Exoskeletal Networks for Forearm Supination

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Introduction & Specific Aims— The arm plays a crucial role in stabilizing and positioning the hand for performing activities of daily living (ADLs). The successful execution of ADLs relies on the proper orientation of the hand, which determines its position relative to the target object or tool. However, stroke often causes impairment in both the proximal and distal motor units, which can adversely affect the ability to position and orient the hand, thereby compromising the completion of ADLs. Forearm supination control may be particularly compromised, making it difficult to manipulate or grasp objects.[1] Despite the potential for technology to enhance functionality and reduce the physical and emotional strain of care, as well as healthcare expenses, the field of rehabilitation technology has not given equal emphasis to hand orientation as it has to hand location. Practical devices that support supination are scarce, particularly those that are suitable for uncontrolled environments, aesthetically pleasing, capable of facilitating real-life activities, easy to use and wear, and lightweight and comfortable for extended periods. **This project aims to develop forearm assistive technology to improve upper extremity function following a stroke, using an ExoNET, which utilizes a network of passive, multi-joint springs to generate the desired joint torque in multiple degrees of freedom (DOF).** Our innovative algorithms provide a means for tailoring the arrangement of springs within the device to meet the unique requirements of each user. The graphical user interface (GUI) allows clinicians, care partners, or patients to make adjustments to the design and structure of the device in real-time. The use of passive springs ensures that the device is lightweight, portable, and safe to operate. Moreover, the device does not require any charging or rebooting, providing a convenient and hassle-free solution for individuals with motor impairments. **Our specific aims are: 1) To develop and evaluate an ExoNET for supination assistance for stroke survivors, and 2) To extend this ExoNET design to simultaneously engage elbow interactions.** This project is expected to offer innovative solutions to the challenges of actuating the upper extremity, and we plan to combine the ExoNET with the hand exoskeleton described in project D2 in the future.

I. Background & Significance

Stroke is a major contributor to long-term neurologic disability and often results in sensorimotor impairments. These impairments frequently involve the inability to grasp and manipulate objects, which can significantly impact an individual's daily activities and quality of life. Arm function reduction often results in compensatory strategies that lead to muscle imbalances and injury.[2,3] A decline in arm function can contribute to the development of *learned non-use*, a detrimental cycle of decreasing muscle strength and secondary complications such as contracture.[4] While there have been encouraging therapeutic interventions aimed at improving forearm and wrist function, they often fail to achieve complete recovery. The EXCITE and ICARE trials[5,6] described improvements on clinical scores, yet substantial deficits remained. Such deficits most radically impact bimanual tasks. Reduced forearm pronation/supination is a critical issue often compounded by deficits in nearby joints. Unwanted synergies can result in unintended actions of the forearm when using the elbow, further exacerbating the issue. Additionally, reductions in forearm range of motion affect hand positioning[7] and strength[8] when reaching and grasping tools and objects. This highlights the substantial impact of such deficits on employment opportunities and self-care. While promising, therapeutic efforts to remediate the forearm and wrist do not lead to full recovery, leaving many adults with lifelong deficits.[9] Several researchers have attempted supination devices that have been more promising,[10-14] but the field still lacks a device that can be simultaneously wearable, inexpensive, lightweight, easy-to-use, and unintimidating. There is great potential for such a tool in the clinic, community treatment centers, rehab gyms, and the home.

We propose the use of spring elements as an alternative to motors and without a rigid skeleton. Such passive exoskeletal devices have shown promise in assisting walking[15] and running,[16] but passive, multi-joint ExoNETs have yet to be developed for the forearm. The ExoNET is built from combinations of the MARIONET, which varies torque by changing the moment arm[17,18] and has appeared in several applications.[18-21] One example supplemented muscle torques for gait.[22] ExoNETs possess significant advantages as they are cost-effective, user-friendly, and safe. They leverage the user's anatomy and do not depend on any stiff links. Additionally, every tension element within ExoNETs produces a sinusoidal torque pattern that is dictated by the design's geometry. These torque patterns serve as mathematical *basis functions* that can be optimized and linearly combined to achieve any desired torque profile.[23] Spring ExoNETs can also intelligently recycle energy and do not require motors, controllers, sensors, or power. We propose developing an ExoNET for the forearm.

The multijoint synergy problem commonly observed in stroke patients is particularly critical for aim 2. In addition to limited voluntary forearm supination, involuntary shoulder movements often exacerbate the issue, creating an unwanted synergy. [24,25] The multi-joint spring-like properties of ExoNET designs can couple and "re-bias" the system so that as the elbow extends and typically causes unwanted pronation, the ExoNET can provide a supination torque.

II. TECHNICAL APPROACH

Our proposal involves the utilization of ExoNET design principles to create a passive device that can aid in forearm movement for stroke survivors. We aim to focus on the development of the device while also conducting an initial evaluation of safety, feasibility, and efficacy.

Development. Many commercially available exoskeletons are not practical for use in assistance or therapy, as they are often intimidating, bulky, complex, and expensive. To overcome these limitations, we aim to design an assistive device that simplifies forearm actions through the use of passive elastic impedance elements spanning multiple joints, without necessitating a skeleton. Our proposed device will specifically incorporate elastic impedance elements. Torque generated by any diagonal spring element is a vector product of the spring element's moment arm and force. The moment arm is calculated by geometrically tracking the locations of each element's origin on the proximal body segment and the insertion on its distal segment, relative to the joint centers of rotation. The elastic forces are governed simply by an empirically-determined elastic function (**Fig. 2**). The overall torque profile of a multi-element, multi-joint ExoNET is a summation of each element's torques.

Subsequently, a structural optimization process is employed to discern the optimal placement of each elastic component, thereby determining its moment arm and pre-stretch to meet the range of targeted torque profiles at various locations within the user's workspace. The pre-tensioning of an element is influenced by its resting length (**Fig. 2**), resulting in a network of tunable, multidimensional springs. Inspired by medieval plate armor, *ExoScales* are constructed from a formable polymer and provide rigid mounting sites on bony regions of the limb (**Fig. 3**). The use of *ExoScales* ensure that the mountings are properly positioned, supported, and lightweight.

Design Process. Our approach to design has been influenced by prior research work[23] and proposes a potentially advantageous alternative to exoskeletons that exclusively rely on parallel rigid linkages with the limbs. At the outset of our design process, we implement several strategies, such as immersing ourselves in the user environment, collecting feedback from users, and developing rough working prototypes. Our design philosophy prioritizes the significance of *failing early and often*, as well as recognizing that *consumers may not always know what they need*. We have already undergone multiple mock-up prototype cycles (**Fig. 4**). To gain an understanding of its future efficacy, we will invite participating clinicians to observe and provide feedback on the experiment. Our system will employ customized design that can be modified as the occupational therapist works with the stroke survivor on therapeutic tasks. The device's adjustment will enable the patient to employ the device in assistance mode for ADLs and anti-assistance mode for therapy sessions. Our objective is to supply enough voluntary supination torque to overcome the pronation bias caused by the typical synergy pattern observed in stroke survivors.

Validation Testing. We propose feasibility and safety experiments that comprise our two aims. These experiments will also provide preliminary efficacy data to power future studies. In **Aim 1,** a pilot study and clinical trial will be employed. The pilot study will comprise 2-5 individuals without a history of stroke or neurological disorders and 5-7 individuals post-stroke who are ages 40-70 and more than 6-months post-trauma. We will identify participants that have range of motion deficits that significantly involve the elbow, forearm and wrist (typically an upper extremity Fugl Myer score of 30-50). In this preliminary safety and feasibility study, each participant will complete 1 training session with the forearm ExoNET at the SRALab. In this two-hour session, the participant will work with a therapist to don and doff the device and to perform practice of pronation/supination tasks chosen by the therapist. Subjects will serve as their own control and throughout the session and will be exposed to six conditions: 1) no device (baseline evaluation), 2) device with slack springs (sham/control), 3) device in assistance mode (evaluate assistance direct effects), 4) no device (second baseline/rest), 5) anti-assistance mode (anti-assistance as form of therapy), 6) no device (evaluate after-effects of anti-assistance). The results from the pilot study will power the clinical trial, which will be conducted to determine and compare the effects of assistance and anti-assistance modes of the forearm ExoNET on the clinical outcomes of patients. This study will consist of 15 individuals post-stroke with the same inclusion criteria as the pilot study. Each participant will complete 9 training sessions with the forearm ExoNET at the SRALab. For each two-hour session, the participant will again work with a therapist to don and doff the device and to perform practice of pronation/supination tasks chosen by the therapist and customized tasks determined by the patients that they would like to regain functionality in completing. Subjects will serve as their own control and two baselines will be collected prior to the study initiation. The study will be designed as a crossover where each patient receives: 1) assistance mode vs. slack springs, 2) anti-assistance mode vs. slack springs, and 3) no device.

Because bias can be easily introduced by the words said by researchers[26], we will blind the study by disallowing rater, operator, and subjects from knowing which treatment is being administered, and when. Evaluations of arm control with and without the device will be performed before (Pre) and after (Post) the training sessions, and at a follow-up session one-week later (FU). A research therapist will administer the Action Research Arm Test (ARAT).[27] Furthermore, secondary measurements will be employed to quantify level of active supination utilizing inertial measurement unit (IMU) sensors and muscle activity with electromyography (EMG) sensors. These additional measurements will determine the initial level of impairment, decrease the probability of risk, and permit the identification of any associations with primary outcomes. These also include Manual Muscle tests [28]; range of motion (ROM) of joints;[29] visual acuity using a standard eye chart;[30] blood pressure; sitting respiration and heart rate.

A repeated measures ANOVA will be performed to test the effect of the device. We assume that 15 participants will be sufficient to enable to estimates an initial effect size and variance to power future intervention studies should this initial feasibility trials show promise. **We hypothesize that** the participants will experience gains (in ARAT) that are significantly above the baseline levels after the 9 training sessions when using the ExoNET. **We additionally hypothesize that** the forearm ExoNET in assistance mode will have direct effects on the patient leading to increase active supination ROM.

Aim 2 of our study aims to expand our design to address the issue of unwanted synergies often observed in stroke survivors, where supination is limited at extended elbow angles. We will consider how elbow actions can aid in assisting with the unwanted synergy of between voluntary elbow extension typically leading to unwanted pronation.[23,24] Our approach involves utilizing multijoint ExoNETs that take advantage of the motions and forces at adjacent joints. We plan to add spring actuators that cross the elbow and are tuned to match the desired torque field, which will engage the entire forearm to assist with ability and movement. By adding this feature, we can "re-bias" the needed supination torques to counteract unwanted synergies. Our optimization approach will provide the best estimate for a custom configuration for each patient, but the therapist can make further adjustments to the elastic elements on the spot. These procedures and approaches will be repeated, with the added advantage of elbow extension leading to increased assistive supination torque. This will provide preliminary efficacy data to power future studies.

A potential follow-up study to this proposal could be a long-term implementation study. During this study, stroke patients would wear the forearm ExoNET in assistance mode during their daily lives. Data would be collected to assess whether the device improves their impaired limb's functionality during activities of daily living (ADLs) and evaluate patient acceptance of the device.

III. FIGURES

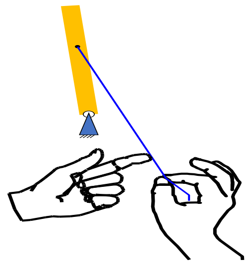

Figure 1. ExoNETs are built from multiple tension elements that manipulate torque by positioning the line of action.

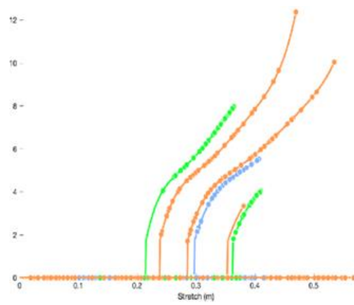

Figure 2. Tension-stretch combinations for elastic cords for an ExoNET solution. Constitutive relations reveal various joint configurations used in the optimization.

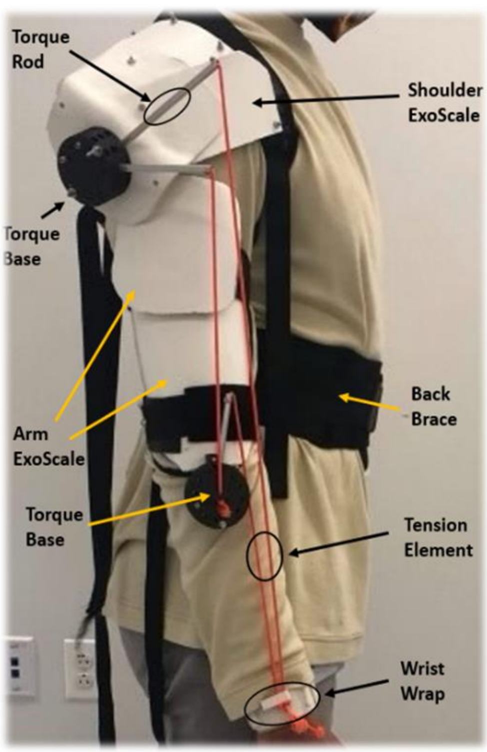

Figure 3. Our prior design of an ExoNETs for shoulder & elbow interactions. This illustrates an easily worn device that provides multi-joint springs for gravity cancellation in this configuration. Other torque fields are possible through spring reconfiguration.

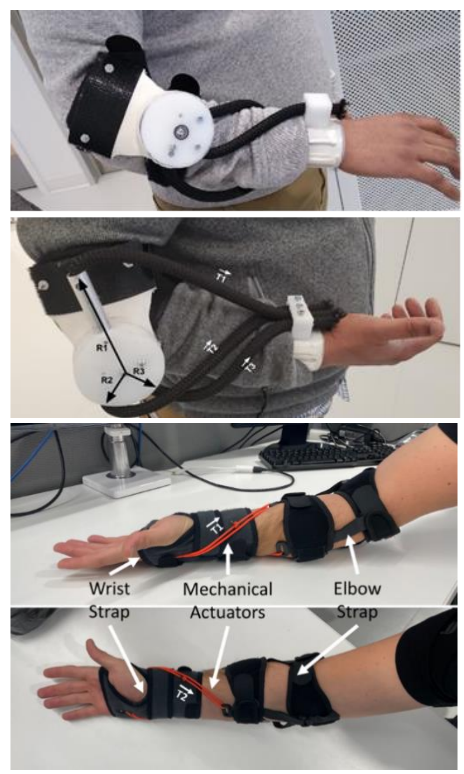

Figure 4. (Top) First mock-up and (Bottom) latest mock-up of the Forearm ExoNET. Note one challenge with this is the wrapping of elements over the arm, making the arm a mechanical cam and requiring new mechanical analysis techniques.

IV. References

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