Article

Investigative and Usability Findings of the Move-D Orthotic Brace Prototype for Upper Extremity Tremors in Pediatric Patients: An Unblinded, Experimental Study

Sharief Taraman 1,2,3,*, Amy Moss 4, Hieu Le 5, Lois Sayrs 6 and Tianyi Li 7

1 Children’s Health of Orange County (CHOC) Neuroscience Institute & The Sharon Disney Lund Medical Intelligence, Information, Investigation, and Innovation Institute, Orange, CA 92868, USA
2 Department of Pediatrics, School of Medicine, University of California-Irvine, Irvine, CA 92697, USA
3 School of Engineering, Chapman University, Orange, CA 92867, USA
4 Beach Kids Therapy Center, San Clemente, CA 92673, USA; amy@beachkidstherapy.com
5 The Innovation Lab, Division of the Innovation Institute, La Palma, CA 90623, USA
6 CHOC Children’s Research Institute, Orange, CA 92868, USA
7 School of Engineering, University of California Irvine, Irvine, CA 92697, USA
* Correspondence: staraman@choc.org

Abstract: Tremors affect pediatric and adult populations, with roughly 3% of people worldwide experiencing essential tremors. Treatments include medication, deep brain stimulation, occupational/physical therapy, or adaptive equipment. This unblinded experimental pre-test–post-test study was performed (April–September 2021) at Children’s Health of Orange County, evaluating the effectiveness of Move-D, a novel orthotic brace, on pediatric tremors. Ten participants (14–19 years old) experiencing upper extremity tremors (5 essential, 2 dystonic, 1 coarse, 1 postural, and 1 unspecified) were enrolled. Participants completed a usability survey and performance was measured utilizing the Bruininks–Oseretsky Test of Motor Proficiency, second edition, with and without the brace, using one-sided \( t \)-tests of mean differences. Move-D improved age-equivalent scores for fine motor precision by 20.5 months and upper limb coordination by 15.1 months. Manual coordination percentile rankings increased by 2.9%. Manual dexterity performance was unaffected. The usability survey revealed that 7/10 participants agreed or strongly agreed that they could move their arm freely while wearing the brace, the brace reduced their tremors, and they felt comfortable wearing the brace at home. Through standardized testing and findings from the usability survey, Move-D showed an improvement of functional abilities in a pediatric population with tremors.

Keywords: orthotic; exoskeleton; device; pediatric; essential tremor; muscle tremors; assistive devices

1. Introduction

Tremors are involuntary, rhythmic muscle contractions. The etiologies of tremor are broad. As tremor is a symptom of many conditions, the exact incidence and prevalence are difficult to estimate; however, the prevalence of tremor increases with age such that estimates in age groupings of octogenarians, nonagenarians, and centenarians range from 1.2–42.9% [1] (p. 9). The incidence of pediatric tremor is estimated to range from 2.2 to 33.1% [2] (p. 4). There are currently limited treatment options available for pediatric movement disorders that manifest tremors and spasms. Innovation in orthotic braces for children with movement disorders is crucial given the lack of progress in treatment specifically for this population [3] (pp. 731–732). Current orthotic brace options often cause discomfort and are not always well-tolerated by pediatric patients, leading to decreased compliance and ineffective treatment [4] (pp. 3–6). By creating more user-friendly orthotic braces, children with movement disorders can potentially experience improved mobility leading to increased independence in activities of daily living and quality of life. Additionally,
Innovative approaches to orthotic design, such as the incorporation of assistive technology, may help to address the unique challenges faced by pediatric patients with movement disorders. Overall, investing in innovative orthotic braces for children with movement disorders is essential to address the current gap in treatment options and improve outcomes for this vulnerable population.

Treatments for tremor include medication, surgery, and physical, occupational, and behavioral therapies [3] (pp. 722–731). Wearable orthotics on the market, such as robotic exoskeletons, are designed with adult populations in mind and due to their large size, likely do not provide sufficient stabilization to substantially reduce tremors in pediatric patients. According to recent research comparing four groups of technological approaches for tremor management (robotic exoskeletons, soft robotic exoskeletons, functional electrical stimulation neuroprosthesis and afferent neuroprosthesis), the robotic exoskeleton device achieved the most significant tremor reduction. However, several limitations in wearability and comfort have yet to be addressed. Despite the robotic exoskeleton’s effectiveness, users considered that they hampered their social relationships because of their bulky aspect, noise and size [5] (p. 10). Furthermore, they are difficult for the pediatric patient to operate independently and are limited by the fact that they cause muscle fatigue. Some devices use electro-nerve stimulation to reduce tremors. However, constant electrical stimulation over the motor threshold on hands to suppress tremors also led to muscle fatigue due to induced contraction which decreased the effectiveness of this device [3] (p. 10). It should be noted that there have been limitations to previous research regarding the effectiveness of tremor reduction using orthotic braces or electrical stimulation devices as often the sample size is small, and the research is based on trials conducted in a short duration of time.

With limited options of tremor-reducing devices available for pediatric populations, the Sharon Disney Lund Medical Intelligence, Information, Investigation, and Innovation Institute at Children’s Health of Orange County (CHOC) challenged clinicians to find a solution. In response, CHOC, the BioEngine Program at the University of California-Irvine School of Engineering, and the Innovation Lab collaborated with a pediatric patient (first initial: D), who suffers from dystonic tremors, to create a novel orthotic brace affectionately named Move-D.

The motivation for developing the Move-D orthotic brace was to improve the quality of life for individuals suffering with tremors by enhancing functional independence and successful participation in activities of daily living (ADLs), such as dressing, writing, typing, eating, and playing. It was hypothesized that increased stabilization at the elbow in combination with applying slight pressure to the ulnar nerve (as provided by the Move-D brace) will result in a reduction in upper extremity tremors, hence improving functional movement and efficiency when completing ADLs.

The Move-D orthotic brace prototype is an enhanced adjustable dampening brace for upper extremity tremors that aims to address the limitations of currently available devices. Move-D is designed to be lightweight, portable, easy to operate without external assistance, comfortable, tremor reducing, and adjustable to the patient’s growth. The Move-D brace reduces tremors by stabilizing the upper extremity, from the shaft of the humerus to the wrist joint. A dampening knob allows the participant to adjust the level of resistance needed to successfully complete a given task. Brace length and circumference may also be adjusted. We hypothesized that the Move-D brace is effective at improving the functional movement of the upper extremity to enhance the performance of ADLs and that participants would rate it highly in terms of usability.

2. Materials and Methods

The objective of this study was to evaluate the usability and effectiveness of the Move-D brace prototype at reducing/dampening upper extremity tremors and its impact on fine and gross motor skill level. Internal Review Board (2010151) approval was obtained
through CHOC and written informed consent was obtained for each participant. This study was in part funded by the Innovation Institute and CHOC.

2.1. Brace Design

The Move-D orthotic brace (Figure 1) spans the upper arm, elbow, and forearm. Velcro straps at the upper arm and forearm secure the brace in place, ensuring that the hinge is located at the elbow. Located posteriorly on the brace above the hinge is a soft protrusion that applies pressure along the course of the ulnar nerve. During the early design phase of the Move-D prototype, it was discovered that the combination of the resistance provided by the brace and the pressure along the ulnar nerve helped reduce tremors. The resistance provided by the brace can be adjusted at the user’s discretion through the rotation of the dampening knob located at the elbow joint. The therapist and participant can determine the degree of resistance required to optimize functional performance. Fine motor tasks will require more resistance, whereas gross motor tasks will require less resistance. The level of resistance was determined according to the participant’s comfort level while flexing and extending their upper extremity. Left- and right-handed model options are available.

The inspiration behind Move-D came from a pediatric patient (first initial: D) diagnosed with cerebral palsy with severe bilateral dystonic tremors. Using a client-centered designed approach, patient D was instrumental in providing crucial feedback to enhance the comfort and functionality of the brace. Move-D is now in its second prototype phase. Earlier revisions were made in response to client feedback to optimize comfort. These revisions included altering the Velcro strap’s width and location on the brace, adding a strap stop for easy donning, increasing padding thickness and removability for easy cleaning, and creating more pronounced finger divots on the dampening knob for easier adjustment.
Move-D is a lightweight (<1 lb) mechanical brace that distributes weight evenly along the length of the arm, providing proprioceptive input both proximally and distally. The evenly distributed weight of the brace is designed to prevent undue stress on the elbow and maintain joint integrity. Move-D’s telescopic feature and adjustable straps permit participants to customize stability in both the distal and proximal areas of the upper extremity allowing the brace to target both dystonic and essential tremors. In addition, the telescopic feature grants longevity of use as it elongates and grows with the patient.

2.2. Study Population

Research participants were recruited from April 2021 to September 2021 through CHOC physician referrals and occupational therapists. Eligibility was determined using various qualification markers including medical history and diagnosis of tremors. Phone interviews were also conducted where participants were asked for specific areas of deficit and to subjectively rate how their tremors impact their activities of daily living skills on a scale from 1 to 10 (1 = mild to 10 = moderately severe). Finally, clinical observations were made of the participants’ tremors while they filled out consent forms prior to being evaluated.

The age range of eligible participants fell between 12 and 21 years. Participants had to be currently experiencing mild to moderate tremors in their dominant upper extremity which limited their functional performance in daily living tasks. Deficits in this area would include decreased performance in writing, drawing, manipulating clothing fasteners, drinking from an open cup, and using kitchen utensils to feed themselves.

Exclusion criteria included cognitive impairment with an inability to follow instructions or inability to sustain attention for more than 10 min, aphasia of a level sufficient enough to limit comprehension and completion of the treatment protocol, increased muscle tone limiting upper extremity range of motion, tremors affecting the non-dominant arm instead of the dominant arm, diagnosis of a progressive neurological disease/disorder, and open wounds or active infection. Additionally, included in the exclusion criteria were participants currently taking medications that cause or eliminate tremors. Participants taking medication that dampen tremors were included in the study; however, study assessments were scheduled when tremors were most prominent just prior to the normal dosing schedule.

A total of 12 participants met the qualification criteria; however, two participants reported that they were not interested in participating in the research study. One group of ten participants (14–19 years of age) experiencing upper extremity tremors of various degrees and etiologies were enrolled and completed the study. Of the ten participants, five participants had a diagnosis of essential tremor, two with a dystonic tremor, one with a coarse tremor, one with a postural tremor, and one with an unspecified tremor. Tremor type was confirmed by a board-certified pediatric neurologist with 10 years of post-residency experience in evaluating pediatric movement disorders. Research evaluations were conducted from 29 May 2021 to 18 September 2021. No participants dropped out of the study and no adverse effects were reported (Figure 2).
2.3. Research Protocol

Assessments were conducted in a research exam room at CHOC. The room contained a small table with two chairs and ample floor space for the gross motor portion of the assessment. Each of the 10 participants completed all aspects of the presented evaluation protocol. The participants were assessed with and without the use of the brace in areas of fine motor, manual dexterity, and upper limb coordination using a subset of tests from the Bruininks–Oseretsky Test of Motor Proficiency, second edition (BOT-2).

2.4. Bruininks–Oseretsky Test of Motor Proficiency

The BOT-2 is a standardized, individually administered test that uses engaging, goal-directed activities to measure a wide array of fine and gross motor skills in individuals 4–21 years of age. It is a reliable and efficient measure of fine and gross motor control [6] (p. 1). This study utilized the BOT-2 to evaluate each participant’s fine motor precision, manual dexterity, and upper-limb coordination skills with and without wearing the Move-D brace. In this study, the BOT-2 was used to evaluate task completion without assistance (baseline/control data) and when wearing the brace (experimental data). The test scores were collected and analyzed to determine how effective the brace was at reducing tremors. This study included one group of ten participants who individually completed three BOT-2 subtests, once when wearing the brace and once when not wearing the brace. The participants were exposed to approximately one hour of testing in total. To limit the influence of variables such as testing fatigue, odd-numbered participants completed the BOT-2 evaluation without the brace first, and then completed the second trial of BOT-2 while wearing the brace. Even-numbered participants completed the first trial of the BOT-2 evaluation while wearing the brace and the second trial without it.

The BOT-2 standardized assessment and scoring protocol were used to generate the data by converting each participant’s raw score on the fine motor precision, manual dexterity, and upper limb coordination domains of the BOT-2 to their age equivalents in months or percentiles where appropriate. Participant age-equivalent baseline/control data were then compared to experimental data. Participants completed two separate
trials of BOT-2 testing. The results from the baseline/control data were then compared to the experimental data using one-sided \( t \)-tests of mean differences. Statistical significance was set at \( \alpha = 0.05 \) with 95% confidence intervals. Bayes effects were also calculated using known variances. All data were collected and analyzed by the research team on each day that the participants were evaluated. Both descriptive statistics and inferential statistical analysis were utilized to determine the effectiveness of the Move-D brace at reducing tremors and enhancing functional performance in both fine and gross motor activities. There was no need to complete follow-up interviews or any further data collections.

Upon completion of the BOT-2, participants were asked to complete a usability survey. Participant feedback was collected and analyzed to inform the refinement of the prototype’s design. For non-English-speaking participants, a certified translator read the survey items to the participant and recorded the answers on the survey form.

2.5. Fine Motor Precision

The fine motor precision subtest of the BOT-2 consists of activities that require the precise control of finger and hand movement. It has five drawing items, one paper-folding item, and one cutting item. The drawing tasks include filling in shapes, drawing lines through paths, and connecting dots. The paper manipulation tasks include both cutting and folding paper. Because the emphasis is placed on precision, the items in this subtest are untimed. Each task was individually scored based on the examples listed within the administration manual [6] (p. 5).

2.6. Manual Dexterity

The manual dexterity subtest uses goal-directed activities that involve reaching, grasping, and bimanual coordination with small objects. The activities performed include picking up plastic pennies and placing them into a box, stringing small blocks, sorting cards, and placing pegs into a pegboard. Emphasis is placed on accuracy; the items are timed, and the examinee is told to perform the task as quickly as possible. Each task was timed for 15 s, with tasks #2–5 conducted twice. The time required to complete the activity was used as a measure of dexterity. Although the manual dexterity activities are not usually part of everyday tasks, the skills required to perform them are meant to correspond to those used in common daily activities such as holding and using feeding utensils, manipulating buttons, and sorting coins to make change [6] (p. 5).

2.7. Upper Limb Coordination

The upper limb coordination subtest consists of activities designed to measure visual tracking with coordinated arm and hand movement. Tasks included catching, dribbling, and throwing a tennis ball. Four of the items require the use of one hand and three require the coordination of both hands [6] (p. 6).

2.8. Usability

After the completion of BOT-2 testing, participants were asked to complete a usability survey while wearing the brace. Survey questions included whether or not the participant found the Move-D brace comfortable, easy to don, and beneficial in reducing tremors during task completion.

This crossover within-subject study design has 80% power to detect an effect size of 1.75 with a minimally important difference (MCID) of 0.72 in the fine manual precision (FMP) scale score based on previous findings [7] (p. 852).

3. Results

3.1. Demographics

The median age of the study participants was 16 years (range, 14–19 years). All participants were right-hand-dominant. Seven subjects were biologically female (Table 1).
Participants’ raw scores on the fine motor precision, manual dexterity, and upper limb coordination domains of the BOT-2 were converted into age equivalents in months or percentiles where appropriate. Participant age-equivalent baseline/control data were then compared to experimental data (Table 2). A large effect was seen for upper limb coordination with an average improvement of +15.1 points (2.4; 27.8; \( p < 0.05 \)). Participants completed two separate trials of BOT-2 testing, once without assistance and once while wearing the brace. The results from the baseline/control data (results of testing without assistance) were compared to the experimental data (results of testing when wearing the brace) using one-sided \( t \)-tests of mean differences. Statistical significance was set at \( \alpha = 0.05 \) with 95% confidence intervals. Bayes effects were also calculated using known variances to assess the relative strength of the hypothesis after observing a significant effect under assumptions of 80% power, with \( \alpha = 0.05 \) (Table 3). The largest effect size was observed for upper limb coordination with significant improvement based on the BOT-2 scale and age-equivalent scores (Table 3). Fine motor skills also showed significant average improvement from the baseline. All 10 eligible participants engaged in all aspects of the study with no need for follow up and none had missing data elements indicating 100% compliance and no early exits. Throughout the testing procedure, there were no reported adverse effects caused by the Move-D brace, such as skin irritation and/or upper extremity fatigue. This was also supported through the results from the usability survey the participants completed at the end of the study.

**Table 1. Participant Information.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
<th>Median [IQR]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>16 years *</td>
<td>16 (15, 17)</td>
</tr>
<tr>
<td>Sex:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>7 (70.0%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3 (30.0%)</td>
<td></td>
</tr>
<tr>
<td>Dominant hand:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>10 (100%)</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

*Minimum age, 14 years. Maximum age, 19 years

**Table 2. Change from Baseline with the Brace in BOT-2 * in age equivalence (months) or percentile.**

<table>
<thead>
<tr>
<th>Participant #</th>
<th>Fine Motor Precision (Months)</th>
<th>Manual Dexterity (Months)</th>
<th>Upper Limb Coordination (Months)</th>
<th>Manual Coordination (Percentile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>+12</td>
<td>0</td>
<td>+4</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
<td>+36</td>
<td>+9</td>
</tr>
<tr>
<td>3</td>
<td>+84</td>
<td>+6</td>
<td>+21</td>
<td>+9</td>
</tr>
<tr>
<td>4</td>
<td>−2</td>
<td>+6</td>
<td>+18</td>
<td>+3</td>
</tr>
<tr>
<td>5</td>
<td>−4</td>
<td>−2</td>
<td>−2</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>+48</td>
<td>−45</td>
<td>0</td>
<td>−8</td>
</tr>
<tr>
<td>7</td>
<td>0</td>
<td>+6</td>
<td>+42</td>
<td>+12</td>
</tr>
<tr>
<td>8</td>
<td>0</td>
<td>−66</td>
<td>+36</td>
<td>0</td>
</tr>
<tr>
<td>9</td>
<td>+7</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10</td>
<td>+72</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Table 2. Cont.

<table>
<thead>
<tr>
<th>Participant #</th>
<th>Fine Motor Precision (Months)</th>
<th>Manual Dexterity (Months)</th>
<th>Upper Limb Coordination (Months)</th>
<th>Manual Coordination (Percentile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (95% CI)</td>
<td>+20.5 (−3.8, 44.8)</td>
<td>−7.9 (−26.4, 10.6)</td>
<td>+15.1 (2.4, 27.8) a</td>
<td>+2.9% (−1.3, 7.1)</td>
</tr>
<tr>
<td>Effect Size</td>
<td>0.603</td>
<td>−0.305</td>
<td>0.849</td>
<td>0.493</td>
</tr>
<tr>
<td>Post hoc Power b</td>
<td>55%</td>
<td>1%</td>
<td>80%</td>
<td>42%</td>
</tr>
</tbody>
</table>

* Positive numbers represent improvement; negative numbers represent worsening. a Statistically significant at \( p < 0.05 \); b post hoc power calculation based on a one-sided test for observed effect size and 0.05 level of significance.

Table 3. \( \delta \) in BOT-2 * (without vs. with brace).

<table>
<thead>
<tr>
<th>Metric</th>
<th>Mean (SD) N = 10</th>
<th>( p )-Value (One-Sided)</th>
<th>Effect Size</th>
<th>Post hoc Power</th>
<th>Bayes Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual coordination scale score</td>
<td>1.90 (3.57)</td>
<td>0.08</td>
<td>0.532</td>
<td>46%</td>
<td>1.75 b</td>
</tr>
<tr>
<td>Standard score</td>
<td>1.9 (3.96)</td>
<td>0.09</td>
<td>0.480</td>
<td>40%</td>
<td>1.72 b</td>
</tr>
<tr>
<td>Percentile rank</td>
<td>2.9 (5.88)</td>
<td>0.08</td>
<td>0.493</td>
<td>42%</td>
<td>0.86 d</td>
</tr>
<tr>
<td>Fine motor scale score</td>
<td>1.5 (2.42)</td>
<td>0.04 a</td>
<td>0.620</td>
<td>57%</td>
<td>2.59 b</td>
</tr>
<tr>
<td>Fine motor age equivalence (months)</td>
<td>21.4 (33.46)</td>
<td>0.04 a</td>
<td>0.640</td>
<td>59%</td>
<td>1.93 b</td>
</tr>
<tr>
<td>Manual dexterity scale score</td>
<td>−0.40 (2.63)</td>
<td>0.32</td>
<td>−0.152</td>
<td>12%</td>
<td>3.16 c</td>
</tr>
<tr>
<td>Manual dexterity age equivalence</td>
<td>−7.0 (26.57)</td>
<td>0.21</td>
<td>0.263</td>
<td>19%</td>
<td>3.13 c</td>
</tr>
<tr>
<td>Upper limb scale score</td>
<td>2.4 (2.76)</td>
<td>0.02 a</td>
<td>0.870</td>
<td>81%</td>
<td>0.09 e</td>
</tr>
<tr>
<td>Upper limb age equivalence</td>
<td>14.1 (19.08)</td>
<td>0.02 a</td>
<td>0.739</td>
<td>70%</td>
<td>0.42 d</td>
</tr>
</tbody>
</table>

* Positive numbers represent improvement; negative numbers represent worsening. a Statistically significant at \( p < 0.05 \); b anecdotal evidence in support of an effect from the device; c moderate evidence in support of an effect from the device; d strong evidence in support of no effect from the device; e strong evidence in support of an effect from the device.

3.2. Fine Motor Precision

With the brace in place, soft pressure stimulation over the ulnar nerve in combination with resistance provided by the dampening hinge was observed to decrease tremulous movement during prototype development (Figure 1). Furthermore, fine motor precision test results (Figure 3) revealed that 4 out of 10 (40%) participants showed an improvement in fine motor precision skills when wearing the brace. Of those four participants, #3 (Figure 4), #6, and #10 demonstrated dramatic improvement, as their skill level increased by an average of 68 months when wearing the brace.
3.3. Manual Dexterity

Manual dexterity test results (Figure 5) revealed that 5 out of 10 (50%) participants demonstrated slight improvement (mean 7 months) when wearing the brace. The results for two participants (#6 and #8) showed a negative impact when wearing the brace, as age equivalence decreased by 55 months on average. It is felt that the results for Participant #6 are invalid, as the brace was too large for her body frame and thus did not provide any real stabilization of her upper extremity when completing manual dexterity tasks. Notably, Participant #6 had an improved fine motor precision score. Nevertheless, even when we excluded Participant #6 and Participant #8 from analysis, manual dexterity showed a trend toward improvement for participants with use of the brace (Table 2).
when we excluded Participant #6 and Participant #8 from analysis, manual dexterity showed a trend toward improvement for participants with use of the brace (Table 2).

**Figure 5.** Change in manual dexterity.

### 3.4. Upper Limb Coordination

Upper limb coordination test results (Figure 6) revealed that 5 out of 10 (50%) participants showed significant improvements in upper limb coordination skills when wearing the brace, as the mean skill level increased by 30.6 months.

**Figure 6.** Change in upper limb coordination.
3.5. Standard Scoring

Scaled scores for Manual Dexterity and Upper Limb Coordination subtests were combined to generate a Standard Score, which correlated to a percentile ranking for Manual Coordination provided by BOT-2 [6] (pgs. 178–179, 186). The Manual Coordination percentile reflects the individual’s Manual Coordination skill level when compared to peers of the same age [6] (p. 28). The Manual Coordination test results (Figure 7) revealed that 5 out of 10 (50%) participants showed improvement in Manual Coordination when wearing the brace. These participants averaged a 7.4 percentile increase when wearing the brace, compared to not wearing the brace. (Table 2) shows that the percentile increase was statistically significant ($p = 0.02$) when excluding the one participant for whom the brace was too large.

![Manual Coordination](image)

**Figure 7.** Change in manual coordination.

The manual coordination percentile reflects the individual’s manual coordination skill level compared to that of peers of the same age [6] (p. 28). The manual coordination test results (Figure 7) revealed that 5 out of 10 (50%) participants showed improvement in manual coordination when wearing the brace.

4. Discussion

This study was designed to determine the effectiveness of Move-D, a novel orthotic brace, and its ability to reduce upper extremity tremors in pediatric populations. It was hypothesized that increased stabilization at the elbow in combination with applying slight pressure to the ulnar nerve (as provided by the Move-D brace) would result in a reduction in upper extremity tremors, hence improving functional movement and efficiency when completing ADLs.

The results presented above provide preliminary evidence supporting our hypothesis, as participants wearing the Move-D brace demonstrated improved fine and gross motor skills. In the fine motor precision subtest, 4 out of 10 participants demonstrated a 52-month improvement on average. In the upper limb coordination subtest, 5 out of 10 participants demonstrated a 30.6-month improvement on average. Half of all participants demonstrated an average increase of 7.4% in manual coordination skills. The potential for improvements in manual dexterity skills warrants further study as half of the participants demonstrated a 6.8-month increase but the overall mean of 10 participants was −7.9 due to one of the participants being an outlier.

Due to the study’s small sample size (N = 10), the limited patient demographic diversity in terms of the male to female participant ratio (Table 1), and other factors,
including the severity of the tremor and the origin/type of tremor (dystonic verse essential tremors), further testing is recommended to enhance both internal/external validity and the generalization of results.

In this study, soft pressure stimulation over the ulnar nerve in combination with resistance provided by the dampening hinge was observed to decrease tremulous movement in patients wearing the Move-D orthotic brace (Figure 1). Ulnar nerve stimulation or pressure has previously been shown to improve motor movements. Some evidence exists that mechanical ulnar nerve stimulation stimulates opioidergic neurons in the arcuate nucleus of the hypothalamus and subsequently activate opioid receptors on accumbal GABA terminals leading to a net decrease in dopaminergic transmission [8] (pg. 14–15). Other research has shown that applying bursts of non-invasive electrical stimulation alternately to the median and radial nerves of the wrist lead to a 60–80% reduction in the spiral drawing Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) [5] (p. 19). Hence, it may be beneficial to further investigate the differences in tremor reduction when applying slight pressure over the ulnar nerves versus radial nerves.

The Move-D orthotic brace stabilizes the elbow, which demonstrated potential effects in upper limb coordination and fine motor precision tasks. The most positive effect was observed for upper limb coordination where five participants had a positive effect, four participants had a neutral effect, and only one participant had a negative effect. In the fine motor precision domain, five participants had positive scores and two had negative scores. Notably, the upper limb coordination and fine motor precision subtests required less range of motion in the shoulder compared to the manual dexterity subtest. Furthermore, participants frequently used compensatory strategies for additional upper extremity support when engaged in upper limb coordination and fine motor precision tasks. For example, participants gained stability by resting their elbow on the tabletop during fine motor precision tasks. When performing upper limb coordination tasks, participants would position their upper arm against the lateral portion of their torso for the additional stabilization of their upper extremity. Tasks on the manual dexterity subtest required the combination of gross motor and fine motor control, making it more challenging to rely on compensatory strategies for stabilization, thus, impacting overall functional movement.

In contrast, the brace was less effective during manual dexterity tasks. Such tasks require the shoulder joint to maneuver through a greater range of motion (flexion/extension and adduction/abduction), in addition to requirements for wrist flexion/extension, ulnar/radial deviation, and finger opposition for manipulating small objects. Perhaps, future revisions of the Move-D brace including extending the brace to reach past the ulnar styloid process to enhance wrist stabilization has the potential to improve functional performance of both fine motor precision tasks and manual dexterity tasks.

The usability survey results showed agreement or strong agreement with the following statements: 70% could move their arm freely while wearing the brace; 70% felt the brace reduced their tremors; and 70% felt comfortable wearing the brace at home. These findings are encouraging, as this is only the first version of the Move-D brace prototype.

4.1. Study Limitations

The findings of this study show promise in the future research of the Move-D brace. Before future research is conducted, limitations need to be considered. This study is limited by the small sample size, wide variability in effects, and the cohort imbalance between male and females, all of which may limit the generalizability of the study results. There may also have been ceiling effects for fine motor skills that could not be adequately assessed in this small sample size. The frequency with which participants used the environment (e.g., torso and table) to stabilize the device was not studied to determine its association with effects. The improper fit observed for one study subject suggests that fit should also be assessed as a confounder of observed effects. In addition, we did not assess the device for patients younger than 14 years of age and, therefore, the device may not be appropriate for patients younger than 14 years old.
4.2. Future Directions

Further studies that include a larger sample size of both pediatric and adult populations as well as a longer duration of evaluation are planned. Additionally, feasibility studies utilizing various metrics such as the spiral drawing TETRAS [5] (p. 19), the subject-rated Bain and Findley Activities of Daily Living (BF-ADL), and a digitized tablet to provide precise quantification of tremor during writing/drawing tasks will help to evaluate further potential effects of Move-D on functional performance in ADLs [9] (pp. 1–3).

With further design refinements such as making the brace easier to don, reducing the profile, and additional wrist stabilization attachments, the Move-D orthotic brace could be a simple and cost-effective option to reduce upper extremity tremors and thus enhance quality of life in patients with movement disorders with support through future health economic outcome research studies.

5. Conclusions

Overall, the results showed that the Move-D orthotic brace enhanced dynamic and static performance for both fine motor precision skills and upper limb coordination. Out of 10 participants, 7 felt that the brace minimized tremors and did not limit their range of motion. Perhaps the most rewarding findings of this study were reports that patients felt more confident in their skills when wearing the brace.

6. Patents

Involuntary Movement-Dampening Device filed with the U.S. Patent and Trademark Office.

Author Contributions: Conceptualization, A.M. and S.T.; methodology, A.M. and S.T.; validation, S.T.; formal analysis, L.S. and S.T.; investigation, A.M., T.L. and S.T.; resources, H.L.; data curation, A.M. and T.L.; writing—original draft preparation, A.M. and H.L.; writing—review and editing, A.M., L.S., T.L. and S.T.; supervision, S.T.; project administration, H.L.; funding acquisition, S.T. All authors have read and agreed to the published version of the manuscript.

Funding: This research was in part funded by The Innovation Lab and CHOC.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of CHOC (protocol code: 2010151; date of approval: 14 December 2020).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available upon request from the corresponding author.

Acknowledgments: The authors acknowledge Dylan Law and McKenzie Law for the design input, Ben Dadacay, Myong Kim, Matt Keller, and Pere Cvitanovic for design, engineering, and project support, Christine King, Quan Nguyen, Kimmai Phan, Adriana Rodriguez, and Salma Serhal for design and engineering support, Virginia Allhusen and Linda Do for research support.

Conflicts of Interest: Authors Sharief Taraman, Amy Moss, and Tianyi Li hold intellectual property related to the device.

References


Disclaimer/Publisher’s Note: The statements, opinions and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of MDPI and/or the editor(s). MDPI and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions or products referred to in the content.