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Abstract—To better understand the upper-limb needs and challenges survivors of neurological events face, and the issues associated with existing technology, customer discovery conversations were conducted with 153 people in the ecosystem (60 patients, 30 caregivers, and 63 medical providers). Patients with upper-limb effects fell into two populations: spastic (stiff, clenched hands) and flaccid (limp hands). Focusing on the first category, a set of design constraints was developed based on the information collected from the customer discovery. With these in mind, the OrthoHand Extend was designed and prototyped as a powered wrist-hand stretching orthosis (exoskeleton) to aid in recovery. The orthosis was tested on two patients, one survivor of stroke and one of traumatic brain injury. Finally, a mathematical modeling technique was developed to characterize joint stiffness based on experimental testing. The prototype met most of the target design constraints and was able to consistently open both patients’ hands. Donning and doffing times averaged 76 and 12.5 s, respectively, for each subject unassisted. These are approximately twice as fast than the next closest times shown in literature. This device has the potential as effective therapy devices accessible to patients in the home, and lays the foundation for clinical trials and further device development. The study was approved by the Vanderbilt University Institutional Review Board, study number 221203.

Index Terms—Stroke, neurological impairment, wrist hand orthosis, spasticity, tone, therapy, stretching.

I. INTRODUCTION

NEUROLOGICAL events such as stroke and traumatic brain injury affect millions of people across the globe every year. During the neurological event, a part of the brain dies and loses connection to the rest of the body. For many, this results in upper-limb impairment such as lack of hand control, including difficulties grasping and opening, and instability. This is a debilitating, life-changing event that leaves survivors dependent on others for even the most basic tasks. Over time, their struggles compound, resulting in fatigue, frustration, and a host of additional problems. In addition to physical impairment, they often endure related mental and financial hardships. As a result, patients need a low-cost device meeting their basic needs for gross motor skills recovery and contracture prevention.

Limitations of existing orthoses are rigidity, operation procedure, sizing, and/or cost. Passive orthoses are inexpensive compared to powered ones, but lack the ability to actively move the patient’s hand, and either hold it in a static position (static splints) or cause the hand to move unnaturally by coupling wrist motion to finger motion (linkage based). While elegant in their own right, the powered ones, such as the Myomo, GloreHa, EnableMe, and Bioness, [1-4] tend to be cost-prohibitive and often bulky.

Although traditionally, exoskeletons and orthoses have been constructed with rigid links and actuation [7-10], over the last decade research in this area has shifted to soft robotics [6-31]. Soft robotics can be ideal for rehabilitation due to its human-friendly interaction and novel materials.

Many WHOs (wrist hand orthoses) have been developed, but most of them [9-10,13-27] are for assistance rather than therapy. They come in limited sizing, can be difficult for subjects to don (independently or not) and the dynamic ones often pull rather than push the fingers (which can cause tendon issues). The few research prototypes that have been developed for therapeutic purposes [8, 29-31] all involve complex designs that require a trained person to assist the patient with donning and use. Soft orthoses are intrinsically lighter than rigid ones, but all of these [13-16,20-25,36] still require the hand to support upwards of 120 g, if the weight is even published.

There are two passive orthotic glovers on the market for the globe every year. During the neurological event, a part of the brain dies and loses connection to the rest of the body. For many, this results in upper-limb impairment such as lack of hand control, including difficulties grasping and opening, and instability. This is a debilitating, life-changing event that leaves survivors dependent on others for even the most basic tasks. Over time, their struggles compound, resulting in fatigue, frustration, and a host of additional problems. In addition to physical impairment, they often endure related mental and financial hardships. As a result, patients need a low-cost device meeting their basic needs for gross motor skills recovery and contracture prevention.

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OrthoHand Extend, the prototype subsequently described, has been designed using criteria based on the verbalized desires of neuro patients, caregivers, and medical providers. This device involves a design shift from typical soft robotics structure to a low-profile inflatable bag, and it employs the unique principle of pushing rather than pulling the hand open. It is designed to be usable by patients independently and directly addresses their medical needs.

II. ORTHOSIS DESIGN

In order to more fully comprehend the upper-limb needs and challenges survivors of neurological events face, and to determine a target end user, the authors conducted informal customer discovery conversations with 153 members of the ecosystem (60 survivors, 30 caregivers, and 63 medical providers) as part of the National Science Foundation I-Corps Program. This customer discovery helped to bridge the knowledge gap regarding the generic information and standard of care that is common to the medical community but unbeknownst to many engineers. Discussions with survivors and caregivers yielded additional insights into the unique experiences of individuals from their own perspectives. The authors then realized upper-limb patients fell into two populations: spastic/toned (stiff, clenched hands) and flaccid (limp hands). For the subsequently described body of work, the authors chose to focus on a simple technological solution for the first category of patients. This group struggles to open their hands due to involuntary clenching, or “freezing” of the hands in a curled position, and needs help stretching on a regular basis to relieve their manual tone. Based on the information collected from the customer discovery, the authors developed a set of design constraints and then prototyped OrthoHand Extend, a powered wrist-hand stretching orthosis to aid in recovery.

The set of design constraints and features derived from customer discovery are as follows:

1. Easy to don and doff: Since the patients’ hands are stiff, ease of donning is essential. They are unable to control their fingers and must manually push them into position, making individual finger motion practically impossible and often requiring the help of a caregiver in a procedure that can last several minutes. Ideally, a patient could singlehandedly put the orthosis on his hand or remove it in less than one minute.

2. Dynamic: flexible and comfortable. Many patients complained that their static splints are painful due to the constant aggressive stretch, so they need something comfortable or they will not wear it. And since common a side effect of neurological impairment is reduced sensation in the affected limb, preventing abrasion is critical to prevent skin damage and infection.

3. Therapeutic stretching: All patients need to stretch their hands to prevent contractures and regain function. To alleviate the mental and physical burdens of constantly opening and closing their hands, and because most patients lack voluntary control, the orthosis should cyclically stretch the affected hand.

4. Intelligent: intuitive control and sensory feedback. Any device for a neurologically impaired person must be easy to use and safe. Powering and controlling the device should be simple, and force or pressure monitoring should prevent overextension of joints.

5. Affordable. As most neuro patients are no longer able to maintain a full-time job and often require caregiver assistance, they also face financial challenges. A device should be as low cost as possible so they can afford it, ideally below $100.

6. Portable: lightweight and untethered. In order for a patient to easily transport and use a device, it must be unchained from external equipment. Furthermore, the proportion of weight on the distal limb should be minimized (ideally < 0.5 kg) in order to reduce the required torque to lift the arm and hand, with heavier components located more proximally.

For this prototype, the authors chose to prioritize the first three design constraints: easy to don & doff, flexible & comfortable, and therapeutic stretching. The other design constraints (intelligent, affordable, and portable) will be addressed in future work as the project develops.

OrthoHand Extend, shown in Fig. 1, is essentially an inflatable bag with Velcro straps. Designing for flexibility and comfort necessitated a soft robotics approach. The bag is made of nylon coated with TPU, and the stitching and 1/4” tubing inlet are sealed with a commercial sealant to prevent leaks. Designed to fit the 50th percentile male hand, but easily scalable to other sizes, the bag is an hourglass shape 30 cm long, 19 cm wide at the widest part, and 12 cm wide at the narrowest part. The simple structure facilitates ease of donning in a way that a glove with individual fingers would not. There is one strap for the forearm, two straps for the fingers, and one strap for the thumb. The straps fasten with Velcro for secure, adjustable positioning and ease of donning and doffing. The finger straps’ placement falls on the metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints of the hand in order to relieve tension naturally, as recommended by occupational therapists consulted during the design process. The hourglass shape is designed to minimize wasted air while applying sufficient force to open the hand and support the wrist. This wrist support is essential because a patient with spastic hands typically experiences wrist contraction as well, and therefore needs to extend the wrist joint simultaneously with the thumb and fingers. The entire prototype weighs only 63 g, far below the distal weight limit of 500 g and the minimum of other published research prototypes at 120 g [12]. Furthermore, it is quite inexpensive with materials under $5, and simply sewn together.
Fig. 1. OrthoHand Extend. The photos, clockwise from top left, show the prototype with: (a) straps unfastened, (b) straps fastened, (c) flat hand, donned, (d) clenched hand, dorsal view, (e) clenched hand, angled view, and (f) clenched hand, palmar view.

At present, the prototype is actuated via an air compressor, powered through a DC power supply, and controlled through a computer interface, as explained in section III. B. Pressure Testing. This allows for testing device functionality and evaluating the primary design features in a timely manner. Future development will involve addressing the remaining design constraints of portability with on-board power and control.

III. EXPERIMENTAL TESTING AND RESULTS

Two neuro patient test subjects were recruited from a brain injury rehabilitation clinic through the recommendation of an occupational therapist. One subject was an elderly male just over a year post-stroke, who had medium hand spasticity (tone). The other subject survived a traumatic brain injury nearly two years prior and had lower tone. Details about each subject are shown in Table I. The study was approved by the Vanderbilt University Institutional Review Board, study number 221203, and all subjects provided informed consent to participate.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Don Time (s)</th>
<th>Doff Time (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject 1</td>
<td>82</td>
<td>12</td>
</tr>
<tr>
<td>Subject 2</td>
<td>70</td>
<td>13</td>
</tr>
<tr>
<td>Average</td>
<td>76</td>
<td>12.5</td>
</tr>
</tbody>
</table>

TABLE II

A. Donning and Doffing

The donning and doffing tests consisted simply of the subject strapping the orthosis on their arm and then removing it. Each subject was timed for the procedures and observed to determine if they could complete them independently.

Both subjects were able to don and doff the orthosis without assistance. Their donning and doffing times are listed in Table II.

B. Pressure Testing

The authors constructed a setup to regulate and measure air pressure in the orthosis during the experiments. A diagram of this setup is shown in Fig. 2. An air line was connected to a Festo proportional directional control valve (MPYE-5-M5-010-B), powered by a 24V DC supply and controlled by Simulink Real-Time via a Humusoft data acquisition card (MF634). The valve was connected to an analog pressure sensor (Festo SDE-16-10V/20 mA), which attached to the orthosis via ¼” pneumatic tubing. First, a pressure regulator on the pressure supply line was opened, and then pressure was slowly, manually increased to inflate the bag until the subject’s hand opened (see Fig. 3). The regulator was then set as the desired peak pressure for the open loop cyclic stretching tests.

Each subject came separately to the lab to test the orthosis. Three types of tests were performed: donning and doffing, grip force, and cyclic stretching. The sequence of events for each session was as follows:

1. Measure initial resting and maximum grip forces;
2. Don orthosis (time);
3. Measure bag pressure required to open hand;
4. Cyclically inflate/deflate bag to stretch hand;
5. Doff orthosis (time);
6. Interview subject for feedback;
7. Measure final resting and maximum grip forces.

Fig. 2. Experimental setup. This block diagram shows the experimental setup. The arrows indicate flow of power (red, solid), signal (green, dotted), and air (blue, dashed) for device inflation.
The cyclic stretching test involved five, one-minute sessions in which the bag was inflated and deflated over a 4 second cycle of sinusoidal valve orifice position. The subjects alternated between one minute of stretching and one minute of resting for a total of five sets. During the test, each subject was carefully observed and communicated with to ensure their hand was not in pain. At the suggestion of the occupational therapist after reviewing the results, Subject 1 returned for a second session to stretch longer (three minutes of a 12-second cycle biased towards inflated: 8 s inflate, 4 s deflate). Five sets of this were intended to be completed, but during the fourth set, the subject complained of hand soreness where the stitching on the straps contacted his skin, so the test was discontinued.

Pressures required for the orthosis prototype to open each subject’s hands are shown in Table III. Higher tone corresponded to higher opening pressure.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Tone Level</th>
<th>Opening Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject 1</td>
<td>Medium</td>
<td>5 psig</td>
</tr>
<tr>
<td>Subject 2</td>
<td>Low</td>
<td>4 psig</td>
</tr>
<tr>
<td>Empty</td>
<td>n/a</td>
<td>3.5 psig</td>
</tr>
</tbody>
</table>

For each subject, the orthosis took approximately three cycles to fully inflate, at which point it continued cycling at a steady state. Performance averages over ten steady state stretching cycles are shown for each subject for the first and last (fifth) one-minute session in Fig. 4. One can see that the performance consistency increased between the first and last tests as each subject’s hand relaxed.

**C. Grip Force**

Grip force testing was conducted at the beginning and end of each session to see if stretching the hand affected grip force. Force was measured with a digital hand dynamometer and reported in kilograms. Two types of forces were measured: “resting” grip force to determine the tension in the affected hand, and maximum grip force to quantify how much force the subject could voluntarily exert with the same hand.

Resting and maximum grip forces before and after stretching are shown in Table IV for each injured subject and each session. Subject 1 was tested twice because no significant grip force reduction was observed after the original session. The hand dynamometer does not register forces less than 1 kg, so any force below that threshold is indicated as “< 1”.

<table>
<thead>
<tr>
<th>Subject, Session</th>
<th>Resting Grip Force, Before (kg)</th>
<th>Max Grip Force, Before (kg)</th>
<th>Resting Grip Force, After (kg)</th>
<th>Max Grip Force, After (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject 1, Session 1</td>
<td>1.2</td>
<td>8.1</td>
<td>&lt; 1</td>
<td>7.9</td>
</tr>
<tr>
<td>Subject 2, Session 1</td>
<td>&lt; 1</td>
<td>8.8</td>
<td>&lt; 1</td>
<td>5.7</td>
</tr>
<tr>
<td>Subject 1, Session 2</td>
<td>&lt; 1</td>
<td>7.7</td>
<td>&lt; 1</td>
<td>9.0</td>
</tr>
</tbody>
</table>

In order to estimate maximum possible forces the orthosis could endure, a strong, healthy subject was also tested. This subject was a 25-year-old male rock climber selected for his superior grip strength. First, his maximum grip strength was measured with the hand dynamometer. After resting, he was then instructed to don the orthosis and clench it in his fist as
tightly as possible, while the inflation pressure was slowly increased until either the prototype ruptured or the hand opened.

When testing maximum pressure with the strong healthy subject, the prototype withstood the subject’s grip. The bag inflated to 35 psi without rupturing, at which point the subject complained of pressure from the edge of the strap against his hand, and the test was discontinued. The maximum grip force of this strong healthy subject was 55 kg.

D. Subject Feedback

Following the testing, the subjects were informally interviewed to determine their perspective on the orthosis and testing session. The authors wished to determine what the subjects liked about the device, how it could be improved, and if they had any additional suggestions for device or protocol development.

Both test subjects remarked on the comfort of OrthoHand Extend, due to its flexible structure yet stable straps. Additionally, they both expressed approval for the Velcro straps contributing to ease of donning. Neither subject complained of discomfort during or after the 5-minute stretching sessions as long as the orthosis was properly positioned on the hand. During Subject 1’s second (extended) stretching session, he expressed feeling soreness at 11 minutes, at which point the session was terminated and the orthosis removed. Upon inspecting his hand, the skin on the dorsal side was tender to the touch and sustained marks from the stitching on the straps. The residual discomfort did not last long or dampen his enthusiasm for the device, and it was concluded that stretching sessions should be kept to 10 minutes or less in order to avoid possible discomfort, and that the stitching on the device should be lower profile to avoid abrasion.

III. MATHEMATICAL MODELING

A lumped parameter model was developed to describe the compliance of the hand. This model will be useful for determining joint stiffness as a metric to quantify and monitor patient improvement over time. Ideally, joint stiffness would decrease as the patient consistently performs therapeutic stretching and exercises for recovery. This model is two-dimensional (in the sagittal plane) and discretizes the hand as rigid links that are sequentially connected and able to rotate in the plane in the presence of applied and internal forces and moments. This simplification is justified because the finger diameter is sufficiently smaller than the hand length and depth.

This model is derived by lumping all four fingers as one and only considering the three segments of this lumped finger along with the palm. In particular, we treat each link as having a center of mass and a moment of inertia. Each link is tied to its neighboring links with rotational springs and damping terms to represent angular compliance and resistance. As the orthosis inflates, each link is subject to a normal force. This is modeled as an equivalent external force and is computed by the product of the equivalent pressure-induced force and resultant area (product of link length and depth of lumped finger/wrist system), applied at the center of each link. The coordinate system and free body diagram of the system is shown in Fig. 5.

In this work, we use a maximal generalized coordinate representation to describe the system. The states \( q \) for this model for links \( i = 2 \) to \( 5 \) include:

\[
q = [x_2, y_2, \theta_2, ..., x_5, y_5, \theta_5]^T,
\]

where \( x_i \) and \( y_i \) are the position of the respective link center, and \( \theta_i \) is the link angle with respect to a global frame as shown in Fig. 4. The dynamics of the system are derived using a constrained Lagrangian approach. Consider a set of constraints of the form \( \phi(q) = 0 \) representing the constraints that tie the links together at the joints. The associated Lagrangian \( L \) is given by

\[
L = T - V + \phi^T \lambda,
\]

where \( T \) is total kinetic energy of the system, \( V \) is total potential energy, \( \phi \) is the set of constraint equations, and \( \lambda \) is the vector of Lagrange multipliers. The dynamics of the system are formulated as:

\[
\frac{d}{dt} \left( \frac{\partial L}{\partial \dot{q}_i} \right) - \frac{\partial L}{\partial q_i} + \sum_{j=1}^{n} \lambda_j \frac{\partial \phi_j}{\partial q_i} = 0.
\]

There are a total of 8 constraints in this system. There are 6 constraints that ensure link-to-link continuity by relating the positions of consecutive centers of masses. These equations describe the hinge point ahead of the center of mass of the \( i \)-th link, and behind the \((i+1)\)-th link as the same points and are given as:

\[
x_i + \frac{L_i \cos(\theta_i)}{2} + \frac{L_{i+1} \cos(\theta_{i+1})}{2} - x_{i+1} = 0 \quad (3)
\]

\[
y_i + \frac{L_i \sin(\theta_i)}{2} + \frac{L_{i+1} \sin(\theta_{i+1})}{2} - y_{i+1} = 0. \quad (4)
\]

To pin one end of \( L_2 \) to the origin of the coordinate system, \( x_2 \) and \( y_2 \) are each constrained such that:

\[
x_2 - \frac{L_2 \cos(\theta_2)}{2} = 0
\]

\[
y_2 - \frac{L_2 \sin(\theta_2)}{2} = 0.
\]

The system of equations can be formulated in matrix form as follows:

\[
M \ddot{q} + A^T \lambda = F. \quad (5)
\]

Here \( M \) is the diagonal inertia matrix containing link masses and moments of inertia, \( A \) is the sparse constraint matrix given by

\[
A = \frac{\partial \phi}{\partial q} \text{ of size } 8 \times 12,
\]

and \( F \) collects all internal and external generalized forces and torques. For a detailed derivation of this model, refer to [32].

Baumgarte stabilization [33] was implemented to ensure constraints were numerically enforced over simulation runtime.
Without such an enforcement scheme, constraint equations may be violated due to accumulation of integration truncation errors [34, 35]. The stabilized constraints were derived by differentiating the set of original constraint equations twice:

\[
\phi(q) = 0, \quad \dot{\phi}(q) = \frac{\partial \phi}{\partial q} \dot{q} = A(q) \dot{q} = 0, \\
\ddot{\phi}(q) = A(q) \ddot{q} + \dot{A}(q) \dot{q} = 0,
\]

and incorporating them into a stable 2nd order dynamic relationship that rapidly brings any constraint violations to zero by choosing appropriately fast and damped parameters \(\zeta\) and \(\omega_N\):

\[
\ddot{\phi}(q) + 2\zeta\omega_N\dot{\phi}(q) + \omega_N^2\phi(q) = 0,
\]

\[
A(q)\ddot{q} = -\dot{A}(q)\dot{q} - 2\zeta\omega_NA(q)\dot{q} - \omega_N^2\phi(q).
\]

The combined set of equations (5) and (6) describe the evolution of the states (1) and are solved simultaneously:

\[
\begin{bmatrix}
M & A^T \\
A & 0
\end{bmatrix}
\begin{bmatrix}
\ddot{q} \\
\alpha
\end{bmatrix}
= 
\begin{bmatrix}
F \\
0
\end{bmatrix}.
\]

(7)

Here, \(\gamma = -\dot{A}(q)\dot{q} - 2\zeta\omega_NA(q)\dot{q} - \omega_N^2\phi(q)\) and \(F\) is the sum of internal \((F_{int})\) and external \((F_{ext})\) generalized forces. In particular, the generalised internal torques in \(F\) are of the form:

\[
F_{\theta,i_{int}} = -K_i(\theta_i - \theta_{i-1} - \theta_{i-1,0}) + K_{i+1}(\theta_{i+1} - \theta_i - \theta_{i+1,0}) - B\dot{\theta}_i.
\]

Here, \(K_i\) is the rotational spring constant of the \(i^{th}\) joint and \(B\) is a damping coefficient implemented for faster convergence. The \(K_i(\theta_i - \theta_{i-1} - \theta_{i-1,0})\) term reflects the rotational spring torque generated from the deviation of the proximal joint from its equilibrium position, given by the constant \(\theta_{i-1,0}\). Similarly, \(K_{i+1}(\theta_{i+1} - \theta_i - \theta_{i+1,0})\) represents the rotational spring torque from the distal joint. The generalized external forces (due to the orthosis) in \(F\) are given by:

\[
F_{x,i_{ext}} = -F_{orth,i} \sin(\theta_i) \\
F_{y,i_{ext}} = F_{orth,i} \cos(\theta_i).
\]

The external force for link \(i\), \(F_{orth,i}\), is a product of the pressure in the orthosis and the effective area that contacts the orthosis at each link. These forces are applied normal to each link, and their effective contact areas are given in Table V.

<table>
<thead>
<tr>
<th>Joint</th>
<th>Effective Area, (A_c) (mm(^2))</th>
</tr>
</thead>
<tbody>
<tr>
<td>wrist</td>
<td>4750</td>
</tr>
<tr>
<td>MCP</td>
<td>3500</td>
</tr>
<tr>
<td>PIP</td>
<td>1960</td>
</tr>
<tr>
<td>DIP</td>
<td>1680</td>
</tr>
</tbody>
</table>

The goal of this modeling work is to determine the rotational spring constants \(K_i\) of each joint. This was done by numerically integrating the system of equations (7) in MATLAB 2022b using the \(ode15s\) solver with an initial random set of \(K_i\) (all set to 1 Nm/rad). The configuration error, \(\epsilon\), defined as the difference of the desired and steady-state joint angle values (after all dynamics settle), was used to find a new set of \(K_i\) iteratively until the error fell below a certain threshold (set at 0.05) as follows:

\[
K_{i,\text{new}} = K_{i,\text{old}} - Ce
\]

where \(C\) is a positive constant, proportional to the magnitude of \(K_{i,\text{old}}\) to help with convergence. The intuition for the negative sign is that if the error is positive, the current joint needs to be less stiff to reach the desired angle. It should be pointed out that this has no physical interpretation, per se; it is merely a numerical method for finding the joint stiffnesses that match the simulation’s configuration to the physically observed configuration.

The initially curled hand position is set as the spring equilibrium position for each joint. As the orthosis inflates, the links straighten to a final position. The orthosis is modeled as a constant-perimeter balloon constrained maximally to the inflation dimensions, shown in Fig. 6.

![Fig. 6. Inflated orthosis dimensions. The inflated orthosis is on the bottom, and the dimensions to certain points are on the top diagram, profile view. The left end is the distal end, and the right is the proximal.](image)

To first validate this modeling approach, a mechanical hand was designed, 3D printed, and integrated with springs with known stiffness values (see Fig. 7).

![Fig. 7. Mechanical Hand. This figure shows the phantom hand prototype, constructed of 3D-printed ABS links, connected by revolute joints with torsional springs of known stiffnesses.](image)
It was empirically observed that the inflated orthosis does not provide additional force on the hand beyond a certain angle. In particular, this effect is more significant on the distal joints. A healthy subject’s joint angles resting on the orthosis were used to estimate an “offset” angle for each link (i.e., the orthosis does not provide a force on any link that is larger than a certain, empirically derived angle). This effect was modeled as a linear decrease in the pressure exerted by the orthosis from the initial configuration of each link to the estimated offset angle. For example, an offset angle of $\alpha > 0$ modifies $F_{\text{orth},i}$ to:

$$F_{\text{orth},i} = P \left( \frac{\theta_i + \alpha}{\theta_{i,0} + \alpha} \right) A_{\text{e},i}. \quad (8)$$

Here $P$ is the gauge pressure in the orthosis, $\theta_{i,0}$ is the initial angle of the joint and $A_{\text{e},i}$ is the effective area of the corresponding joint. The term $\left( \frac{\theta_i + \alpha}{\theta_{i,0} + \alpha} \right) = 1$ at the initial joint configuration $\theta_i = \theta_{i,0}$ and represents the maximum force applied to the joint. When $\theta_i = -\alpha$, the expression reduces to 0 and describes the scenario when the orthosis is unable to exert any additional force on the joint. Note $\theta_i < 0$ for all angles as shown in Figs. 8 and 10. Offset angle values of 10, 30, 30, and 45 degrees were used for the wrist, MCP, PIP, and DIP joints respectively, and we find there is reasonable agreement (average error of 4 deg per joint) between the simulation and the experimental configuration of the mechanical hand, as shown in Fig. 8.

![Simulation of Mechanical Hand Joint Angles](image)

**Fig. 8.** Simulation results of final configuration static matching of the 3D printed mechanical hand. Known spring constants are used to show the predicted and actual mechanical hand configuration.

After validating the modeling approach on the mechanical hand, the analysis was then extended to determine joint stiffnesses of a test subject’s impaired hand. Using photographs from Subject 1’s testing, the link lengths and initial and final relative link angles were determined (see Fig. 9 for an example). The mass of the hand was estimated to be 0.5 kg (corresponding to the 50th percentile male hand mass), with the weight distributed between the palm and fingers at a 60:40 ratio and the finger segments’ mass proportional to length. These values were used in combination with the measured inflation pressure of the bag (5 psig) to simulate the hand opening and determine joint stiffnesses.

**Fig. 9.** Subject dimensions. This figure shows the segment data for a subject’s hand prior to stretching. The black line is a known distance of 100 mm used for calibration, and the red lines indicate link lengths (forearm L1, dorsal palm L2, proximal finger segment L3, middle finger segment L4, and final finger segment L5).

Figure 10 plots the experimental starting configuration in black, the experimental (desired) final configuration in blue, and the simulation match based on the iteratively-derived spring constants in red.
The goals for donning and doffing were for the subjects to do each independently in under a minute. These were largely successful. Both subjects were able to put on and remove the orthosis without assistance. In addition to the flat design of the device that was able to be donned by placing the hand on top of the device, they expressed approval of the Velcro straps for ease of donning. Their times for donning were between 1-1.5 minutes each, which are acceptably close to the 1-min goal and

have the potential to improve with practice (i.e. if this were a take-home device). Taking off the orthosis was quick and easy, and both subjects did so easily in under 15 seconds. These results in particular shine relative to existing research prototypes, which are more difficult to don and doff due to individual finger attachments. The minimum of currently published times for donning and doffing are 3 minutes and 23 seconds, respectively, [36] approximately twice that of the prototype described here. Existing literature states only the times for donning and doffing and not the level of assistance patients received.

As shown in Table II, the required pressure to open the subjects’ hands increased with increasing tone. These results make sense and are further corroborated by the fact that the orthosis took the least amount of pressure to inflate without a hand in it.

Based on the maximum pressure test results and its performance throughout the testing session, the orthosis prototype can exceed the strength required to open a toned hand by an order of magnitude, while also offering the safety of being incapable of overextending finger joints. The pressure required to open the injured subjects’ affected hands ranged from 4-5 psig, and the bag was able to inflate to 35 psig without rupturing. Although the manual tone of the subjects tested ranged from low to medium, the range of allowable pressures is such that the prototype should be sufficiently strong enough to stretch hands with more aggressive tone as well.

During the cyclic stretching, the orthosis behaved consistently, as evidenced by the small standard deviations. Furthermore, it is clear that the performance became even more consistent from the first to the last tests as the subject’s hand relaxed. In fact, on the last tests, the standard deviation is so small that the difference between cycles (evidenced by the gray band) is barely visible. The pressure curves are also as expected for a nonlinear, constant surface area system. One can see that pressure is essentially zero until the bag is full of air, and then observe a swift increase in pressure as the volume remains fairly constant. The actual pressure peaks close to the desired magnitude with a slight (approximately 0.5 s) lag, and then decreases with input pressure. It is important to note that no vacuum was applied, only an exhaust valve was slowly opened, so any air leaving the bag was due to the subject’s hand naturally contracting to push it out. Per visual observation, the hand became significantly straight with the orthosis fully inflated, and it contracted back near its original level as the pressure was removed. The bag did not completely empty during deflation, which is beneficial because that means the subject’s hand did not completely close (an undesirable position). Exact joint angles were difficult to quantify during the cycle, simply due to the bag and straps obscuring parts of the hand.

The grip force test results were inconclusive as to the effects of manual stretching on grip force.

Maximum grip force decreased substantially for Subject 2 after stretching, but not for Subject 1. Because Subject 1 did not show significant grip force reduction after the 5-minute
stretching session, he was re-tested on another day with an 11-minute session. However, still no grip force reduction was noted, and in fact, maximum grip force for Subject 1 increased slightly after his second session. The reasons for this are unknown, but it could be because Subject 2 had lower tone, and so his hand was easier to relax. It is also noteworthy that Subject 1 was overly competitive with trying to beat his previous measurements and peek at the numbers, while Subject 2 did not attempt to do so. Overall, changes in grip force are inconclusive. It remains unknown if the orthosis can offer a short-term therapeutic benefit, as grip force may be a longer-term effect. More testing is needed to investigate whether short term therapeutic benefits are possible and/or if longer term use will offer benefits.

Both subjects had positive feedback regarding the orthosis and testing experience. They said the device is something they would use both at home and in public with no qualms, due to an eagerness to facilitate their recovery. Subject 1 was particularly enthusiastic, asserting that it was a “fabulous stretching concept that could really open up possibilities,” and he would take “any chance for improvement, I need to practice every day for results.” Both subjects speculated on the potential benefits of the orthosis for facilitating activities of daily living, as less stiff hands could enable them to regain independence and efficiency with many activities. They specifically mentioned cooking, cleaning, eating, and opening water bottles as desired abilities that this device could hasten.

The occupational therapist consulted throughout the prototype development and study process had very positive feedback and helpful insights. She praised the concept and effectiveness of OrthoHand Extend for gently stretching stiff hands via pushing with a distributed load rather than pulling on the fingertips (an often overlooked issue which could cause irreparable musculoskeletal damage). She also spoke approvingly of the strap placement in locations conducive to muscle relaxation, and the fact that the orthosis supports the wrist in addition to the hand because an affected wrist tends to contract/curl as well. Regarding use, the therapist said she would recommend this device for at-home use with manually impaired patients two to three times per day for light stretching (up to 15 minutes) before performing a manual activity. She also recommended that future control involve a longer stretching cycle biased towards “open”, for example, 8 seconds inflated and 4 seconds deflated for a 12 second cycle.

The therapist also informed the authors that hand spasticity can be affected by a gamut of factors, including temperature, pressure, how much sleep someone had, mental state, etc., and so can vary from day to day. She acknowledged that stretching and using the hand helps substantially but is not the only factor in recovery or performance, and patients must practice daily for best results.

The effect of mental state on hand spasticity was directly observed with Subject 1 early in the testing process. When asked to don the device for the first time, the subject struggled for a while with a very stiff hand and told the authors he was nervous in front of them. The authors then distracted him via conversation, and saw that his affected hand visibly relaxed. At that point, the experiments resumed and were more easily completed.

A constrained Lagrangian formulation was used to model a hand as a set of sequential rigid links with torsional compliance and damping. Simulation results indicate that stiffness decreases toward the distal joints for a single patient test case. Model validation with a 3D printed mechanical hand and known stiffness constants indicate that this model is a potentially useful tool to quantify and monitor changes in patient joint stiffness. One limitation of this modeling approach is that though the wrist is one joint, each lumped finger joint is based on 4 separate fingers with non-collinear axes and lengths. A higher fidelity model could be used to determine the spring constants of each finger joint by extending this work to 3 dimensions and modeling each finger separately, but this approach was determined not to provide significant additional benefit since the current device cannot separately exercise each finger, and so was not pursued. A second limitation of this approach is that all the measurements obtained are approximate due to the joint collinearity approximation. Additionally, this was only done on one patient, so the precise joint stiffnesses do not extend beyond the subject. However, it is not the exact joint stiffnesses that are of importance, but rather the relative joint stiffnesses and changes over time. The benefit of the modeling is in the ability to characterize each patient’s hand stiffness at each therapy session, thereby monitoring progress. Ideally, patient hand stiffness would decrease over time as they recover, so therapists could use this approach to ascertain and quantify progress beyond the typical qualitative assessment.

The primary limitations of this study are the low number of test subjects and brief time span. Although two test subjects are sufficient for validating a proof-of-concept design, the results obviously do not have statistical power and therefore do not generalize to the entire neurologically impaired population. Also, a 5 to 10 minute stretching session is not long enough to measure chronic benefits of the orthosis. Future work would be to advance the prototype to the point that it could be used in a clinical or even a home setting, where participants would have daily access. Then researchers could measure its effects on a greater number of participants over several months to determine more generalized and long-term benefits.

V. Conclusion

The design of OrthoHand Extend is simple and effective, solving some issues with existing technology and current research. The primary design considerations of easy to don, soft, inexpensive, and therapeutic stretching have been met. The initial evaluation of functionality was successful and sets the stage for further prototype development (portability and controls) and evaluation of long-term effectiveness.

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