkages are fixed to the fingers with semi-rigid finger rings that leave the finger pads exposed, to accommodate patients who do possess some sensation in their fingers. Furthermore, in order to adjust finger lengths variation between patients, the final link length is adjustable. For comfort while wearing the system, the wrist actuator is also stitched into a stretchable fabric sleeve worn on the forearm, along with the microcontroller unit, motor drivers, communication modules and batteries, while the forearm sleeve is fixed securely to the arm with Velcro closures.

The control of the orthosis will revolve around the ability to predict the finger configuration necessitated by the grasped object through the use of a predictive controller. The common grasps can be described accurately using a

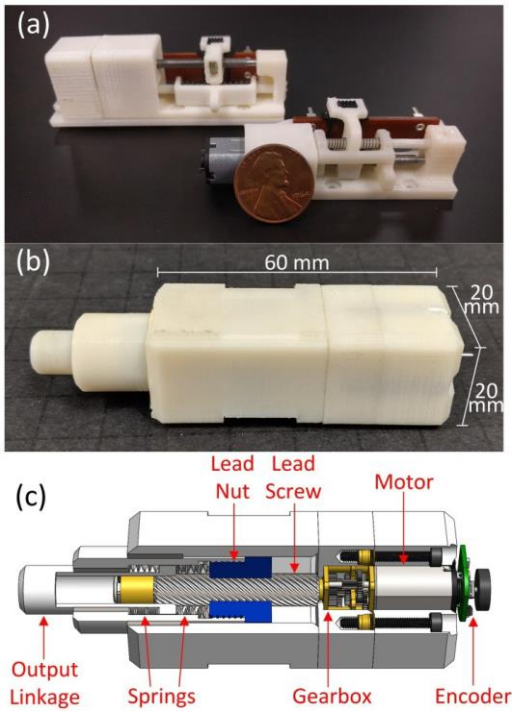

Figure 3. (a) Proof of concept actuators; (b) proposed actuator prototype; (c) detailed actuator configuration

set of six vectors in latent space [49] that encompass the motions of the 21 DOF of the human hand [50]. The latent space for the system is the domain containing the geometrical mapping of the complex hand motions into a smaller collection of six coordinated motions. The 33 common grasps from [26] can be grouped via PCA according to their spatiotemporal relationships [51] or to their interaction and configuration geometries [7].

As the springs in the SEA deform when the fingers interact with the object, the necessary final grasp configuration for that object can be predicted by mapping each joint velocity to the latent space. The required grasping force per finger, as determined by the grasp paradigm and validated through benchmarking by the researchers, can then be exerted. The prediction will be performed using a novel matching algorithm. The definition of these latent variables varies from subject to subject but follow very similar trends, as shown in [52], allowing a general model to be applied. However, the efficacy of a calibration stage performed with the user's healthy hand, if possible, will be explored in lab testing.

The operation of the glove will be initiated via a voice command correlating with one of six grasp groups that will be processed via the onboard ARM Cortex-M4 microcontroller using readily available open source libraries from ARM [53]. The libraries provide lightweight voice recognition neural networks, allowing the system to recognize a user's tonal frequency when providing commands following a short training session. The verbal grasp commands are: Cylinder, Sphere, Tripod, Tip, Lateral, and Extension. More user-friendly names may be chosen with assistance from ION therapists. To give an example, in this categorization, the group "Cylinder" contains the grasps for large, medium, and small cylinders, characterized by increasing amounts of equal flexion along all the fingers. After receiving this command, the orthosis would thus flex all fingers simultaneously until contact is detected through joint velocity changes, at which time it would be able to command the degree of flexion required for the level of cylindrical grasp needed to grasp the detected object. Once the algorithm ascertains the orthosis has reached a set degree of similarity with a grasp, the motion will stop. To release, the user simply says "Open" and the orthosis will return to a neutral position.

Goal: The robotic hand orthosis will be considered a viable design if it can provide a controlled 40 N of force to each finger linkage, complete the finger flexion within 0.4 seconds, and can perform fundamental grasping and pinching motions in lab testing .

Expected Outcomes: This aim is intended to produce a mature and robust prototype that can be used in the feasibility test outlined in Aim 2.

Potential Problems and Alternative Strategies: The orthosis linkages are designed to be fixed to the fingers with Velcro-tightened finger sleeves. However, should an issue with finger slippage arise, the mechanism can be sewn onto a neoprene glove at key points to provide more fixation points. The overall glove mechanism is exposed for easy access for testing and adjusting, however a second, larger glove can be worn over the entire device to reduce the mechanical appearance if so desired.

Aim 2: Perform a pilot study on a small group of patients with hand paralysis due to brachial plexus injury

Overall Strategy: The objective of this aim is to perform a feasibility study of the robotic hand orthosis through direct testing on affected patients. Six participants suffering from partial to full unilateral (one-sided) hand paralysis due to brachial plexus injury will wear the orthotic device to perform a list of everyday tasks. The patients will then report if the use of the robotic orthosis has resulted in an improvement in the dexterity and mobility of the hand.

Preliminary Studies: While surgical interventions exist for brachial plexus injuries, the methods used in returning motion and control to the upper and lower arm have not had the same level of success when applied to the hand. Patients who have suffered such an injury generally average scores in the 50s when evaluated with the DASH prior to surgery, and in the 40s following surgery [23], [54]. The preoperative scores indicate a severe disability, and the postoperative scores show large variation due to the hit-or-miss nature of the surgeries. The difficulty of restoring hand functionality via surgery is the cause of much of the remaining disability. A robotic orthosis has the potential to provide a significant increase in hand functionality for such patients.

Research Design: The Southampton Hand Assessment Protocol (SHAP) provides an excellent standardized test that include a series of 26 actions that include both abstract motions as well as selected ADLs for evaluation of hand functionality [18]. The actions can be grouped according to six major prehensile grasps to which the actions correspond. Patients are evaluated based on the time

taken to perform each action on a standardized point score. The performance can be scored by grasp groups or by overall performance, with 100 representing performance on par with mean performance for a healthy respondent and the score decreasing to zero for a subject falling outside several standard deviations from the mean performance. Adult patients suffering from brachial plexus injuries have been found to have overall SHAP scores in the single digits to low teens, representing extremely low function [25], [55]. As a standardized numeric score, the SHAP provides an excellent metric for testing the performance of patients with and without the use of the orthosis. Patients will be recruited from the pool of patients who have suffered a brachial plexus injury and are receiving treatment at ION facilities. Inclusion criteria are: adult brachial plexus injury to the upper extremity, over 18 y/o with pan plexus injuries, lower root injuries (C7, C8, T1), no significant hand/wrist contractures or associated deformities, no open wounds in affected hand or wrist, able to provide consent for treatment and follow general directions. Children younger than 18 years old will not be included due to the increased effectiveness of surgical remedies in juvenile cases [20]. A smaller version of the orthosis will be built in order to accommodate the younger participants' hands. Once patients have been recruited, they will be asked to perform the SHAP evaluation without the orthosis and their assessment will be recorded. The patients will then receive a short (<30 min) training period with the robotic hand orthosis to familiarize themselves with its operation. Once comfortable with the device, they will then attempt the SHAP while wearing the orthosis and their assessment will again be recorded. The reported data will be evaluated, and compared based on length of time from injury as well as upon the types of hand motions required by each action. The time from injury will aid in assessing the impact relative to the duration the patient has been faced with the disability, which may affect both their enthusiasm for such a solution as well as any variations in effect. Survey data regarding fit, control functionality, and device performance will be collected. This data will help drive further design improvements, efficiencies, and added functionalities.
Goal: The robotic hand orthosis will be considered a feasible device if the SHAP assessments show a statistically significant improvement (α=0.05) for the cohort (N=6). As this current trial is a feasibility study, the authors expect to demonstrate the efficacy of the device.
Expected Outcomes: This aim is intended to demonstrate that the robotic hand orthosis can be used to improve the dexterity of an injured hand, and that the control methods are intuitive and user friendly. In addition, the patients' inputs can lead to further improvements for the orthosis and in the future possibly an orthosis that can be prescribed for patients suffering from decreased hand motility.
Potential Problems and Alternative Strategies: Patients may feel more comfortable using an assistive orthosis after having been exposed to it. If the participants indicate this is true following the initial testing, a follow-up testing may be conducted to determine the performance improvements.

Timetable

This is a 24-month project with the following tasks and timeline: Complete design and perform physics-based simulations (mos. 1-8), fabricate, integrate, test and refine capabilities of a robust prototype (mos. 8-16), perform feasibility tests with patients and use the results to improve design (mos. 16-24). Prof. Ben-Tzvi will lead the design process of the robotic hand exoskeleton orthosis. Monthly in-person meetings during the design phase of the project at ION in Roanoke, Virginia will allow the design team to receive expert advice and input from Dr. Bravo, as well as from occupational/physical therapists familiar with brachial plexus injuries. Weekly in-person meetings between the two teams will commence once the project has progressed to the feasibility study, led by Dr. Bravo. Both teams will work together to conduct the trials. Throughout the duration of the project, weekly teleconferences will be held when there is no in-person meetings scheduled in order to keep all members of the project up to date.

Future Directions

The robotic hand orthosis presented is envisioned to potentially return a measure of functionality to those suffering from full or partial paralysis of the hand, resulting in a significant increase in quality of life. Upon the successful completion of the feasibility study and the incorporation of insights gained from it, a larger clinical trial to test and demonstrate the functionality of the glove on a wider patient pool could be conducted. Ultimately, the orthosis could be one day prescribed to patients following a unilateral paralysis-inducing injury. In addition, the compliant nature of the orthosis lends itself to uses in rehabilitation as well as grip assistance for patients with other types of hand disabilities. The system could be utilized by physical therapists to perform guided therapy. In patients with some finger function, the SEAs can be modified to detect motion and amplify it in a controlled fashion.

Recruitment and Retention Plan

The participants in this study will be recruited on a volunteer basis by Dr. Bravo and his office through in-office contact. As the study is a one-time event, retention strategies are not required.

Study Timeline

One year after notice of award, Dr. Bravo and his office will begin inquiring among patients with a brachial plexus injury on interest in volunteering for an hour in order to test the orthosis. As participants are recruited, team members from Professor Ben-Tzvi's lab will travel to the Carilion Institute for Orthopaedics and Neuroscience to conduct the tests at the participants' availability. Approximately 18-20 months following the notice of award, the study will be concluded.

Protection of Human Subjects

Recruitment of human subjects will start following reception of IRB approval and the completion of the prototype. All investigators have received appropriate training in experiments using human subjects.

Risks to Human Subjects

Human Subjects Involvements and Characteristics: Subjects will be adults, male or female, over 18 years of age. There will be no restrictions related to race or ethnic group. Subjects will have suffered a brachial plexus injury that left the hand of the injured armed with some degree of paralysis or impaired motion. The subjects will be asked to perform a list of actions with and without a robotic hand orthosis and compare their ability to perform their actions in a survey. All experiments with human subjects will take place at the Carilion Clinic Institute for Orthopaedics and Neurosciences (ION). The doctors, occupations/physical therapists, and researchers at ION are familiar with performing evaluations of hand function as well as hand research.

Inclusion criteria:

1. Patients with Brachial Plexus injury
2. Pan plexus or lower root injuries (C7, C8,T1)
3. 18 y/o - 69 y/o
4. No significant hand/wrist contractures or associated deformities
5. No open wounds in affected hand/wrist
6. Able to provide consent for treatment and follow general directions

Sources of Materials: Research material to be obtained from subjects will include length of time since injury, qualitative survey data on the fit and operation of the orthosis, participant performance on the Southhampton Hand Assessment Procedure (SHAP), a clinically approved and standardized hand function test, both with and without the use of the proposed orthosis. Images of the hand as well as videos showing operation of the device with no identifying information may be recorded. This material will be secured in password protected, encrypted files only accessible by the study investigators. Any material used in publications will not contain identifying information.

Potential Risks: The actions performed in this study are limited to actions performed by the hands in day-to-day life, and they represent minimal risk of injury to the subject. Additionally, malfunction of the robotic orthosis is an additional source of risk in this study. However, this event is unlikely. The specific concerns relating to this as well as the actions taken to mitigate them are presented in the following section.

Adequacy of Protection Against Risks

Recruitment and Informed Consent: The subjects will be recruited from the ION outpatient clinic pool. The potential subjects will meet with the study investigators and will be offered the IRB-approved informed assent form. If participants need additional time to think about their participation, they will be sent home with the assent form for their review. The researchers will be available at any time to answer questions regarding the study. Participation is voluntary and may be discontinued at any time.

Protection Against Risk: Subjects will be seated or standing during the hand function trial, whichever the subject deems more comfortable. The adjustable portions of the orthosis will be adjusted for each subject to ensure comfort and ease of use. To protect against physical risk, subjects will be closely monitored during the trial and data collection in the event of any malfunction or discomfort while using the hand orthosis. The study will be conducted in the presence of both engineers who designed the orthosis as well as physical therapists and other medical professionals in order to ensure the safety of the participants.

To protect against identity risk, study data will be identified only by a subject code and the document that links the code to the subject name will be password protected and stored separately from the data files pertaining to the study.

The risk of Robotic Hand Orthosis malfunction is very small but must be considered. Therefore, the following is a list of possible orthosis issues and the steps taken to prevent their occurrence.

Pinch Points: The orthosis will be designed specifically with the ergonomics in mind, and will be fitted over a form-fitting, thin glove in order to reduce chances of pinching. Additionally, mechanical stops will provide protection against pinches.

Hyperextension/hyperflexion of fingers and wrist: As stated previously, the orthosis will be designed with mechanical stops to prevent the fingers and wrist from moving in excess of their natural range of motion. In addition, electronic/software limit stops will detect if each planned range of motion passes its desired range and will immediately shut down the system.

Power Failure: In the event of power loss, the orthosis may be removed while in any grasp formation through unclasping the fingertip fixtures then sliding the hand out of the device.

Controller Malfunction: Should the controller malfunction, the mechanical limitations of the device will protect the hand from any injurious motion while the user or researcher switches off the device.

Potential Benefits of the Proposed Research to the Participants and Others

Subjects will not benefit directly from the study conducted. However, the data collected will help drive development of an orthosis that can help return day-to-day hand functionality to themselves and others with similar injuries, thereby increasing quality of life and ability to find gainful employment. The demonstration of the feasibility of such a device can lead to improved assistive devices that can empower those suffering with hand disabilities to improve their quality of life. Thus, the small risks presented by the study are reasonable compared to the potential benefits of the research.

Importance of the Knowledge to be Gained

Current robotic hand orthoses are often bulky, require external power/actuation/control, and may be difficult to operate by ambulatory patients exhibiting full hand paralysis in conjunction with partial arm disability. The orthosis we are developing is uniquely compact, portable, and intuitively controllable. The knowledge gained from this study will help contribute to research in robotic orthoses and exoskeletons that will have a positive future impact on patients with a variety of hand injuries and impairments.

Data and Safety Monitoring Plan

The proposed study will collect data including length of time since injury, qualitative survey data on the fit and operation of the orthosis, participant performance on the Southhampton Hand Assessment Procedure (SHAP), a clinically approved and standardized hand function test, both with and without the use of the proposed orthosis. Images of the hand as well as videos showing operation of the device with no identifying information may be recorded. No identifying information of the participant will be recorded during the study, including but not limited to name, address, email, or phone numbers. Study data will be identified only by a subject code and the document that links the code to the subject name will be password protected and stored separately from the data files pertaining to the study. The only other identifying information will be contained on record of consent, which will be securely filed in accordance with Virginia Tech IRB and HIPAA standards at the Carilion Institute for Orthopaedics and Neuroscience.

As this is a small, low risk trial that is not collecting personal information, Dr. Bravo and Professor Ben-Tzvi will be responsible for carrying out the Data and Safety Monitoring Pam (DSMP). The trials will be conducted at a medical facility in the presence of doctors and therapists, so there will be trained medical monitoring at all times during the study in the unlikely case of any adverse events.

Overall Structure of the Study Team

The study team will consist of members from two separate locations, although the study itself will be conducted at only one of the locations. The structure is as follows.

Orthosis Design Team – builds the orthosis and is present during the study to provide device support. Based at Virginia Tech Robotics and Mechatronics Laboratory (RML)

- Professor Pinhas Ben-Tzvi
- RML PhD student TBD

Medical Team – provides medical design guidance for the duration of the design process, conducts the study assessment, and provides medical support. Based at Virginia Tech Carilion School of Medicine/Carilion Institute for Orthopaedics and Neuroscience

- Dr. Cesar Bravo
- Physical therapist/Occupational therapists TBD

Statistical Design and Power

As the study is only a pilot feasibility study for the proposed orthosis, the planned enrollment is for N = 6 subjects. With such a small sample, the mean performances of the participants with and without the orthosis will be evaluated via a two sample t-test due to its consideration of sample size. The null hypothesis to be tested is $\mu_o = \mu$ and the alternative hypothesis is $\mu_o > \mu$, where μ_o is the mean value of the performances with the orthosis, and μ is the mean performance without the orthosis. The significance level for this test is $\alpha = 0.05$

As the orthosis is expected to restore functionality to subjects who have minimal to no hand functionality, the impact will be significant. Therefore the expected effected size for this study is 3 or greater, resulting in a power of 1.0 for the given sample size.

Dissemination Plan

The applicant will register the study at ClinicalTrials.gov within 21 days of the enrollment of the first participant and will submit the results of the feasibility assessment once statistical analysis is complete, no later than one year after the study's completion. This registration and submission of results is in keeping with the university policies. The consent documents for the trials will explicitly inform the participants that the results of the trial will be posted to ClinicalTrials.gov

In addition, the PI and his research team will submit articles for publication in trade journals, scientific journals, and scientific conferences. These articles will describe novel algorithms and technologies developed during the research and describe the results of the clinical trials. The PI and his research team will also create a project page on the lab's web site that discusses the research, clinical studies, and results, including reports, photos, videos and links to supporting organizations, publications and other information.

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