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Investigating Inter-Day Variations in the Physical Effects of Exoskeletons: Requirements for Long-Term Biomechanical Studies

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Abstract: Exoskeletons potentially reduce physical strain on workers. However, studies investigating the long-term effects of exoskeletons in the workplace are rare, not least because demonstrating physical long-term impacts faces several challenges, including the collection of reliable biomechanical data with the exoskeleton. By examining the potential impact of using an exoskeleton on inter-day measurements, we can provide valuable insights into the suitability of long-term studies. Therefore, this study aims to investigate the inter-day variation in muscle activity (MA) and kinematics of the trunk and legs during lifting, carrying, walking, and static bending with and without a passive back exoskeleton. The majority of results show no significant differences in inter-day variation. However, we found minor significant unilateral variation in knee and ankle kinematics when using the BSE during the lifting, carrying, and walking tasks, as well as in MA of M. biceps femoris when measuring without the BSE during the lifting tasks. Cohen's d showed small effect sizes, ranging from $-0.0045 \leq d \leq 0.384$ for all significant p-values. While we classify the observed significant differences as minor, it is still crucial to consider day-to-day variations in long-term studies. However, by implementing high levels of standardization in study designs, including precise exoskeleton fitting, consistent assistance level, familiarization with measurement systems, and standardized working tasks, the impact of the exoskeleton on inter-day measurements can be minimized. Additional field studies are necessary to validate our findings in real work conditions.

Keywords: occupational health; reproducibility of results; statistical parametric mapping; muscle activity; kinematics

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1. Introduction

Exoskeletons provide physical support and potentially reduce strain while performing tasks in the workplace [1]. In addition to the benefits of exoskeleton use in terms of reduced muscle activity (MA) and improved endurance [2], studies to date also confirm their potential negative effects on kinematics and MA, including a limited range of joint motion and a higher load on muscle groups [3–5]. As such, it is not yet possible to predict the long-term consequences of movement changes and altered MA patterns caused by using exoskeleton in the workplace [6].

Studies addressing the long-term effects of wearing an exoskeleton at work are scarce, not least because demonstrating long-term relief or strain on the musculoskeletal system from wearing exoskeletons faces several prerequisites [7]. The collection of reliable day-to-day biomechanical data is particularly challenging, because the signals can be affected by intrinsic and extrinsic factors, such as sensor position or fluctuating movement patterns of the target group of workers [8,9].

The most important prerequisite for conducting a biomechanical long-term study is the use of measurement parameters and systems, which can provide comparable results at different points in time. In addition to others, the measurement of MA using surface electromyography (sEMG) and the assessment of movement patterns using wearable sensors, such as inertial measurement units (IMUs), are suitable for this purpose [10]. Both measurement systems enable the comparison of workloads and movement patterns between different individuals and days [11,12] and are reported as being reliable during static [9,13,14] and dynamic conditions [9,15,16].

In order to ensure inter-day reliability of measurement with the described systems, a high degree of execution standardization is required, e.g., consistent fitting and support of the exoskeleton, familiarization with the work task, as well as the normalization task of sEMG measurements [17], and accurate placement of sEMG and IMU sensors [18]. However, even with high standardization, we cannot exclude the exoskeleton-user interaction as a factor influencing the measurements reliability. An exoskeleton, as a rigid mechanical system, has the same effect on the user's body at all times during standardized use. However, we cannot rule out the possibility that the interaction between the user and the exoskeleton may vary on inter-day measurement due to intrinsic factors, which would skew the results. Results of biomechanical studies using exoskeletons vary widely even when using similar or the same exoskeletons [19], which can also be explained by individual user characteristics [10].

Several investigations have already demonstrated significant biomechanical inter-day variation in dynamic and static work tasks without an exoskeleton [16,20–22] using methods such as interclass correlation coefficient (ICC), coefficient of variation (CV) and standard error of measurement (SEM). However, these methods do not enable such a detailed analysis, as required for clinical inference, or the determination of reliability at different stages of a work movement, because they are pooling discrete time points (e.g., peaks) or the entire time series (e.g., root mean square or mean frequency). Previous studies applying exoskeletons in inter-day measurements have only used subjective evaluation criteria to assess the exoskeletons effect [23–26]. To date, only one study by Kozinc et al. [27] has addressed inter-day repeatability and found good reliability in the repeated administration of a test battery for functional assessment of a back supporting exoskeleton. However, they did not measure any biomechanical parameters.

Whether the interaction between exoskeletons and user influences the reliability of the measurements of kinematics and MA on consecutive days has not yet been determined in any study. The objective of this study is therefore to investigate the inter-day variation for MA and kinematics of trunk and leg, in lifting, carrying, walking, and static bending, and examine whether the utilization of a passive back exoskeleton may have an impact on day-to-day results comparability. In order to assess potential inter-day differences throughout the entire duration of the motor tasks, we utilized statistical parametric mapping (SPM) to compare the parameters of each task between day one and day two, both with and without the exoskeleton.

2. Materials and Methods

2.1. Passive Back Exoskeletons

To ensure that any results were related to the use of a specific exoskeleton model, we decided to select two different back exoskeletons with similar mechanisms for this study, the V2.5 (Laevo) and the PaexoBack (Otto Bock). Both models are attached to the user's hip and secured to the upper body with a chest pad. The leg shells of both models are attached to the thighs in a similar position. Both exoskeletons transfer forces from the lower back to the chest and leg pads. A feature of both exoskeletons was that the support could be switched on and off manually while wearing them.

2.2. Subjects

Twenty subjects participated in the study, representing an average user population for the occupational sciences. We therefore recruited the participants from a subject list of the Federal Institute for Occupational Safety and Health including individuals of working age, mostly with either recreational or with no previous sport experience. They were, respectively, ten healthy men and women aged 26 to 49 years (age 34 ± 7 years, height: 174.7 ± 8.2 cm, weight: 74.4 ± 11.6 kg, BMI: 24.2 ± 2.4 kg/m^2), mostly with either recreational or no previous sport experience. Subjects were asked to abstain from physical activity the day before and the days of the tests, to avoid the effects of cumulative muscle fatigue. All subjects signed an informed consent form before the test. Ethical approval was obtained from the local institutional ethics committee.

2.3. Procedure

Subjects performed four different tasks (lifting, carrying, walking, and static bending task), with and without wearing an exoskeleton on two consecutive days. All subjects started with the lifting task, followed by the carrying, walking, and static bending tasks. The order of the two conditions (with and without exoskeleton) within the tasks was systematically varied across subjects. The subjects were randomly assigned to one of two exoskeleton groups, PaexoBack and V2.5, by drawing a number. The number 1 represented the PaexoBack group, while the number 2 represented the V2.5 group. This randomization process ensured an unbiased distribution of participants across the two exoskeleton groups. The time interval between the two examinations was 24 h to 48 h.

In order to familiarize the subjects with the exoskeleton and to minimize any training effect during the measurements, the entire study procedure was performed over two additional training days. On each of the two training days, the entire study protocol was conducted. This included both the testing of MVIC normalization contractions and the complete procedure of the work tasks with and without the exoskeleton, as described in Sections 2.3.1–2.3.4.

On the first training day, the exoskeleton was adjusted to the participants' body dimensions according to the manufacturer's instructions, and these same settings were used for all subsequent days.

2.3.1. Task 1—Lifting and Lowering a Box

The first task was a repetitive box-lifting and lowering task with a load of 10 kg for male subjects and 5 kg for female subjects (Figure 1). The subjects stood in front of the box and performed six lifting and lowering cycles using their own technique: The lift started in an upright position. The subjects lifted the box and straightened up into an upright position. After a two-second standing phase with the box in the hand, the lowering phase began. The box was returned to the ground position and the subjects straightened up again. After standing upright without the box, the next cycle started.

Figure 1. Task 1: lifting and lowering a box with the exoskeleton PaexoBack.

2.3.2. Task 2—Carrying a Box

The subjects were instructed to carry a box with a load of 10 kg for male and 5 kg for female over a distance of 20 m at their own pace (Figure 2). The subjects lifted the box at the marked starting point and straightened up into an upright position to start walking. At the end of the walk, the box was placed back on the ground in a marked position.

Figure 2. Tasks 2 and 3: carrying a box (**left**) and walking without load (**right**) with the exoskeleton PaexoBack.

2.3.3. Task 3—Walking without Load

The same distance as when carrying the box was completed by the subjects without the box at their own pace (Figure 2). As we wanted the study to represent realistic use scenarios of the exoskeleton and in working conditions, the support function of the exoskeleton was switched off for the walking distance.

2.3.4. Task 4—Static Bending Task

Subjects were instructed to stand at a marked position in front of an engine block (Figure 3). They assumed a forward bending trunk posture (30–40°) and removed spark plugs from the engine block. The total duration of the task was 60 s.

Figure 3. Task 4: Static bending task with the exoskeleton PaexoBack.

2.4. Measurements

2.4.1. Kinematics

The movements were recorded using a full body inertial motion capture system (MTw Awinda, Xsens Technologies, Enschede, Netherlands). The 17MTx sensors were placed directly on the skin using skin adhesive, to achieve the most accurate measurement result possible (Figure 4) and position standardized via procedural instructions. Prior to the experiment, participants' body dimensions and calibration poses were measured according to Xsens calibration protocol with the MVN software (MVN Analyse Pro 2021.0.1), to fit and scale the MVN biomechanical model to the subject. The kinematic data was collected at a sample rate of 60 Hz and exported in an excel format.

Figure 4. Sensor placement of sEMG and Xsens sensors.

2.4.2. Electromyography

We equipped the subjects with sEMG sensors, connected to a mobile sEMG system (Ultium, Noraxon). Beforehand, skin was prepared to achieve stable electrode contact and high skin conductance by lowering the impedance. For this purpose, hair was removed from the skin positions to be covered with a disposable razor. The skin was cleaned with alcohol and treated with an abrasive gel. This method is suggested for clinical use [28]. Adhesive gel dual disposable electrodes served as sEMG electrodes; we placed these on dominant body side on the M. erector spinae thoracic (EST) and lumbar (ESL), M. obliquus externus abdominis (OE), M. vastus medialis (VM), M. biceps femoris (BF), M. tibialis anterior (TA), and M. gastrocnemius medialis (GM) according to SENIAM guidelines (Figure 4). We took care to place the electrodes on the midline of the abdominal area, perpendicular to the length of the muscle fibers between the muscle tendon junction and the nearest innervation zone. The muscles were chosen and the electrodes were attached, standardized in such a way that they did not come into contact with the exoskeleton.

An MVIC was performed for all muscles prior to the test. Based on the results of a previous study [17], the performance of the MVICs was also trained on the two previous days, in order to achieve the highest possible level of standardization.

The rectified sEMG signal was set to a sampling rate of 2.000 Hz per channel and filtered using a fourth-order Butterworth filter with a bandpass of 20–500 Hz for GM and TA. To remove heart artefacts in OE and RA signals, a hampel filter was applied, which is a useful method to remove sEMG signal outliers [29]. SEMG signal was root mean squared (RMS) with a window size of 250 ms and normalized using MVICs.

2.5. Data Processing

For tasks 2 (carrying a box) and 3 (walking without load), the gait cycles were considered as follows: A step of a gait cycle started with the right foot terminal contact and its subsequent terminal contact (toe off to toe off). The first and last step of a gait cycle were not considered. A total of eight steps per subject were included in the further analysis. The lifting cycles were divided into lifting and lowering, as described in Section 2.3.1. Five lifting and lowering cycles per subject were included in the analysis. For the bending task, the middle 50 s were selected and divided into 2 s segments. The first and last 2 s segments were selected for further analysis.

The joint angles and muscle signals acquired during each measurement were normalized to a standardized time scale of 101 points. Subsequently, all time-normalized data was averaged per measurement day, comprising the eight gait cycles and five lifting/lowering cycles for each subject. This resulted in a single time-normalized dataset per measurement day for each individual, which was utilized for further comparative analysis using SPM. All data processing steps were programmed and executed in R (R Core Team) [30].

Statistical Parametric Mapping

To assess the reliability of the measurements, we employed statistical parametric mapping (SPM) to compare the parameters of each task between day one and day two. SPM offers a comprehensive statistical analysis framework that enables the identification of significant differences across the entire duration of the motor task. All SPM analyses were conducted in MATLAB Version: 9.13.0 (R2022b), using the open-source software package from spm1D 0.4 [31]. Prior to the analysis, all data were tested for normal distribution. Paired *t*-tests were then used to compare the paired conditions of day one and day two.

The entire time series data representing the lifting, carrying, and walking cycles, as well as the static holding sections, were compared for both kinematic and sEMG data of day one and day two. At each time point, a scalar output statistic called SPM{t} was computed and evaluated by determining the critical threshold at $\alpha = 0.05$ significance level. If the trajectory of SPM{t} crosses this critical threshold at any time point, they were marked as statistically significant. For significant areas, the effect size Cohen's d (d) was also determined.

3. Results

All subjects completed the training sessions and both measurement days. One subject's gait data could not be used for further analysis because the gait pattern was too abnormal. Therefore, this subject was excluded from the analysis of tasks 2—carrying a box—and 3—walking without load. For the other tasks, all the data collected were used. The results for each task are presented below. The blue plots represent the comparison of day 1 and day 2 with the exoskeleton, and the red plots the comparison without the exoskeleton. Regions of significant difference from the SPM results are indicated with background shading (Figures 5–9).

In combination with the shaded regions indicating significant differences, the SPM {t} value plots directly below each plot can be used as an indicator of practical significance. If a significant difference can be detected in a region, Cohen's d is also shown in the plot next to the corresponding *p*-value, as representation of the effect size. For the kinematic data, we present the variables that are particularly relevant to the exoskeleton and have been used in previous studies [1]. These include ankle, hip, knee and spine flexion.

The first task we analyzed was the lifting and lowering (task 1). In the kinematic data, there was no significant difference between the measured joint angles on day 1 and day 2 for lifting. However, for lowering the box, a significant difference in knee flexion was measured with the exoskeleton, as seen in Figure 5. The joint angle at the start of weaning is significantly greater on day 1 ($p = 0.038$, d = 0.384) than on day 2. The difference is also visible on the left side of the body at the same point, but is not significant. This section may be divided by subheadings. It should provide a concise and precise description of the experimental results, their interpretation, as well as the experimental conclusions that can be drawn.

For the sEMG data, there is a significant difference in MA of the BF in the downward movement on day 1 and day 2 for both lifting and lowering in Figures 6 and 7 (lifting: $p = 0.001$, d = −0.243; lowering: $p = 0.040$, d = −0.268) without the exoskeleton. For the other muscles there were no measurable significant differences in MA from day 1 to day 2. For the task of carrying a box, we found a significant difference in knee flexion for the exoskeleton measurement in the kinematic data (Figure 8). There was significantly higher knee flexion in the terminal contact area for the right knee on day 2 ($p = 0.037$, d = −0.14). For the left body side, we could not confirm this effect.

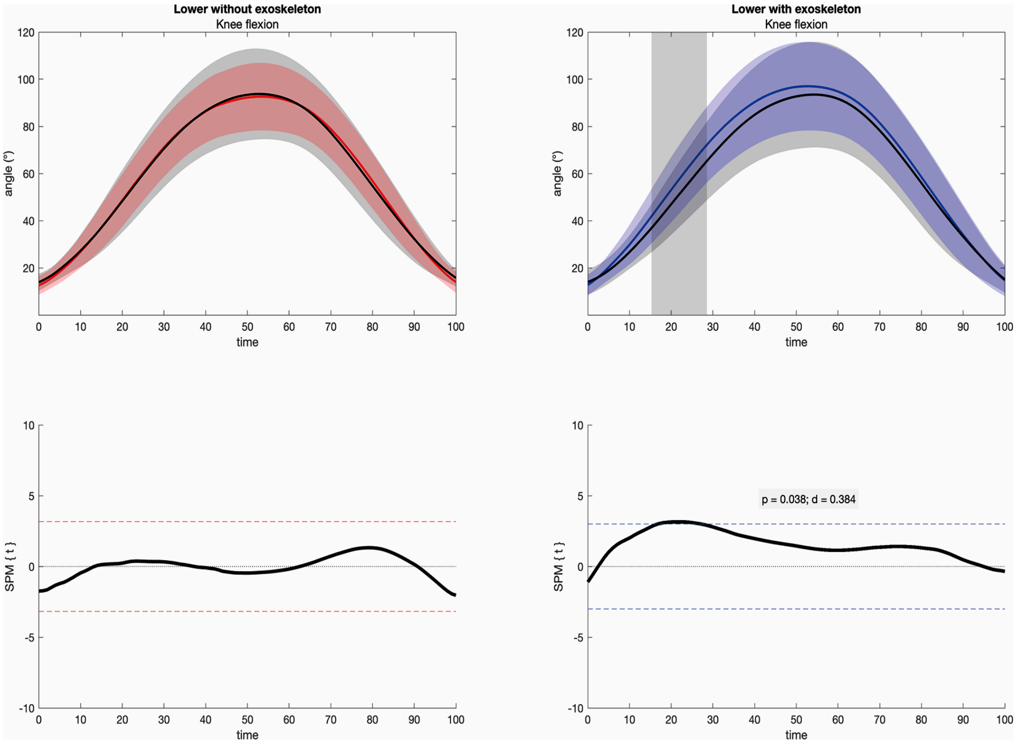

Figure 5. SPM *t*–test results and profile plots of kinematic data in lowering a box, comparing joint angles (°) of the right body side in knee flexion on day 1 (blue resp. red lines) and day 2 (black lines). The blue plot represents the comparison of the measurements with exoskeleton, and the red plot shows the measurements without exoskeleton (n = 20).

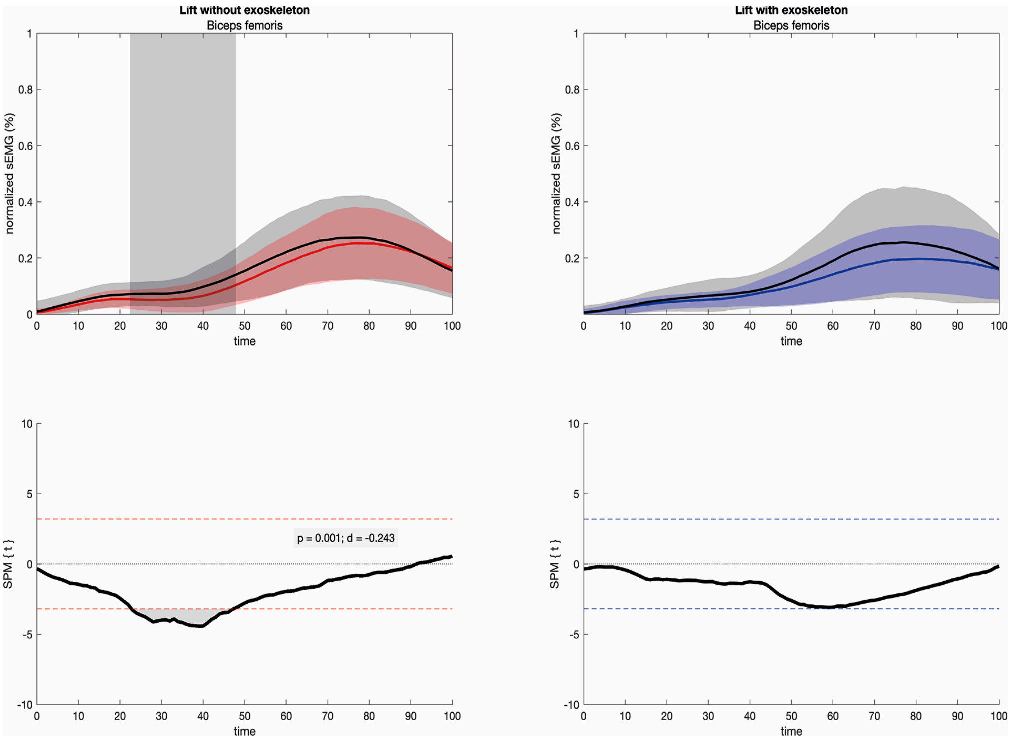

Figure 6. SPM *t*–test results and profile plots of MA in lifting a box, comparing normalized sEMG (%) of leg muscles BF on day 1 (blue resp. red lines) and day 2 (black lines). The blue plot represents the comparison of the measurements with exoskeleton, and the red plot shows the measurements without exoskeleton (n = 20).

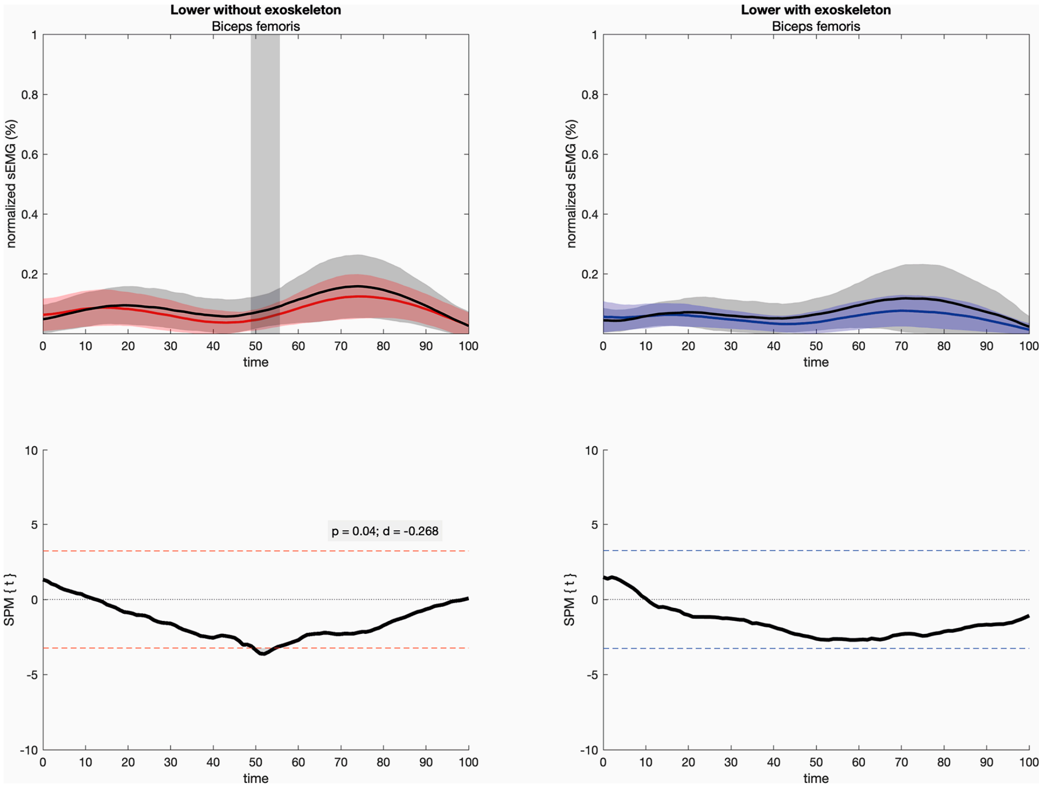

Figure 7. SPM *t*–test results and profile plots of MA in lowering a box, comparing normalized sEMG (%) of leg muscles BF on day 1 (blue resp. red lines) and day 2 (black lines). The blue plot represents the comparison of the measurements with exoskeleton, and the red plot shows the measurements without exoskeleton (n = 20).

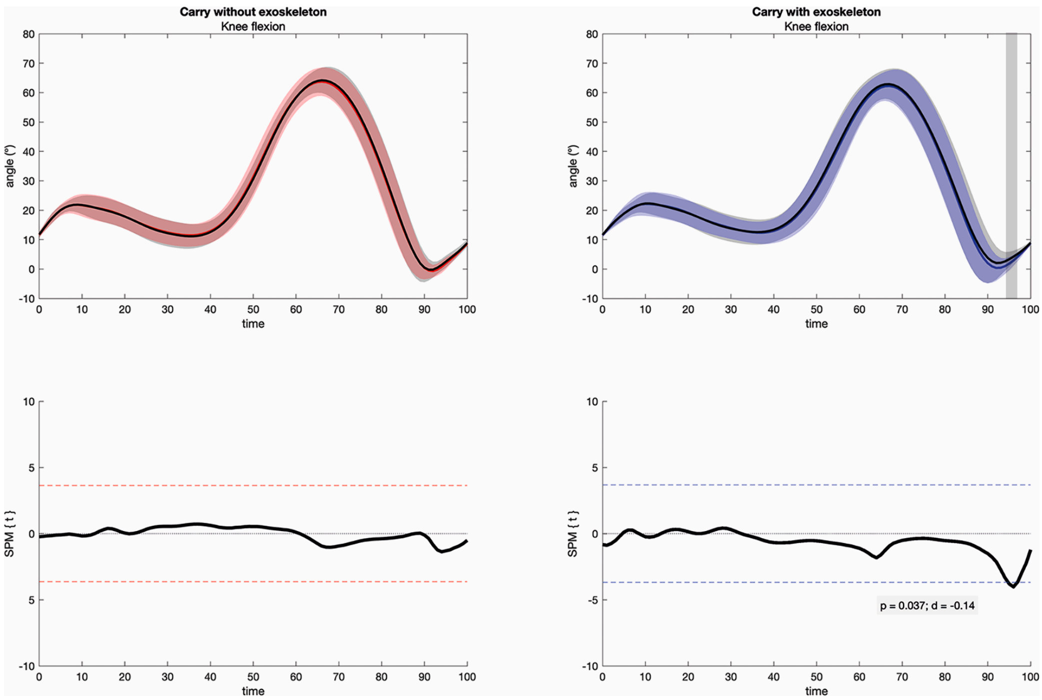

Figure 8. SPM *t*–test results and profile plots of kinematic data in carrying a box, comparing joint angles (°) of the right body side in knee flexion on day 1 (blue resp. red lines) and day 2 (black lines). The blue plot represents the comparison of the measurements with exoskeleton, and the red plot shows the measurements without exoskeleton (n = 19).

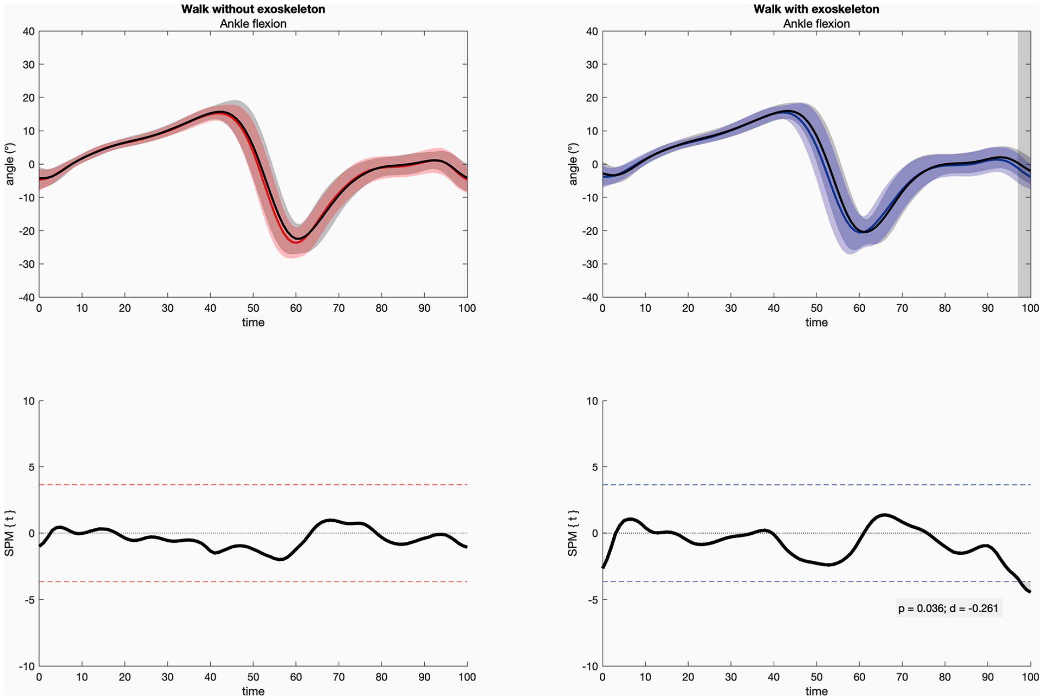

Figure 9. SPM *t*–test results and profile plots of kinematic data in walking without load, comparing joint angles (°) of the right body side in ankle flexion on day 1 (blue resp. red lines) and day 2 (black lines). The blue plot represents the comparison of the measurements with exoskeleton, and the red plot shows the measurements without exoskeleton (n = 19).

We found similar results to those in walking without load. The difference was significant in the kinematic data with the exoskeleton in the area of terminal contact, but this time in the joint angle of right ankle flexion (Figure 9). It was significantly greater on day 2 than on day 1, when the exoskeleton was worn during the measurement ($p = 0.038$, d = −0.261).

In contrast, the measured MA was comparable for all muscles on day 1 and day 2 detected in the carrying and walking tasks.

For the static bending task, no significant differences were found in either the kinematic data or the MA data. This was true for both the baseline (the first 2 s after the start of the measurement) and the end of the measurement (the last 2 s of the measurement). Here, all differences between day 1 and day 2, with and without exoskeleton, were in a non-significant range with $p \geq 0.05$.

4. Discussion

This study was designed as a preliminary study for a long-term biomechanical evaluation of exoskeletons in the workplace. We investigated the inter-day variation for MA and kinematics of trunk and leg, in lifting, carrying, walking, and static bending, with and without a passive back exoskeleton and examined whether the utilization of a passive back exoskeleton may have an impact on the day-to-day results comparability.

When biomechanical methods are obtained on different measurement days in a long-term study, we need to be sure that these effects are not due to fundamental measurement variations caused by confounding factors. We therefore based our study design on previous research and considered several factors that can improve the reliability of inter-day biomechanical measurements [10].

Firstly, we emphasized the importance of standardized setup and use of the exoskeleton so it was adapted to the individual requirements of each subject according to the manufacturer's specifications and the optimal, most comfortable support performance. Over the course of two familiarization days, any discomfort in using the exoskeleton was identified and appropriate adjustments were made. This is important because several studies have reported discomfort with the exoskeleton [23,32], which could affect the exoskeleton–user interaction. We established a high level of standardization in the exoskeleton's assistance performance, which has been a critical issue in previous studies. At the same time, the two training days were designed to counteract any training effects.

In addition to the use of validated measurement systems [9,15], we included standardized sensor placement via procedural instructions [15] as well as sufficient two-day familiarization with the working tasks. As a previous study we conducted suggests that two days of familiarization may provide a high degree of standardization to ensure reliable MVIC normalization for an occupational target group [17], we also included MVIC normalization tasks in the two training days.

The results show minor but significant differences between the measurements of day 1 and day 2. Regarding the IMU measurements, we found differences especially in the day-to-day measurements with the exoskeleton. For example, we measure significant unilateral differences during the lifting tasks in the area of knee flexion ($p = 0.038$), as well as in the carrying and walking task, in the area of initial contact in knee and ankle flexion ($p = 0.037$ & $p = 0.036$). For the muscle activation, we found significant differences in the measurements without exoskeleton, in the M. biceps femoris, during lifting ($p = 0.001$), and also during lowering a box ($p = 0.040$).

In order to quantify our resulting significant differences, we also determined the effect size Cohen's d. It ranged from $-0.0045 \leq d \leq 0.384$ for all significant p-values. After analyzing relevant publications, we assume that our d values < 0.3 can be classified as small effects [33–35], with exception of the measurement of M. biceps femoris when lifting a box ($p = 0.001$), where the effect size is d = 0.384. In this context, Button et al. [34] also discuss the influence of sample size on the effect size. They report that a decrease in the effect size is to be expected as the sample size increases. In our case, this means that the measured effect size of M. biceps femoris > 0.3 can also be regarded as low, as our sample is a small number of subjects (n = 20) according to ibid.

The minor yet significant differences, with small effect sizes, affirm that the impact of the exoskeleton on the user's body remains relatively consistent from day to day. However, considering the context of previous studies, it is crucial to take into account the measured differences for long-term investigations. This is particularly important as earlier studies predominantly report unfavorable outcomes when assessing the reliability of biomechanical parameters in inter-day measurements, especially in dynamic tasks. For example, Sood et al. [36] found poor day-to-day reliability of muscle activity in the shoulder muscles in a laboratory-based simulation of overhead work at different working heights. Van Helden et al. [16] performed dynamic voluntary movements of the trunk during functional reaching tasks and measured moderate to poor reliability of the back muscles. Brandt et al. [22] also found moderate results when assessing the muscle activity of the back muscles during box lifts with different weights and lifting tasks. Ghofrani et al. [37] also confirmed these results regarding the muscle activity. In terms of kinematic day-to-day reliability, Graham et al. [38] revealed significant differences when evaluating a repetitive dynamic trunk flexion/extension task in automotive manufacturing. Howarth and Graham [21] also found poor to moderate results in the evaluation of joint angles during a repetitive pipetting task on three different days. In this context, they also highlight the importance of standardized sensor placement. Koumantakis et al. [20] found poor repeatability in the repetition of predefined joint angles during trunk flexion exercises. Certainly, when comparing our findings to previous studies, it is important to consider that we compared the parameters of each task between days one and two across their entire duration. By using statistical parametric mapping (SPM) and analyzing the entire time series data, we were able to avoid potential limitations that may arise from reducing movement phases to discrete points in time or summarizing time series, as done in previous research. Instead of focusing solely on specific points or summary statistics, SPM allows for a comprehensive analysis of the complete temporal profile of the measurements. This approach provides a more detailed and accurate representation of the data, ensuring that potential impairments or biases resulting from data reduction methods are minimized. The ability to detect significant differences in the temporal profile of the movement allows for a more nuanced understanding of the data. However, it also means that drawing generalized conclusions becomes more difficult in terms of comparing our results to those of previous studies.

In addition our chosen analytical method, it should be noted that the high degree of measurement standardization in our study influences the comparability of our results to those of previous studies. By executing two familiarization days, we counteracted habituation affecting the inter-day measurement sEMG and kinematic results. During the familiarization phase, we placed special emphasis on acclimating the participants to the measurement systems with their calibration and the MVIC normalization procedures, which are essential for the standardized execution of measurements. We have endeavored to achieve consistent and highly standardized MVC measures for sEMG normalization as important prerequisite for inter-day reliability, because we expected our subjects to possible lack of experience in producing high muscle forces limits the ability to reproduce a relatively constant MVIC [39]. It is therefore reasonable to assume that our normalized sEMG data additional value to a high level of reliability. Appropriately, Van Helden et al. [16] report in their study, in which such MVIC-familiarization was not performed, that the relative inter-day reliability was higher for absolute sEMG amplitudes compared to normalized sEMG amplitudes. This finding underscores the importance of familiarization in MVIC normalization.

However, other previous studies do not describe any familiarization approaches when measuring inter-day reliability of muscle activity [16,37] or kinematics [20,21]. Ibid counteracted day-to-day changes through habituation effects by performing a sufficient number of repetitive tasks during the measurement, but no separate training was performed prior to the measurements for movement familiarization. Therefore, we assume that the extensive measures for familiarization contribute to a minor inter-day variance in our study, whereas habituation occurring during the day-to-day measurements may possibly explain the moderate to poor results in reliability of previous studies.

The results demonstrate that the interaction between the user and exoskeleton during inter-day measurements can result in significant differences. While we classify the observed significant differences as minor, we conclude that achieving consistent inter-day measurements is possible, despite minor variations in measurements obtained using exoskeletons. Still, our results strongly indicate that high standards of measurement are mandatory in a long-term study with exoskeletons. It is necessary to carry out further studies in this field, optimally under field conditions with a large sample size, to enable a generalizability of the results.

5. Conclusions

We show the feasibility of reliable biomechanical measurements over repeated days with and without a back-supporting exoskeleton. To ensure reliable measurements, a high degree of standardization is required, including standardized placement of sEMG and IMU sensors and sufficient familiarization with the work tasks and the exoskeleton. Despite potential non-significant differences through a relatively large standard deviation in our sEMG results, we offer an approach to achieve a high degree of day-to-day reliability in measuring long-term biomechanical effects.

By using an ergonomically relevant subject population, we are able to transfer the results to further field evaluations. At the same time, by using two different exoskeleton models, we can assume that the interaction of the passive back exoskeletons with the users is independent of the model. Due to the unique characteristics of our study, further studies under field conditions are necessary to confirm our findings.

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Conflicts of Interest: The authors declare no conflict of interest.

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