



ADVANCE

ARBEITSPHYSIOLOGISCH-BIOMECHANISCHE ANALYSE EINES PASSIVEN
EXOSKELETTS ZUR UNTERSTÜTZUNG VON BERUFLICHEN HEBE- UND
BEUGEVORGÄNGEN

ADVANCE

*WORK PHYSIOLOGICAL-BIOMECHANICAL ANALYSIS OF A PASSIVE
EXOSKELETON TO SUPPORT OCCUPATIONAL LIFTING AND FLEXING
PROCESSES*

FOR REVIEW BY THE
ETHICS COMMITTEE
OF THE
EBERHARD-KARLS-UNIVERSITY OF TÜBINGEN

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I Abstract

Introduction: Industrial tasks that are characterized by high loads, a high repetition rate, and / or awkward body postures, put employees at higher risk to develop work-related musculoskeletal disorders (WRMSD), especially low back pain. To counteract the prevalence of WRMSD, human-robot interaction could improve the power of a person and reduce the physical strain. For the lower back, a reduction of spinal loading could be helpful. The passive upper-extremity exoskeleton Laevo® is developed to support physically heavy work: it supports the back during bending and should, consequently, result in less low back pain (Laevo®, the Netherlands).

Objectives: The *primary* aim of this study is to assess to what extent wearing the exoskeleton changes knee compression force, reduces muscular load on the back muscles, and changes the muscular load on other body parts such as the legs and shoulders in different tasks (static vs. dynamic) and different postures (trunk flexion vs. trunk flexion and rotation). The secondary aim of this study is to investigate the relation between trunk flexion angle, load carried and muscular stress of the back muscle. The *tertiary* aim of this study is to estimate internal loadings on the spine, using a lumbar spine model. The *quaternary* aim of this study is to assess the performance of subjects during functional activities (e.g., stair climbing) when wearing the exoskeleton.

Methods: For the *primary* aim, we will test six different experimental conditions in the laboratory, which are a combination of exoskeleton (with vs. without Laevo®), task (static vs. dynamic), and knee angle only for the dynamic task (flexed vs. extended). Within each combination, we will test three different working directions (front vs. left vs. right), realized by changing the working posture (trunk flexion vs. left trunk rotation vs. right trunk rotation). Using the single Williams design for six conditions, we estimated our sample size to include 36 subjects (i.e., a multiple of six). Using a force plate, acceleration and postural sensors, we can estimate knee compression force using 2D inverse modelling. With an electromyographic system, we can record the muscle activity of selected target muscles at different body parts (i.e., legs, trunk, and shoulders). The heart rate will be recorded using electrocardiography. For the *secondary* aim, we will test four different conditions, which are a combination of exoskeleton (with vs. without Laevo®) and knee angle (flexed vs. extended). Within each combination, we will test three different loads carried (0kg, 8kg, 16kg) and five different trunk flexion angles (0°, 30°, 60°, 60°, 30°). We will record muscle activity, position, heart rate and ground reaction forces. For the *tertiary* aim, we will use the lumbar spine model developed by the research group Biomechanics and Biorobotics of the research cluster Simulation Technology of the University of Stuttgart. The model includes a detailed lumbar spine with non-linear discs, ligaments, and muscles. Using the measurements of the experiment, this model is able to predict how internal forces in the lumbar spine change as a result of external forces (i.e., wearing and using the Laevo® exoskeleton). For the *quaternary* aim, we will test three different functional tests. The main outcome for the quaternary aim is performance, which could be either time recorded or difficulty rated on a standardized 11-point numeric rating scale.

Analyses: For the *primary* aim, the effects of exoskeleton (with vs. without), task (static vs. dynamic), knee angle (flexed vs. extended; only for the dynamic task), and working posture (trunk flexion vs. left trunk rotation vs. right trunk rotation) will be assessed using a four-factor repeated-measures analysis of variance (RM-ANOVA) or a generalized estimating equation (GEE) which is more robust.

For the *secondary* aim, the effects of exoskeleton (with vs. without), knee angle (flexed vs. extended), load carrier (0kg vs. 8kg vs. 16kg), and trunk flexion angle (0° vs. 30° vs. 60°) will be assessed using a RM-ANOVA or GEE. For the *quaternary* aim, the effect of exoskeleton (with vs. without) on performance of each functional test will be assessed using a paired T-Test.

Data protection: All participating subjects will receive a refund of € 45 after study completion. Subjects will sign an informed consent and their data will be numerically pseudonymized to guarantee anonymity.

II Keywords

Passive exoskeleton; forward trunk flexion; trunk rotation; inverse dynamics; muscle activity; modelling

III Attachments

Attachment 1: Experimentelle Bedingungen, randomisiert

Attachment 2: Anwerbetext zur Studie

Attachment 3: Probandeninformation

Attachment 4A: Einwilligungserklärung

Attachment 4B: Datenschutzerklärung

Attachment 5: Ein- und Ausschlusskriterien

Attachment 6: Allgemeine Angaben

Attachment 7: Nordische Fragebogen

Attachment 8: Selbsteinschätzung von Beschwerden

Attachment 9: Beschwerden Intensität & Körperregion

Attachment 10: NASA-TLX

Attachment 11: Bewertungsfragebogen

Attachment 12: EU-Konformitätserklärung – Laevo® Exoskelett | Laevo B.V.

Attachment 13: EU-Konformitätserklärung – PS11 Messgeräte | Thumedi GmbH & Co. KG

Attachment 14: EU-Konformitätserklärung – PS12 Messgeräte | Thumedi GmbH & Co. KG

Attachment 15: EU-Konformitätserklärung – Force Plate | Bertec GmbH

Attachment 16: EU-Konformitätserklärung – Force Sensor | ME Meßsysteme GmbH

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1 Abbreviations

%RVE	percentage of the reference voluntary electrical activity
2D	two-dimensional
3D	three-dimensional
ANOVA	analysis of variance
EMG	electromyography
\vec{F}	force
\vec{G}	gravitational force
IED	inter-electrode distance
L5	fifth lumbar vertebra
LCT	Lift and Carry Test
M	moment
MPF	median power frequency
φ	angle
RPD	rating of perceived discomfort
RMS	root-mean-square
RVC	reference voluntary contraction
RVE	reference voluntary electrical activity
SCT	Stair Climbing Test
SimTech	Simulation Technology
SLS	Single-Leg Stance
SUS	System Usability Scale
T3	third thoracic vertebra
TAM2	Technology Acceptance Model 2
UKT	University Hospital Tübingen
WP	work package
WRMSD	work-related musculoskeletal disorders



2 Background

Due to the exposure to physically demanding work, repetitive movements and awkward body postures in industry (van Rijn et al., 2010), a considerable amount of employees develops work-related musculoskeletal disorders (WRMSD; Wang et al., 2017). Low back pain is one of the most prevalent disorders in the general population (Scott et al., 2010), but is also apparent as WRMSD (Irwin et al., 2007). Because industry cannot be completely automated, human-robot cooperation is a solution to provide assistance or support for human motions or actions, but does not influence the flexibility or creativity of motions and actions (MacDougall, 2014).

One type of human-robot cooperation is the exoskeleton, which is a wearable, external system improving the power of a person (de Looze et al., 2015). Exoskeletons can be distinguished by their technical functions, i.e. as an active or a passive system and by its target body part it supports. Exoskeletons are mainly used for rehabilitation or other medical purposes supporting daily activities like walking, standing up, or grasping (Viteckova et al., 2013). However, exoskeletons in occupational settings are not often used, mainly because there are no specific guidelines available for safety or technical issues. This means that exoskeletons will not yet be implemented on a large scale in industry to assist work-related activities. Aspects such as perceived discomfort, body alignment and weight of the exoskeleton are important aspects that need to be considered when optimizing exoskeletons for implementation in occupational settings. However, several reviews have been conducted already, including a review on the two key applications of exoskeleton systems (Yang et al., 2008), on the characteristics of exoskeleton robot systems for power assistance (Lee et al., 2012), on the compatibility of lower limb exoskeletons with the user (Viteckova et al., 2013), and on the effectiveness of wearing exoskeletons on the physical loading of the body (de Looze et al., 2015).

The review of Yang et al. (2008) gives a great overview of the main two fields of application of exoskeletons, which are teleoperation and power amplification. Lee et al. (2012) in their review report on the different classifications of exoskeletons, including (1) power assistant or power augmented systems, (2) anthropomorphic, quasi-anthropomorphic, or non-anthropomorphic, (3) active, passive, or quasi-passive, and (4) the level of human-robot interactions. Both reviews point out that a lot still needs to be achieved with regard to the level of the exoskeleton's anthropomorphicity, as it appears to be very difficult to mechanically pursue natural human motion. Viteckova et al. (2013) add to this challenge the problem of the high energy consumption of active exoskeletons and the composition of the exoskeletons which, with a high weight, require high metabolic consumption of the wearer. The review of de Looze et al. (2015) was the only one specifically evaluating the effect of wearing exoskeletons on the physical loading of the wearer's body. They found that muscular activity was reduced by 10-40% when wearing passive systems and up to 80% when wearing active systems. However, they also point out that several challenges need to be overcome, including degeneration of the exoskeleton's target muscles, high levels of discomfort and increased physical load on other than the exoskeleton's target body parts, and true impact on potentially reducing injury prevalence (de Looze et al., 2015).

Overall, exoskeletons need to be tested in highly controlled situations, because many practitioners see exoskeletons as a chance to optimize ergonomic work design. One way to test exoskeletons is in laboratory studies, evaluating their direct influence on the wearer and the work performance. Recently, the passive upper-body exoskeleton Laevo® has been studied in detail (Laevo®, Delft, the

Netherlands). Bosch et al. (2016) assessed the effect of wearing the Leavo[®] exoskeleton on the activity of the back muscles during trunk forward flexion and possible negative side effects for other muscles such as the abdominal and hip extensor muscles. They simulated an assembly task (10 work cycles of 20-30 s) and a static posture (endurance time up to 9 min) while the trunk was in 40° forward flexion. The tasks were performed with and without wearing the Laevo[®] exoskeleton. As expected, the lower back muscle activity decreased in both tasks with 35-44%. Additional measurements showed that the muscle activity decreased in the upper back with 44-50% and in the hip extensor with 20-24%. The activity of the abdomen muscles did not change when wearing the Laevo[®]. Despite these considerable decreases in muscular activity, the perceived discomfort in the chest increased, because this is the place where the exoskeleton exerts pressure to the body. Bosch et al. (2016) also observed that users wearing the Laevo[®] exoskeleton tend to overstretch their knees. This overstretch may be due to the pressure of the chest pads on the body, which pushes the upper body backward and hampers knee flexion.

The study of Bosch et al. (2016) is a good first step to map the operation of the system and its effects on the physical load of the user. The results are promising with respect to muscular activity at the upper body, but unclear is what happens to the compression forces of the knee, what happens to the user's posture during dynamic work tasks, and what happens to the physical load when the user is diverting from the symmetry line (sagittal plane) while bending. This information is necessary to assess the influence of this exoskeleton on the body, prior to a field feasibility study and its long-term implementation and use in the field.

3 Objectives

This study has three objectives:

1. Assess to what extent wearing the Laevo[®] exoskeleton (with vs. without) changes knee compression force, reduces muscular load on the back muscles, changes muscular load on other body parts such as the legs and shoulders, and changes discomfort in different tasks (static vs. dynamic) and different postures (trunk flexion vs. trunk flexion and rotation).
2. Estimate internal loadings on the spine, using a lumbar spine model, and see what the influence is of wearing the Laevo[®] exoskeleton.
3. Assess the performance of subjects during functional activities (e.g., stair climbing) when wearing the Laevo[®] exoskeleton (with vs. without).



4 Study design and study population

4.1 Study design

4.1.1 Independent variables

In the study, three independent variables will be investigated:

- Exoskeleton: with vs. without;
- Task: static vs. dynamic;
- Knee angle: flexed vs. extended (only for the dynamic task)
- Working posture: straight lifting/bending vs. lifting/bending with left/right trunk rotation.

4.1.2 Outcomes

In each experimental condition, the following outcomes will be assessed:

- Muscular loading;
- Knee joint loading;
- Force on legs and chest due to the exoskeleton's pads;
- Performance on functional tests;
- Subjective rating of perceived discomfort;
- Participant evaluation of the exoskeleton;
- Spinal loading.

4.2 Study population

We will select healthy, male participants in the age of 18-40 years old. For the main experiment, we constructed a *single Williams design* (Bate and Jones, 2006) based on three independent variables with two levels each that resulted in **six** different orders of conditions (Figure 1A). The single Williams design corrects for possible first-order carry-over effects. Using the results published by Bosch et al. (2016), we estimated the sample size including only the comparison of with and without Laevo® exoskeleton. Based on the reported outcomes of back discomfort, we estimate a sample size of 29 subjects.

Combining both calculations, we strive to include a multiply of the *single Williams design*, i.e. a multiple of six, which would be 30. However, we prefer to include 6x6

		Period					
		1	2	3	4	5	6
Subject	1	A	B	F	C	E	D
	2	B	C	A	D	F	E
	3	C	D	B	E	A	F
	4	D	E	C	F	B	A
	5	E	F	D	A	C	B
	6	F	A	E	B	D	C

Figure 1A. The single 6x6 Williams design, based on a balanced, uniform cross-over design.

		Period			
		1	2	3	4
Subject	1	A	B	D	C
	2	B	C	A	D
	3	C	D	B	A
	4	D	A	C	B

Figure 1B. The single 4x4 Williams design, based on a balanced, uniform cross-over design.

		Period		
		1	2	3
Subject	1	A	B	C
	2	B	C	A
	3	C	A	B
	4	C	B	A
	5	A	C	B
	6	B	A	C

Figure 1C. The double 3x3 Williams design, based on a balanced, uniform cross-over design.

subjects, leading to a number of 36 subjects (**Attachment 1**). The order of the three working positions (forward trunk flexion vs. left trunk rotation vs. right trunk rotation) will be randomized separately, using a *double Williams design*, i.e. 6 different orders.

For the additional postural angle and weight measurements that will be performed in a full-factorial design, we will measurements consisting of exoskeleton status (with or without Laevo®), knee angle (flexed, extended), static trunk forward flexion angle (0°, 30°, 60°, 60°, 30°), and carried weight (0kg, 8kg, 16kg). The conditions will be offered in a randomized order, based on the two independent variables exoskeleton status and knee angle, generated by a single Williams design with four different orders (**Figure 1B**). The static trunk flexion angles are always performed in ascending and descending order, i.e. 0°, then 30°, then 60°, then 60°, then 30°, which does not need randomization. The order of the three carried weights will be randomized separately, like the working positions, i.e. by using a *double Williams design* leading to 6 different orders (**Figure 1C**).

For the additional functional tests, which are three (i.e., Stair Climb Test [SCT], Timed Up-and-go Test [TUG], course) and always performed in the same order, we randomized by exoskeleton status by drawing lots.

4.3 In- and exclusion criteria

4.3.1 Inclusion criteria

- Age between 18 and 40 years;
- Male;
- BMI < 30 kg/m²;
- The participant will give his voluntary informed consent after receiving oral and written information of the content and goal of the study.

4.3.2 Exclusion criteria

- Aged <18 and >40 years;
- Female;
- People under the influence of intoxicants, analgesics, or muscle relaxants;
- Alcohol abuse;
- People with cardiovascular diseases;
- People with a heart pacemaker;
- People with a disability who, due to their restriction at a workplace of this kind, will not be able to participate;
- People with Diabetes Mellitus;
- People with severe muscle contractions of the lower extremities, back or arms;
- People with acute ailments or pain;
- People who are unable to complete the examination program due to language or cognitive obstacles;
- Depending on the degree of severity, people with diseases of the veins and joints of the lower extremities, spine, muscle disorders, symptomatic neurological-psychiatric diseases, acute pain syndromes, maladies or other current diseases.

4.4 Recruitment

Subject will be recruited by means of asking fellow colleagues / students in Tübingen to voluntary study participation. When necessary, additional announcement e-mails will be sent to employees / students from the University and Hospital of Tübingen (UKT), and to former subjects who agreed to be informed about future studies (**Attachment 2**), emphasizing the voluntary principle.

5 Timetable

The project has three overarching work packages (WP; **Table 1**), each containing a number of smaller work packages. The complete duration of the project is 14 months, with study start in July 2018, **which includes preparations for the Ethical Committee.**

Table 1. The timetable in months for the proposed study that is intended to start in July 2018. Numbers represent the work package (WP) and letters represent the smaller sub-work package.

Year	2018						2019							
Month	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
1	■	■	■	■	■	■	■	■	■	■	■	■	■	■
1A	■	■	■	■	■	■								
1B					■	■	■							
1C							■	■	■	■				
1D								■	■		■	■	■	
1E														
1F										■	■		■	■
1G												■	■	■
1H		■												
1I				■		■		■						
1J	■							■	■					■
2	■	■	■	■	■	■	■	■	■	■	■	■	■	■
2A	■	■	■	■	■	■								
2B					■	■	■							
2C							■	■	■	■				
2D								■	■	■	■	■		
2E														
2F										■	■	■	■	■
2G												■	■	■
2H		■												
2I				■		■		■						
2J	■							■	■					■
3	■	■	■	■	■	■	■	■	■					
3A	■	■	■	■	■	■								
3B		■	■	■	■	■								
3C	■	■	■	■	■	■								
3D				■	■	■	■	■	■					
3E		■												
3F				■										
3G	■								■				■	■

5.1 WP 1: static work tasks

This WP runs over the complete 14-month duration of the project, including ten smaller WPs. The WP starts with the design of the study design (A), followed by some pilot measurements (B). When the final study design is set, subjects will be recruited (C) who will perform the experiment (D). During data collection, a preliminary analysis (E) will be performed to get insights into data analyses and provide the project partners with an interim report. At the end of data collection, the main

analyses (F) will be performed, which are needed to evaluate the data and prepare them for publication (G). At the beginning of the project, the experimenters should make sure that all equipment is available or bought (H) and that there is a procedure to pay the participants (I). Along the project, the complete project team will meet a couple of times (J) and some money is reserved to visit national and international conferences (J).

5.2 WP 2: dynamic work tasks

This WP runs exactly parallel to WP 1, because the experiment will be designed so that all participants perform a combination of one static and one dynamic simulated work element. This means that the same subset of smaller WPs accounts in the same way as for WP.

5.3 WP 3: lumbar spine model

This WP is performed not by the Institute of Occupational and Social Medicine and Health Services Research, but by the research cluster Simulation Technology of the group Biomechanics and Biorobotics as part of the University of Stuttgart. As in the other two WP's, this WP also relies on measurement data, meaning that input for the modelling is considered both in the development of the study design (A) and during the pilot measurements (B). The model of the lumbar spine already is available, but needs to be adjusted so that information of the Laevo® exoskeleton can be incorporated (C). When data collection has started, the collected data can be used to improve and validate the model (D). As for WP 1 and WP 2, the appropriate equipment has to be available or bought (E), participants should receive a refund (F), and knowledge gained during this project will be shared with the project team (G) and with colleague scientists at national and international conferences (G).

6 Study procedure

6.1 Experimental tasks

In preparation to the measurements, we determined the details of the static and dynamic tasks in combination with the trunk angles. The static task will mimic bimanual sorting in a 40° forward bent position or a 40° forward bent position with 45° left or right rotation of the upper body (**Figure 2**).

The working distance and working height will be calculated by the individual's body segment lengths, the given forward trunk flexion angle of 40°, the resulting shoulder angle of 40° (holding the upper arm orthogonal to the base), and a defined elbow angle of 135°, counted from the base below the ankle position. The working distance to the side is ~20 cm also counted from the position of the ankle. The static tasks will be performed for 1.5 min in each position, with a passive break of 30 s in between successive positions (total duration is 4.5 min, **Figure 2B**). In between consecutive blocks (i.e., exoskeleton status and knee angle), participants get a passive break of ~2 min. This procedure is repeated two times for exoskeleton status (with vs. without), lasting ~11 min in total.

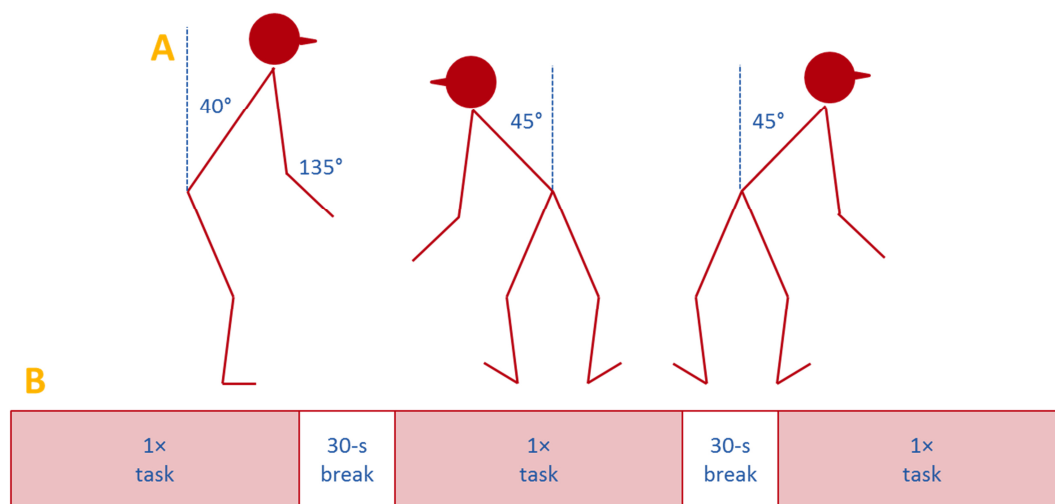


Figure 2. (A) The static task performed in three positions: trunk forward flexion (left), trunk forward flexion with rotation to the left (middle), and trunk forward flexion with rotation to the right (right). (B) The timeline for each exoskeleton status (with vs. without), within which three working postures are measured, separated by 30-s passive breaks.

The dynamic task will mimic a bimanual box replacing task in a 70° forward bent position or a 70° forward bent position with 45° rotation of the upper body (**Figure 3A**). The box handled will be ~10 kg with grips on both short sides, holding an arm angle of 135°. The working distance to the front is ~50 cm and to the side ~50 cm counted from the position of the ankle. The dynamic task will be performed as follows: the box has to be taken from the height of the bending position (70°), moved to an upright standing position, and placed back in bending position (70°) without or with rotation sideward. The dynamic task will be performed in two series of 5 repetitions in each working posture (forward trunk flexion, trunk rotation to the left, trunk rotation to the right), lasting 25 s per repetition, with a 35-s passive break s after each series of 5 repetitions and a 60-s passive break after each working position (total duration is 6.5 min). In between consecutive blocks (i.e., exoskeleton status and knee angle), participants get a passive break of ~3 min. This complete procedure (**Figure 3B**) is repeated four times for exoskeleton status (with vs. without) and knee angle (flexion vs. extension), all in all lasting ~35 min.

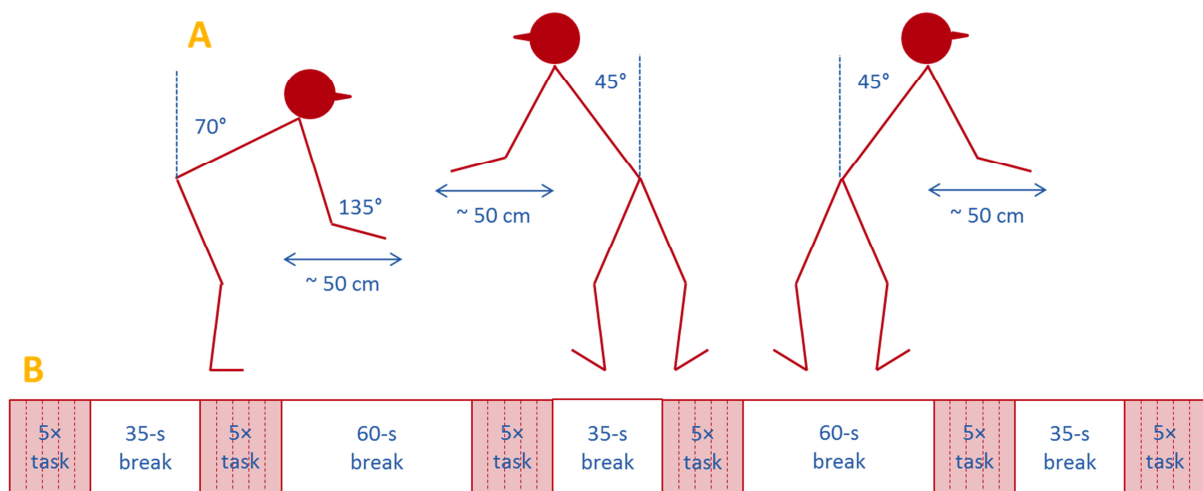


Figure 3. (A) The dynamic task performed in three positions: trunk forward flexion (left), trunk forward flexion with rotation to the left (middle), and trunk forward flexion with rotation to the right (right). (B) The timeline for a combination of exoskeleton status (with vs. without) and knee angle (extended vs. flexed), within which three weights are handled, separated by 60-s passive breaks.

6.2 Modelling of the lumbar spine

A lumbar spine model has been developed by the research group “Biomechanics and Biorobotics” of the research cluster “Simulation Technology (SimTech)” of the University of Stuttgart, which can predict internal forces during flexion movements (Rupp et al., 2015). The structure and properties of the model are outlined in **Figure 4**, which includes a detailed lumbar spine with non-linear discs, ligaments, and muscles.

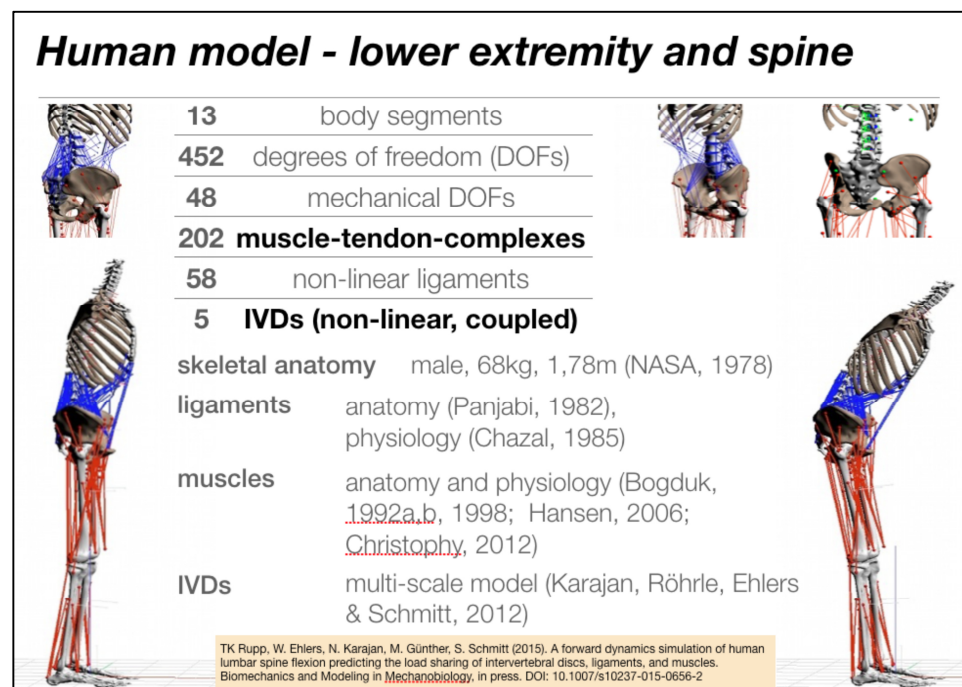


Figure 4. Model of the lumbar spine (Rupp et al., 2015).

With the lumbar spine model, we aim to investigate how internal forces in the lumbar spine change as a result of external forces of an exoskeleton during trunk flexion. This is the first time that an



exoskeleton is coupled to a detailed biomechanical model of the lumbar spine. We will also try to elaborate the modelling of the static task elements in trunk flexion and rotation by additional analyses of dynamic trunk flexion movements.

6.3 Static trunk forward flexion angle while holding a load

From a technical point of view, we are interested in the natural relationship (i.e. without Laevo®) between the spinal angle and the muscular stress on the back muscle (e.g., M. erector spinae longissimus lumbalis). In addition, we are interested how this relationship changes when subjects are wearing the exoskeleton, and when carrying different loads. Participants will perform a set of twelve different tests, which are a combination of exoskeleton status (two levels: without vs. with Laevo®), knee angle (extension vs. flexion), static trunk forward flexion angle (five levels; 0°, 30°, 60°, 60°, 30°), and load carried (three levels; 0kg, 8kg, 16kg). The trunk flexion angles will be performed in succession, meaning that a person will start upright (0°), slowly and uniformly move towards a slight forward flexion (30°), slowly and uniformly move in a deeper forward flexion (60°), go deeper and slowly and uniformly move back to the deep forward flexion (60°), and slowly and uniformly move back into a slight forward flexion (30°) (Figure 5A). Using a full-factorial design with the independent variables exoskeleton status and knee angle, participants will perform a total of four blocks. Within each block, the load carried is performed for the trunk flexion angles, lasting ~30 s. In between consecutive conditions within a block (i.e., carried weight), participants get a passive break of ~30 s (total duration is ~2.5 min). In between consecutive blocks (i.e., exoskeleton status and knee angle), participants get a passive break of ~3 min. This procedure is repeated four times for exoskeleton status (with vs. without) and knee angle (extended vs. flexed), all in all lasting ~20 min (Figure 5B).

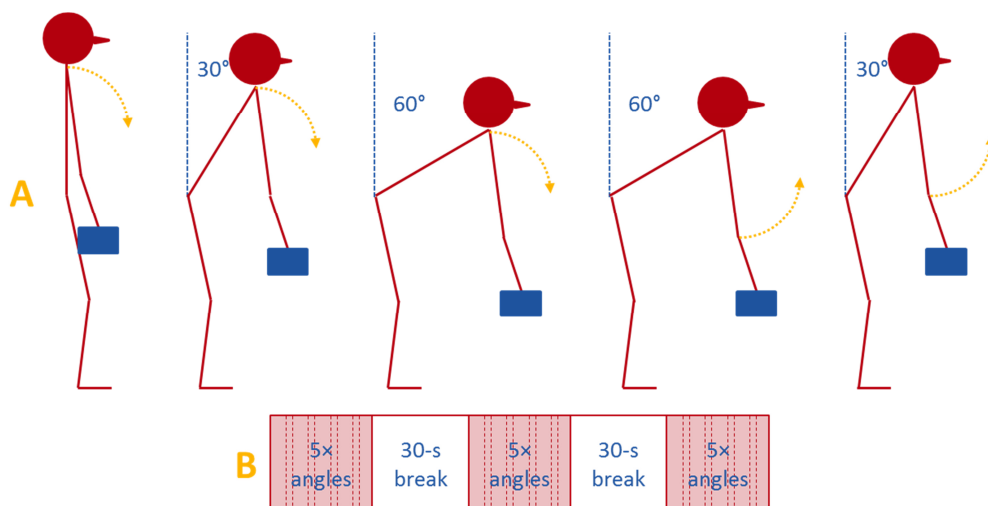


Figure 5. (A) Different trunk forward flexion angles while holding different loads, performed with and without the Laevo® exoskeleton, with extended and flexed knees, while holding loads of 0kg, 8kg or 16kg. (B) The timeline for a combination of exoskeleton status (with vs. without) and knee angle (extended vs. flexed), within which three trunk flexion angles are measured in ascending and descending order, separated by 30-s passive breaks.

The arms will always be extended, and the weight will be bimanually carried, meaning that the total weight (8kg and 16kg) will dividing over both hands (2×4kg and 2×8kg). The participant will receive direct visual feedback on a monitor of the trunk flexion angle.

6.4 Functional tasks

Functional tests are usually used for patients and elderly to estimate their level of performance. We use a small selection of available functional tests to see how participants perform with and without wearing the Laevo® exoskeleton. The following **three** tests are selected, each of which has its own outcome with interpretation:

1. **Stair Climb Test (SCT)**: ascend and descend an isolated set of 5 or 9 stairs (18 cm) using a single handrail is measured (Bennell et al., 2011));
 - a. Outcome: time (seconds) taken to complete the number of steps negotiated;
 - b. Interpretation: smaller values represent better performance, and number of steps negotiated in set time, where larger values represent better performance.
2. **Timed Up & Go (TUG)**: assessment of a basic mobility skill (Bennell et al., 2011). The subject is sitting on a regular chair with arm rests, rises from the chair, walks 3 m to the front, turns, walks back to the chair, and sits down. The subject is wearing regular footwear (Bennell et al., 2011; Dobson et al., 2013);
 - a. Outcome: time (s) taken to rise from a chair, walk 3 m, turn, walk back to the chair, then sit down;
 - b. Interpretation: smaller values (faster time) represent better performance.
3. **Course**: containing three different work station simulations; (A) a static screwing task in a 40° trunk flexion angle; (B) a dynamic logistic pick-and-place task replacing boxes from one side to another; (C) a dynamic lifting task moving objects from a grid box to a table.
 - a. Outcome: time (s) taken to complete the course three times after another without any breaks and heart rate (Hz) will be continuously recorded;
 - b. Interpretation: smaller time values (faster time) represent better performance; smaller heart rate values represent less strain.

The functional tests are performed in a predefined order: (1) SCT, (2) TUG, (3) course. The order of exoskeleton status will be randomized by drawing lots. For the SCT and TUG tests, the exoskeleton will be worn but turned off; for the course the exoskeleton will be worn and turned on.

6.5 Experimental procedure

Participants will visit the work physiology laboratory at the Institute of Occupational and Social Medicine and Health Services Research two times. During the first visit, the participants will be officially included in the study after they have read the general information (**Attachments 3**), have signed the informed consent form (**Attachment 4**), and have met the eligibility criteria (**Attachment 5**). When the participant is included, he will be familiarized with the Laevo® exoskeleton, the simulated static and dynamic assembly tasks, and the functional tests. Finally, the participant will fill out two short questionnaires providing some general information (**Attachment 6**) and information about his history of musculoskeletal complaints (**Attachment 7**). The first visit will take ~1 hour.

During the second visit, the participants will perform the experiment, taking ~4 hours in total. The study procedure is displayed in **Figure 6**. First, participants will be prepared with the measurement equipment, i.e. electrodes will be placed to record muscle activity and heart rate and position sensors to record postures and movements. After preparation, the participants have to perform reference measurements to normalize the recordings of muscle activity (electromyography; EMG)

and to correct the possible systematic error in the recordings of the body posture. The experiment consists of three phases: first, the participants will perform the six experimental conditions (with vs. without Laevo®, static vs. dynamic, knees extended vs. knees flexed); second, the participants will perform the twelve angle-force conditions, grouped into four blocks (with vs. without Laevo®, knees extended vs. flexed); third and last, the participant will perform the three functional tests. In between each of these three sets of measurements, the participant will have a passive break of 5 min and is allowed to drink or eat. After the static and dynamic tasks, participants are asked to fill out a questionnaire (combination of NASA-TLX and self-developed questions; see Chapter 7.9). After all the measurements are finished, the participants are asked to fill out a final questionnaire evaluating the usability of the Laevo® exoskeleton (combination of SUS, TUI and self-developed questions; see Chapter 7.9).

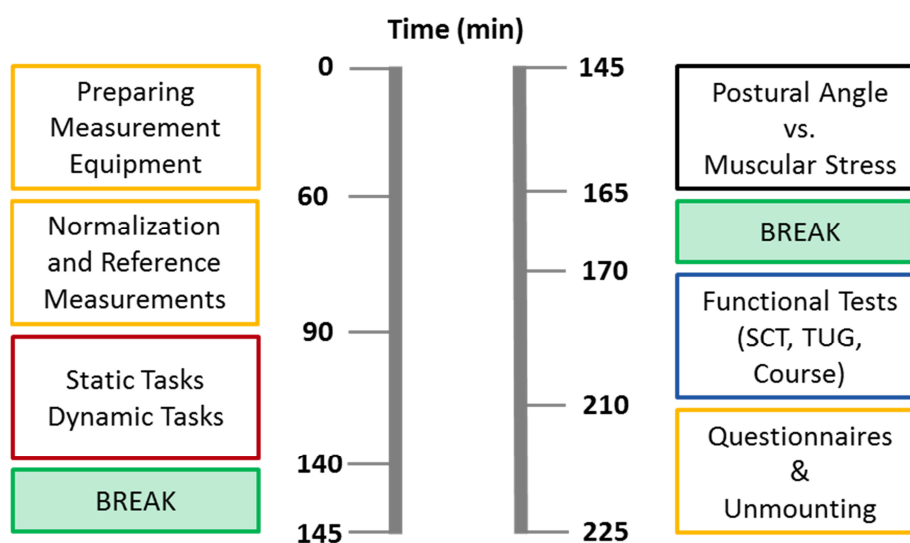


Figure 6. The experimental protocol is presented along with a timeline (min). Note that the main experimental conditions are displayed in red boxes and the functional tests in blue boxes. The order of both sets is randomized across participants as described previously. The test to determine the relation between postural angle and muscular stress is displayed in a black box, which will also be performed in a randomized order. The yellow boxes represent the start and end of the complete experiment, i.e. preparing and tidying up the participants.

6.6 Output

The collected data will be analyzed and prepared for statistical analyses if possible. All results will be presented to the cooperation partners in workshops and/or interim and final reports. In addition, the results will also be presented at symposia (e.g., annual GfA-congress, annual DGAUM- congress, annual FAP- congress) and published in peer-reviewed international journals (e.g., triennial PREMUS-congress, triennial IEA-congress, triennial ICOH-congress), to make the results accessible to the scientific community.

7 Measurement methods and analyses

7.1 General data

At the first visit to the laboratory, participants have to fill out the Standardized Nordic Questionnaire (Nordic Musculoskeletal Questionnaire) to provide us with information about their musculoskeletal history and some basic anthropometrics, including age, sex, body height, and body weight (**Attachments 6 & 7**).

7.2 Muscle activity

The Laevo[®] exoskeleton aims to reduce the physical load on the back of the wearer, but it might influence the physical load to other body parts such as the shoulders and legs. To record the activity of selected muscles at all these body parts (**Table 2**), we will use surface EMG. This method uses recording electrodes (42×24 mm, Kendall[™] H93SG ECG Electrodes, Covidien, Zaltbommel, the Netherlands) that are attached to the skin's surface overlaying the muscle of interest with an inter electrode distance (IED) of 26 mm. The differential signal (bipolar derivation) of two electrodes placed over one muscle belly recorded by an amplifier (PS12, THUMEDI[®] GmbH & Co. KG, Thum-Jahnsbach, Germany), gives a firm estimation of that muscle's electrical activity in microvolts (μV). This electrical activity pattern enables us to estimate the magnitude of the muscle activity (amplitude) and the overall firing frequency of the muscle (power frequency). The amplitude can be calculated by the overall root-mean-square (RMS) of the power spectrum of the EMG signal. The median power frequency (MPF) can be calculated as the median of the power spectral density of the EMG signal.

7.3 Kinematics: posture and force

Combining ground reaction forces with linear segment accelerations and joint angles (and their derived angular acceleration) enables the estimation of compression forces and force moments in joints. Our joint of interest is the knee, of which we will estimate the compression forces and force moments during the forward bent situations; the situations in which there is strong trunk rotation, estimations may become inaccurate and unreliable. Several approaches exist to estimate joint forces and joint moments, including forward dynamics, static body analyses, and inverse dynamics. We will use inverse dynamics to estimate the forces and moments around the knee, for which we need the (1) position of the lower and upper legs, (2) the ground reaction forces below the feet, (3) the angular accelerations of the ankle and knee joints, and (4) segment parameters like segment length, segment weight, and segment moment of inertia.

For the position, we will use position sensors that are integrated in modules of the PS12 system (Thumedi[®] GmbH & Co. KG, Thum-Jahnsbach, Germany). The position sensors will be placed on the lower leg, upper leg, and back providing us with the position in flexion and lateral flexion angles each of the three segments.

Ground reaction forces below the feet will be recorded using a force plate (Bertec 3D-Kraftmessplatte FP9090-15-1000, Velamed GmbH, Köln, Germany) with digital amplifier (Bertec, AM6500, Velamed GmbH, Köln, Germany). The segment parameters will partly be measured (segment lengths) and partly be estimated (segment weights and moments of inertia) using the four summary tables as provided by Krishnan et al. (2016).

Table 2. Six muscles of interest with a description of the posture and force level of their reference voluntary contraction (RVC) and maximal voluntary contraction (MVC). The RVC will be performed once for ~10 s, with 1-min rest intervals in between contractions of the same muscle and no rest in between RVCs and MVCs of different muscles.

Segment	Muscle	Reference voluntary contraction	Force level
Lower leg	M. gastrocnemius medialis	Stand upright, unilateral isometric maximum planter flexion contraction, i.e. going to the maximum / tip of the toes with full strength (MVC) (Rieman et al., 2011)	Weight own body
Upper leg	M. vastus lateralis	Lay prone, 90° knee flexion, foot neutral (90° ankle flexion), keep position while a rope with a weight hanging over a pulley was attached around the front-side of the ankle	5 kg 10 kg
	M. biceps femoris	Lay prone, 90° knee flexion, foot neutral (90° ankle flexion), keep position while a rope with a weight hanging over a pulley was attached around the back-side of the ankle	5 kg 7 kg
Lower back	M. erector spinae longissimus lumbalis	Lay prone, upper body and hips off the bench and extended legs fixed with straps, arms hang orthogonal to the ground below the shoulder. (1) Back (hip) extension without resistance (Abboud et al., 2014) (2) Back (hip) extension with 15-kg resistance (3) Back (hip) extension against fixed barrier (MVC)	Weight own upper body (+ 15 kg)
Abdomen	M. rectus abdominis	Lay supine, upper body and hips off the bench and extended legs fixed with straps, arms cross in front of the chest. (1) Back (hip) flexion without resistance (2) Back (hip) flexion with 10-kg resistance	Weight own upper body (+ 10 kg)
Shoulder/neck	M. trapezius descendens	Stand upright; arms in 90° arm abduction and slightly in the frontal plane, elbows extended (not overstretched), holding a weight in each hand	2×0 kg 2×2 kg

The angular accelerations can be derived from joint angles, which we will record using position sensors that are also integrated in modules of the PS12 system (Thumedi® GmbH & Co. KG, Thum-Jahnsbach, Germany). The position sensors will be placed on the foot, lower leg, and upper leg, providing us with the flexion and lateral flexion angles of each segment with respect to the earth's radius of gyration. For joint angles, we can subtract one segment angle from another. In addition, we will also record position of the spine by placing one sensor at the fifth lumbar vertebra (L5) and one at the third thoracic vertebra (T3).

For the inverse modeling calculations, we will use a 2D model in which joints are represented as hinges and segments as rigid bodies (Figure 7). We are interested in the net moment of the upper leg around the lower leg ($M_{U,L}$ in Figure 7) and the force of the upper leg acting on the lower leg ($\vec{F}_{U,L}$ in Figure 7).

The contact pressure between the Laevo® exoskeleton as exerted on the chest will be measured using a $\varnothing 38$ mm × 10 mm force sensor (Type KM38, ME-Meßsysteme GmbH, Henningsdorf, Germany) that will be integrated in the chest pad.

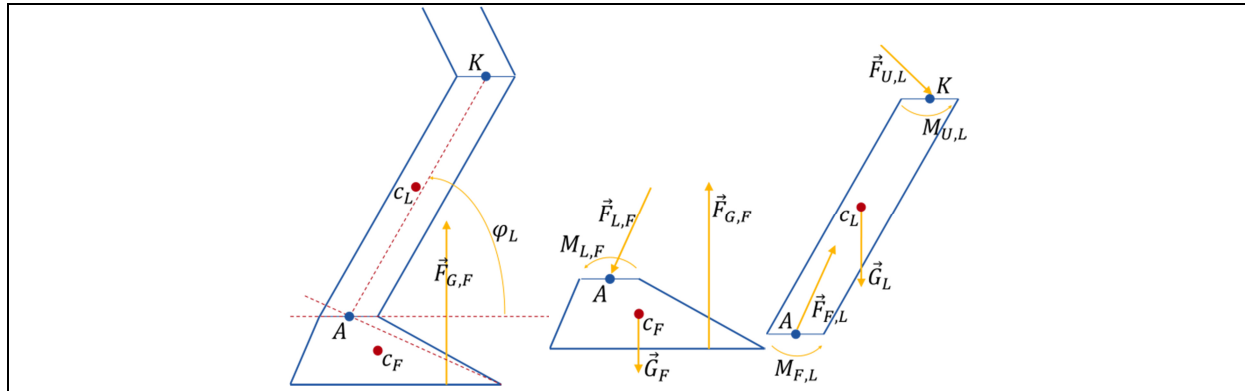


Figure 7. Illustrative inverse dynamic segment model of the lower leg and foot (left) with a sketch of the free body diagrams of the foot (middle) and lower leg (right). The symbols represent kinematic parameters: ankle (A), knee (K), center of mass of the foot (c_F), center of mass of the lower leg (c_L), flexion angle of the lower leg (φ_L), ground reaction force ($\vec{F}_{G,F}$), force of the lower leg acting on the foot ($\vec{F}_{L,F}$), force of the foot acting on the lower leg ($\vec{F}_{F,L}$), force of the upper leg acting on the lower leg ($\vec{F}_{U,L}$), gravitational force of the foot (\vec{G}_F), gravitational force of the lower leg (\vec{G}_L), net moment of lower leg around foot ($M_{L,F}$), net moment of foot around lower leg ($M_{F,L}$), and net moment of upper leg around lower leg ($M_{U,L}$).

7.4 Reference measurements

A reference posture will be recorded while the subject is standing upright with his back straight against a vertically levelled wall, his arms alongside his body, and his hand palms facing forward. The angles from this recording all represent zero angles, and will be used to correct the experimental recordings for any systematic offsets.

EMG is recorded in microvolt (μV) and may vary considerably between subjects. For this reason, we will normalize the activity of all measured muscles to a reference voluntary electrical activity (RVE) assessed during reference voluntary contraction (RVC; [Table 2](#)). During the reference contraction, the experimenter encourages the subject to stay in the reference posture. Each reference contraction will take ~ 10 s and will be performed once, of which the most stable 5-s plateau of one of the contractions will be used for EMG normalization and referred to as percent reference voluntary electrical activity (%RVE; Mathiassen et al., 1995). The reference measurements take ~ 30 min in total.

7.5 Heart rate

The heart rate will be continuously recorded by electrocardiography (ECG) using ECG recording electrodes (42 \times 24 mm, KendallTM H93SG ECG Electrodes, Covidien, Zaltbommel, the Netherlands). The two electrodes will be attached to the skin's surface, placed ~ 5 cm cranial and ~ 3 cm left-lateral from the distal end of the sternum and over the anterior to midaxillary line at the fifth left rib. The heart rate signal will be recorded by the same amplifier as EMG (PS12-UD, THUMEDI[®] GmbH & Co. KG, Thum, Germany).

7.6 Discomfort

Participants will rate their overall subjective feeling of discomfort (RPD) on an 11-point numerical rating scale (McCaffery and Beebe, 1989) ([Attachments 8 & 9](#)), ranging from 0 (no discomfort at all) to 10 (maximally imaginable discomfort). When participants experience a feeling of discomfort > 0 , we ask them to define the body region (Kuorinka et al., 1987) causing this sensation.

7.7 Functional tests

To assess how wearers of the Laevo® can walk around and use the exoskeleton in between work tasks, a set of two functional tests will be assessed by measuring time duration and/or difficulty and/or on an 11-point numeric rating scale. For each functional test, the outcome(s) to be recorded is listed below:

1. Stair Climb Test (SCT): time (s) taken to complete the number of steps negotiated (Bennell et al., 2011);
2. Timed Up & Go (TUG): time (s) needed to rise up from the chair, walk, turn, and sit back down on the chair again (Dobson et al., 2013).
3. Course: time (s) needed to complete the course and average heart rate (Hz) over the course.

7.8 Relation static trunk forward flexion angle, carried load and muscular stress / spinal load

With the data collected from the twelve tests that last ~30 s, we will be able to draw curves for every load carried across different trunk forward flexion angles. These curves will provide us with information whether the relation between increased trunk forward flexion is linear or not with respect to outcomes such as muscular activity of the lower back muscle (i.e., M. erector spinae longissimus lumbalis) or the abdomen muscle (i.e., M. rectus abdominis). In addition, separate lines within these graphs account for exoskeleton status (with vs. without exoskeleton), knee angle (extension vs. flexion) and weight carried (0kg vs. 8kg vs. 16kg), during which the relation between the trunk flexion angle and the muscular activity level could change too.

7.9 Participant evaluation

To evaluate the workload of the complete set of experimental conditions, we will use the NASA-TLX (Hart and Staveland, 1988; **Attachment 10**), which assesses six dimensions of workload (i.e., mental demand, physical demand, temporal demand, own performance, effort, and frustration). Subjects will rate only three of these dimensions on a scale from 0 to 100 (physical demand, temporal demand, and effort). We will assess overall partial workload by averaging or adding the scores of the three dimensions (Hoonakker et al., 2011). In addition, we will analyze the scores of the subscales (Hart, 2006; Hoonakker et al., 2011). Next to the NASA-TLX, we will also ask eight self-developed questions (**Attachment 10**).

To evaluate participants view on the usability and acceptance of the Laevo® exoskeleton in the performed tasks and on the acceptance of the Laevo® exoskeleton in work settings, we will ask six self-developed questions, use the ten questions of the standardized and validated questionnaire System Usability Scale (SUS), and use a selection of seven questions from the standardized Technology Usage Inventory (TUI) from the domains *usability* (n = 3) and *skepticism* (n = 4). The final set of questions (n = 23; see **Attachment 11**) will take approximately 10 minutes.

The SUS is a quick and easy to use method to collect the usability evaluation of users of a system (Borsci et al., 2009), in this case the system is the Laevo® exoskeleton. The SUS is also seen as a tool to measure the subjective perception of interaction with a system (Brooke, 1996). The SUS is recommended as satisfaction metric to complement other performance metrics such as time on task,

which in this study is done with the functional tests. The assessment of the SUS is the level of agreement on a Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) (Brooke, 1996).

The TUI is a questionnaire that can be used for research purposes or in the field of technology acceptance research (Kothgassner et al., 2013). It could support technique developers in the user-centered evaluation of new technologies, such as virtual simulations. The TUI records technology-specific and psychological factors that contribute to the actual use of the technology, containing the following eight scales: curiosity, anxiety, interest, usability, immersion, usefulness, skepticism, and accessibility. The TUI also includes the Intention to Use (ITU) scale, which contains three questions. The assessment of the TUI is the level of agreement on a Likert scale ranging from 1 (not true) to 7 (true). From the original TUI, we will only include the questions from the domains usability ($n = 3$) and skepticism ($n = 4$).

7.11 Statistical analysis

This study aims to answer the research question “what is the influence of exoskeleton, task, and posture on muscular activity, knee joint loading, spinal loading, and discomfort?”. Using a within-subject design, i.e. a randomized, balanced cross-over design, the data should be analyzed using a repeated-measures analysis of variance (ANOVA). This model contains three independent, within-subject factors: exoskeleton (with vs. without), posture (forward bend vs. rotation), and task (static vs. dynamic). The outcome parameters include muscular activity (i.e. RMS of EMG) of the selected muscles (**Table 2**), knee compression force, spinal loading, and discomfort. We will use JMP software (JMP® 13.1.0, SAS Inc., Cary, NC, USA) or SPSS software (IBM® Statistics® 25.0, Armonk, NY, USA) to perform the repeated measures ANOVA and accept statistical significance for $p < 0.05$.

The outcomes of the functional tests are based on numeric rating scales and / or are time-related, and will be statistically evaluated using a paired T-Test to compare the conditions with and without Laevo®. The results from the tests combining exoskeleton with trunk forward flexion angle and with load carried will be plotted to see if the relationship between the trunk forward flexion angle (x-axis) and the muscular stress of the erector spinae muscle (y-axis) changes per load carried (different lines) and exoskeleton (with vs. without; different lines).

The relationships between static trunk forward flexion angle and muscular activity will be assessed using regression analysis and compared between different loads carried (while keeping the exoskeleton status constant) and between exoskeleton statuses (while keeping the carried load constant).

The results of the two questionnaires that evaluate the acceptability and usability of the Laevo® exoskeleton will be narratively discussed.

8 Risk for the participant

The experiment has no threatening risks for the participant and all measurement equipment is certified in declarations of conformity (**Attachments 12-16**). Note that there can be some side-effects of study-related procedures about which we will inform the participant, including:

- Skin irritation or reddening due to skin preparation and of the attachment of the adhesive electrodes; in rare cases, participants may experience allergic reactions;
- When the electrode cables are tight and pull the skin, participants could experience tingling or tension sensations in the area of the adhesive electrodes due to this cable pull;
- Sensations of tension or muscle fatigue along the duration of the experiment;
- Due to participants performing the experiment have to stand during the measurements, it might occur that participants experience possible sensations of dizziness, loss of blood pressure, and a very low risk of impotence due to the ~60-min periods of interrupted standing;
- Minor risk of muscle aching the day after the experiments due to maximum voluntary muscle contraction.

9 Data protection

The participants as well as their personal and recorded data will be numerically pseudonymized by assigning a randomly generated two-digit identification number to the examined participant (e.g., S30P___). Relating analyzed outcome data to the natural person is only possible by inspection of the decoding list. This list, together with the informed consents of all volunteering participants, will be stored separately from the measured data in the storage of the Institute of Occupational and Social Medicine and Health Services Research. All participant data will be stored for a period of ten years after publication of the results. The destruction of the data in paper form is carried out by means of the disposal boxes for data protection at the University Hospital, and the destruction of the data in electronic form is carried out by means of transferring the data off the memory cards of the devices.

The measurements as part of this proposal are all recorded on portable computers that are accessible by means of a password only and cannot be accessed by any network. The pseudonymized data are processed within the University Hospital (UKT) network, of which the time of the measurement collection is removed from the operating software whenever possible. The measuring devices are configured identically for all measurements to exclude a possible association between the measurement configuration and the participants. After completing the data analysis, the data of the participants are stored together with the photo documentation on Blu-ray discs.

Only employees directly involved in the study have access to the data. In addition, all employees of the Institute for Occupational and Social Medicine and Health Services Research who are involved in the study are subject to medical confidentiality.

At the start of the study, participants are asked whether they wish to be informed about the primary results of the study. In case of several interested parties, an information event will be organized for the participants after completion of the data evaluation. If there is only little interest, a brief written presentation of the primary results will be spread and sent to interested parties by e-mail.

10 Study finance

The financing of the study, including personnel costs and facility costs for technical equipment and assistance, are funded by several industrial companies (**Table 3**). The study participants will receive a compensation of about € 10 per hour. The familiarization day is without refund, the testing day will take approximately 4 to 5 hours, which results in a total amount of € 45.

Table 3. Funding of the project is divided over eight partners, although not every partner collaborates in every work package.

Partner \ Work package	<u>WP 1</u> Static task element	<u>WP 2</u> Dynamic task element	<u>WP 3</u> Lumbar spine modelling
Daimler AG			
AUDI AG			
BMW AG			
MTU Aero Engines AG			
Iturri Gruppe			
Deutsche Post AG			
BASF			
Dachser Intelligent Logistics			

11 Personnel Staff

In work packages (WP) 1 and 2, employees from the Institute of Occupational and Social Medicine and Health Services Research of the University Hospital Tübingen & University of Tübingen will be responsible for each of the steps. In WP 3, all the modelling work is done by the group Biomechanics and Biorobotics of the cluster Simulation Technology (SimTech) of the University of Stuttgart.

11.1 Work packages 1 & 2

The main contributors to these two work packages are:

- Benjamin Steinhilber (15% of 100%-employment = 15%)
 - o Project leader: responsible for the study design, data interpretation;
- Tessy Luger (15% of 100%-employment = 15%)
 - o Project leader: responsible for the study design and supervising the following stages of the study;
- Robert Seibt (100% of 65%-employment = 65%)
 - o Technician and researcher: responsible for study design, measurement equipment, pilot and final measurements, data analysis, and data interpretation;
- Marlene Röttgen (6.7% of 75%-employment = 5%)
 - o Project management;
- PhD student, Mona Bär (100% of 65%-employment = 65%)
 - o Preparing, performing, analyzing and interpreting measurements.

11.2 Work package 3

- Benjamin Steinhilber (15% of 100%-employment = 15%)
 - o Project leader: responsible for the study design, data interpretation;
- Tessy Luger (15% of 100%-employment = 15%)
 - o Project leader: responsible for the study design and supervising the following stages of the study;
- Marlene Röttgen (6.7% of 75%-employment = 5%)
 - o Project management;
- PhD student, Mona Bär (100% of 65%-employment = 65%)
 - o Model building and validation.

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