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Effects of a passive back exoskeleton on the mechanical loading of the low-back during symmetric lifting

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ABSTRACT

Low-back pain is the number one cause of disability in the world, with mechanical loading as one of the major risk factors. Exoskeletons have been introduced in the workplace to reduce low back loading. During static forward bending, exoskeletons have been shown to reduce back muscle activity by 10% to 40%. However, effects during dynamic lifting are not well documented. Relative support of the exoskeleton might be smaller in lifting compared to static bending due to higher peak loads. In addition, exoskeletons might also result in changes in lifting behavior, which in turn could affect low back loading.

The present study investigated the effect of a passive exoskeleton on peak compression forces, moments, muscle activity and kinematics during symmetric lifting. Two types (LOW and HIGH) of the device, which generate peak support moments at large and moderate flexion angles, respectively, were tested during lifts from knee and ankle height from a near and far horizontal position, with a load of 10 kg.

Both types of the trunk exoskeleton tested here reduced the peak L5S1 compression force by around 5–10% for lifts from the FAR position from both KNEE and ANKLE height. Subjects did adjust their lifting style when wearing the device with a 17% reduced peak trunk angular velocity and 5 degrees increased lumbar flexion, especially during ANKLE height lifts.

In conclusion, the exoskeleton had a minor and varying effect on the peak L5S1 compression force with only significant differences in the FAR lifts.

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1. Introduction

With a lifetime prevalence between 75 and 84%, low-back pain (LBP) is the number one cause of disability in the world (Hoy et al., 2014) and with the current aging of the population the prevalence is expected to increase (Hartvigsen et al., 2018). Besides psychosocial risk factors, peak and cumulative compression of the spine, especially during lifting, have been shown to be important risk factors for the development of LBP (Coenen et al., 2014; Coenen et al., 2013; da Costa and Vieira, 2010; Kuiper et al., 2005; Norman et al., 1998).

Recently, body worn assistive devices (back exoskeletons) have been developed, to reduce mechanical loading of the spine in the workplace, while preserving the versatility that manual work allows. Back exoskeletons are designed to take over a part of the

moments produced by the lumbar extensor muscles, needed to counteract moments due to gravity on the upper body and on loads handled. In so-called passive back exoskeletons, spring-like components are used to generate an extension moment while bending forward, see for extensive reviews de Looze et al. (2016) and Toxiri et al. (2019).

Several exoskeletons, including the exoskeleton tested in the current study, have shown reductions of back muscle activity by 10% to 40% during static holding tasks (Bosch et al., 2016; Kobayashi and Nozaki, 2008; Koopman et al., 2019; Ulrey and Fathallah, 2013a, b). However, in dynamic lifting, peak L5S1 moments are much higher, and can reach for instance 250 Nm when lifting a 15 kg box (Kingma et al., 2001), compared to about 120 Nm in static forward bending without a load (Koopman et al., 2019). If the support level of the exoskeleton cannot be adapted to the high demand in lifting, the relative support provided by an exoskeleton will be much lower during lifting compared to static bending. Therefore, the impact of current exoskeletons in lifting can be questioned.

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A specific challenge in evaluation and design of back exoskeletons is posed by the flexion-relaxation effect. This effect occurs in pronounced trunk bending, when passive tissues are stretched far enough to generate a major part of the required extension moment so that back muscles are de-activated (Floyd and Silver, 1955). When flexion-relaxation occurs, the extension moment generated by the subject shifts from active to passive structures in the trunk. This moment shift may result in similar or even higher forces on the spine, because, compared to active muscles, passive structures act over moment arms relative to the spinal joints, equivalent to (muscle parallel elasticity) or smaller than (e.g. spinal ligaments) those of active muscles (Dolan et al., 1994). Consequently, especially if kinematics change with using an exoskeleton, a reduction in back muscle electromyography (EMG) (Alemi et al., 2019; Bosch et al., 2016; Kobayashi and Nozaki, 2008; Ulrey and Fathallah, 2013a, b) does not necessarily imply a reduction in spine loading. In addition, application of supportive extension torques with flexion-relaxation being present may be counterproductive, because, if the sum of the passive moment and the moment provided by the exoskeleton exceeds the net joint moment, the participant will need to activate abdominal muscles to maintain or reach the same posture (Koopman et al., 2019). So, it remains to be seen how effective passive exoskeletons will be in reducing peak L5/S1 compression force in dynamical lifting.

Therefore, the present study investigated the effect of a passive exoskeleton on peak compression forces, moments, muscle activity and kinematics during lifting. Two versions (LOW and HIGH) of the device (Laevo BV, The Netherlands), which generate peak support moments at large and moderate flexion angles, respectively, were tested during lifts from knee and ankle height from a near and far horizontal position, with a load of 10 kg. We hypothesized that both devices reduce peak compression forces at the L5/S1 joint, with HIGH being more effective at lifts from knee height and LOW at lifts from ankle height. No differences were expected in the effect of the exoskeletons between the NEAR and FAR lifts as trunk flexion was expected to be similar. In addition, we investigated to what extent effects of the devices can be explained by changes in lifting kinematics between the different lifting conditions.

2. Methods

2.1. Exoskeleton

In this study, a passive exoskeleton (Laevo V2.4 Delft, Netherlands; Fig. 1) was tested. Via three contact places on the body: thighs, pelvis and chest, forces are applied by the device. While bending forward, a force is applied at the chest and the upper legs due to a spring-loaded joint in series with an elastic beam, generating a moment in parallel to the back-muscle moment. The mass of the exoskeleton was 2.3 kg. Two different versions of the device were tested, namely LOW, showing a gradual increase in support between 30 and 140 degrees of Laevo joint flexion, and HIGH, showing a peak support around 50 degrees of Laevo joint flexion (Fig. 2). The exoskeleton joint has an end stop, beyond which no further rotation is possible. Further bending results in deformation of the much stiffer flexible beams, explaining the sharp increase in the chest pad force after about 140 degrees in both exoskeletons.

2.2. Calibration trial

Two subjects performed dynamic trunk bending trials at speeds ranging from 80 to 250 degrees/s, while wearing both the LOW and HIGH version of the exoskeleton. Force was measured using a force transducer placed on the chest pad. Orientation of the chest pad

Fig. 1. Laevo (V2.4) (Intespring Delft, Netherlands). (1) Rotational chest pad (2) Flexible beam (3) Spring-loaded joint. During the experiments, three LED's were used to measure the Laevo joint angle. The users's trochanter major is to be aligned with the hip center of rotation of the device.

was tracked using a marker cluster. The exoskeleton joint angle was captured using three LED's (Fig. 1). The exoskeleton torque was calculated around the exoskeleton joint using the cross product of the force and the vector from the point of application of the force to the center of rotation of the joint. A substantial difference in support was found between bending (solid) and extending (dashed). However, no effect of speed was found. Combined, these findings suggest that the difference between the downward and upward phases was due to friction rather than damping in the system. Note that during lifting tasks the exoskeleton moment was calculated around L5/S1 and not around the exoskeleton joint itself, as was done during the calibration trial and in Fig. 2.

2.3. Subjects and experimental procedures

Eleven healthy male subjects (age: 24.1 ± 2.7 years, mass: 74.8 ± 7.4 kg, height: 1.84 ± 0.07 m), participated in the study, which was approved by the medical ethics committee of the VU medical center (VUmc, Amsterdam, The Netherlands, NL57404.029.16). After providing written informed consent, subjects were fitted and familiarized with the exoskeleton and anthropometric data were obtained. After the EMG electrodes and optical markers were placed on the subjects, the experiment started in which subjects lifted a box (dimensions: width $\times$ height $\times$ depth = $35 \times 10 \times 25$ cm) of 10 kg, representing a common lifting task in practice within the NIOSH limits (Waters et al., 1993). To obtain information on a range of relevant tasks, lifts were performed from two horizontal and two vertical positions. The handles were located at 10 cm above ankle height (ANKLE) or at 10 cm above knee height (KNEE) from a horizontally near (NEAR) or far (FAR) position, in which the middle of the box was 35 cm or 60 cm in front of the ankle joint. Lifts started and ended standing upright without the box and three repetitions were performed for each of the conditions. The subjects had to perform these lifts once without the device (WITHOUT), once with the LOW and once with the HIGH exoskeleton. Participants were free to choose their own lifting speed and lifting technique. The order of the device conditions and tasks was randomized over subjects. Since changing

Fig. 2. Angle-force relationships measured with two subjects (averaged) for both LOW and HIGH during dynamical trunk bending with varying speeds. On average, peak trunk angular speeds were 120, 175 and 230 degrees/s, respectively for blue, green and red. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

between device conditions took around 10 min, sufficient rest between tasks was ensured.

2.4. Instrumentation and data pre-processing

A single custom-made 1.0×1.0 m force plate was used to measure ground reaction forces at 200 samples/s. Kinematics were collected at a sample rate of 50 samples/s using an opto-electronic 3D movement registration system (Certus, Optotrak, Northern Digital Inc.). LED cluster markers were attached to body segments (feet with lower legs (modeled as one segment), upper legs, pelvis, trunk (T10), head, upper arms and forearms with hands). In addition, three single LED markers were attached to the exoskeleton (base, joint, and bar), to measure the 'hip' joint angle of the exoskeleton (EXO joint). Prior to the measurements, for each participant, cluster markers were related to anatomical landmarks using pointer measurements (Cappozzo et al., 1995). Ten pairs of surface EMG electrodes were attached to the trunk muscles (Rectus Abdominis (RA), External Oblique (EO), anterior part of Internal Oblique (IO), Iliocostalis (IL), and Longissimus pars lumborum (LL); see Kingma et al., 2010) after abrasion and cleaning with alcohol. EMG data were recorded at 2000 samples/s using the Wireless Cometa Wave Plus 16-channel EMG system, online filtered with a band pass filter (10–1000 Hz). EMG data were synchronized using a pulse generated at the instant the recording of the kinematics and kinetics started.

2.5. Data analysis

Kinematic and kinetic data were low-pass filtered using a bi-directional 2nd order Butterworth filter at cut-off frequencies of 5 and 10 Hz, respectively. L5S1 flexion–extension moments, generated by subject plus exoskeleton (M_{L5S1_total}) were calculated based on the ground reaction forces and lower-body kinematics, using a bottom-up inverse dynamics model (Kingma et al., 1996) with improved anthropometric modeling (Faber et al., 2009). A global equation of motion (rather than a segment by segment calculation) was used, as described by (Hof, 1992). Using the method described in Koopman et al. (2019), the exoskeleton flexion–extension moment around L5S1 (M_{L5S1_Laevo}) was calculated using a cross product of the 3D moment arm and the 3D chest pad force, predicted based on the Laevo angle, and subtracted from M_{L5S1_total} to calculate the flexion–extension L5S1 moment generated by the subject ($M_{L5S1_subject}$). Off-line, EMG signals were full-wave rectified and low-pass filtered at 2.5 Hz (Potvin et al., 1996). EMG data were normalized to maximum voluntary contractions (McGill, 1991) and used as input to an EMG-driven trunk muscle model. The model has been described in more detail previously (van

Dieën, 1997; van Dieën and Kingma, 2005), and consists of 90 muscle slips crossing the L5S1 joint (Bogduk et al., 1992; McGill, 1996). For muscle slips crossing the L4 and T12 levels, nodes were used as points about which these long muscles were wrapped to follow lumbar curvature. Muscle forces were estimated as the product of the optimized maximum muscle stress, normalized EMG amplitude and correction factors for the instantaneous muscle length (Woittiez et al., 1984) and contraction velocity (van Zandwijk, 1998). For each participant, a best fit between net moments and muscle moments was obtained by optimizing, over all lifts performed in the WITHOUT conditions by a participant, three values for each participant: the maximum muscle stress, i.e. the scaling factor between EMG amplitude and muscle stress, the position of the passive length-tension curve relative to the muscle optimum length, and a scaling factor for the passive length-tension curve. The optimized values were also used in the WITH condition, without optimizing them again. Finally, to obtain compression forces at the L5S1 intervertebral joint, muscle forces and net reaction forces were summed after projecting them on the axes system connected to the L5S1 disc center. Lumbar angles were obtained by Euler decomposition of thorax relative to the pelvic anatomical axes (order: flexion–extension, lateral bending, axial rotation).

2.6. Statistics

All variables were checked for violation of the assumption of a normal distribution, but no violations were detected. Outcome variables were peak L5S1 compression forces, peak flexion–extension moments (M_{L5S1_total} and $M_{L5S1_subject}$), peak lumbar flexion, peak trunk angular velocity and peak back (averaged over sides and IL & LL) and peak abdominal (averaged over sides and RA & EO) muscle activity. For all variables, a four-way repeated measures ANOVA was conducted with device (WITHOUT, LOW and HIGH), height (ANKLE & KNEE), position (NEAR & FAR) and repetition as within subject factors. As repetition did not show any significant effects, all repetitions were averaged and subsequently a three-way repeated measures ANOVA was performed. When a significant main effect of device or an interaction with device was found, device effects were further explored using Bonferroni post-hoc tests. A significance level of $p < 0.05$ was used.

3. Results

The fit between the flexion–extension $M_{L5S1_subject}$ and the flexion–extension EMG driven model moment was acceptable with correlations (R^2) ranging from 0.84 to 0.91, and mean squared dif-

ferences ranging from 14.6 to 22.5 Nm (5–8% of the highest average peak moment) over subjects.

In contrast with our hypothesis, no significant main effect of device on the peak L5S1 compression force was found. However, the peak L5S1 moment generated by the subjects was significantly lower compared to WITHOUT, i.e. around –13 Nm (–6%) and –7 Nm (–3%) for LOW and HIGH, respectively. Peak trunk angular velocity showed a main effect of device without any interaction effects (Table 1). Specifically, peak trunk angular velocity was significantly reduced by around –16% and –18% for LOW and HIGH, compared to WITHOUT. Despite this substantial reduction in peak angular trunk velocity, peak M_{L5S1_total} was not reduced for LOW and HIGH when compared to WITHOUT (Table 1, Fig. 3). Peak back muscle activity was, on average, reduced compared to WITHOUT by around –8% for both LOW and HIGH, both being significant, without interactions with lifting location or height. In contrast,

peak L5S1 compression, peak $M_{L5S1_subject}$, peak M_{L5S1_total} and peak lumbar flexion showed at least two interactions with device (Table 1).

3.1. Knee height lifts

For both NEAR and FAR, the peak $M_{L5S1_subject}$ was lower for LOW (–11 & –13 Nm) than for HIGH (–5 & –7 Nm) compared to WITHOUT, while we had expected HIGH to be more effective during lifts from KNEE height. The reason for this might be in the angle-torque relation of the devices (Fig. 2). During the KNEE lifts, peak trunk flexion was already beyond 45 degrees where the HIGH exoskeleton has its local maximum of moment generation. In fact, in KNEE lifts, only for the LOW exoskeleton and only in the FAR condition, a significant reduction (–9%) in peak L5S1 compression force was found compared to the WITHOUT condition. The absence

Table 1
p-values and effect sizes of repeated measures ANOVA's with Device condition (WITHOUT, LOW and HIGH) (where ^{a,b} indicate significant differences between WITHOUT and LOW and WITHOUT and HIGH), Height condition (ANKLE and KNEE), Position condition (NEAR and FAR) and their interactions. Pairwise comparisons were performed for variables with a significant interaction effect with the factor device. Significant ($p < 0.05$) results were indicated in bold.

	Main effect	Interaction	Interaction	Interaction
	Device	Device * Height	Device * Position	Device * Height * Position
	p (η^2)	p (η^2)	p (η^2)	p (η^2)
Peak L5S1 Compression	0.154 (0.17)	0.023 (0.31)	0.020 (0.32)	0.008 (0.39)
Peak M_{L5S1_total}	0.198 (0.17)	0.001 (0.55)	0.028 (0.33)	0.429 (0.01)
Peak back muscle activity	0.004^{a,b} (0.43)	0.577 (0.05)	0.445 (0.08)	0.772 (0.03)
Peak $M_{L5S1_subject}$	<0.001^{a,b} (0.68)	0.875 (0.02)	0.007 (0.42)	0.034 (0.31)
Peak Lumbar flexion angle	0.707 (0.04)	0.013 (0.42)	0.021 (0.38)	0.618 (0.06)
Peak Trunk angular velocity	<0.001^{a,b} (0.75)	0.127 (0.19)	0.149 (0.17)	0.616 (0.05)
Peak abdominal muscle activity	0.599 (0.05)	0.308 (0.11)	0.719 (0.03)	0.168 (0.16)

Fig. 3. Peak L5S1 compression, peak moments (M_{L5S1_total} and $M_{L5S1_subject}$), peak back muscle activity, peak lumbar flexion angle and peak trunk angular velocity. A main effect of Device was indicated with D. Interaction effects were indicated with DH (Device*Height), DP (Device*Position) and DHP (Device*Height*Position). Horizontal bars indicated a significant difference between the two bars.

of significance in other knee height lifts might be explained by the small effect, in combination with subject to subject variation. The devices did not affect peak lumbar flexion in KNEE height lifts.

3.2. Ankle height lifts

During the lifts from the ANKLE NEAR location, peak M_{L5S1_total} was slightly higher in the exoskeleton conditions compared to WITHOUT, though only significantly for HIGH, in spite of a reduced lifting speed. As a result, despite exoskeleton support, peak $M_{L5S1_subject}$ was not significantly lower in exoskeleton conditions compared to WITHOUT. As the peak lumbar flexion angle was increased (5 degrees) with respect to WITHOUT and values were near the maximal range of motion, most likely a shift from active to passive force generation occurred. As a result, back muscle activity decreased, without a decrease in $M_{L5S1_subject}$. The decreased muscle activity also did not cause decreased peak L5S1 compression, as the passive components also cause compression of the spine.

During the ANKLE FAR lifts, subjects had to bend quite far ($>80\%$ ROM). Consequently, some participants reached the hard stop of the device (Fig. 2) and the support of the exoskeletons strongly increased up to 50 Nm in these participants and peak $M_{L5S1_subject}$ significantly decreased on average by -7% , for both LOW and HIGH. In line with this and in line with lower back muscle activity, compression forces during the ANKLE FAR lifts were significantly lower for HIGH (-7.3%) compared to WITHOUT.

4. Discussion

Effects of the exoskeletons on the peak compression forces were rather small (8–9%) and not consistent over tasks. In contrast with our hypothesis, LOW was more effective than HIGH in KNEE FAR lifts, whereas HIGH was most effective during the ANKLE FAR lifts. Also unexpectedly, effects of the exoskeletons were larger in the lifts from FAR compared to NEAR. These findings can largely be explained by the non-monotonic angle-torque relations of the devices (Fig. 2). During the KNEE lifts, flexion of the device was around 80 degrees, while the peak support moment of HIGH occurs around 45 degrees. Therefore, support of the HIGH already dropped and was actually lower compared to LOW. Subjects did adjust their lifting style when wearing the device by increasing lumbar flexion, especially during ANKLE height lifts. Besides this adjustment, participants also reduced peak trunk angular velocity by around 17%, indicating a reduced lifting speed for all lifts when wearing the EXO.

During the ANKLE FAR lifts, flexion angles of the exoskeletons (around 140 degrees) were beyond the hard stop (the point where the exoskeleton's joint is locked and further movement is only allowed by bending of the bars). As the stiffness of the bars is higher, the torque generated by the exoskeleton sharply increases after this point. Therefore, effects of the exoskeletons were slightly larger in the FAR lifts compared to NEAR, which resulted in larger reductions in $M_{L5S1_subject}$.

During the ANKLE lifts, M_{L5S1_total} with the exoskeletons was higher compared to WITHOUT, even though trunk angular velocity was lower. Additional analyses showed that although trunk angular velocity was lower, angular acceleration was not significantly reduced at the instant of peak loading. The small increase in M_{L5S1_total} can be explained by minor changes in the horizontal distance of the L5S1 joint to the load and in trunk inclination. Despite the effect of the exoskeletons on back muscle activity, no main effect of the exoskeleton conditions on peak L5S1 compression force was found. One of the reasons might be the fact that participants did bend the lumbar spine more when wearing the exoskeleton,

especially during the ANKLE lifts. When approaching the maximum range of motion, passive structures will get stretched and take over part of the required moment from the active muscles. However, this will not lead to a reduction of spinal compression as the moment arms of the passive structures relative to the spinal joints are equal to or smaller than those of the active muscles. Therefore, it is important to be cautious in solely interpreting back muscle EMG.

With a maximal reduction in peak compressive force of around 10%, one might ask how relevant this reduction will be in practice. Based on compressive strength data of cadaveric specimens, a 10% reduction could substantially reduce the population at risk (Brinckmann et al., 1989; Jäger, 2018). However, the effect of the exoskeletons was not found across all tasks and efficacy might therefore be less in an industrial application. The reduced back muscle activity might have positive effects in terms of muscle fatigue. However, when this is due to a shift from active to passive force generation this will most likely have little or even a negative effect on the compression force. In addition, this may have other negative consequences like creep deformation of passive tissues (Solomonow et al., 2003).

The fit of the EMG-driven model, used to estimate compression forces, was acceptable with an R^2 between 0.84 and 0.91, which is comparable to other EMG assisted modeling studies (Marras and Granata, 1997; van Dieën and Kingma, 2005). The peak compression forces found in this study were within the range of expected values during dynamical lifting of loads of around 10–15 kg (Bazrgari et al., 2008; Kingma et al., 2016; Marras and Davis, 1998). The effect of the exoskeletons during lifting was somewhat small in comparison to other devices, that showed reductions of back muscle activity up to 30% (Abdoli et al., 2006; Abdoli and Stevenson, 2008; Alemi et al., 2019). However, it should be noted that in these studies no information on lumbar flexion and/or compression forces was available. If flexion increases when wearing an exoskeleton, EMG reduction can be due to a shift from active to passive forces. Therefore, these studies may have overestimated the mechanical effects of the devices. We corrected for such effects through our EMG driven model. Additionally, differences can be due to lower absolute moments and absence of device hysteresis in static conditions. Indeed, in static bending with the same devices, larger relative effects were found (Koopman et al., 2019). In lifting, during peak compressive loading the movement is upward and therefore peak support of the exoskeletons is 10 Nm lower than expected (Fig. 2). Except beyond the hard stop, the exoskeleton supports up to 20 Nm, instead of 30 Nm, which is only around 10% of the total moment. To increase the support during lifting, the difference in torque generation capacity between moving downwards versus moving upwards, or the hysteresis of the exoskeleton, should be reduced.

Potential sources of bias and limitations of this study should be carefully considered. Errors in spinal forces estimated by our EMG-driven model may be due to factors such as cross-talk, bad representation of deep and wide muscles, EMG normalization, ignoring spine translations and considerations of L5S1 moments only (Arjmand et al., 2009; DeLuca and Merletti, 1988; Gagnon et al., 2011; Staudenmann et al., 2005; Stokes et al., 2003). However, these sources of error are not likely to affect our comparison between conditions, as these sources of error are not likely to vary strongly between the conditions. In addition, as it is unclear how the mass of the exoskeleton (2.3 kg) is distributed over the body (i.e. the portion of the mass carried by the pelvis) we neglected this effect in the inverse dynamic analysis. However, the added mass of the exoskeleton itself was captured in the GRF and as the mass portion around the hips will have a small moment arm with respect to L5S1 we are confident that this limitation only has a minor effect. Another limitation is that results were solely based on male partic-

participants as the chest pad of the tested version of the device was not designed for use by women. Our participants were mainly young and fit, which might not represent the general working population. However, we do not think that the effects of the exoskeletons will vary much across the population, except that the relative effect for heavier subjects will be less. As the focus of the study was on the low back, effects around the knee joint were not considered. It might be that loading around the knee was increased as an effect of the exoskeleton. However, these effects are expected to be limited (de Looze et al., 2016). The current exoskeleton design with only one joint for trunk flexion is incapable of providing postural guidance which has been shown to alter lifting kinematics (Picchiotti et al., 2019).

Contact points of the exoskeleton with the participant's bodies may have differed slightly between participants, which might cause variation in support across subjects. While different sizes of the exoskeleton were available, these were not used as this didn't improve the fit with the subject in the current group of participants.

In conclusion, both trunk exoskeletons tested here reduced the peak L5/S1 compression force by around 5–10% for lifts from the FAR position from both KNEE and ANKLE height. In all other conditions no significant effect of the device was found because small changes in lifting style and lifting speed likely obscured the minor effect of the EXO. Although peak back muscle activity was reduced over all conditions, this did not coincide with a positive effect on the peak L5/S1 compression force in NEAR conditions due to changes in muscle length. Therefore, caution should be taken in interpreting EMG results in isolation, especially during tasks involving substantial lumbar bending. To improve the effectivity of the exoskeleton, the internal friction should be reduced, and the magnitude of the support should be increased.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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