Published in final edited form as:

IEEE Trans Neural Syst Rehabil Eng. 2016 December ; 24(12): 1277–1283. doi:10.1109/TNSRE.2015.2492860.

User Evaluation of a Dynamic Arm Orthosis for People With Neuromuscular Disorders

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Abstract

This paper presents the results of an online survey conducted with users of a functional upper extremity orthosis called the Wilmington Robotic EXoskeleton (WREX). The WREX is a passive anti-gravity arm orthosis that allows people with neuromuscular disabilities to move their arms in three dimensions. The paper also describes the design of a novel lightweight 3-D printed WREX used for ambulatory children. Three different versions of the WREX are now offered to patients. Two can be mounted on a wheelchair and one to a body jacket for ambulatory patients. An online user survey with 55 patients was conducted to determine the benefits of the various WREXs. The survey asked ten questions related to upper extremity function with and without the WREX as well as subjective impressions of the device. Results show a statistically significant improvement in arm function for everyday tasks with the WREX.

Keywords

Arthrogryposis multiplex congenital (AMC); exoskeleton; muscular dystrophy (MD); orthosis; spinal muscular atrophy (SMA); user survey

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This paper includes supplementary material found online at <http://ieeexplore.ieee.org>.

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I. Introduction

CHILDREN affected by a neuromuscular disease such as muscular dystrophy (MD), arthrogryposis (AMC), cerebral palsy (CP), or spinal muscular atrophy (SMA) may have profound muscle weakness in their arms that prohibits them from moving their hands in space and performing activities of daily living such as eating and writing. Various options are available that may increase range of motion of the arms and hands and give the user a higher level of independence, including dynamic arm supports and orthopedic procedures. Orthopedic procedures such as posterior releases, tendon transfers, and humeral osteotomies have been advocated to improve functional elbow flexion in children with AMC [1], [2]. Unfortunately, none of these procedures has resulted in significant improvement in outcome [3]. Dynamic arm supports offer more range of movement.

Duchenne muscular dystrophy (DMD), the most common form of muscular dystrophy, has a prevalence of 1 per 5600 males [4]. It is a progressive disease, and strength is gradually diminished [5]. SMA has a similar phenotype to MD and affects 1 in every 10 000 live births [6], [7]. Like MD, SMA affects the larger muscles closer to the body rather than those at the extremities, making anti-gravity hand movement difficult. AMC is a rare congenital disease that occurs in 1 of every 3000 births [1]. Symptoms are muscle weakness and joint stiffness. It is quite typical of children with this condition to have weak biceps muscles, therefore making feeding difficult. Some subjects with CP have also used the WREX to relieve the weight of their arm to make tasks easier to perform. Depending on the severity of the condition, a child could be ambulatory or use a wheelchair.

A. Upper Extremity Orthoses Background

A few orthoses are commercially available, mainly in North America and Europe. One is the balanced forearm orthosis (BFO) [8], [9], which is a system of links that is attached to the wheelchair and allows movement primarily in the horizontal plane. The user can tilt his or her forearm up and down to facilitate self-feeding. A version of the BFO comes with an elevating arm that is buoyed by an elastic band but is seldom used as it cannot provide complete vertical movement and is difficult and time consuming to fit. The Rancho-Jaeco multi-link arm support [10] offers a more aesthetic alternative to the BFO. It has modular components and can easily be set up and interchanged between the two arms; however, it does not provide vertical movement. The ARMON, available in Europe, is a wheelchair-mounted passive exoskeleton that allows the arm to move against gravity. It uses adjustable springs as the power source and is used for people with neuromuscular conditions. It allows a large range of gravity-free motion [11]. Another commercially available device is called the Dynamic Arm Support (DAS) [12]. This is also a spring-loaded upper extremity orthosis for people with arm weakness, and it attaches to a wheelchair. Other commercially available dynamic orthoses include the Mobility Arm (Nitzbon, Hamburg, Germany), TOP/HELP (Focal Meditech, Tilburg, The Netherlands) and the Wilmer Elbow Orthosis (Ambroise, Enschede, The Netherlands). These are described in a thorough review of upper extremity orthoses [13].

Section III describes the development of the 3-D printed WREX and the development of the survey that was conducted with 55 patients to ascertain quantitative and qualitative outcomes

of usage of the WREX. This is followed by results of the survey and conclusions and discussions.

II. Materials And Methods

The WREX [14] is a body-powered, 4-degrees-of-freedom orthosis consisting of a series of linkages and joints that conform to the contours of the arm. It provides gravity-eliminated movement by using rubber bands on each of the two main links (forearm and upper arm) (Fig. 1). The location of the end of the bands along with the stiffness modifies the anti-gravity force, which yields an identically statically balanced mechanism that negates the weight of the human arm. This allows someone with arm weakness to move his or her arm in 3-D space. The WREX has a number of adjustable elements: 1) the humeral members are telescoping and can be adjusted to fit different sized people; 2) the number of bands can be changed to get more or less lift; 3) the arm trough can be moved anterior/posterior and up/down for comfort and optimal movement; and 4) the shoulder joint structure has roll/pitch/yaw for optimal placement and orientation.

Two sizes of the WREX are made to be attached to a wheelchair or a table top (Fig. 2). A third version of the WREX is partially made with a 3-D printer and is for younger, ambulatory children. This is attached to a custom-fitted body jacket. Details on the design are provided in the next section.

A. Design of 3-D WREX

The four joints for WREX [15] are divided into two rotations at the shoulder and two rotations at the elbow (Fig. 3). This allows positioning of the elbow and hand in 3-D space but does not allow for pure axial rotation about the humerus or pronation/supination about the elbow. The two perpendicular joints at the shoulder combine to allow abduction–adduction and flexion–extension. The two elbow joints combine to allow elbow flexion–extension and partially compensate for the absence of humeral rotation at the shoulder. The gravity compensation technique used here is an approximation of the technique described in Rahman *et al.* [16]. This approximation does not require the need to use zero free-length springs (zero free-length springs have a characteristic where the unstretched length of the spring is zero [16]. Since this is physically impossible, the spring can be looped around an intermediary point to achieve the same effect. However, this introduces undesirable friction), which adds complexity to the device. In practice, when the WREX is used, errors are introduced that make the gravity balancing imprecise. These errors are mainly due to nonlinear passive tissue resistance in anatomical joints, spasticity, and joint misalignment.

A modified WREX—Baby WREX—was developed for young children (aged 2–5 years) who are able to walk. This device had to be lightweight and mounted to the body of the patient. The thoracolumbarsacral orthotic (TLSO) that is commonly used to maintain a scoliotic curvature of the spine was modified to act as the body jacket (Fig. 4). The jacket is reinforced with steel strips to which the WREXs are mounted. These provide a sturdy base that the TLSO material alone is not sufficient enough to provide. The TLSO is a custom jacket based on a mold of the patient. The material is polyethylene with a soft lining. The

jacket is worn over clothing. Additionally, we custom-mold arm troughs into which the children place their arms. The troughs are attached to the forearm piece of the WREX.

The baby WREX (Fig. 5) uses a combination of ULTEM plastic (Stratasys, Eden Prairie, MN USA) and metal parts to make a lightweight WREX (~0.5 Kg). The long members are roughly the size of the upper arm and forearm and are made of steel, as the ULTEM is not strong enough. The steel pieces come in a few lengths. The appropriate length is chosen based on the age and size of the child. The shoulder and elbow joints are made of ULTEM. These parts are printed on a Fortus 3-D printer (Stratasys). This provides a quick and lighter way of manufacturing these joints. All the joints of the baby WREX have ball bearings for smooth movement. Linear off-the-shelf elastic elements (Sammons Preston, Cedarburg, WI USA) are used. These are latex-free and come in different colors indicating different stiffnesses. The number of rubber bands can be adjusted based on the strength and size of the child. The child then dons the entire system. The weight of their arms is then transferred to their torso through the combination of the rubber bands and joints. This allows them to move their arms easily. The main links of the baby WREX can be interchanged for longer links as the child grows. A bigger TLSO can also be remade for the child as he or she grows.

B. Survey

Many children and adults have been using the WREX for the last 2 to 4 years. An online survey was conducted to determine effectiveness of the WREX (Appendix A in the supplementary material) with these children. This survey was reviewed by the Institutional Review Board and was considered to be exempt from research as the questions were considered to be nonsensitive. The survey included a set of functional questions that were asked of patients or caregivers. Patients were asked to respond to ten questions on their functional ability *without* the use of the WREX. The same questions were asked of them *with* the use of the WREX. The answers were provided on a five-point Likert scale ranging from “performing the task without any difficulty” to “unable to do”. The survey was compiled in REDCap (Vanderbilt University) and put together on a website. The link to the site was distributed by e-mail. The user or caregiver was prompted to fill in demographic information (name, disability, and date of birth) and whether the WREX was still in use. Additionally, they were asked how the WREX is attached (wheelchair, jacket, other), how long they have used it, and which arm it is mounted to. Patients were also asked to provide subjective impressions of the WREX. Inclusion criteria were if patients had used the WREX in the last 3 years and were less than 18 years of age when first fitted with the WREX. For each task, the 33 scores for performance *with* the WREX were averaged, and the 33 scores for performance *without* the WREX were averaged. A paired 2-sample t test was used for difference of means for each task. A p -value of 0.050 was used for all statistics for significance.

III. Results

The survey was completed by 55 respondents who used the WREX. Of these, 27 have AMC, 9 have SMA, 8 have MD, 5 have CP, and 6 have some other disability. The demographics of subject use of the WREX are shown in Table I.

As shown in Table II, the tasks that showed significance were *typing on a keyboard, using a mouse, picking things up, using a spoon or fork, putting food in mouth, and drinking from a glass*. The tasks that did not show significance were *writing, using a TV remote, eating in a restaurant, and caring for oneself without caregiver help*. When the average scores both with and without the WREX were summed across all tasks, the overall performance of these tasks showed significance. Fig. 6 shows a graphical representation of the difference in performance scores for each task and the difference in overall performance scores.

An unpaired 2-sample t test was used to test for difference of means between those who used the WREX attached via jacket and those who used the WREX attached via wheelchair for each task. The mean difference between performance scores *with* and *without* the WREX was the mean value used for each group in the hypothesis test. The only task that showed significance was *picking things up* ($p = 0.022$). This indicates that for this task, there was a significantly greater improvement for the children who use a wheelchair-mounted WREX over those that wore a jacket. As Fig. 7 indicates, there was a substantial difference between the wheelchair and jacket groups in terms of improvement seen because of the WREX. Both groups showed improvement with the WREX, but the wheelchair group showed more.

To test for significance across different disabilities, a one-way ANOVA hypothesis test for difference of means was used for each task and for the overall score *with* and *without* the WREX. No significant differences were seen across the disabilities. Subjective comments from users are provided in Appendix B in the supplementary material.

IV. Discussion

The questionnaire shows that subjects' ability to perform everyday tasks improved considerably with the WREX and that they used it for prolonged periods. Some of the tasks showed significant improvement while others showed less improvement. The tasks that showed significant improvement with the WREX were *typing, using a mouse, picking up things, using a spoon/fork, putting food in mouth, and drinking from a cup*. These tasks, for the most part, involve a vertical movement component while the tasks that improved less were more horizontal planar. This indicates that the main contribution of the WREX is helping in anti-gravity motions.

Twenty-two of 55 respondents were no longer using the WREX, even though on average the nonusers used the WREX for 17.73 months. The survey was designed such that if the child was no longer using the WREX, they were not asked to answer the ten survey questions. They still provided subjective comments on WREX use (Appendix B in the supplementary material). Reasons for not using the WREX were the following:

- interferes with bathroom use;
- caregivers intimidated by WREX;
- too bulky/heavy;
- inexact gravity balancing;
- child is too young;

- stiff wrist hinders eating;
- has outgrown the jacket;
- too bouncy for iPad use;
- gait becomes unsteady;
- prefers using feet for manipulation.

These is a wide variety of reasons, and some can be remedied with an improved design, such as a lighter and smaller design with precise gravity-balancing. This information also tells us to look at the context of WREX use in their lives before it is prescribed (i.e., how does it fit into their lives? Will it interfere with other critical functions such as wheelchair operation, toileting, and walking?)

For some subjects, the WREX improved certain tasks whereas for others, it did not help in the same tasks, such as use of a tablet. This reinforces the fact that users have to be selected with some thought. Considerations should include joint contractures, feeding ability (tube-fed or orally), technology tolerance, walking ability, family/caregiver support, psychosocial considerations, and others. All these conditions aligned well for most of the respondents. In a few cases, the WREX has become an indispensable part of their lives; one patient has continually used an early wheelchair-mounted WREX for 11 years.

Results tend to show that of the people still using the WREX, the one attached to a wheelchair is worn by more people and for longer periods than one attached to a jacket. On the basis of feedback from the users, we think this is because of bulkiness of the jacket, restricted mobility because of the jacket, jacket becoming too small and a new size not being acquired, lack of freedom of movement that is present in a wheelchair, and weight of the entire system. Future work will involve making the WREX lightweight and smaller and making the body-mounting system softer, less invasive, and not custom molded.

The WREX itself should have improved movement against gravity for the entire range of movement. However, it was observed and commented by users that it is not easy to move in certain areas including extreme vertical ranges (i.e., when it is easy to move the hand up, it is not as easy to move the hand down). This is due to inexact alignment of the WREX and the person, weight shifting, and imprecise gravity compensation. This continues to be an area of investigation. We intend to use zero-free length springs and cams to provide an exact anti-gravity force. However, imprecise gravity compensation may be an inherent limitation of a passive system due to change in position from one use to another.

Adjustability and fitting of the WREX system can be improved. This is reported to us by caregivers who may have to readjust the settings. Currently, it requires some skill to fit and adjust the WREX to an individual. One way to make it easier is to have a knob that can adjust the tension in the bands. Likewise, a mechanism that can easily adjust the lengths of the links is needed.

Elbow flexion- or extension-assist is built into the WREX by having bands at the elbow. This assumes that the children have enough strength in one or the other direction to

overpower the bands. This is particularly useful for children that have difficulty in bending their elbows to allow them to feed themselves.

In our experience, and from qualitative feedback from the survey, we have found that the acceptance of WREX depends on the following factors.

Loose joints

Absence of joint contractures at the elbow and shoulders makes the WREX more useful as this provides a greater range of motion of the hand. Elbow passive range of motion should be close to 100°. Shoulder passive range of motion should be approximately 90°.

Hand function

The ability to grasp light objects should be present. This makes using the WREX more meaningful as the child can feed himself or use a pencil or play with toys.

Residual strength

The WREX requires some strength to move. This would be equivalent to level 1 in the manual muscle test scale. The WREX does not work for people who have no strength in their arms. Some parents reported that their children can flap their arms when they are under water. This would be a good indication that the patient could benefit from the WREX.

Parental and child outlook

Some parents are very proactive and will go to great lengths to investigate and try out the devices such as WREX even though the gains in movement may be minimal. These movements, however small, are meaningful if they allow a child to bat a balloon or hit a switch. This switch may allow them access to a communication device that can open up a whole new world for them. On the other hand, some parents have high expectations of the device and are not satisfied unless there are dramatic improvements in function and independence. This is a psychosocial factor, and it is difficult to predict success for the WREX. The child's outlook toward technology and gadget tolerance is another factor. We have found that younger children take to the WREX. As they get older, peer pressure and "looking different" becomes a factor and they do not use it as much, particularly if it is attached to the body. As children pass through adolescence and reach their mid-teens, they are more receptive to the technology as long as it proves functional.

Fitting and maintenance

The WREX requires careful adjustment and fine tuning when fitting, particularly when it is attached to the body jacket. If the fitting is not performed correctly, there is a high probability that it will be abandoned before too long. Some of the issues that can contribute to incorrect function are incorrect number of bands used; device joints misaligned with the anatomical joints, which can cause the device to bind up; and device not being leveled correctly, resulting in limited anti-gravity assistance. Although the WREX comes with a user manual, this is seldom consulted when fitting.

Cost

The cost of the WREX system ranges from \$2000 to \$8000, depending on which system users get and whether they get services such as occupational therapy along with it. Currently, private insurance in the U.S. often pays part of the cost. The level of payment is not sufficient to cover the expenses of retailers to widely offer and maintain the WREX. We hope to make payments much easier going forward by showing that this is a necessary and vital technology for children and adults.

The effect of the WREX is immediate. When the WREX is fitted and adjusted correctly, patients start to move against gravity. The reaction from the child and parent is typically instantaneous and positive. The child starts to interact with toys or an iPad immediately or can eat something independently for the first time. For some of the children, particularly those for whom the WREX is jacket-mounted, there is more of a learning curve. They have to learn to keep their torso vertical for best movement from the WREX. Children who have learned compensatory movements such as flinging their arms, bending their head down, or using their other hand for support still resort to these movements even with the WREX. These children take longer to get used to the WREX as they realize they have another movement option now.

One of the shortcomings of this study is that the survey instrument has not been validated. The survey is a custom questionnaire that was specifically designed for WREX users. Existing questionnaires such as the PODCI [17] were not specific to gross upper extremity movements that the WREX affords. Other tests such as the Fugl-Meyer [18] and Wolf tests [19] are too general and would not yield sensitive enough outcomes.

V. Conclusion

The WREX has been shown to make a significant difference in arm function for users while performing everyday tasks. It has been used for an average of 22.8 months. Sixty percent of users continued to use the WREX at the time of the survey. Sixty-nine percent of wheelchair-mounted WREX users continue to use it, and 48% with the jacket-mounted model continue to use it. Reasons for abandonment include weight, interference with other activities, joint contractures, and imprecise gravity balancing. Users showed more improvement in function with the wheelchair-mounted WREX than the body-mounted model. Aesthetics, fitting, and reimbursement are areas for improvement for the WREX. To see the survey and the list of user comments, please refer to the supplementary files found online at <http://ieeexplore.ieee.org>.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Fig. 1.
Larger-sized WREX shown attached to a wheelchair.

Fig. 2.
Smaller WREX attached to a wheelchair in child-friendly colors.

Fig. 3. Configuration of WREX showing the four degrees of freedom. The upper arm uses a parallelogram structure, while the forearm has a single link to which an arm trough is attached. The entire linkage has four joints set up in the following order: 1, 2 for shoulder joints; 3, 4 for elbow joints.

Fig. 4. TLSO custom fit to an ambulatory child. The WREXs are attached to the TLSO. This WREX consists of plastic and metal parts.

Fig. 5.
(a) Baby WREX mounted to a jacket and to the right arm, (b) bilateral mounting to a jacket of a young boy with arthrogryposis.

Fig. 6.

Bar graph depicting the individual mean task performance scores and standard errors with and without WREX and the overall mean performance scores and standard errors with and without WREX. A lower score indicates a task is easier to perform.

Fig. 7.

Bar graph depicting mean total performance scores and standard errors with and without the WREX for those who used the WREX attached via jacket and for those who used the WREX attached via wheelchair.

TABLE I
Number of Subjects Using WREX Either on a Wheelchair (w/c), on a Jacket, or Other Mounting

	w/c	Jacket	Other	Time worn(mo)
<i>Subjects still wearing WREX</i>	18	13	2	25.7
<i>Subjects not wearing WREX</i>	8	14	-	17.7
Total	26	27	2	22.8

TABLE II

Mean Performance Scores With and Without WREX, Mean Difference, Standard Deviation, Standard Error, and *p*-Value

Task	Mean without WREX	Mean with WREX	Difference	SD	SE	<i>p</i>
<i>Typing on a keyboard</i>	3.73	3.06	0.67	1.27	0.22	0.005
<i>Using a mouse</i>	3.64	2.94	0.70	1.47	0.26	0.010
<i>Picking things up</i>	3.82	2.70	1.12	1.08	0.19	1.26E-06
<i>Using a spoon or fork</i>	3.79	2.94	0.85	1.44	0.25	0.002
<i>Putting food in mouth</i>	3.67	2.73	0.94	1.39	0.24	4.89E-04
<i>Drinking from a glass</i>	4.21	3.49	0.73	1.07	0.19	4.51E-04
<i>Writing</i>	3.42	3.03	0.39	1.30	0.23	0.091
<i>Using a TV remote</i>	3.46	3.27	0.18	1.16	0.20	0.374
<i>Eating in a restaurant</i>	3.82	3.33	0.48	1.40	0.24	0.054
<i>Caring for oneself</i>	4.91	4.76	0.15	0.76	0.13	0.258
Total	38.45	32.24	6.21	8.80	1.52	3.01E-04