Clinical benefits and acceptability of two commercial arm exoskeletons for patients with muscular dystrophy

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Abstract— **Restore a lost function is a special experience for people affected by neuromuscular evolutive diseases as muscular dystrophy. Upper limb stiffness and activity limitations have a crucial role in reducing patients autonomy and worsening quality of life. Even if the commercial products might assure a benefit to some users and meet most of their requirements, so far a validation of the use of such devices by people with neuromuscular diseases is missing. We aim at field-testing the improvement in arm functions provided by the use of two commercial devices (Jaeco Wrex and Armon Ayura) and assessing their impact on users quality of life and independence. This step is essential to assure a widespread access to these devices for most of the potential users, possibly presenting direction and guidance to health providers. The results acquired from the first three subjects, with a different disease progression, showed that the functional improvements gained with the use of these exoskeletons are limited and largely depends on the user's impairment. Results showed that if the patient is severely impaired, the exoskeletons are not sufficient to gain functional movements. In contrast, if the patient is moderately impaired, both devices help the subject, even if some limitations of the movements occur. Finally, if the subject is slightly impaired, both devices decrease the performance. However, all the patients have appreciated the good usability of both devices.**

I. INTRODUCTION

NOWADAYS, technology advancements can produce a high impact on people with disabilities. However, people with Muscular Dystrophy (MD) could remain slightly on the side and only partially benefit. The reduced number of patients has limited the research specifically aimed at bridging the gap between the availability of new technologies and the peculiar condition of these subjects. Most effort has been reasonably devoted to wheelchairs, so to assure autonomous mobility, and respiratory assistance, essential for survival [1]. On the contrary, few efforts have been devoted to the assistance of upper limb functions. With the increased life expectancy, upper extremity function becomes more and more important for people affected by MD [2]. MD encompasses more than 40 inherited myopathies characterized by progressive muscle wasting and weakness, among those the main forms are: Duchenne MD (DMD); Becker MD (BMD) and Limb Girdle MD type 2 (LGMD2). Although the various MDs vary in their severity and progression, all are progressive and disabling over time. Very little is known about severity, course and impact of upper limbs limitations in MDs, and only recently scales have been validated to detect modifications during time [3] but even less is known about adequate and effective aids able to reduce functional upper limb limitations. The key concept of the USEFUL project (funded by Telethon foundation) is to contrast the everyday experience of MD people of losing functions by providing them with a system able to exploit their own residual capabilities in arm movements so to keep them partially autonomous as long and as much as possible. Nowadays, the absence of an extensive validation of such anti-gravity assistive devices prevents the health-care systems to recognize these devices in the accreditation lists, limiting their accessibility.

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TABLE I
TECHNICAL DETAILS OF THE TWO EXOSKELETONS

Name	Assisted Degrees of Freedom (DoFs)	Overall DoFs	Weight [kg]
Wrex	2 (shoulder and elbow flexion)	4	2
Ayura	2 (shoulder flexion and tilt)	3	6.4

II. MATERIAL AND METHODS

This project aims at validating a system consisting of an arm exoskeleton mounted on a wheelchair, comparing two commercial devices for arm gravity compensation, to measure their impact on the independence and quality of life of people with MD.

Clinical Trial design. The study (registered on ClinicalTrails.gov, GUP 15021) proposes on-field validation of Jaeco Wrex, a passive exoskeleton, and Armon Ayura, a motorized arm exoskeleton, in a randomized controlled trial with crossover design (Table I). The clinical study is multicentric and received the Ethical Committee approval.

The two exoskeletons. One exoskeleton is the Wrex by Jaeco. It is a passive solution for gravity compensation, which uses elastic bands to support the patient arm; the number of bands varies depending on the weight of the patient arm and his/her strength. The other exoskeleton is the Ayura by Armon Products. It is an active (motorized) solution for gravity compensation, provided with buttons that enable the tilt and shoulder elevation movement. Ayura can be electrically connected to patients wheelchair if the patient is using a motorized wheelchair, otherwise, it has to be connected to a standard domestic power line.

TABLE II

CLINICAL DETAILS OF THE PATIENTS

Patient Code	Age	Sex	Pathology	MRC Muscle Scale		
			Proximal	Middle	Distal	
P1	18	M	DMD	1	1	2/3
P2	52	M	LGMD 2A	1/2	1/2	3
P3	57	M	BMD	3/3+	3/3+	4

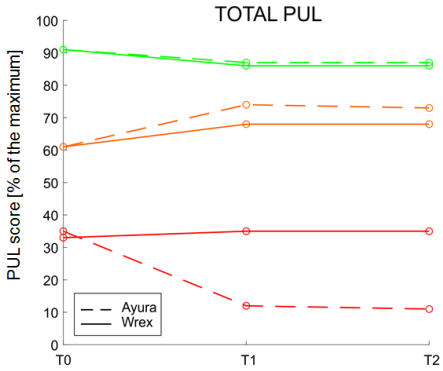

Fig. 1. Total PUL score for a severely impaired (P1 - red), for a moderate impaired (P2 - orange) and for a slightly impaired (P3 - green) subject. T0 evaluation is without the device, while T1 and T2 are performed with the device, the Wrex (continuous lines) or the Ayura (dashed lines)

Inclusion criteria and outcome measurements. Patients with DMD, BMD, and LGMD, wheelchair bounded, have to sign informed consent and need to comply with the study. They must have a score at the Medical Research Council (MRC) scale for upper limb muscles ranging from 2 to 4 for at least one muscular district (proximal, middle or distal) and they must not show additional diseases. Here, we show the results obtained from the first three patients who have been enrolled in the trial and who have completed the assessment with both devices. Table II reports patients' details. It is possible to notice that the three patients are affected by different forms of MD and different levels of impairment in the residual force of their arm. P1 is the most severely impaired patient, P2 is in an intermediate situation, while P3 has still a sufficiently good force in his upper limb. For both devices, the assessments have been performed at baseline, without the device (T0), wearing the exoskeleton, after a 3-days training (T1), and wearing the exoskeleton, after a 2-weeks home training (T2). As a result, the complete protocol with the two devices lasts more than one month. The primary outcome measure is the Performance of the Upper Limb (PUL)[1] [4], while other outcome measures evaluate the usability of the two devices (System Usability Scale - SUS).

III. RESULTS

We have analyzed the PUL scores divided into muscular districts (shoulder, elbow, and wrist). P1 did not show improvements of the shoulder with both devices (0%), only Ayura improved the elbow movements (from 6% at T0 to 21% at T1 and T2) and for the wrist Ayura decreased the initial performance (80%) to 9%, while Wrex did not significantly change it. Also P2 did not show improvements of the shoulder with both devices (0%), but both Ayura and Wrex improved the elbow movements (from 63.5% at T0 to 85% at T1 and T2) and for the wrist Ayura slightly increased the initial performance (87.5%) to 92.5%, while Wrex slightly decreased it (83%). P3 showed a decrease of the shoulder performance with both devices (from 63% to 50%), unchanged elbow movements (100%) and slightly decreased wrist performances with both devices (from 94% to 91%). Analysis of the overall PUL scores showed that the improvement gained with the use of these exoskeletons depends on the subject. Specifically, if the patient is severely impaired (P1), the Wrex is not sufficient to gain functional movements while Ayura improves elbow performance, but impedes wrist movements. In contrast, if the patient is moderately impaired (P2), both devices help the subject, with a better improvement provided by Ayura, even if some movement limitations occur. Finally, if the subject is slightly impaired (P3), both devices decrease the performance since they mostly limit subject's movements rather than assist him/her. Fig. 1 shows the overall PUL results (as percentage of the maximum possible score). The SUS showed that both systems have a good usability, with a score of $84\% \pm 10\%$ for Wrex and a score of $76\% \pm 16\%$ for Ayura. As in the PUL results, the usability of both devices was higher for P2 ($91\% \pm 4\%$) with respect to P1 ($76\% \pm 7\%$) and P3 ($76\% \pm 21\%$).

IV. DISCUSSION

We observed that for similar muscular strength, evaluated by means of MRC, it is possible to have very different benefits from the use of the devices. Moreover, we perceived that even very impaired subjects in terms of MRC may take advantage of the devices if they have good trunk control and/or have developed abilities to compensate a low MRC value. This is particularly true for LGMD2, that thanks to the slow disease progression, are able to learn how to compensate the weakness. We have also observed that in all the evaluated patients who completed the tests, no differences between T1 and T2 in terms of PUL scores are present, suggesting that a short training is sufficient to reach maximal gain. This is also confirmed by the high usability indexes obtained by both devices. In order to have a more robust and statistical interpretation of the clinical trial, the number of recruited subjects has to increase.

[1]PUL provides an overall score capable of characterizing motor performances of the upper limb in multiple tasks or "items", the protocol can assess the three major level dimensions (shoulder, elbow, and wrist levels).

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