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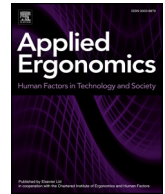
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The effect of a passive trunk exoskeleton on functional performance in healthy individuals



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ABSTRACT

The objective of this study was to assess the effect of a passive trunk exoskeleton on functional performance for various work related tasks in healthy individuals.

18 healthy men performed 12 tasks. Functional performance in each task was assessed based on objective outcome measures and subjectively in terms of perceived task difficulty, local and general discomfort.

Wearing the exoskeleton tended to increase objective performance in static forward bending, but decreased performance in tasks, such as walking, carrying and ladder climbing. A significant decrease was found in perceived task difficulty and local discomfort in the back in static forward bending, but a significant increase of perceived difficulty in several other tasks, like walking, squatting and wide standing. Especially tasks that involved hip flexion were perceived more difficult with the exoskeleton.

Design improvements should include provisions to allow full range of motion of hips and trunk to increase versatility and user acceptance.

1. Introduction

Low-back pain is one of the major health problems, causing large-scale personal suffering (Woolf and Pfleger, 2003), work absenteeism (Wynne-Jones et al., 2014) and socioeconomic costs (Lambeek et al., 2011). Affecting 60–80% of people at some point in their lifetime (Waddell and Burton, 2001) and being one of the most common health reasons given for work loss (Wynne-Jones et al., 2014; Burton, 1997; Garg and Moore, 1992), low-back injuries continue to be an occupational health problem. Despite increasing awareness of the need for prevention, the prevalence of musculoskeletal disorders (MSD) has not decreased (Lotz et al., 2009).

With recent advances in technology interest has shifted from adaptations of the work environment or worker behavior, towards body worn assistive devices, also called (non-actuated) exoskeletons, which support the user when performing tasks that involve high back loads. To date, most devices that have been developed to reduce back loading and to prevent low-back pain are mainly in the experimental stage and are not used in practice yet. Several experimental studies found reduced low-back loading during lifting, bending and static holding tasks when using assistive devices that passively support the user's trunk against gravity (Abdoli-E. & Stevenson, 2008; Bosch et al., 2016; Graham et al.,

2009; Ulrey and Fathallah, 2013; Wehner et al., 2009). These studies have generally been performed using controlled manual materials handling tasks in artificial laboratory settings. Bosch et al. (2016) assessed the effect of wearing the passive exoskeleton “Laevo” (Inte-spring, Delft, The Netherlands), which is commercially available and already used at different work sites, on discomfort and endurance time in forward bending work. They found lower discomfort in the lower back and an increase in endurance time when wearing the exoskeleton. A similar study was conducted by Graham et al. (2009). They performed one of the few studies to assess user acceptance in the field. Participants were wearing a personal lift assist device (PLAD) and performed an on-line assembly task at an automotive manufacturing facility. Participants reported no interference of the PLAD with the task and an offloading of their back. Despite the problem of pressure points at legs and shoulder, the device reached high user acceptance.

However, the tasks performed in the above studies mainly required static holding of a forward bent trunk posture. In contrast, most physically demanding jobs, such as warehousing, construction work or healthcare comprise combinations of many different tasks besides lifting, such as carrying, walking and working in different postures. Assistive devices might reduce the mechanical load in one specific task but might obstruct performance in other tasks. Thus, the practical

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implementation of exoskeletons might be limited due to low user acceptance, based on discomfort at the physical user interface with the device (de Looze et al., 2015) and movement limitations by the device. By being limited to only one stereotypical task, these studies do not represent the variability in tasks and trunk movement patterns that characterize many work environments. Thus, results presented above cannot be generalized to environments with more versatile working tasks. Therefore, evaluating the functional performance, i.e. the ability to perform relevant functional tasks beyond manual materials handling, is essential to assess user acceptance of exoskeletons in realistic work situations. This will provide insight into design problems of existing devices, necessary to improve designs and make them more usable and acceptable in a realistic work setting.

The purpose of this study was to assess the effect of a passive exoskeleton on functional performance in healthy individuals in 12 different work-related tasks, based on objective and subjective outcome measures. We selected a series of tasks based on their relevance and occurrence in physically stressful jobs, such as construction, logistics and manufacturing. Among these tasks, three types can be considered: (1) tasks in which the user potentially benefits from the exoskeleton, such as lifting and working in a static forward bend position, (2) functional tasks in which the user is potentially hindered by resistance against movement generated by the device and (3) basic movements requiring participants to use a large range of motion (ROM). We expected positive effects of the device for the first set of tasks (1) and negative effects for the latter ones (2 and 3). By testing a passive exoskeleton that is already used at work sites (Laevo; Intespring, Delft, The Netherlands), we aimed to test these assumptions and to create a benchmark for further developments of low-back assistive devices.

2. Methods

2.1. Passive exoskeleton

The device tested in this study was the passive exoskeleton “Laevo” (Intespring, Delft, The Netherlands), which is currently available on the market and used in various companies (Fig. 1). It is worn around the waist with a belt and consists of pads at the anterior side of the chest and thighs and posterior at the level of the pelvis. The chest component is connected to the thigh component via the pelvis belt, through rigid bars running over a smart joint with spring-like characteristics. This joint generates a supporting extension moment at the level of the lower back when bending forward. The chest pad can rotate in the frontal plane of the trunk to allow trunk rotation.

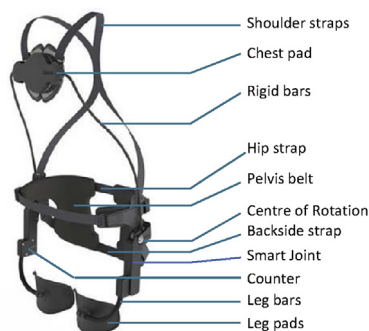


Fig. 1. Laevo (Intespring, Delft, Netherlands). The hip center of rotation of the device is to be aligned with the user's trochanter major. The straps are used for personal length adjustment and do not have a mechanical role other than keeping the device in place. The chest pad can rotate in the frontal plane to facilitate walking. The Smart Joint allows hip/trunk flexion/extension. Number of hip/trunk flexions while wearing the device is measured by the counter.

2.2. Participants

Eighteen men with no low-back pain history, average age of 27.7 ± 5.1 years, average height of 1.78 ± 0.06 m and average weight of 74.7 ± 8.0 kg participated in this study. Their average Work Ability Index (Ilmarinen, 2009), was 9 on a scale of 10, with a range from 6 to 10. The participants received an information letter prior to the experiment and signed an informed consent form on the measurement day. The experiment was approved by the medical ethical committee of VU medical center (VUmc, Amsterdam, The Netherlands, NL57404.029.16).

2.3. Testing procedure

Each measurement session began with fitting and adjusting the exoskeleton to the participant. Height, weight, trunk height and chest circumference of the participants were measured and a first questionnaire related to their work ability was completed. Before the start of the test battery every participant could walk a few steps, do some squats and move a bit in the exoskeleton to get habituated to it. Participants then performed a series of functional tasks in two conditions 1) with the exoskeleton (Exoskeleton condition) and 2) without the exoskeleton (Control condition). The starting condition and the sequence of the tasks were randomized to prevent order and habituation effects. Functional performance was assessed with objective outcomes and with subjective outcomes: perceived task difficulty and comfort of the device, by using questionnaires after each of the tasks. An overall impression questionnaire regarding the exoskeleton was completed by the participants at the end of the session. All measurements were done on the same day.

2.4. Selected tasks

The selected tests and related objective and subjective outcome measures are summarized in Table 1. The tasks were selected to provide a test battery of realistic working tasks and to test the exoskeleton's versatility. The first selection of tasks was based on the list of tasks that are considered in the functional capacity evaluation (FCE, Isernhagen Work Systems), an assessment method that realistically and reliably judges work-related physical performance capacity (Reneman et al., 2004). Other tasks were added based on workplace observations. We did not prescribe a given technique for task execution to keep the assessment of functional performance as close as possible to real-life situations.

2.4.1. Lower lifting

This task is part of the FCE. It is an incremental test, that assesses the maximum weight a person can lift safely. Since lower lifting is one of the main activities that exposes people to high back loads and hence a main risk factor for low-back pain, we included this task, with a maximum weight of 23 kg to stay within the limits proposed in the National Institute for Occupational Safety and Health (NIOSH) guidelines (Waters et al., 1993). No specific lifting technique was advised, participants were free to select mode of execution, since we wanted to keep the situation close to real work conditions. Due to the limited maximum mass, we expected a ceiling effect in this task. We therefore emphasize the effect of the exoskeleton on the subjective performance for this task.













2.4.2. Carrying

As carrying is a combination of walking and lifting and is often required in manual material handling, this component of the FCE was included.

2.4.3. Forward bend standing, one-handed bank position

Static holding is often required in manual work and is also included in the FCE. We chose two different postures that are frequently used at

Table 1
Functional performance tests and their respective procedure and outcome measures.

Test	Procedure	Objective outcome measure	Subjective outcome measures		
			GD	LD	PTD
1. Lower lifting	 4-6 lifts from floor level, weight is added to the box (2.5, 3, 5, 7.5 or 10 kg). Start weight is 5 kg and maximum = 23 kg. Increasing the weight depends on coordination and participant's perception.	Max weight lifted (kg)	x		x
2. Carrying	 Carrying the max. weight determined in the lower lifting test in a box for 10 m. Time recording stopped when the participant passed the 10-m mark.	Performance time (s)	x		x
3. Forward bending	 Standing with flexed trunk between 30 and 60°. Performing a simple manual task on a table at knee height, max 5 min.	Maximal holding time (s)	x	x	x
4. One-handed bank position	 Holding bank position with one hand on the floor. Performing a simple manual task on the floor, max 5 min.	Maximal holding time (s)	x	x	x
5. 6 Minutes Walk Test	 Walking as far as possible in 6 min.	Distance (m)	x		x
6. Sit to stand	 Sitting down on a chair and getting up 5 times. Participant started in sitting position and time recording stopped when participant sat down the 5th time.	Performance time (s)	x		x
7. Stair Climbing	 Climbing up- and downstairs as fast as possible for 20 steps. No use of handrails. Time recording stopped when both feet were on the floor again.	Performance time (s)	x		x
8. Ladder Climbing	 Climbing up and down a ladder twice. Time recording stopped when both feet were on the floor again.	Performance time (s)	x		x
9. Bending the trunk	 Bending forward as much as possible, knees extended.	Distance fingertip to floor (cm)	x		x
10. Wide Stance	 Standing with feet 20 cm apart, gradually increasing distance by 20 cm.	Maximal distance (cm)	x		x
11. Rotation of the trunk	 Rotating the trunk 5 times to both side.	None	x		x
12. Squatting	 Squatting down to the floor 3 times, touching the floor with the fingers.	None	x		x

GD: General discomfort; LD: Local Discomfort; PTD: Perceived Task Difficulty.

work sites and that involve a small trunk inclination angle (Forward Bending Stand) and a large trunk inclination angle (One Handed Bank Position, i.e. sitting in a kneeled position supported by one hand on the floor while the other hand performs a task).

2.4.4. Walking

Walking is done at almost any work place. To assess walking, we chose the “6 Minutes Walk Test”, which is commonly used to measure walking performance (Bellet et al., 2012). Since walking performance is dependent on aerobic capacity, but also on walking economy and potentially also on mechanical load and discomfort, this test appears suitable for assessing the effect of wearing an exoskeleton on the functional walking capacity.

2.4.5. Sit to stand

This task was chosen to assess the effect of the exoskeleton on relevant transfer movements. The “Sit to Stand” is a test that is frequently used in clinical settings (Bohannon, 2011). We considered this task as relevant, given the fact that the exoskeleton should not hinder the user in sitting down or getting up during work.

2.4.6. Stair climbing and ladder climbing

Stair Climbing, as part of the FCE protocol, is considered to be an important work-related activity. After observations of occupational tasks, we also added ladder climbing, given its frequent appearance in various branches of industry that also entail heavy lifting.

2.4.7. Rotation of the trunk, squatting, bending the trunk

These basic movement tasks were chosen to assess to what extent range of motion would be limited by the device.

2.4.8. Wide stance

This basic movement task was added to the test battery after workplace observations, realizing that wide stance was often performed to ensure safe standing when performing manual work. The potential hindrance by the device due to the leg pads was a reason to include this task.

2.5. Outcomes

The functional performance was measured based on objective and subjective outcome measures. In this way, not only the objective performance with the device, but also the user experience of working with the trunk exoskeleton could be assessed.

2.5.1. Objective outcome measures

For tests 1,2 and 5–8 the participant was instructed to perform the task “as fast as possible, but still in a safe and comfortable way”. Time recording, by means of a stopwatch, started when the researcher said “go” and stopped when the participant finished the task (see Table 1). Since tests 11 and 12 were chosen to assess the range of motion in terms of subjective experience only, no objective outcomes were measured.

The simple manual task that was performed for tests 3 and 4 was a sorting task, in which the participant had to sort colored confetti by

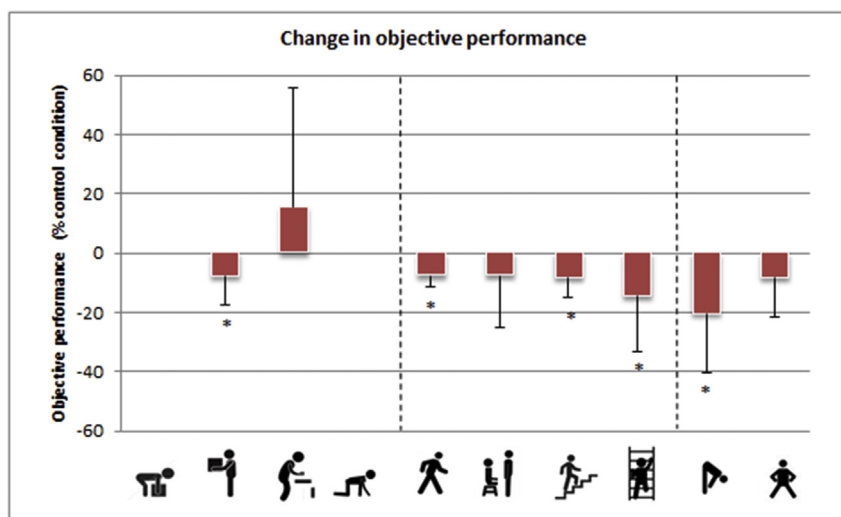


Fig. 2. Change in objective performance for the various tasks. To facilitate comparison of the different tasks, values were normalized to score in the control condition (without exoskeleton). The dotted lines represent the division between the groups of tasks (fully described in Table 1), in which the user is potentially assisted (left side), tasks, in which the user is potentially hindered by resistance against movement generated by the device (middle) and basic tasks requiring participants to use a large range of motion (right side). If there was no change in functional performance a bar for that task is not visible. * Significant change in functional performance between exoskeleton (with) and control condition (without).

color into rows of ten. This task was chosen, because it can be done at any speed for 5 min and requires a high precision. Before the static holding tasks, the participants were instructed to choose a comfortable posture to ensure that they used the device in the correct way. They were not allowed to change that posture during the task but were allowed to stop at any time due to local discomfort in the lower back.

2.5.2. Subjective outcome measures

The subjective outcome measures were all assessed by using a visual-analog scale (VAS). A visual-analog scale is considered to allow a finer distinction between participants opinion by reducing the variation of individual interpretation compared to numerical rating scales (Kersten et al., 2012).

2.5.2.1. Perceived task difficulty. After each task, the participant was asked to indicate the perceived difficulty of the task on the VAS, ranging from “very easy” to “very difficult”, with the question: “How difficult was the task you just performed?”. This VAS was presented on paper and the participant had to place a cross on the scale. The perceived task difficulty was assessed in both conditions.

2.5.2.2. General discomfort. In the Exoskeleton condition, the participant was also asked to indicate the general discomfort of the device (“Indicate the comfort of the device in the task you just performed”). The participant had to place a cross on the VAS scale, that ranged from “very comfortable” to “very uncomfortable”.

2.5.2.3. Local discomfort. Local Discomfort was only assessed for the static holding tasks 3 and 4. After each task, the participant was asked to indicate the local discomfort experienced in different body areas on a VAS scale, ranging from “no discomfort” to “maximal discomfort”. The chosen body areas were chest, abdomen, upper back, lower back, upper legs ventral and upper legs dorsal side. This choice was made based on body areas that were expected to be loaded or unloaded by the device.

2.5.2.4. User impression. The overall user impression was assessed with a User's Impression questionnaire, that the participants had to fill in at the end of the assessment. Adjustability, range of motion and efficacy of the device were addressed in the questionnaire through VAS scales (see Appendix 1 for more detailed information).

2.6. Data analysis

To test for statistically significant differences in functional performance between Exoskeleton and Control condition, each of the

objective outcome measures was analyzed with a paired *t*-test. For perceived task difficulty and local discomfort, the VAS scale values were compared between Exoskeleton and Control condition using the non-parametric Wilcoxon test, since there is sufficient evidence that VAS scales generate ordinal data (Kersten et al., 2012). To assess whether the objective outcome measures are related to general discomfort, a Spearman rank order correlation was conducted. Alpha of 0.05 was used as the critical level of significance. Corrections for multiple testing were made by dividing α by the number of tests performed for each outcome within each group of tasks. For the general discomfort and the user's impression, descriptive data are presented, since these parameters were only assessed in the Exoskeleton condition. All statistical analyses were performed using SPSS for Windows (IBM, SPSS Statistics 23.0, USA).

3. Results

When wearing the exoskeleton, the objective performance decreased in 7 out of 10 tasks and showed a trend towards improvement in only one, namely forward bend stand (Fig. 2).

Significant reductions in performance between exoskeleton and control condition were found for carrying time ($5.2s \pm 0.9$ vs. $4.8s \pm 0.8$; $p = 0.002$), walking distance ($533\text{ m} \pm 44$ vs. $577\text{ m} \pm 42$; $p = 0.000$), stair climbing time ($14.2s \pm 2.1$ vs. $13.2s \pm 2.1$; $p = 0.000$), ladder climbing time ($15.1s \pm 1.8$ vs. $13.4s \pm 1.7$; $p = 0.002$), and fingertip to floor distance when bending the trunk ($10.6\text{ cm} \pm 8.6$ vs. $8.8\text{ cm} \pm 7.1$; $p = 0.009$). There were no significant differences in maximum holding time of forward bending, sit-to stand time and maximum distance in wide standing. For the tasks lifting and one-handed bank no change in functional performance was found.

The perceived task difficulty increased in many of the tasks when wearing the exoskeleton, and decreased in one of the tasks that were expected to be supported by the device (Fig. 3).

In the group of tasks in which the user is potentially assisted by the exoskeleton, a significant difference was only found for forward bending, with a lower perceived task difficulty in the exoskeleton condition compared to the control condition (2.2 ± 2.55 vs. 5.3 ± 3.98 ; $p = 0.010$). In the group of tasks in which the user is potentially hindered by the device, a significant increase of perceived task difficulty in the exoskeleton condition compared to the control condition was noted for walking (2.15 ± 1.55 vs. 0.20 ± 1.10 ; $p = 0.014$), sitting (0.65 ± 2.08 vs. 0.20 ± 0.48 ; $p = 0.004$), rotating (0.75 ± 1.63 vs. 0.10 ± 0.20 ; $p = 0.003$), squatting (1.70 ± 2.68 vs. 0.20 ± 0.75 ; $p = 0.000$) and wide standing (2.45 ± 4.75 vs.

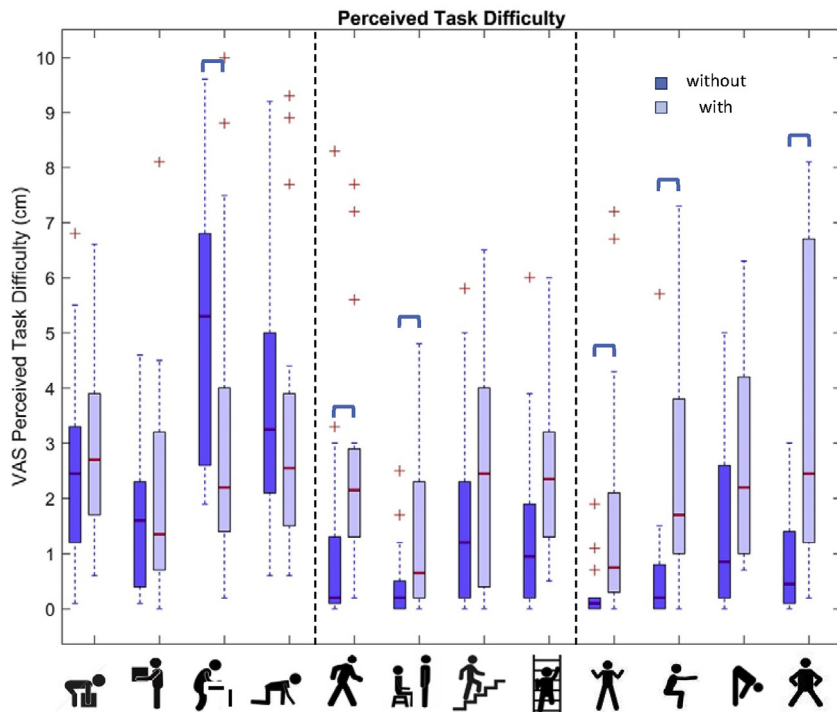


Fig. 3. Boxplots of perceived task difficulty. (The red line represents the sample median. The distances between the tops and bottoms are the interquartile ranges. Whiskers show the min and max values; outliers are represented as a +). The dotted lines represent the division between the groups of tasks (fully described in Table 1), in which the user is potentially assisted (left side), tasks, in which the user is potentially hindered by resistance against movement generated by the device (middle) and tasks requiring participants to use a large range of motion (right side). Brackets indicate significant differences between the exoskeleton (with) and control condition (without). 0 = very easy, 10 = very difficult. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

0.45 ± 1.28; p = 0.001).

The general discomfort caused by the device for each task when wearing the exoskeleton is shown in Fig. 4, with 0 = very comfortable and 10 = very uncomfortable. Highest general discomfort was found when bending the trunk (5.35 ± 3.4). Lowest general discomfort was found for trunk rotation (2 ± 1.85). The most prominent locations where general discomfort was experienced were chest, upper legs (14 out of 18 participants) and hips (6 out of 18 participants).

To assess whether a decrease in performance, as seen in Fig. 2, can be explained by the experienced general discomfort, as seen in Fig. 4, a

Spearman rank order correlation was conducted. Over all tasks no correlation was found between general discomfort and objective performance.

Figs. 5 and 6 show the local discomfort in the static holding tasks forward bending and one-handed bank position for the body regions chest, abdomen, upper back, lower back, upper legs ventral and dorsal side. The local discomfort in the forward bending task showed a significant increase at the chest when wearing the exoskeleton (0.35 ± 1.45 vs. 0.15 ± 0.20; p = 0.015) and a significant decrease of local discomfort in the lower back (1.30 ± 1.48 vs. 4.35 ± 4.68;

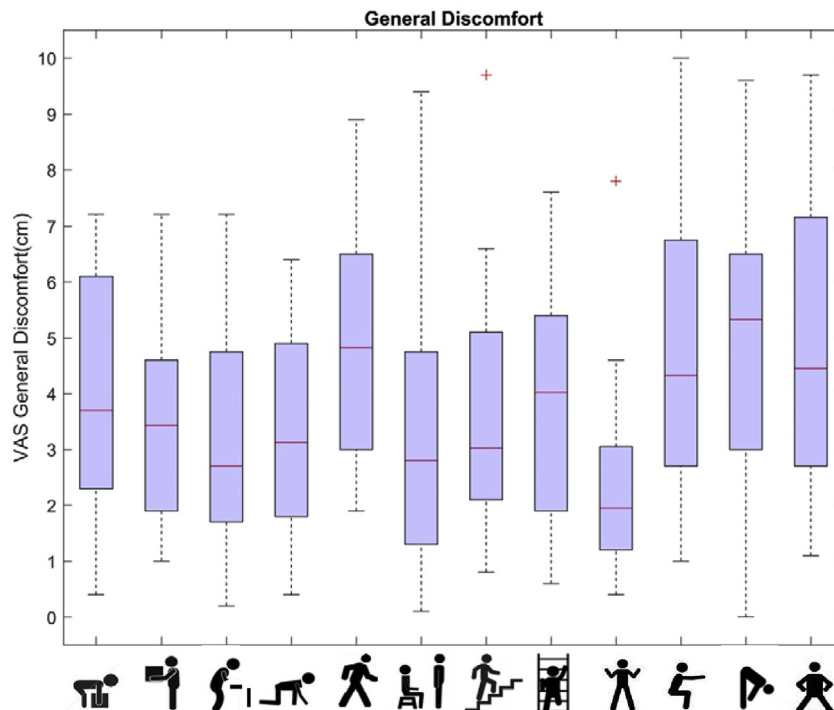


Fig. 4. General discomfort caused by the device in the exoskeleton condition for each task. 0 = very comfortable, 10 = very uncomfortable.

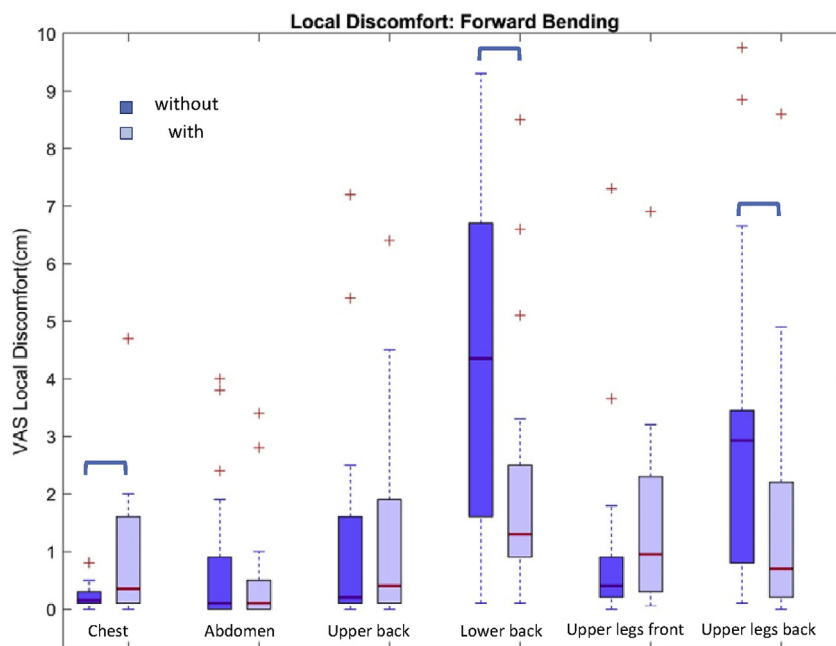


Fig. 5. Local discomfort in the forward bending task. Brackets indicate significant differences between the control (without) and exoskeleton condition (with); 0 = no discomfort, 10 = maximal discomfort.

$p = 0.001$) and upper legs (dorsal side) (0.70 ± 1.99 vs. 2.93 ± 2.45 ; $p = 0.011$). In the one-handed bank position decreased local discomfort in the upper back (0.40 ± 1.65 vs. 1.40 ± 2.33 ; $p = 0.023$) was found in the exoskeleton condition compared to the control condition.

The issues addressed in the user's impression questionnaire and their respective median values are presented in Table 2. Adjustability, including donning and doffing and length adjustment, was rated as easy to moderate. Range of motion with the device did also receive moderate values. The efficacy of the device in terms of reduction of back loading and support of the tasks was experienced as limited. The interference of the exoskeleton with the tasks was considered to be low. For more detailed information see Appendix 1.

4. Discussion

The main goal of this study was to evaluate the effect of a passive trunk exoskeleton on the functional performance in healthy individuals. We expected an increase in the functional performance in the tasks in which the user's trunk is supported against gravity. In addition, we expected a decrease in functional performance in the tasks in which the user is required to use a large range of motion, which might be hindered by resistance generated by the exoskeleton.

We expected an increase in the objective performance (maximal weight lifted) and a decrease in perceived task difficulty for lifting, considering studies that found reduced back loading during lifting

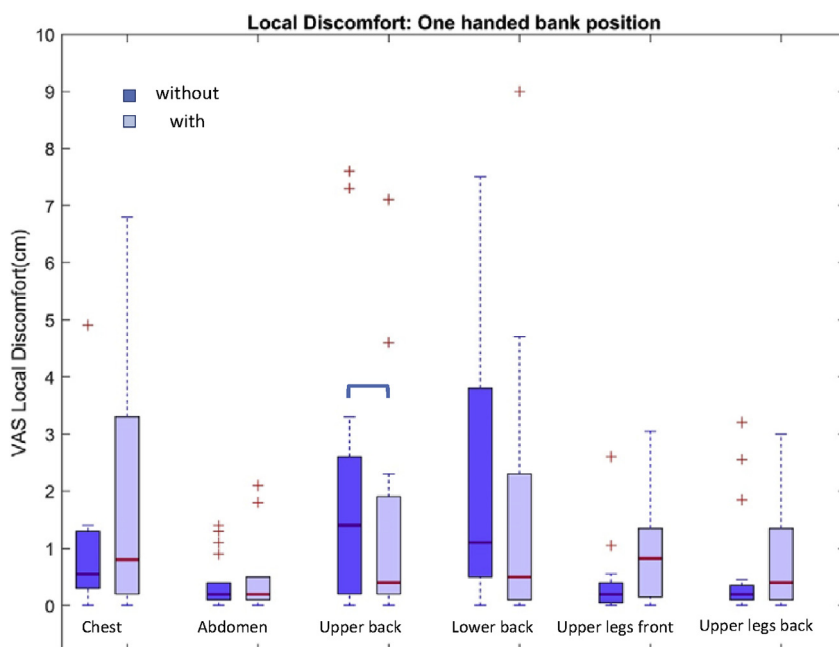


Fig. 6. Local discomfort in the one-handed bank position task. Brackets indicate significant differences between the control (without) and exoskeleton condition (with); 0 = no discomfort, 10 = maximal discomfort.

Table 2
User's Impression assessed by VAS scales.

		Median	Interquartile range	VAS scale
Adjustability	Donning and Doffing	2.1	1.2–6.1	0 = very easy 10 = very difficult
	Length Adjustment	4	2.1–6.9	0 = very easy 10 = very difficult
Range of Motion		4.1	3.1–5.9	0 = not restricted 10 = heavily restricted
Efficacy	Reduction of back loading	6.3	4.1–7.8	0 = high reduction 10 = no reduction
	Support of tasks	6.4	4.9–7.6	0 = high support 10 = no support
	Interference with tasks	3.3	2.0–5.9	0 = no interference 10 = high interference

when wearing assistive devices (Abdoli-E. & Stevenson, 2008; Graham et al., 2009; Ulrey and Fathallah, 2013; Wehner et al., 2009). However, neither objective lifting performance nor the perceived task difficulty showed any difference between exoskeleton and control condition. A possible explanation is likely found in a ceiling effect due to the limited maximal load mass (23 kg) that we used. This limitation was due to the fact that we were not allowed to exceed limits proposed in the NIOSH guidelines. The unchanged perceived task difficulty, while wearing the device, might further be explained by some problems participants experienced when lifting from the ground. Shifting or turning of the chest pad, leading to general discomfort and upward shifts of the whole device occurred, resulting in an inefficient functioning of the exoskeleton. The results from the user's impression questionnaire related to adjustability also indicate that problem, showing values ranging from 2.1 to 6.9 for length adjustment of the exoskeleton. These problems might outweigh any potential positive effect as a result of low back load reduction. This could be solved by an improved adjustability of the device to the different user's physiques.

For static holding tasks, in which we expected the user to be assisted, no increase in objective performance when wearing the exoskeleton was found. Although the change of performance for forward bending was not significant, the perceived task difficulty and the local discomfort in the lower back during this task decreased significantly by 3 units on the VAS scale, when wearing the exoskeleton. Also, the local discomfort in the upper legs (back) was reduced by 2.2 units on the VAS scale in the exoskeleton condition. This indicates that participants were able to hold the posture in both conditions, but did experience more difficulty and more discomfort, when not wearing the exoskeleton. Similar effects can be seen in the one-handed bank task. The accompanying increase in local discomfort in the chest and the trend towards increased local discomfort at the front side of the upper legs during these two tasks can be explained by the chest and the leg pads of the device. Similar results in discomfort were shown in a study by Graham et al. (2009). Their participants also reported an off-loading of the back, but did experience pressure points at the legs and shoulders, where the device was in direct contact with the user. Based on these outcomes a passive exoskeleton can be effective in assisting the user in static holding tasks, including trunk flexion. This effect might be improved in terms of wearing comfort at the contact points with the user's body, although the magnitude of this discomfort was low. Bosch et al. (2016), investigated a previous version of the Laevo device. They also found

lower local discomfort in the lower back and increased local discomfort at the chest when wearing the exoskeleton in forward bending work. Opposite to our results, they did find an increase in maximal holding time. This can be explained by the difference in applied methodology. In the study of Bosch et al. (2016) the researcher decided when to stop the task, based on the participants rating on the Borg Scale during the task. When the participants rated 2 (i.e. "slight discomfort") in any of the back regions the maximal holding time was noted. In the present study, however, we had the participants decide whether and when to stop the task due to discomfort in the back. Most of them fulfilled the total 5 min of the task. This may have led to biased results in the maximal holding time, explaining the lack of effect of the passive trunk exoskeleton on the objective performance in forward bending in our study.

During load carrying no effect on objective performance was found. Although the moment around the low-back increases with carrying, due to the load in front of the body, the passive trunk exoskeleton did not improve the performance for this task. This can be explained by the fact that the support of the passive exoskeleton relies on trunk flexion to generate resistive torques in the hinge of the device. Since the carrying task does not require trunk flexion, no extra support is obtained in this task.

Tasks for which we expected potential hindrance by resistance of the exoskeleton against movement, including tasks requiring participants to use a large range of motion, indeed showed a decrease in objective performance and an increase in perceived task difficulty. Especially in tasks that involved hip flexion or trunk flexion, objective performance decreased and perceived task difficulty increased. This problem of restricted range of motion can be found in all studies that asked for subjective feedback on passive lifting devices (Abdoli-E, Agnew and Stevenson, 2006; Godwin et al., 2009; Graham et al., 2009). Godwin et al. (2009) reported moderate ratings of hindered ROM when wearing the device. This can be compared to our results on user impression which scored between 3.1 and 5.9 for restriction of range of motion (see Table 2). The task walking showed both, a decrease in objective performance and an increase in perceived task difficulty, indicating a need for design improvement for this task. The hindrance during walking tasks could be solved by disengaging the leg pads, an option that the most recent version of the Laevo device does already provide.

The general discomfort values show that especially walking and range of motion tasks seem to be uncomfortable. Nevertheless, general discomfort did not appear to be performance limiting, since it did not show a correlation with objective performance. Besides, we did not test the effect of time period on the general discomfort and objective performance. Discomfort values might be different when testing over a longer period of time and all-day measurements may be needed to clearly assess the relationship between general discomfort and objective performance. Final user impression scores were moderately positive, the VAS values for Efficacy show that participants felt moderately supported by the device (6.4) and reported a moderate back load reduction (6.3). The general interference with the performed tasks overall was reported to be low (3.3). This indicates, that a certain degree of versatility is provided, but that the support of the device can be improved for some of the tasks to diminish the negative effects on objective performance and perceived task difficulty. Therefore, further developments need to focus on higher adaptability of the device to different tasks, providing unrestricted range of motion and wearing comfort by the exoskeleton.

There are several limitations to this study. First, the time to get habituated to the device before performing the different tasks was relatively short. Since there was no fixed try-out protocol at the start of the experiment some participants might have been habituated more than others when starting the test battery. In future studies, it would be beneficial to have an identical habituation protocol for each participant. Another limitation is, that the test protocol was performed in a

laboratory. The selected tasks represented a variable work setting. However, the controlled laboratory setting limited the risk of severe adverse effects and hence we cannot evaluate potential safety risks. Therefore, a future field study is needed to assess the effect of an exoskeleton on the functional performance and on safety in a real work setting. Also, we only assessed functional performance, but did not observe how the change in performance could be explained in terms of change in movement strategy. Future research should address that topic in more detail. Furthermore, this study was limited by a short duration of the tasks tested. The effect of the exoskeleton in long-term use and the effect of a longer time period on perceived task difficulty and discomfort require further study.

5. Conclusion

In conclusion, the present study shows that the passive trunk exoskeleton affected functional performance in healthy individuals both, positively and negatively. It decreased the local discomfort in the back in static holding tasks and the local discomfort at the dorsal side of the upper legs in static forward bending and therefore assisted the user when performing these tasks. The exoskeleton showed adverse effects on tasks that require large ROM of trunk or hip flexion including

walking. It was shown that perceived discomfort by the device is not directly related to performance in the short-term use of the exoskeleton. Based on these results it can be concluded that this type of exoskeletons has its most important application in working environments with stereotypical tasks, such as assembly work in a forward bent position, but has important limitations in environments that require more versatility. Directions for improvement of the design to allow more versatility and its acceptance and applicability in more work settings include the possibility to disengage the device to allow unrestricted hip flexion and to improve general comfort of the device.

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Appendix 1

User's Impression Questionnaire

Category	Related Question
Adjustability 1	How easy is the device to put on and put off?
Adjustability 2	How easy is the device to adjust?
Range of Motion (ROM)	Are you restricted in your freedom of movement?
Efficacy 1	Does the device reduce the loading on your back?
Efficacy 2	Does the device support you in performing the tasks you did?
Efficacy 3	Does the device interfere with the tasks you did?

Participant	Adjust 1	Adjust 2	ROM	Efficacy 1	Efficacy 2	Efficacy 3
1	2,2	3,7	2,5	6,3	4,7	2,6
2	1,9	7	4,4	7,2	7,2	7,1
3	0,6	1,6	3,9	2,9	4,1	2,9
4	8,1	8	7,1	8,2	8,4	8,2
5	0,6	5,3	3,6	9,4	8,4	4,3
6	3,4	7,2	6,8	5	5,7	6,2
7	2,2	2,3	5	6,8	6,9	6,8
8	0,1	4,3	3,1	3,8	5,2	1,6
9	2,5	3,3	6	5,8	4	1,8
10	2	1,5	2,4	3,2	7,8	1,2
11	6,9	8,3	6,7	6,3	6,5	5,1
12	7,8	6,7	7,4	3,6	8,4	2,3
13	1,2	2,9	3,1	5,4	6,3	0,3
14	2	0,4	1,8	8	5,7	2,5
15	1,3	2	2,3	2,5	4,5	1,9
16	7,3	7,2	4,3	6,6	4,8	3,6
17	0,8	1,4	5,7	8,4	7,6	7,3
18	6,9	4,9	3,8	9,9	7,5	4,8
Median	2,1	4,00	4,10	6,30	6,40	3,25
Interquartile Range	4,90	4,80	2,83	3,70	2,68	3,93

Appendix 2

Task Description

TASK 1: Lower lifting



Equipment:

- The box width: 39.5 cm; length: 29 cm; height: 11,5 cm;
- grip thickness: 2,5 cm; inter-grip distance: 52 cm
- Weights (5, 10, 15, 18, 21 and 23 kg loads are lifted)

Outcome measures:

- Maximal load lifted (kg)
- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)

Protocol: The starting position is in upright stance. The subject lifts the box, holds it (~1s) and puts it down with his/her chosen technique. Each load is lifted once. The load increases in the following order: 5 kg, 10 kg, 15 kg, 18 kg, 21 kg and 23 kg. Increasing the weight depends on coordination and participant's perception.

Instruction to subject: Lift the box from the floor, hold it for about a second in the upper position, and put it down. You can choose your own technique. After each lift I will ask you whether I can increase the weight.

TASK 2: Carrying



Equipment:

- Stopwatch
- 10 m clear pathway (with clearly marked starting and stopping points)
- The box (same as in Test 1) and the load (maximal load, lifted in Test 1)

Outcome measures:

- Performance time (s)
- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)

Protocol: The subject lifts the load with his/her own technique, then walks 10 m as fast as possible. Only the walking time (not lifting) is recorded. Mark the starting and ending points. Stop recording time when both feet are over the 10 m line. The subject should not run, but walk as fast as possible.

Instruction to subject: Lift the load slowly, then carry it to the 10 m line (start on our cue). Stop after the line and put down the load slowly. Perform this task as fast as possible, but still in a safe and comfortable way. Do not run.

TASK 3: Forward bending



Equipment:

- Stopwatch
- Table (at knee height)
- Paper sheet (see below)
- Circular paper pieces (20 pieces of each color)

Outcome measures:

- Performance time (s)
- Perceived task difficulty (VAS scale)

- Discomfort (VAS scale)
- Local Discomfort (VAS Scale)

Protocol: The subject stands next to the table. Both hands are manually operative and should not support the body (e.g. placing on hands on the table, thighs, etc.) Subject is free to choose the posture, but not allowed to change it during the task. The manual task of the subject is to sort one color of the paper pieces into rows of 10.

Instruction to subject: This is a postural tolerance task. You have to sort the colored pieces into rows of 10 while standing in front of the table. You can choose your own posture. You are not allowed to change that posture during the task. You must not put your hands on your thighs or on the table. You can use both hands in this task. The maximum time of this task is 5 min. If the local discomfort in your back gets too high you can stop this task earlier at any time.

TASK 4: One-handed bank position



Equipment:

- Stopwatch
- Paper sheet (see below)
- Circular paper pieces (20 pieces of each color)

Outcome measures:

- Performance time (s)
- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)
- Local Discomfort (VAS Scale)

Protocol: The subject assumes the position. The paper sheet should be between his/her hands. There should be 3 hands distance from the anterior aspect of the thigh and the posterior part of the palm of the supporting hand, which should not be moved during the test. Subject is free to choose the posture, but not allowed to change it during the task. The manual task of the subject is to sort one color of the paper pieces into rows of 10. The subject works with one hand, but is allowed to switch hands.

Instruction to subject: This is a postural tolerance task. You have to sort the colored pieces into rows of 10 while holding this position (demonstrate). Place your hand here (allot the appropriate distance). You are not allowed to change your posture during the task. You may change the supporting hand, but at no time you should support yourself with both hands. You can use both hands in this task. The maximum time of this task is 5 min. If the local discomfort in your back gets too high you can stop this task earlier at any time.

TASK 5: 6 Minutes Walk Test



Equipment:

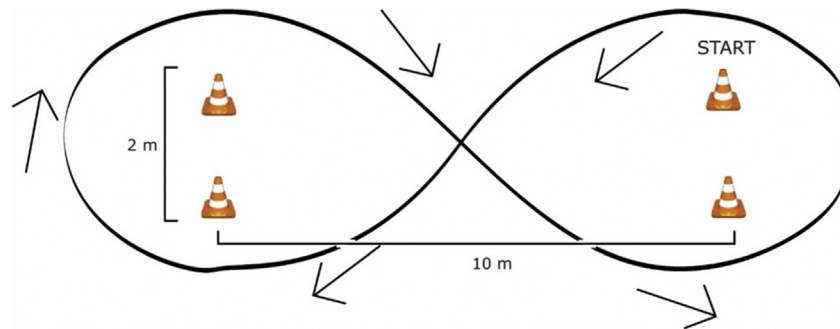
- Stopwatch
- 4 cones

Outcome measures:

- Distance covered (m)
- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)

Protocol: The cones are placed in a rectangle (10 × 2 m; see the image below). The starting position is next to one of the pairs. The test includes the subject to walk for 6 min in the shape of eights (see the image). The aim is to cover as much distance as possible. Each distance from one cone pair to another counts as 12 m.

Instruction to subject: Walk in eights (show him/her the moving pattern) for 6 min. Perform this task as fast as possible, but still in a safe and comfortable way. Do not run.



TASK 6: Sit-to-stand



Equipment:

- Stopwatch
- Chair

Outcome measures:

- Performance time (s)
- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)

Protocol: The subject starts in an upright standing. The aim is to sit down and stand up 5 times as fast as possible. It is important that fully extended posture is reached at the top, and that the full weight of the body is transferred on the chair while sitting down (to prevent bouncing movement). Therefore, the subject must lift the feet from the floor when he/she sits down to ensure that the weight of the body is transferred to the chair.

Instructions to subject: Sit down and stand up 5 times in a row, while crossing your arms in front of your chest. Make sure that your whole weight is on the chair in the bottom position and that you do not bounce off the chair. Make sure that you fully extend your hips when standing up (show incorrect and correct movement). Perform this task as fast as possible, but still in a safe and comfortable way.

TASK 7: Stair climbing



Equipment:

- Stopwatch
- Stair case (min. 10 stairs)

Outcome measures:

- Performance time (s)
- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)

Protocol: The subject stands in an upright position at the bottom of the staircase. On our cue, he/she climbs the stairs as fast as possible, without skipping steps. At the top of the stairs the subject turns around and goes downstairs again. Use of handrails is not allowed. Time is stopped when subject touches the floor with both feet again.

Instruction to subject: Walk the staircase all the way up, turn around and walk down again. Do not skip the steps. You are not allowed to use the handrails. Perform this task as fast as possible, but still in a safe and comfortable way.

TASK 8: Ladder climbing**Equipment:**

- Stopwatch
- Free standing ladder

Outcome measures:

- Performance time (s)
- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)

Protocol: The starting position is an upright standing, with both feet on the floor and both hands on the ladder. On our cue, the subject climbs up the ladder, the final position being with both feet on the 6th step (which should be clearly marked). Then climbing down in the same manner, the final position being the same as the starting position of the first part.

Instruction to subject: Climb the ladder as fast as possible. You should reach the 6th step (indicate it) with your feet. Pause at the top, then climb down on our cue (demonstrate the task).

TASK 9: Bending of the trunk**Equipment:**

- A measuring tape

Outcome measures:

- Distance to floor (cm)
- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)

Protocol: The subject starts in upright standing position. The test starts with bending the trunk and the hips to reach down as far as possible, keeping the knees fully extended. The lowest position should be held for 3 s, then the subject returns to starting position.

Instructions to subjects: Bend down and reach as far as possible (show the movement). Hold this position for three seconds and straighten up. Make sure you do not bend the knees (correct during the test if needed).

TASK 10: Wide stance**Equipment:**

- Pre-prepared scale on the floor with 13 marks at intervals of 20 cms (see picture below)

Outcome measures:

- Maximal distance
- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)

Protocol: The subject starts in an upright standing at the middle mark. He/she then aims to reach out as far as possible by abducting the hips. The subject gradually increases the distance between his/her feet by putting them on the next mark. He/she should be able to come up from the final position without the help of the hands or falling down. If this occurs, the measured distance does not count.

Instruction to subject: Stand like this and reach out with your feet as far as possible (show the task yourself). Be sure that you are able to come back from the final position without falling down or using your hands, otherwise the test is invalid.



TASK 11: Rotation of the trunk



Equipment: None.
Outcome measures:

- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)

Protocol: The subject assumes upright standing position. He/she rotates the trunk 5 times to each side, holding the elbows at 90 degrees and hands together.

Instruction to subject: Rotate the trunk to each side 5 times like this (show the movement).

TASK 12: Squatting



Equipment: None.
Outcome measures:

- Perceived task difficulty (VAS scale)
- Discomfort (VAS scale)

Protocol: The subject starts in an upright standing position. Then he/she squats down three times and the bottom position is held for three seconds, touching the floor with the fingers.

Instruction to subject: Squat down and hold the position (~3s), then raise up (show the movement). Repeat three times.

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