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Abstract

Background: The Wilmington Robotic Exoskeleton (WREX) is a body-powered, four degrees of freedom orthosis that allows gravity-minimized movement of the arm at the shoulder and elbow. We sought to measure patient satisfaction and performance with use of the WREX during activities of daily living, play, and at school.

Method: Twenty-five families completed a phone interview based on the Canadian Occupational Performance Measure (COPM). These families all had a child, aged 2 to 21 years, who had a neuromuscular disorder and who had used the WREX for at least eight months. The parents rated their child's performance of and satisfaction with important activities both with and without the WREX. The scores were assessed for change between the two conditions.

Results: Twenty-four out of the 25 parents reported that their child had greater levels of performance and satisfaction when they were wearing the WREX. The mean change in performance score was 3.61 points, and the mean change in satisfaction score was 4.44 points.

Conclusion: Families who have a child diagnosed with a neuromuscular disorder and who uses the WREX perceived improved performance and satisfaction with the WREX during self-chosen meaningful activities.

Keywords

neuromuscular, orthosis, robotic exoskeleton

Cover Page Footnote

The results of this study were presented as a poster session at the 2015 Nemours Annual Pediatric Therapy Conference, Wilmington, DE, on April 16, 2015.

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Many neuromuscular conditions negatively affect children's performance of desired tasks, which leads to frustration and dependency on others. Spinal muscular atrophy is a group of inherited diseases characterized by muscle wasting and occurs once in every 10,000 live births (Spinal Muscular Atrophy, 2015). Proximal musculature is affected first and contracture from loss of active movement often follows. Muscular dystrophy, which affects one in every 3,500 male births, is a progressive inherited disease that results in weakness and dysfunction (Strehle, 2009). Arthrogryposis is the phenotype of multiple joint contractures developing prior to birth. A variety of causes are linked to this condition (Arthrogryposis Multiplex Congenita, 2015). In all of these diseases, treatment is limited to improving quality of life. There are presently no cures or disease-modifying pharmaceutical agents available.

Children with these diseases are extremely adaptive, but their long-term spine health remains a concern when the trunk and neck are repeatedly flexed to compensate for upper extremity weakness (Strehle, 2009). The compensatory postures these children use present social and physical barriers as they age. Medical complications resulting from these diseases include scoliosis, joint contractures, cardiomyopathy, chronic chest infections due to respiratory weakness, gastrointestinal motility issues, and urogenital dysfunction (Strehle, 2009). The purpose of this study was to measure the benefit of using an upper extremity orthosis—the Wilmington Robotic Exoskeleton (WREX)—to manage activities of daily living and rate the performance of and satisfaction with these tasks

using the Canadian Occupational Performance Measure (COPM). A video of the WREX can be seen at <http://www.nemours.org/pediatric-research/area/neuromuscular.html>.

Literature Review

In the 1950s, researchers and therapists began developing assistive devices to help this population access their environment by augmenting their ability to reach for objects (Chyatte, Long, & Vignos, 1965). Since then, several upper extremity orthotic systems designed to support reach have been introduced to the therapy community. A few of these have had commercial success (Rahman et al., 2007). The ARMON (Dutch word for arm support) is a wheelchair-mounted exoskeleton that allows the arm to move against gravity. Powered by adjustable springs, it is used for people with neuromuscular conditions (Herder, Vrijlandt, Antonides, Cloosterman, & Mastenbroek, 2006). The DAS (Dynamic Arm Support; Assistive Innovations, New York, NY) is another wheelchair-mounted, spring-loaded orthosis for people with arm weakness. Other commercially available dynamic orthoses include the Mobility Arm (Nitzbon, Hamburg, Germany), TOP/HELP (Focal Meditech, Tilburg, Netherlands), and the Wilmer Elbow Orthosis (Ambroise, Enschede, Netherlands). For a detailed review of these and other similar devices see Van der Heide et al., 2014. Although some of these devices have been commercialized and are being used, particularly in Europe, there is a dearth of information regarding objective outcomes of their use. The goals of this study were to report on the outcomes of use of the WREX.

The WREX is a body-powered, four degrees of freedom orthosis that allows gravity-minimized movement of the arm at the shoulder and elbow. There are two versions of this device: one comprises a set of aluminum links that conform to the arm and are attached to the child's wheelchair, and the other is a plastic/metal hybrid unit mounted to a custom-fitted body jacket. The latter is appropriate for younger ambulatory children. Both versions are customized to a child's size and strength by adjusting the lengths of the links and by attaching rubber bands to the forearm link and the upper arm link. Customization allows for a statically balanced mechanism that negates the weight of the arm. Figure 1 is a picture of the wheelchair-mounted device. This device has been described in previous studies (Haumont et al., 2011; Rahman et al., 2007; Rahman Basante, & Alexander, 2012). A unique feature of the device designed for younger children is that some parts are printed from a 3D printer, which allows for less expensive, lighter, and more easily replaceable parts. The WREX is different from many other commercially available balanced forearm orthoses in that it allows vertical and horizontal movement of the arm, thus providing unencumbered reach anywhere in front of the child.

The WREX was evaluated by measuring performance (Rahman et al., 2007) with the Jebsen Taylor Hand Function Test in a sample of 17 children with neuromuscular disease. The small

sample size and limited data precluded any significant findings; however, several of the children who were unable to complete the test tasks without the WREX were able to complete them while wearing the WREX. The average time it took to complete five of the seven tasks also decreased. Another study examined the impact of the WREX on function in a small group of children (Haumont et al., 2011). In this study, the children and their families completed a questionnaire related to their use of the WREX in performing daily activities, and the children participated in motion analysis. The results demonstrated marked improvement in self-report of upper extremity function and biomechanical analysis of their movement patterns. The children reported increased independence with feeding and increased participation in both school activities and hobbies. Motion analysis demonstrated improvements in range of motion and the potential to limit future contractures.

A concurrent study using an online questionnaire to rate the performance of 10 common activities of daily living while wearing the WREX and while not wearing the WREX was conducted (Gunn, Shank, Eppes, Hossain, & Rahman, 2015). Fifty-five participants completed the online survey. Wearing the WREX resulted in a statistically significant improvement in self-ratings of function in the following tasks: typing on a keyboard, using a mouse, picking things up, using a spoon or fork, and drinking from a glass.



Figure 1. The Wilmington Robotic Exoskeleton (WREX) mounted to a wheelchair.

Method

This study consisted of a retrospective, single-group design using repeated measures at a single time point. The families of children who had been using the WREX were surveyed about their child's ability to complete self-chosen tasks with and without the orthosis. Our institutional review board deemed this study exempt because it did not involve sensitive questions.

Participants

Twenty-five families completed a survey via a phone interview. Mothers most often completed the interviews, but in several cases both mothers and fathers participated. The children in this sample ranged in age from 2 to 21 years. All of the children received the device from the same institution. The mean age was 8.72 (SE, 1.38) years. The families of 16 boys and nine girls participated in the interviews. The children had a broad range of neuromuscular diagnoses: arthrogyposis (14), cerebral palsy (3), spinal

muscular atrophy (2), muscular dystrophy (2), and "other" (4). These children had been wearing the WREX regularly for a range of eight months to 120 months (mean, 25 months). Fifteen of the children were ambulatory and wore the device mounted to a thoracolumbarsacral orthosis (TLSO). Ten of the children had the device mounted to their wheelchairs. Seventeen of the children had bilateral devices. Seven of the children had devices to assist their right arm, and one of the children had a device to support the left arm. Inclusion criteria were (a) arm weakness between 1 and 3 on the Manual Muscle Test (American Physical Therapy Association, 2001), (b) greater than 50 degrees of passive elbow range of motion, and (c) greater than 90 degrees of passive shoulder flexion. Exclusion criteria were severe elbow and shoulder contractures. All of the families lived in the continental United States.

Instruments

The COPM has been used extensively in

occupational therapy research (Bowman & Llewellyn, 2002; Law et al., 1998). It uses a semi-structured interview format with standardized methods for administration and scoring, and it has established reliability and validity (Bosch, 1995; Chan & Lee, 1997; Cup, Scholte op Reimer, Thijssen, & van Kuyk-Minis, 2003). The intent of the COPM is to capture perceived changes in performance and satisfaction over time. Administration yields two scores: a performance score and a satisfaction score. Each score has a range of 1 (*poor performance or lowest satisfaction*) to 10 (*excellent performance or high satisfaction*). The scores themselves are not particularly meaningful, but change in the scores over time is considered clinically meaningful when the change is 2 points or more per scale.

Procedure

The interviewer was an occupational therapist invested in developing an ongoing therapeutic relationship with these families. The interviewer had 15 years experience conducting interviews using the COPM.

Eighty-two families were called up to three times and invited to participate in a phone interview to collect information regarding their personal experiences with the WREX device. Out of the 82 families called, 26 were reached. One family was excluded because they had just received their WREX and did not feel comfortable answering questions about it at the time. The other twenty-five families agreed to complete phone interviews. The participants were asked to participate in a 10 to 20 min interview using the COPM. Following the protocol for the COPM, a discussion took place to

identify areas of performance important to both the parents and their child that were limited by their child's medical condition. If needed, when considering importance, this list of performance areas was narrowed down to no more than five areas.

Following this conversation, the parents were asked to rate their child's ability to perform each identified task without the assistance of the WREX. The scale for performance ranged from 1 (*completely unable to perform*) to 10 (*able to perform very well*). Then they were asked to rate their level of satisfaction (related to the performance of each task) on a scale of 1 (*not satisfied at all*) to 10 (*very satisfied*). The parents were then asked to rate their child's ability to perform the same set of tasks when using the WREX using the same performance and satisfaction scales. Each interview concluded with a discussion about specific likes and dislikes relating to the device, its design, and its fit to the child's individual needs. The responses were recorded on the COPM interview forms.

The interviews provided two sets of data: one set of performance/satisfaction data without any device and one with the WREX device. For the purpose of this study, we compared the two sets of data against each other to see to what degree the parents perceived the WREX as enhancing their child's ability to function.

Data Analysis

For each child involved in the study, four scores were calculated: A COPM performance score without the use of an assistive device, a COPM satisfaction score without the use of an assistive

device, a COPM performance score with the use of the WREX device, and a COPM satisfaction score with the use of the WREX device. These scores were calculated based on the standardized protocol of the COPM. A paired t test was used to compare the mean change in COPM scores with and without use of the WREX. We chose parametric tests, as the shape of the data is not very skewed and there were no violations of the assumptions for parametric tests. All tests were two-tailed and the level of significance was set at $p < 0.05$. Statistical software R (version 3.01) (Revolution Analytics, Redmond, WA) and SPSS version 22.0 (IBM, Armonk, NY) were used for the data analyses.

Results

Nineteen of the 25 families reported changes greater than 2 points on both the performance score and the satisfaction score between no device and when the device was used. Five of the 25 families reported a change in score ranging between 0 and 2 points on one or both scales. One family reported a negative change of greater than 2 points on both

scales, suggesting the WREX device hindered performance and satisfaction. This family felt that the WREX was too cumbersome and interfered with the child's mobility.

The parents identified a number of common themes in the performance activities that were important to them (see Table 1). The COPM categorizes performance activities into sets of self-care, productive, and leisure activities. In the collective set of self-care activities, self-feeding was by far the most common activity, identified by 23 families. Other commonly identified self-care activities included improved body awareness and facial grooming. In the collective set of productive activities, 16 families identified writing, typing, or using an iPad as very important activities to them. Lastly, the participants identified a wide variety of leisure activities important to them. The most common was being able to play with age appropriate toys that were not designated for special needs children. Fifteen families identified access to regular toys as a theme.

Table 1

Common Themes in the Identification of Performance Activities Identified as Important to Families of Children with Neuromuscular Disorders

Self-care activities		Productive activities		Leisure activities	
Identified activity	Number of families who indicated it was in top 5 of importance	Identified activity	Number of families who indicated it was in top 5 of importance	Identified activity	Number of families who indicated it was in top 5 of importance
Self-feeding	23	Written communication (writing, keyboarding, iPad use)	16	Ability to play with toys not designed for special needs children	15
Body awareness	4	School skills (holding paper, gluing, cutting, coloring, etc.)	7	Social skills (giving hugs, shaking hands, using social media)	4
Grooming (hair care, brushing teeth, wiping face, scratching own itch)	12	Ability to reach needed objects during school-related tasks	4	Dramatic/creative plays skills (acting, playing musical instruments, dancing)	4

Examining the scores of the group as a whole, we calculated the mean performance and satisfaction scores without the assistance of the WREX and again with the assistance of the WREX. A paired *t* test was used to compare the mean

change in COPM scores with and without use of the WREX. Paired *t* tests were calculated demonstrating a significant improvement in both performance and satisfaction with the use of the WREX. The results are listed in Table 2.

Table 2

Comparison of COPM Scores on Same Tasks With and Without Use of the WREX

COPM Scores	When no device is used to perform chosen activities	When WREX is used to perform same chosen activities	<i>p</i> value
Average Performance Score	3.35 (<i>SD</i> = 1.82)	7.09 (<i>SD</i> = 2.15)	<i>p</i> < 0.005
Average Satisfaction Score	3.12 (<i>SD</i> = 1.71)	7.56 (<i>SD</i> = 2.41)	<i>p</i> < 0.005

Note. COPM, Canadian Occupational Performance Measure; *SD*, standard deviation.

Discussion

The results of this study suggest that families who have a child diagnosed with a neuromuscular disorder perceive improved performance and satisfaction during self-chosen meaningful activities when the WREX is worn. The families identified that wearing the WREX helped enhance their child’s performance of a variety of self-care, school-related, and leisure activities. This was associated with improved satisfaction in functioning. In addition, the families mentioned benefits outside of the performance arena, such as improved eye contact, cognitive enhancement, social awareness, and improved posture. One family identified that performance of activities was diminished by use of the WREX. They felt that the WREX was too cumbersome for their son, who was ambulatory and very active. This outcome is similar to a previous study that examined performance on the Jebsen Taylor Hand

Function Test with and without the WREX (Rahman et al., 2007); however, the Jebsen test was not the most appropriate test as some tasks required finger dexterity, which the WREX does not address.

Our use of the COPM is somewhat unique and may present a validity issue. The use of COPM over the phone was approved a-priori by the COPM institute (personal correspondence, May 2014). The families from this sample live all across the country, making in-person interviews cost prohibitive. In this era of telehealth, we decided to attempt phone interviews. One published study has examined the reliability of using the COPM via phone interview (Kjeken et al., 2005). In addition, the COPM typically has been used to measure the change in performance over time. In this case, the interview was conducted twice, but with respect to change in the environment (i.e., child not wearing the device vs. child wearing the device). There is no research to date to validate use of the COPM in this manner.

Previous studies identify a change in score on either scale of 2 points or greater as clinically meaningful (Law et al., 1998). In this case, the intervention was not treatment provided over time, but rather assistance of a wearable device. Therefore, it is uncertain what the threshold of change needs to be for clinical meaningfulness.

Implications for Occupational Therapy

The findings of this study can educate therapists working with populations with chronic or progressive upper extremity and proximal weakness. Use of the WREX has been demonstrated to increase range of motion and improve both performance and satisfaction relating to important activities of daily living. As was discussed earlier, it also has the potential to reduce some of the medical complications common to these disease processes. Self-reports indicate reduced joint contractures and better posture among WREX users, which could positively affect gastrointestinal and pulmonary function and reduce musculoskeletal pain as these children age. Many families also affirmed that using the WREX helped their child to be more social and expanded their cognitive development by increasing the number of activities in which the child was able to participate. There is no research to date to validate the parents' observations of these improvements outside of the realm of activities of daily living.

Occupational therapists wishing to share this technology with their clients may want to consider the patient characteristics used in this study. The evaluation of potential candidates at this institution includes a team with a physician (either neurologist or orthopedist), therapist, and engineer. Desired

characteristics in a potential client are passive shoulder motion to be equal to or exceed 90 degrees of flexion, total range of passive elbow motion to be 50 degrees or more, and manual muscle strength of Grade 2. In addition, one must consider wrist and hand function. Supplementary wrist braces are often needed in conjunction with specialized hand orthoses or universal cuffs to promote function. Internal motivation to engage in activity is also needed. This is often difficult to gauge, as is cognition, due to the lack of movement without the orthotic. The relationship between cognition and movement is just starting to be explored in the neuroscience literature.

If the child is ambulatory, one must consider how the TLSO and WREX will affect gait and balance. At this time, it is not possible for the child to disengage the arm support while ambulating. This means the arms will be supported in shoulder flexion during movement. It has been our experience that the older children get, the more cumbersome the device is perceived in children who are ambulatory, leading to rejection of the device.

Another consideration for the therapist considering the WREX for a potential patient is the child's social supports and the environment. How invested are the caregivers in maintaining this device? Does the child have at least one parent or therapist who can regularly tighten the screws and check alignment? For children in wheelchairs, small doorframes have been a common complaint. The device is easily removed from the wheelchair for transport, but many families leave it on and it becomes loosened and out of alignment over time.

Some children have a variety of caregivers who will interact with the device, including nurses and teachers. Each of these caregivers will need to have some basic instruction in how to maintain and adjust the device for optimal use and comfort.

Limitations and Recommendations for Future Studies

The limitations of this study include the uncertain reliability/validity of a phone interview versus a face-to-face interview with an interview tool such as the COPM. Although caution is needed when interpreting and applying the results of this study to broader populations, it should be noted that the results are supported by both past research with this population and a concurrent study with a larger sample size. In this era of telehealth, the efficacy of outcome measures completed online, by phone, or by video conferencing needs to be substantiated.

Another limitation of the study is its retrospective nature; subjects completed the survey for both device and no-device conditions at the same time. This could have influenced their discrimination between the two conditions. Future evaluation will use a pre-device and post-device design, where the survey will be conducted before receiving the device and after having used it for a period of time.

Two areas of research that specifically apply to occupational therapy deserve future study. One area concerns ways in which use of the WREX changes over time. In other words, how does the WREX impact the way toddlers function compared with school-aged children or compared with college-aged young adults? The interviews conducted suggest that the WREX is used

differently across developmental stages. For preschool children, the device seems to be well accepted across social and family settings, and children enjoy using the device to help them access a greater number and variety of toys. In elementary school, ambulatory children seem to be less accepting of the device. These children feel more comfortable resorting to old compensatory methods of manipulating objects, or just foregoing activities that are different rather than practicing using the orthosis and looking different from their peers. The parents of the older children in the study reported that their child now understands how the WREX can help him or her and wants the support in order to engage in activities of interest and maximize independence. A second line of future research should attempt to examine the extent to which the WREX benefits users when considering specific patient characteristics. The research to date has generated a list of characteristics that are likely to ensure a good fit to the device, but none as yet have been specifically studied. This will be important not only for successful implementation and development of therapy using the WREX but also necessary for consistent insurance coverage.

Conclusion

The WREX is the only orthosis for the upper extremity available clinically in the US that provides this range of function. There are more such devices available in Europe, but outcomes studies have not been conducted on these. The WREX is inexpensive, relatively lightweight, and provides 3D movement for the hand. However, it is mechanical in appearance and has hard links and joints that do not always move in concert with the

joints of the arm or provide enough “softness” to the user. An ideal WREX user would be someone with arm weakness, low tone, and without joint contractures. Although many people who do not fall into that category use the WREX for function, it becomes less useful as they move away from the ideal.

In this study, there was a statistically significant improvement in both satisfaction with and performance of meaningful activities, as rated by parents, when their child with a neuromuscular disorder was wearing a WREX device. Activities that families frequently identified as important to them were feeding, school skills, and increasing the variety of play activities available to their child. These results were similar to results from previous studies and suggest new lines of research.

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