A Review of Lower-Limb Wearable Exoskeletons for Overground Rehabilitation

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Introduction
Gait disorders are common among people with neuromuscular impairments –60% of the patients¹– and generally have a high impact on their quality of life². Lack of physical activity increases the risk of secondary health conditions such as respiratory and cardiovascular complications, bowel/bladder dysfunction, obesity, osteoporosis and ulcers³–⁶; which can further diminish life expectancy⁷⁸. Therefore, walking recovery is one of the main rehabilitation priorities for patients with a neuromuscular impairment⁹¹⁰.

Wearable exoskeletons are emerging as a revolutionary device for gait rehabilitation, mainly due to both the active participation required from the user promoting physical activity¹⁰ and the possibility to work as an assistive device in the community. In fact, the number of research studies during the past 10 years has shown a large increase following the general tendency of rehabilitation robotics¹¹. Although wearable exoskeletons are starting to be used in clinical practice, their efficacy is still not clear.

This study provides a comprehensive overview on wearable powered exoskeletons for overground rehabilitation without body weight support in people with neuromuscular impairments.

Methods
We searched for scientific publications in four online databases from 2000 until 18th March 2019 using the following search terms: (exoskeleton OR orthos* OR exoskeletal) AND (robot* OR power*OR active) AND (walk* OR gait) AND ((leg OR lower) AND (limb OR extremity)) AND (rehabilitation* OR clinical* OR pilot) NOT (body weight support OR BWS OR treadmill OR upper OR hand OR arm). This literature search resulted in 855 publications, 57 of which were added in a second search for commercial exoskeletons: 175 in PubMed, 348 in Web of Science, 296 in Scopus and 36 in IEEE Xplore. Additionally, 29 studies were identified from commercial exoskeleton websites. Finally, 89 studies were included in this review.

Results
In this review 26 exoskeletons have been identified, from which only five have FDA approval or/and CE mark and are commercially available (i.e., Ekso, HAL, Indego, REX and ReWalk). Regarding the type of neuromuscular disorder, SCI patients are the main target, with 60% of the total amount of patients from all the included studies, followed by stroke (29%) and other disorders (11%; Figure 1). Table 1 shows that exoskeletons for pathologies with more severe gait impairments tend to use exoskeletons with more active joints. We also found that the majority of devices are intended for adults and only one of the 26 exoskeletons is intended for pediatric patients¹².

The number of degrees of freedom (DOF) in wearable exoskeletons ranges from 1 to 6, although the most frequent number is 4 DOF (2 per each leg). Joints can be passive, active or may be fixed (primarily in the ankle). From the 26 exoskeletons selected in this review, 22 present an active knee joint and only seven present passive joints (6: ankle, 1: hip). We also found that 16 out of the 26 exoskeletons actively assist two or more joints (12: hip-knee, 4: hip-knee-ankle), while the rest actively assist a single joint (1: hip, 6: knee, 3: ankle).

Figure 1: Number of patients studied depending on the exoskeleton active joints number (left), mean and standard deviation (SD) of the device weight vs pathology (middle), and mean and SD of the device weight vs exoskeleton active joints number (right)
Exoskeletons with two active joints are the most representative and present the widest variability regarding the weight (22.98 ± 9.86 kg) (Figure 1). Surprisingly, the exoskeletons with two-active joints are heavier than those with three, although the heaviest exoskeleton is REX (38 kg) with three active joints. Interestingly, the majority of SCI patients have been studied with a two-active joint exoskeleton and all of them have an active knee joint. In addition, Exoskeletons for SCI patients have the highest weight (20.31 ± 9.38 kg), independently of the number of active joints (Figure 1).

Outcome measures for evaluating ambulation are the most used in clinical studies (44%). This is followed by biomechanics measures (17%), which is ahead of energy expenditure (14%), balance and level of assistance (13%) and physiological improvements (8%). Finally, the assessment of usability and comfort (3%) is the least frequent (Figure 2).

The most frequent outcome measures are gait speed, the 10 meter walk test (10MWT), the 6 minute walk test (6MWT) and the time up and go test (TUG), which all of them belong to the ambulation assessments category. Regarding the biomechanics category, knee and hip joint angles are the most common outcome measures.

Clinical studies proving safety and efficacy of wearable exoskeletons for rehabilitation therapy are mainly focused on ambulation assessments instead of centered in physiological and psychological changes. Despite the great potential that wearable exoskeletons can offer, only a few studies assess the improvement related to the secondary health conditions. For example, Baunsgaard et al. and Justczak et al. are the only studies that have measured bowel/bladder function. Moreover, they are, together with Jayaraman et al., the only studies looking into quality of life, being the latter the only one measuring the level of depression.

The outcome measures varied across studies and made comparisons difficult. Clinical guidelines with standard sets of outcome measures would provide the possibility for benchmarking among devices. Solutions to unify technologies and provide comparable measures among exoskeletons are being proposed. For example, the EUROBENCH project is working to establish standard benchmarking methods for exoskeletons to facilitate comparisons among the available solutions.

Reference

Table 1. Number of exoskeletons for pathology depending on the number of DOF

<table>
<thead>
<tr>
<th>Pathology</th>
<th>1 DOF</th>
<th>2 DOF</th>
<th>3 DOF</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCI</td>
<td>2</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Stroke</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>

Figure 2. Analysis of the outcome measures used in clinical studies. Percentage is expressed over the total number of studies included in this review.

Discussion

SCI is the main target pathology for wearable exoskeletons, provably due to its high prevalence, high level of impairment and associated costs. Nevertheless, wearable exoskeletons are also starting to be used in other pathologies such as stroke, multiple sclerosis and cerebral palsy.

Although there are exoskeletons with active hip, knee and ankle joints, users still require support devices such as crutches, walkers and canes to guarantee the users’ balance during exoskeleton assisted walking. Therefore, current research is focusing on finding new control algorithms to improve balance.