University of Groningen

Side-effects and adverse events of a shoulder- and back-support exoskeleton in workers

Kranenborg, S. E.; Greve, C.; Reneman, M. F.; Roossien, C. C.

Published in:
Applied Ergonomics

DOI:
10.1016/j.apergo.2023.104042

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Publisher's PDF, also known as Version of record

Publication date:
2023

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):
Kranenborg, S. E., Greve, C., Reneman, M. F., & Roossien, C. C. (2023). Side-effects and adverse events of a shoulder- and back-support exoskeleton in workers: A systematic review. *Applied Ergonomics*, *111*, Article 104042. https://doi.org/10.1016/j.apergo.2023.104042

Copyright
Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the “Taverne” license. More information can be found on the University of Groningen website: https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment.

Take-down policy
If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): http://www.rug.nl/research/portal. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

Download date: 11-09-2023

Applied Ergonomics 111 (2023) 104042

Contents lists available at ScienceDirect

Applied Ergonomics

journal homepage: www.elsevier.com/locate/apergo

Review article

Side-effects and adverse events of a shoulder- and back-support exoskeleton in workers: A systematic review

S.E. Kranenborg[a], C. Greve[a,b,*], M.F. Reneman[b], C.C. Roossien[a]

[a] University of Groningen, University Medical Center Groningen, Department of Human Movement Science, Hanzeplein 1, 9713 GZ, Groningen, the Netherlands
[b] University of Groningen, University Medical Center Groningen, Department of Rehabilitation Medicine, Hanzeplein 1, 9713 GZ, Groningen, the Netherlands

ARTICLE INFO

Keywords:
Musculoskeletal disorders
Human-machine interaction
Prevention

ABSTRACT

Introduction: While the biomechanical effects of exoskeletons are well studied, research about potential side-effects and adverse events are limited. The aim of this systematic review was to provide an overview of the side-effects and adverse events on shoulder- and back-support exoskeletons during work tasks.

Methods: Four in-field studies and 32 laboratory studies were included in this review, reporting on n = 18 shoulder exoskeletons, n = 9 back exoskeletons, n = 1 full body with a supernumerary arm, and n = 1 combination of shoulder and back exoskeleton.

Results: The most frequent side-effect reported is discomfort (n = 30), followed by a limited usability of the exoskeleton (n = 16). Other identified side-effects and adverse events were changes in muscle activity, mobility, task performance, balance and posture, neurovascular supply, gait parameters and precision. An incorrect fit of the exoskeleton and the decreased degrees of freedom are most often reported as causes of these side-effects. Two studies did not find any side-effects. This review also showed that there are differences in the occurrence of side-effects in gender, age, and physical fitness. Most studies (89%) were conducted in a laboratory setting. Most studies (97%) measured short-term effects only. Psychological and social side-effects or adverse events were not reported. Side-effects and adverse events for active exoskeletons were understudied (n = 4).

Conclusion: It was concluded that the evidence for side-effects and adverse events is limited. If available, it mainly consists of reports of mild discomfort and limited usability. Generalisation is limited because studies were conducted in lab settings and measured short term only, and most participants were young male workers.

1. Introduction

30% of the working population in the European Union is exposed to high physical workloads and 46% to uncomfortable body postures (de Looze et al., 2016). Of all the European workers with a work-related health problem, 60% experiences musculoskeletal disorders as their most serious issue, mainly muscular backache (43%) and pain in the upper limbs (41%) (Elprama et al., 2022; de Kok et al., 2020; Theurel and Desbrosses, 2019). To support workers during labour intensive tasks and possibly reduce the incidence of musculoskeletal disorders, a variety of exoskeletons has been introduced to the labour market (Alemi et al., 2019; Ali et al., 2021). Exoskeletons can reduce risk factors associated with musculoskeletal disorders by unloading spinal structures (e.g. lumbar disc) (de Looze et al., 2016; Kermavnar et al., 2021). Unloading of the spine is achieved by exerting passive or active forces perpendicular or parallel to the spinal column which apply at the sternum or rib cage of the user (Ali et al., 2021).

While the biomechanical effects of exoskeletons are well studied (for example on peak muscle activations), it remains unclear whether exoskeleton use causes any side-effects or adverse events. Because no clear consensus on the definition of side-effects and adverse events for exoskeleton devices was observed in the literature, definitions were composed and used in this review based on the Good Clinical Practice and Pharmacy Times definitions (European Medicines Agency, 2016; Leheny, 2017). Side-effects are defined as any unintended effect that occurs as a consequence of exoskeleton use. Adverse events are defined as any unintended and harmful occurrence that results from exoskeleton use. If the event is severely harmful to the user, the term serious adverse event is used. Unlike side-effects, adverse events are not expected by the doctor, patient, worker or manufacturer. Side-effects can be logically

---

[*] Corresponding author. University of Groningen, University Medical Center Groningen, Department of Human Movement Science, Hanzeplein 1, 9713 GZ, Groningen, the Netherlands.

E-mail address: c.greve@umcg.nl (C. Greve).

https://doi.org/10.1016/j.apergo.2023.104042
Received 22 September 2022; Received in revised form 20 April 2023; Accepted 27 April 2023

foreseen based on biomechanical, biomedical or psychosocial principles.

Despite multiple experimental studies and reviews describing the biomechanical effects of exoskeletons, there is no systematic overview of the potential short- and long-term side-effects of exoskeleton use. Similarly, instruction manuals of different exoskeleton types (e.g., PAEXO, Ekso Vest, ShoulderX) often fail to report potential side-effects and adverse events and mainly focus on beneficial biomechanical effects of exoskeleton use (Ekso Bionics, 2021; ottobock., 2021; suitX., 2021).

Implementation of exoskeletons in the workplace should be a decision based on benefits and harms. A systematic overview of potential side-effects and adverse events of exoskeleton use, however, is not available. The aims of this systematic literature review are therefore: a) to establish a systematic overview of all reported side-effects and adverse events of upper limb and back exoskeleton use in workers/during work tasks and b) to establish whether side-effects and adverse events differ based on gender, physical fitness, age and type of exoskeleton (e.g., active or passive support). We will provide recommendations for relevant sub-populations (e.g., gender, physical fitness, and age) and exoskeleton type, recommendations for future experimental studies and recommendations for side-effects and adverse events which should be included in exoskeleton evaluations.

2. Method

This systematic review was conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines (Appendix A).

2.1. Information sources and eligibility criteria

The databases Pubmed and Embase were systematically searched using a combination of Medical Subject Headings (MeSH Terms) and title/abstract terms. Pubmed and Embase are complementary and the two most comprehensive biomedical literature databases containing relevant literature for our research question. CINAHL is much smaller and has a focus on nursing and allied health disciplines, and was therefore not used. The exact search string that was used is described in Appendix B. In the original PROSPERO protocol only in-field studies with workers were included. Based on these criteria only four studies could be included. To analyse more studies, the eligibility criteria were expanded to include studies conducted in a laboratory setting imitating a work-related task (e.g., lifting, carrying, bending). Studies were included if 1. Participants were healthy adult workers (Population), 2. The exoskeleton was intended for reducing the physical load at the

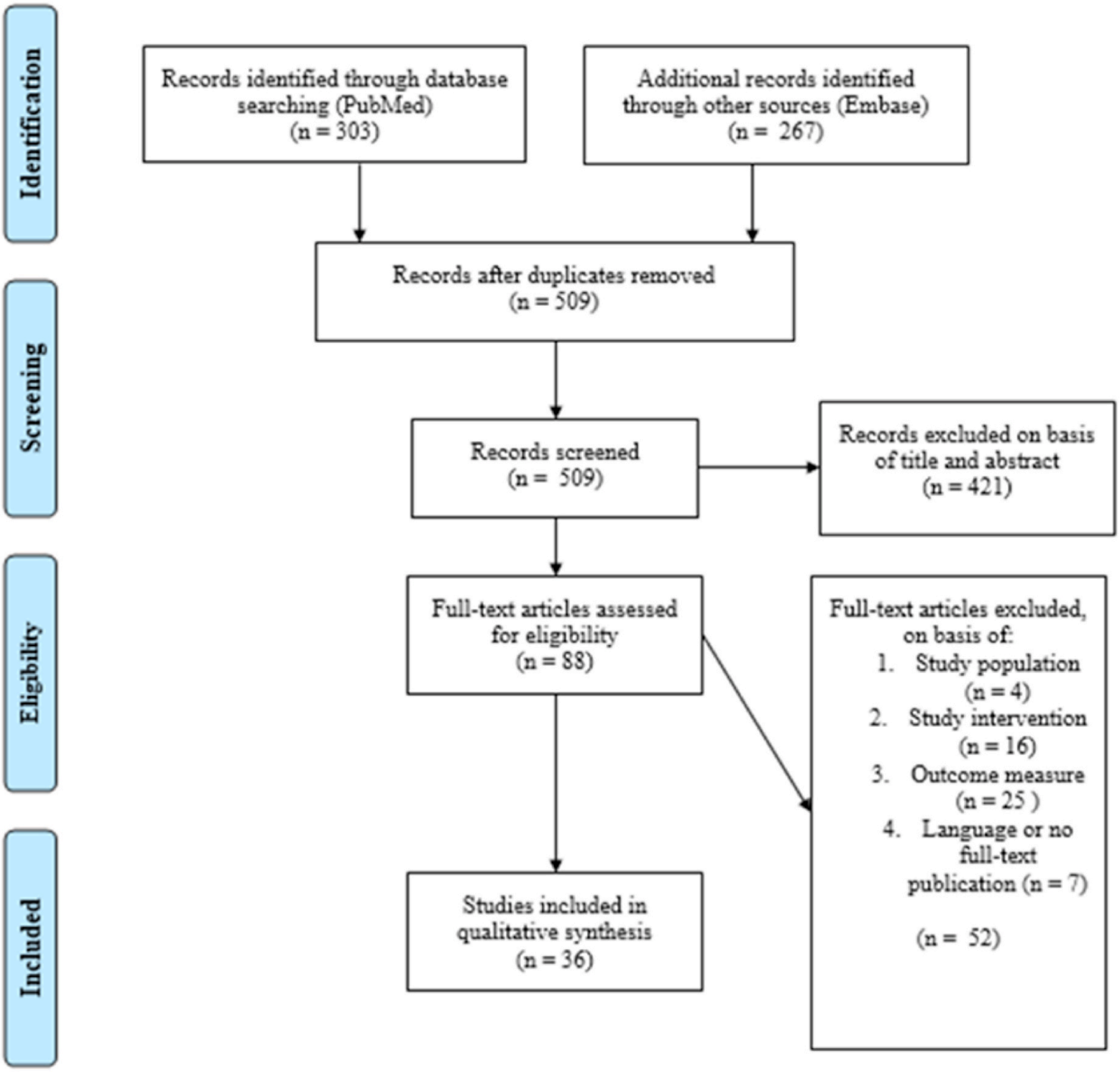


Fig. 1. PRISMA flow diagram of the study selection process for research articles included in this systematic review.

back/trunk and/or shoulders (Intervention). 3. The study was performed in the workplace or in laboratory setting when defined as 'simulation/imitating a work environment' (Intervention), 4. (potential) side-effects and/or adverse events and/or user experience as outcome measure, were measured (Outcome), 5. The full text papers were written in English and Dutch (defined as 'language and full-text publication' in Fig. 1) and 6. Studies published between 2010 until March 2022 were included. Included studies either had no control group, a control group without exoskeleton use or comparing different exoskeleton types (Comparison). Excluded were studies that did not aim to measure side-effects or adverse events (wrong outcome measure), studies that focussed on lower-limb exoskeletons (wrong study intervention), patients following a rehabilitation program, and workers with health problems (wrong study population). No restrictions were applied to study designs.

2.2. *Study selection and risk of bias assessment*

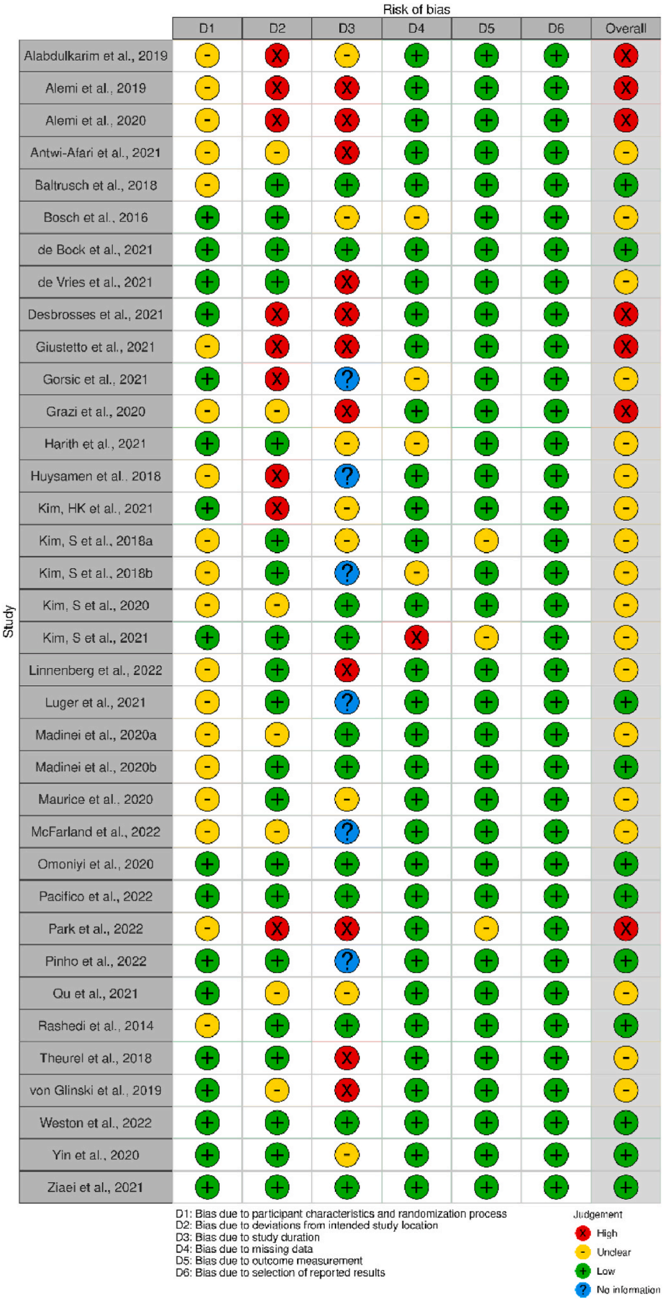
The reference management tools EndNote (EndNote X9, Clarivate, 2022) and Rayyan (Ouzzani et al., 2016) were used to screen and export eligible articles. After duplicate removal, two independent reviewers (Kranenborg, S.E. & de Boer, D.R.) screened the titles, abstracts, and full text against the eligibility criteria. Disagreements between the two reviewers during abstract and full-text selection were resolved by a discussion. If still no consensus could be reached, a third author would decide. The risk of bias and data extraction was assessed by the first author for each included study in accordance with methods recommended by The Cochrane Collaboration against the following criteria (Higgins et al., 2011): D1. Bias arising from the participant characteristics and randomization process (for example, if the included participants can be generalized to the working population), D2. Bias due to deviations from intended intervention (for example, if the tasks are a proper simulation of work-related tasks), D3. Bias due to study duration (short vs long-term), D4. Bias due to missing outcome data, D5. Bias in measurement of the outcome (potential side-effects or adverse events not measured systematically), and D6. Bias in selection of the reported results. The judgements 'low risk', 'high risk', or 'unclear' (either lack of information or uncertainty over the potential for bias) were used. The *robvis* visualization tool was used to create a risk-of-bias plot (McGuinness and Higgins, 2020).

2.3. *Data extraction and analysis*

Data were collected on the study characteristics of the included participants, the types of exoskeletons used, types of tasks that the participants performed, whether the study was an in-field or a laboratory-based assessment, the number and types of observed and measured side-effects and adverse events, and whether a side-effect was intended or not. It is also reported when a study aimed to measure side-effects, but did not observe any. These data were used to evaluate the frequency and severity of potential side-effects and adverse events. There are different definitions of 'discomfort' used in the studies. Only results of discomfort were reported as side-effect or adverse event if discomfort was described as any uncomfortable feeling or feeling of contact pressure due to the human-machine interaction, for example uncomfortable contact pressure because of the chest plate.

3. Results

A total of 36 studies were identified in the systematic search. The included studies were published between 2014 and 2022. In Fig. 1, the complete study selection process is presented in the PRISMA flow diagram (template adopted from Moher et al., 2009). In Fig. 2, the risk of bias plot is shown for all the included studies.



Risk of bias

Study	D1	D2	D3	D4	D5	D6	Overall
Alabdulkarim et al., 2019	-	X	-	+	+	+	X
Alemi et al., 2019	-	X	X	+	+	+	X
Alemi et al., 2020	-	X	X	+	+	+	X
Antwi-Afari et al., 2021	-	-	X	+	+	+	-
Baltrusch et al., 2018	-	+	+	+	+	+	+
Bosch et al., 2016	+	+	-	-	+	+	-
de Bock et al., 2021	+	+	+	+	+	+	+
de Vries et al., 2021	+	+	X	+	+	+	-
Desbrosses et al., 2021	+	X	X	+	+	+	X
Giustetto et al., 2021	-	X	X	+	+	+	X
Gorsic et al., 2021	+	X	?	-	+	+	-
Grazi et al., 2020	-	-	X	+	+	+	X
Harith et al., 2021	+	+	-	-	+	+	-
Huysamen et al.. 2018	-	X	?	+	+	+	-
Kim, HK et al., 2021	+	X	-	+	+	+	-
Kim, S et al., 2018a	-	+	-	+	-	+	-
Kim, S et al., 2018b	-	+	?	-	+	+	-
Kim, S et al., 2020	-	-	+	+	+	+	-
Kim, S et al., 2021	+	+	+	X	-	+	-
Linnenberg et al., 2022	-	+	X	+	+	+	-
Luger et al., 2021	-	+	?	+	+	+	+
Madinei et al., 2020a	-	-	+	+	+	+	-
Madinei et al., 2020b	-	+	+	+	+	+	+
Maurice et al.. 2020	-	+	-	+	+	+	-
McFarland et al., 2022	-	-	?	+	+	+	-
Omoniyi et al., 2020	+	+	+	+	+	+	+
Pacifico et al., 2022	+	+	+	+	+	+	+
Park et al., 2022	-	X	X	+	-	+	X
Pinho et al., 2022	+	+	?	+	+	+	+
Qu et al., 2021	+	-	-	+	+	+	-
Rashedi et al., 2014	-	+	+	+	+	+	+
Theurel et al., 2018	+	+	X	+	+	+	-
von Glinski et al., 2019	+	-	X	+	+	+	-
Weston et al., 2022	+	+	+	+	+	+	+
Yin et al., 2020	+	+	-	+	+	+	+
Ziaei et al., 2021	+	+	+	+	+	+	+

D1: Bias due to participant characteristics and randomization process
D2: Bias due to deviations from intended study location
D3: Bias due to study duration
D4: Bias due to missing data
D5: Bias due to outcome measurement
D6: Bias due to selection of reported results

Judgement
X High
- Unclear
+ Low
? No information

Fig. 2. Risk of bias assessment for the included articles in this review.

In most studies, a high risk of bias is mostly due to laboratory measurements instead of in-field measurements, and due to short-term duration of the work tasks performed. If the paper did not state the duration of the intervention, or the duration of the tasks was different for every participant (e.g., 'execute this task 10 times, as fast as possible'), the risk of bias was classified as 'unclear' or 'no information'.

3.1. *Exoskeletons*

In total, 49 exoskeletons, with 29 different exoskeleton types, were studied in the included articles. Four of these exoskeletons were active exoskeletons (Huysamen et al., 2018; H. K. Kim et al., 2021; Linnenberg and Weidner, 2022; von Glinski et al., 2019), 23 passive exoskeletons (Alabdilkarim et al., 2019; Alemi et al., 2019; Alemi et al., 2020; Antwi-Afari et al., 2021; Baltrusch et al., 2018; Bosch et al., 2016; de Bock et al., 2021; de Vries et al., 2021; Desbrosses et al., 2021; Giustetto et al., 2021; Harith et al., 2021; Kim et al., 2018a; Kim et al., 2018b; Kim et al., 2020; S. Kim et al., 2021; Linnenberg and Weidner, 2022; Luger et al., 2021; Madinei et al., 2020a; Madinei et al., 2020b; Maurice et al., 2020; McFarland et al., 2022; Omoniyi et al., 2020; Pacifico et al., 2022; Park et al., 2022; Pinho and Forner-Cordero, 2022; Qu et al., 2021; Rashedi et al., 2014; Theurel et al., 2018; Weston et al., 2022; Yin et al., 2020; Ziaei et al., 2021), one semi-passive exoskeleton (Grazi et al., 2020) and one exosuit (a passive exoskeleton without rigid frames) (Goršič et al., 2021). Within those 29 devices, 18 different shoulder, 9 different back, one full body with a supernumerary arm and one combination of shoulder and back exoskeletons were distinguished. The last two exoskeletons (defined as 'Other' in Table 1) were included because the main focus of these two exoskeletons was to support the shoulder and back, and are therefore relevant for this review. In Appendix D, an overview of the evaluated exoskeletons types in the included articles are presented.

3.2. Study design (laboratory or field study)

The aim of this study was to establish a systematic overview of all reported side-effects and adverse events of upper limb and back exoskeleton use in workers/work setting. However, very little research has been done in-field and to fully understand the (potential) side-effects and adverse events of using an exoskeleton, the inclusion protocol deviated from the original eligibility criteria in the PROSPERO protocol. Therefore, studies conducted in a laboratory setting imitating a work-related task (e.g., lifting, carrying, walking) were also included in this review. Of the 36 studies, four were field studies with workers (de Bock et al., 2021; Kim S et al., 2021; Pacifico et al., 2022; Ziaei et al., 2021). The remaining 32 studies were conducted in a laboratory setting, in which three studies recruited construction, industry or farm workers as participants (Antwi-Afari et al., 2019; Omoniyi et al., 2020; Pinho and Forner-Cordero, 2022). Table 1 provides an overview of the exoskeleton type and study design (laboratory or field study) of the included studies.

3.3. Participant characteristics

In total, 655 participants were subjected to an exoskeleton evaluation in the 36 included studies. The ratio of male:female participants was 3:1 (no sex was mentioned for 30 participants). The mean (± standard deviation) age, weight and height of the participants was 30.3 ± 2.4 years old, 72.0 ± 7.1 kg, and 174.9 ± 6.5 cm respectively. In the study of Omoniyi et al. (2020), participants characteristics were not presented, except for the age range (25–70 years). Furthermore, 194 participants (29.6%) were workers and 155 (23.7%) of these workers were evaluated in their workplace.

Table 1

Overview of the types of evaluated exoskeletons and study design (laboratory or field) in this review.

Exoskeleton	Actuation	Assessment	N
Back	Passive	Laboratory	17
		Field	1
		Total	18
	Active	Laboratory	3
		Field	0
		Total	3
	Total		21
Shoulder	Passive	Laboratory	21
		Field	4
		Total	25
	Active	Laboratory	1
		Field	0
		Total	1
	Total		26
Other[a]	Passive	Laboratory	2
		Field	0
		Total	2
	Active	Laboratory	0
		Field	0
		Total	0
	Total		2
Total			49

[a] Other types of exoskeletons used in this review: a full body exoskeleton with a supernumerary arm and a combination of shoulder and back exoskeleton.

3.4. Tasks

In the four workplace studies, the tasks were: overhead and non-overhead work tasks consisting of transferring windscreens from a trailer into a low and a high storage rack and placing the windscreens back onto the trailer, and lifting 20 windscreens from the forklift into the storage rack on their left and right side (de Bock et al., 2021); assembly operators performing their regular (overhead) work tasks in the automotive manufacturing facility (Kim, S. et al., 2021); mounting and dismounting cabinet panels along the paining line (overhead work task) (Pacifico et al., 2022); municipal solid waste collectors lifting the garbage bags in standing, sitting, stopping, and squatting postures (non-overhead work task) (Ziaei et al., 2021). In the remaining studies, simulated work tasks were performed in a laboratory setting with the following tasks: Eleven studies measured the participants during overhead work tasks (e.g., repetitive drilling, painting, or mounting tasks). In fifteen studies, the participants needed to lift, walk, and/or lower objects. In four studies, the participants performed non-overhead assembly work at ankle, knee, hip and/or waist level. In one study, the participants walked overground and on a treadmill while wearing the exoskeleton. One study combined overhead and non-overhead assembly work tasks. Shoulder exoskeletons were mainly used for overhead work tasks, while back exoskeletons were mainly used for non-overhead work tasks (lifting, carrying, and working in bended position).

3.5. Side-effects and adverse events

An overview of the total number of intended effects, side-effects and (serious) adverse events found in the 36 included studies is presented in Table 2. In total 109 side-effects and adverse events were reported in 34 of the included studies. None of the included studies had as primary aim to establish the potential side-effects. Side-effects which were mostly reported were discomfort (in 23 out of 36 studies) and limited usability (in 11 out of 36 studies). In Appendix C, Table 3 contains a more extensive report about the outcome measurements used for measuring side-effects and adverse events, the results of the reported side-effects and/or adverse events in the studies and if the reported effects were intended effects of the exoskeleton, side-effects or (serious) adverse events, or when the study measured side-effects but did not find any. In Appendix E an overview of the measured side-effects is shown in combination with which measurement tool was used to measure these effects.

3.6. Conflict of interest

The following three studies reported a conflict of interest (COI) due to a financial or personal interest or due to a patent for the exoskeleton (Table 2): Alemi et al. (2019), Pacifico et al. (2022) and Ziaei et al. (2021). The reasons given for COI mentioned in the papers were: co-authors having a patent for the studied exoskeleton, co-authors having interests in the spinoff company, or co-authors being developer of the used technology. Absence of COI reports was observed in 14 studies. All other studies (n = 19 (53%)) reported no COI.

4. Discussion

The main aim of this systematic literature review was to establish a systematic overview of side-effects and adverse events of upper limb and back exoskeleton use in workers/during work tasks. Whether reported side-effects and adverse events differ between gender, physical fitness,

Table 2
Overview of the number of the measured and/or observed intended effects, side-effects, adverse events, serious adverse events, and the number of no side-effects or adverse events found.

	Intended	Side-effect	Adverse event	Serious adverse event	Total (side-effects + (serious) adverse events	No side-effects/adverse events found
Discomfort	1	27	3	0	30	3
Muscle activity	3	10	3	0	13	2
Mobility	0	6	0	0	6	1
RPE	1	3	1	0	4	5
Usability	0	14	2	0	16	3
Energy expenditure	0	1	2	0	3	0
Perceived effort	1	4	1	0	5	2
Perceived task difficulty	0	1	2	0	3	0
Perceived contact pressure	2	4	0	1	5	0
Perceived physical demand	0	0	1	0	1	1
Perceived work intensity	0	0	1	0	1	0
Balance	0	1	1	0	2	1
Posture	0	2	1	0	3	1
Trip- and slip-related falls	0	0	0	0	0	1
Cardiovascular response	0	0	1	0	1	0
Oxygen consumption	0	0	1	0	1	1
Neurovascular supply	0	1	0	0	1	0
Task performance	0	3	2	0	5	2
Gait parameters	0	3	0	0	3	0
Safety	0	1	0	0	1	0
Health	0	0	1	0	1	0
Productivity	0	1	0	0	1	0
Job & timing	0	1	0	0	1	0
Frustration	0	0	0	0	0	1
Precision	0	1	1	0	2	0
Donning/doffing	0	0	0	0	0	1

age and type of exoskeleton (e.g., active or passive support) was a second aim of this review. In the 36 included articles, 34 studies reported one or more side-effects and/or adverse events, according to the definition of side-effects and adverse events described in the introduction. Two studies did not report any side-effects (Desbrosses et al., 2020; Grazi et al., 2020),. In total, 109 side-effects and adverse events were observed, mostly mild discomfort and a limited usability. Psychological effects and social impact was only measured in two studies (Omoniyi et al., 2020; Qu et al., 2021). 12 reported side-effects showed differences among gender, physical fitness and age. Generalisation of the results is limited because only four in-field studies were included and only one study measured the long-term effects of using an exoskeleton in the workplace. The results suggest that laboratory-based results do not always transfer to all in-field conditions and further investigation on implementation of long-term use of exoskeletons in the workplace is needed. This is recommended for providing better insights in the current safety and health knowledge gaps (Ali et al., 2021; Bessler et al., 2020; de Looze et al., 2016; Howard et al., 2020; Kermavnar et al., 2021; Luger et al., 2021).

4.1. *Side-effects and adverse events*

The most observed side-effect is discomfort. Participants experienced discomfort mostly in the legs, waist, chest and shoulders due to the leg straps, buttock- and waist-belts, chest plates and shoulder straps. One study even reported that the pressure on the arms exceeded the threshold for adequate blood supply, which could cause pain sensation and tissue damage in long-term use. These high pressures might be considered as a serious adverse event (Huysamen et al., 2018; Linnenberg and Weidner, 2022). A main limitation of all included studies was that none of the included articles studied the long-term effects of discomfort and the increased contact pressure, such as skin damage. The difference in definition of discomfort used in the included studies as mentioned in section 2.3, made it difficult to determine if an effect was a side-effect or an intended effect of the exoskeleton use. Some authors describe discomfort as the perceived physical load on the body while doing a task. Because reducing the physical load is the primarily aim of an exoskeleton, many studies reported a reduction in discomfort and therefore discomfort was not reported as a side-effect. However, other studies described discomfort as any uncomfortable feeling or feeling of contact pressure due to the human-machine interaction, which is an unwanted side-effect of using the exoskeleton. Therefore, only results of this last definition of discomfort is reported in this review as side-effect or adverse event.

Another side-effect found in this review is the limited usability. Due to discomfort, fit of the exoskeleton (i.e., heavy, bulky and wrong fit), hindrance of mobility and the feeling of awkwardness while using the exoskeleton, the usability and the intention-to-use decreased. Some participants expressed that movements with an exoskeleton is not always consistent with their normal movements making them to perceive the work task as more difficult (Antwi-Afari et al., 2021; Baltrusch et al., 2018; Huysamen et al., 2018; Omoniyi et al., 2020). A reason for the experienced movement discomfort might be that joints of exoskeletons are often simplified compared to human joints which leads to limitations in the available degrees of freedom (Bessler et al., 2021). In some studies, the effectiveness of the exoskeleton was questioned because of the side-effects found in task performance, precision and gait parameters. Furthermore, the use of an exoskeleton can be effective with a certain work task, but restricting in performing other task. For example, a shoulder exoskeleton is mostly used for overhead tasks, but usability can be reduced in performing non-overhead work tasks. This unintended use of exoskeleton could also lead to side-effects.

The exoskeleton can be effective with a certain specific work task, but could be restricting in performing other tasks. The results also show that exoskeletons are more effective in symmetric tasks compared to asymmetric tasks. Because work tasks often require more asymmetric movements than the simulated work tasks in the laboratory, the results found in the laboratory may not extend to the same results in a work setting.

Remarkably, almost no psychological side-effects or social impact of exoskeletons were reported. In the study of Omoniyi et al. (2020), it was mentioned that the participants had a fear of being trapped when moving into narrow spaces since the exoskeleton is perceived as bulky. This same result was found in the systematic review of Bessler et al. (2020) about the side-effects in gait robots. Qu et al. (2021) reported that participants found that the exoskeleton looks moderately awkward, which decreases the acceptability to use the exoskeleton. These findings are in line with earlier results in the review of Crea et al. (2021) about the challenges of bringing exoskeletons to workplaces. The authors addressed the major gap in literature that still exists regarding social measures, for example attitude toward exoskeletons and the social perception of exoskeletons. Exoskeletons will only be implemented in the work-field if they effectively reduce physical and mental loads, and if they are socially accepted. It is therefore recommended that companies adopt different strategies to gain more (social) support among their workers, for example with demonstrations or training in order to improve workers' expectations about the usability of exoskeletons (Elprama et al., 2020).

4.2. Exoskeleton use in the workplace

Four studies were conducted in a workplace with industrial workers. The remaining 32 studies were all conducted in a controlled laboratory setting. Even though the participants performed simulated work tasks in a laboratory setting, the results are difficult to compare to work tasks performed in a workplace. In the laboratorial studies, participants typically performed static bending or lifting tasks, and less complex tasks. Additionally, the simulated work tasks were often adjusted to the participants body (e.g., overhead work tasks adjusted to their body height, or lifting tasks adjusted to their body weight). In addition, the participants often performed simulated work tasks for only a short duration (circa few hours) with several rest periods in between, whereas the participants in two field-studies wore the exoskeleton for an entire workday (Kim, S. et al., 2021; Ziaei et al., 2021). It is known that results observed in the laboratory are not always transferable during in-field work. An example is how the temperature of the environment could make a difference on how users perceive the comfort of the exoskeleton. In Ziaei et al. (2021) the workers complained about sweating and heat stress while using the exoskeleton. Previous research also showed that wearing the exoskeleton in a cold environment (±10 °C) improves the comfort compared to a warmer environment (±25 °C) (Liu et al., 2021). Therefore, laboratory-based results should be interpreted with caution because these results cannot be transferred to all in-field conditions (de Bock et al., 2021). The small proportion of workplace-based studies reflects a limitation of the knowledge base thus far.

4.3. Study design

There was only one longitudinal in-field study in this review, where participants wore the exoskeleton for 18 months (Kim, S. et al., 2021). This study showed that perceived work intensity and discomfort did not decrease after wearing an exoskeleton for 18 months, even though it was expected that these effects would decrease due to a reduction in peak muscle activity. This may be due to participants adopting different body postures while wearing an exoskeleton (Bosch et al., 2016; Huysamen et al., 2018; Kim, S. et al., 2021). The majority of the included studies only measured the use of exoskeleton for an hour or several hours for 1 or 2 days. Longitudinal research is needed to determine which other side-effects could potentially occur. For example, several studies showed that exoskeleton use leads to a decreased activity of superficial back muscles (e.g. lumbar extensors in a back exoskeleton) and increased activity in abdominal or leg muscles (de Looze et al., 2016; Kermavnar et al., 2021; Luger et al., 2021). However, it is unknown whether this decrease in muscle activity might lead to a side-effect of muscle weakness and deconditioning in the long-term. None of the included studies has addressed the potential long-term side-effects. The observation that only one long-term study was performed reflects a limitation of the study of side-effects of exoskeletons. Future studies should establish the effect of long-term exoskeleton use on back muscle strength.

4.4. Exoskeleton use in subpopulations

There were some differences between males and females reported in muscle activity (n = 3 side-effects reported), discomfort (n = 4), perceived balance (n = 1) and energy expenditure (n = 1). Differences in muscle activity and discomfort was sometimes depended on the type of exoskeleton used. For example, the Laevo exoskeleton caused more discomfort for females in the chest, thighs, waist and buttocks. Males on the other hand often expressed more discomfort in the torso and ribcage. Furthermore, some studies showed that males had less large reductions in EMG, other studies reported higher EMG in females. One study observed that females modify their working posture to a larger extent compared to males (Kim, S. et al., 2020). Another study showed that males had less large reductions in energy expenditure than females (Madinei et al., 2020).

Only one study mentioned differences in physical fitness (Goršič et al., 2021). This study reported that people with a lower fitness tended to experience more difficulties with adjusting to the exoskeleton. However, more research is recommended to draw clear conclusions on the effect of physical fitness on using an exoskeleton.

All study used relatively young and healthy adults, only the study of Omoniyi et al. (2020) had relatively older participants (age range between 25 and 70 years old). They reported that younger persons (<49 years old) tended to report the device as being not supportive enough and not restrictive enough. All studies used healthy participants so differences in BMI was not reported. Differences for health literacy was also not mentioned.

Only four active exoskeletons could be evaluated in this study; all other studies evaluated passive exoskeletons. 23 Passive exoskeletons, one semi-passive exoskeleton and one passive exosuit were also included in this review. The exosuit was less efficient in heavier lifting tasks, and it was therefore recommended to only use the exosuit in tasks with a lighter load (Goršič et al., 2021). Results on passive and active exoskeletons are comparable. Both types of exoskeletons causes discomfort on the contact areas of the exoskeleton on the body, a decrease in neurovascular supply and changes in posture while doing lifting tasks. Some participants did report that active exoskeletons are perceived as bulky, heavy and complex to use. According to Kim, H. K. et al. (2021), active exoskeletons are generally heavier than passive exoskeletons because of the actuators. Since most research is done on passive exoskeletons, it is recommended to also include more active exoskeletons in studies, so that differences between these types of exoskeletons are more clear.

Because most studies were conducted in a laboratory setting with volunteers, the study population was often around the same age and some studies only selected subjects with a healthy BMI so that the exoskeleton would properly fit. Most studies did not measure differences between age and physical fitness. Future research should include measurements on differences between subpopulations, to draw more distinct conclusions.

4.5. Risk of bias and conflict of interest

In most studies, the risk of bias is low or unclear. Most studies evaluated the potential side-effects in the laboratory, it is unclear how these results could be transferable to the working environment. Furthermore, only 1 longitudinal study was included. It remains unclear how long-term wearing of an exoskeleton could influence the potential side-effects and adverse events.

Heterogeneity between type of exoskeleton (back or shoulder) and type of work tasks (overhead or non-overhead) may have impacted the results. It is conceivable to assume that side-effects and adverse events are specific to the task performed. For example, while highly repetitive movements with low loads might irritate the skin, tasks involving heavy lifting but with only few repetitions are more likely to cause immediate discomfort due to high pressure. By including all work-related tasks, heterogeneity was accounted for between tasks and exoskeleton type. However, future experimental studies should aim to minimize heterogeneity of work related tasks and establish task specific side-effects or adverse events.

The studies with a COI did not seem to report more positive results than the studies without COI. Half of the studies (53%) did not report a COI statement, which leaves substantial room for improvement.

4.6. Strengths and limitations

This is the first review that has led to a systematic overview of side-effects and adverse events of exoskeletons intended for the workplace, including knowledge gaps.

A main limitation of the included studies is that evaluating the side-effects and/or adverse events was often not measured in a work-environment but in the laboratory. As mentioned in section 4.2, results from the laboratory may not always be transferable to the work-environment. Additionally, studies that did not measure the side-effects or adverse events were not included in this review, leading to an absence of evidence on how frequently these effects occur. Furthermore, to draw more distinct conclusions, high quality RCT studies are required including potential skin damage due to contact pressure, usability and differences between subpopulations as side-effects. The findings of this systematic review need to be interpreted with care. The used databases for the article screening inspected the entered search terms in titles, abstracts, and keywords of articles. During the screening of the articles, it was noticed that information on side-effects or adverse events is often not contained in those elements but also in the body of the text. This complicated the search for relevant articles. It is recommended to report observed side-effects in the abstract so that all relevant effects can be immediately identified with this method. Furthermore, risk of bias was assessed by a single reviewer, which is not in accordance with the PRISMA guidelines.

4.7. Implications

The results of this systematic review can be used to raise awareness of the potential side-effects that could occur and therefore the safety of using an exoskeleton in the workplace. While the potential benefits of exoskeleton use are well described in the user manuals, potential side-effects and adverse events receive little to no attention. Manufactures should provide the user with complete and accurate information about the benefits and risks of using the exoskeleton to allow the user, clinicians and policy makers to make an informed decision on exoskeleton use. The main known side-effects and adverse events that evaluators should provide are discomfort due to contact pressure and usability (including unintended use of exoskeleton). More research is necessary to investigate long-term side-effects, in-vivo side-effects, psycho-social side-effects, differences for subpopulations, and combinations. This systematic review is a first step to provide objective information on potential side-effects on exoskeleton use and provides the community with recommendations for future research on this subject. Furthermore, this review could also be useful to increase knowledge on safe exoskeleton use in the workplace and therefore improve the acceptability among workers and possibly reduce the incidence of musculoskeletal disorders.

5. Conclusion

This present systematic review evaluated 36 included articles on the short- and long-term side-effects and adverse events on using an upper-limb exoskeleton in the workplace. Of the 109 observed side-effects, the most frequent side-effect found was discomfort due to the human-machine interaction, followed by a limited usability. Other reported side-effects are muscle activity, RPE, perceived task difficulty and effort, balance and posture, neurovascular supply, task performance, gait and precision. Most of the side-effects are related to an incorrect fit of the model, uncomfortable materials (e.g., straps, belts, plates), or a mismatch between the exoskeleton and human joints causing a restricted mobility. Research on psychological and social effects of using exoskeletons was scarce. Differences in muscle activity, discomfort, posture, energy expenditure, level of support and usability were also found between males and females, different ages, and different levels of physical fitness.

To allow evidence based decisions on exoskeleton use in the workplace and improve acceptability among workers, future studies should investigate the effects of long-term (>3 months) exoskeleton use in working environments including measures of psychosocial parameters.

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.

Acknowledgements

The authors would like to thank Diederik de Boer for his help during the study selection.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.apergo.2023.104042.

Appendix B

Search string PubMed

(exoskeleton device[MeSH Terms] OR wearable robot[MeSH Terms] OR exosuit[MeSH Terms] OR orthotic device*[MeSH Terms] OR exoskeleton [Title/Abstract]) AND (upper extremity[MeSH Terms] OR upper limb[MeSH Terms] OR upper-limb[MeSH Terms] OR shoulder[MeSH Terms] OR back[MeSH Terms] OR lumbar[MeSH Terms] OR spine[MeSH Terms] OR cervical[MeSH Terms] OR thoracal[MeSH Terms] OR trunk[MeSH Terms]) AND (work*[Title/Abstract] OR industrial[Title/Abstract] OR workers[Title/Abstract] OR labor[Title/Abstract] OR labour[Title/Abstract])

Search string Embase

('exoskeleton device'/exp OR 'wearable robot'/exp OR 'exosuit'/exp OR 'orthotic device*'/exp OR 'exoskeleton':ab,ti) AND ('upper extremity'/exp OR 'upper limb'/exp OR 'upper-limb'/exp OR 'shoulder'/exp OR 'back'/exp OR 'lumbar'/exp OR 'spine'/exp OR 'cervical'/exp OR 'thoracal'/exp

OR ‘trunk’/exp) AND (‘work*’ OR ‘industrial’ OR ‘workers’ OR ‘labor’ OR ‘labour’):ab,ti.

Appendix C

Table 3
Overview of the outcome measurements used for measuring side-effects and adverse events and the results

References COI: no/yes/ NR (not reported)	Exoskeleton	Outcome measure	Results$^{\text{I=intended effect, SE=side-effect, AE=adverse event, SAV=serious adverse event, N/A=not applicable}}$
Alabdulkarim et al., 2019 COI: no	- Fawcett (shoulder, passive) - The EksoWorks Vest (shoulder, passive) - The FORTIS (full-body, passive) with a supernumerary arm	Muscle activity	Exoskeleton use increased muscle activity in high precision tasks^{SE}
		Precision (number of errors made)	Exoskeleton use increased the number of errors made (70–100%) in high precision tasks^{SE}
		RPE[a]	Increase in RPE in low back and thighs with Fawcett and FORTIS^{SE} FORTIS led to significantly higher RPEs in the legs and feet among males^{SE}
		Muscle activity	Females experienced 58–125% higher total EMG activation than males^{AE}
Alemi et al., (2019) COI: yes	VT-Lowe’s exoskeleton (back, passive)	Discomfort	Slight discomfort due to leg straps and pads on the thighs^{SE}
		Muscle activity	Increase of 16–39% of EMG in the external oblique muscles, variability depended on weight and height of participant^{SE} Exoskeleton less supportive in asymmetric lifting compared to symmetric lifting^{SE}
Alemi et al., (2020) COI: NR	BackX (back, passive) Laevo (back, passive)	Energy expenditure: O2 and CO2 uptake rates	Less reductions in energy expenditure in asymmetric compared to symmetric lifting^{SE}
		Muscle activity	Exoskeleton less supportive in asymmetric lifting compared to symmetric lifting^{SE} Less reduction of trunk extensor muscle activity for males compared to females^{AE}
		Discomfort	Moderate to high discomfort in chest, waist and thigh^{SE} Males reported 36% higher discomfort in lower thigh compared to females^{AE} Laevo 38% higher chest discomfort in all task conditions compared to SuitX, likely due to its chest plate^{SE}
		Perceived balance	No side-effects or adverse events found$^{N/A}$
		Overall usability: fit, comfort and body movement constraints	Ratings of fit: BackX scored better than Laevo^{SE} Concerns from females about chest and thigh pads of Laevo and fit of waist pad and buttock belts^{SE} Concerns from males about contact between torso rods and ribcage while twisting^{SE}
Antwi-afari et al., 2021 COI: no	Passive back exoskeleton	Discomfort	Connection straps at shoulder were too tight^{SE} Increased lifting load led to increased discomfort^{I}
		Muscle activity	Muscle activity increases with increasing lifting load^{I}
		Perceived musculoskeletal pressure	Increase of perceived musculoskeletal pressure with increasing load^{SE}
		Usability	Some participants found the exoskeleton too bulky to use or that their range of movements were not always consistent with their normal movements^{SE}
Baltrusch et al., (2018) COI: NR	Laevo (back, passive)	Perceived task difficulty	Perceived task difficulty increased in tasks when wearing the exoskeleton^{SE} Efficacy in terms of reduction of back loading and support of the tasks was limited^{AE}
		Discomfort	Discomfort in chest, upper legs and hips due to chest and leg pads^{SE} Walking and tasks requiring a large range of motion causes more discomfort due to limited mobility^{SE}
		Task performance	Decrease in performance in tasks requiring a large range of motion^{SE}
Bosch et al., (2016) COI: NR	Laevo (back, passive)	Discomfort	Increase in discomfort in the chest due to the chest pads and in armpits due to pressure and friction of the straps^{SE}
		Posture	Knees were in an over-extended position when using the exoskeleton, which may shift the health risk from the back to the knees^{SE}
De Bock et al., (2021) COI: NR	- ShoulderX (shoulder, passive) - Skelex (shoulder, passive)	Muscle activity	Muscle activity reductions less pronounced during in-field work than in laboratory setting^{SE}
		Discomfort	Increased upper body discomfort and frustration (especially in ShoulderX)^{SE}
De Vries et al., (2021) COI: no	Passive shoulder exoskeleton	RPE	No side-effects or adverse events found$^{N/A}$
		Usability	Issues with arm cuffs and size of the device, causing hindrance during specific working tasks^{SE}
Desbrosses et al., (2021) COI: no	- EXHAUSS Stronger (shoulder, passive) - SKEL-EX V1 (shoulder, passive)	Postural balance	Moderate consequences for balance regulation^{SE}
		Perceived effort	No side-effects or adverse events found$^{N/A}$
		Usability	A light exoskeleton is advised in light overhead work tasks^{SE}
Giustetto et al., (2021) COI: no	Laevo (back, passive)	Discomfort	Increase of discomfort in chest region due to contact pressure between the exoskeleton and body^{SE} Increase of discomfort in feet due to exoskeleton-related differences in postural control (task depended)^{SE}
		Perceived effort	Individual variability and task depended (in dynamic task no improvement in perceived effort)^{SE}
		Muscle activity	Individual variability and task depended^{SE}

(*continued on next page*)

Table 3 (*continued*)

References COI: no/yes/ NR (not reported)	Exoskeleton	Outcome measure	Results$^{\text{I=intended effect, SE=side-effect, AE=adverse event, SAV=serious adverse event,N/A=not applicable}}$
		Task performance	No side-effects or adverse events found$^{N/A}$
Goršič et al., (2021) COI: no	HeroWear Apex back-assist exosuit (back, passive)	Perceived effort	Exosuit is less helpful in lifting heavier loads^{SE}
			Range of movement can be limited in some tasks^{SE}
		Discomfort	Exosuit is mildly annoying due to discomfort^{SE}
			Wearers have different adjustment periods to the exosuit (people with lower fitness tended to experience more difficulties)^{SE}
Grazi et al., (2020) COI: NR	H-pulse exoskeleton (shoulder, passive)	Perceived physical demand	No side-effects or adverse events found$^{N/A}$
		Perceived effort	No side-effects or adverse events found$^{N/A}$
		Frustration	No side-effects or adverse events found$^{N/A}$
Harith et al., (2021) COI: no	Passive shoulder exoskeleton	Discomfort	Upper arm rated as least comfortable, followed by the shoulder due to exoskeleton design^{SE}
		Usability	No side-effects or adverse events found$^{N/A}$
Huysamen et al., (2018) COI: NR	Active back industrial exoskeleton	Contact pressure	Contact pressure 'somewhat strong' in upper legs due to the connection cuffs at the thighs^{SE}
		Perceived effort	Perceived effort increases with higher loads^{I}
		Perceived musculoskeletal pressure	Highest pressure on the trunk, followed by thighs^{SE}
		Posture	Wearing an exoskeleton causes different lifting techniques due to physical restriction^{SE}
		Usability	Some participants found the device complex to use, or movements not always consistent with their natural movements^{SE}
Kim HK et al., 2021 COI: NR	Active back-support exoskeleton	RPE	Increased RPE (could be because of more muscle activity in other body parts or the exoskeleton was psychologically rejected by the participant)^{SE}
		Mobility	Reduction in walking speed^{SE}
		Discomfort	Discomfort while doing tasks^{SE}
		Usability	Exoskeleton is perceived as heavy^{SE}Limited usability^{SE}
Kim S et al., 2018a COI: no	EksoVest (shoulder, passive)	Precision	Increased number of errors in overhead work task compared to overhead work task without exoskeletal vest^{SE}
		Discomfort	No side-effects or adverse events found$^{N/A}$
Kim S et al., 2018b COI: no	Exoskeletal vest (passive, shoulder)	Donning/doffing the exoskeletal vest	No side-effects or adverse events found$^{N/A}$
		Mobility	Reduction of range of motion in the shoulder^{SE}
		Postural balance	Increase (12%) in mean velocity of centre of pressure (COP MV)^{SE}
		Trip- and slip-related falls during walking	No side-effects or adverse events found$^{N/A}$
Kim S et al., 2020 COI: no	- BackX (passive, back) - Laevo (passive, back)	Muscle activity	No side-effects or adverse events found$^{N/A}$
		Perceived balance	Females appeared to modify their working postures to a larger extent than males, depending on the specific work height^{AE}
		Discomfort	Moderately high discomfort in the chest and waist (task depended)^{SE}
			Males experienced more discomfort than females^{AE}
		Usability	Variable results on 'intention-to-use', mainly depended on level of discomfort^{SE}
Kim S et al., 2021 COI: no	EksoVest (passive, shoulder)	Perceived work intensity	No improvement in perceived work intensity with using an exoskeleton^{AE}
		Discomfort	No improvement in reducing strain in neck and shoulder^{AE}
		Physical demand	Minimal or negative impact on the shoulder (task depended)^{AE}
Linnenberg and Weidner, 2022 COI: no	- The Mate exoskeleton (passive, shoulder) - The Lucy exoskeleton (active, shoulder) - The Paexo (passive, shoulder) - Skelex 360 exoskeleton (passive, shoulder)	Neurovascular supply (fatigue and distress, pain, drop of the arms)	Duration of Roost test shortened by 20s; negative influence of the exoskeleton on the vascular or neuronal system (due to arm interface or weight and fit)^{SE}
		Human-machine interface pressure	Pressure in the arm exceeds the threshold for adequate blood supply and can therefore harm in long term^{SAE}
Luger et al., (2021) COI: NR	Laevo (back, passive)	Muscle activity	Knee flexion increased with 21% due to compensating the pressure of the leg pads against the upper leg^{SE}
		Task performance	Task duration was significantly longer^{SE}
		Perceived task difficulty	Increase in perceived task difficulty^{AE}
		Usability	No side-effects or adverse events found$^{N/A}$
		Discomfort	33–133% increased discomfort in the chest^{SE}
Madinei et al., (2020a) COI: no	- Laevo (passive, back) - BackX (passive, back)	Discomfort	Discomfort at the chest with Laevo due to its chest plate^{SE}
			Females experience higher discomfort at waist and thighs when using BackX due to the waist belt and thigh pads^{SE}
		RPE	No side-effects or adverse events found$^{N/A}$
		Muscle activity	Less large reduction of muscle activity in males compared to females^{AE}
		Energy expenditure	Less large reductions of energy expenditure among males compared to females^{AE}
		Usability and user feedback	Hindrance when using Laevo due to shifting and moving of the chest and thigh pads, the fit of the waist pad and buttock belts (for females)^{SE}
			Contact between the torso rods and their ribcage while twisting (for males)^{SE}
Madinei et al., (2020b)	- Laevo (passive, back)	RPE	No side-effects or adverse events found$^{N/A}$

(*continued on next page*)

Table 3 (*continued*)

References COI: no/yes/ NR (not reported)	Exoskeleton	Outcome measure	Results$^{\text{I=intended effect, SE=side-effect, AE=adverse event, SAV=serious adverse event,N/A=not applicable}}$
COI: NR	- BackX (passive, back)		
		Task performance	Increase in task completion time^{AE}
Maurice et al., (2020) COI: NR	PAEXO (passive, shoulder)	Muscle activity	No side-effects or adverse events found$^{N/A}$
		Postural control	No side-effects or adverse events found$^{N/A}$
		Mobility	Arm bracelets were constricting their arms^{SE}
		Discomfort	No side-effects or adverse events found$^{N/A}$
McFarland et al., (2022) COI: no	Passive shoulder exoskeleton	Postural changes	Shoulders externally rotated while wearing the exoskeleton instead of internally causing repetitive stress on the muscular and ligamentous contributions to maintain stability^{AE}
		RPE	Higher RPE in overhead task compared to non-overhead task^{I}
		Discomfort	Higher discomfort in overhead task compared to non-overhead task^{SE}
		Task performance	No side-effects or adverse events found$^{N/A}$
Omoniyi et al., (2020) COI: no	Laevo (passive, back)	Safety	Fear of being trapped while moving through narrow or confined spaces, exoskeleton getting caught on surrounding items^{SE}
		Health	Some participants said the exoskeleton is not supportive enough for long-term health benefits (mainly age <49 years old)^{AE}
		Mobility	Exoskeleton is restricting or limiting movements by hindering their stride^{SE}
		Productivity	Putting on and removing the exoskeleton could affect productivity^{SE}
		Discomfort	Discomfort due to the leg pads and chest plate and the exoskeleton being bulky^{SE}
		Usability	Difficulty with leg pads, body frame and the supportive pad on the chest and additional maintenance work needed (cleaning the device)^{SE}
		Job and timing	Exoskeleton is not suitable for all tasks and difficult to predict when you need the exoskeleton for work and when not (e.g., for sitting you don't need the exoskeleton)^{SE}
Pacifico et al., (2022) COI: yes	MATE Exoskeleton (passive, shoulder)	RPE	No side-effects or adverse events found$^{N/A}$
		Muscle activity	In-field more variability in results compared to laboratory setting^{SE}
		Usability	No side-effects or adverse events found$^{N/A}$
Park et al., (2022) COI: no	BackX (passive, back)	Gait parameters	Reduced step length and increased swing time^{SE}
			Increased step width by 8–12% to enhance lateral stability by increasing the base-of-support (but increases energetic costs in longer-term walking)^{SE}
			Medio-lateral margin of stability decreased in swing-phase (i.e., more unstable stability compared to control condition)^{SE}
Pinho and Forner-Cordero, 2022 COI: no	ShoulderX (passive, shoulder)	Task performance	Wearing the exoskeleton increases task completion time in some tasks^{AE}
		Perceived effort	No side-effects or adverse events found$^{N/A}$
		Discomfort	No side-effects or adverse events found$^{N/A}$
Qu et al., (2021) COI: NR	IPAE exoskeleton (passive, shoulder and back)	Oxygen consumption	No side-effects or adverse events found$^{N/A}$
		RPE	No significant reduction of fatigue^{AE}
		Pressure	Highest perceived pressure on the shoulder^{I}
			As lifting time increases, LPP score increases as well^{I}
		Discomfort	Highest contact pressure on the thighs due to the leg units^{SE}
			Contact pressure on shoulders and wrist due to narrow straps^{SE}
		Usability	Longer use may reduce the acceptance^{AE}
			Exoskeleton looks moderately awkward which decreases the acceptability^{SE}
Rashedi et al., (2014) COI: NR	Exoskeletal vest WADE (passive, shoulder)	Discomfort	Increase in physical demand on the low back (24–48%) due to loose fit of the shoulder straps^{SE}
		Muscle activity	Exoskeleton did not reduce the total load on the worker, but rather shifted the load from the shoulders to the lower back and legs^{SE}
		Mobility	Torso movements relative to the pelvis are constrained because of the rigid vertical exoskeleton connection to the shoulder to the waist part^{SE}
Theurel et al., (2018) COI: no	EXHAUSS Stronger (passive, shoulder)	Muscle activity	No effect on shoulder muscular strain while carrying a heavy toolbox^{SE}
			Increase in average workload in the triceps brachialis (antagonist) during lifting (+95%) and stacking (+116%) tasks^{I}
		Oxygen consumption	Absolute cardiac cost increased (+14%) during lifting tasks^{AE}
		Task performance	Time to complete the task increased with 30%^{SE}
		Perceived effort	Participants did not perceive real improvement when using the exoskeleton^{AE}
Von Glinski et al., (2019) COI: NR	Hybrid assistive limb exoskeleton (HAL) (active, back)	Muscle activity	Increase in muscle activity in quadriceps femoris^{I}
		Cardiovascular response	Heart rate variability did not change^{AE}
		Discomfort	14.3% of the subjects reported discomfort attributed to pressure points in the lower back area^{SE}
		Usability	35.7% would not use HAL in-field, 21.4% maybe^{AE}
Weston et al., (2022) COI: no	- Ekso Bionics Ekso Vest (passive, shoulder) - Levitate AIRFRAME (passive, shoulder) - ShoulderX (passive, shoulder)	Discomfort	Light discomfort in most body regions. Highest discomfort in the shoulder (2.3), upper arms (1.7), hands and wrists (1.4), and the lower back (1.9)^{SE} Discomfort in the shoulder and upper arms was significantly higher for the ShoulderX than the Ekvo Vest and AIRFRAME^{SE}
Yin et al., (2020)	The PULE (passive, shoulder)	Discomfort and feedback	Discomfort in shoulders, upper and forearms^{SE}

(*continued on next page*)

Table 3 (*continued*)

References COI: no/yes/ NR (not reported)	Exoskeleton	Outcome measure	Results[I=intended effect, SE=side-effect, AE=adverse event, SAV=serious adverse event, N/A=not applicable]
COI: NR			
		Perceived effort	Three participants reflected that the supported forces from the exoskeleton was too large, and needed to take some effort to put down their arms[SE]
		Mobility	Upper body movements were constrained because of the rigid parts of the exoskeleton[SE]
Ziaei et al., (2021) COI: yes	Ergo-Vest (passive, back)	Energy expenditure	No improvement in energy expenditure and heart rate (indicating the same physiological workload)[AE]
		RPE	No side-effects or adverse events found[N/A]
		Usability	Wearing the exoskeleton over the uniform, in hot weather, may prevent free passage of air in the inner part of the dress which may cause sweating and heat stress[SE]
		Mobility	No side-effects or adverse events found[N/A]

a. RPE = Ratings of Perceived Exertion.

Appendix D

Table 4
Exoskeleton names and types used in this review. N = number of studies in which the exoskeleton is studied

Exoskeleton	Type of exoskeleton	N
Fawcett Exovest	Shoulder (passive)	1
EksoBionics EksoVest	Shoulder (passive)	2
FORTIS	Full-body with supernumerary arm (passive)	1
VT-Lowe's exoskeleton	Back (passive)	1
BackX™	Back (passive)	5
Laevo V2.5	Back (passive)	9
Skelex	Shoulder (passive)	2
ShoulderX	Shoulder (passive)	3
EXHAUSS Stronger	Shoulder (passive)	2
SKEL-EX V1	Shoulder (passive)	1
HeroWear Apex exosuit	Back (passive)	1
H-pulse exoskeleton	Shoulder (semi-passive)	1
EksoVest	Shoulder (passive)	2
The Mate exoskeleton	Shoulder (passive)	2
The Lucy exoskeleton	Shoulder (active)	1
PAEXO	Shoulder (passive)	2
IPAE	Back and shoulder (passive)	1
Hybrid Assistive Limb (HAL)	Back (active)	1
Levitate AIRFRAME	Shoulder (passive)	1
PULE	Shoulder (passive)	1
ErgoVest	Back (passive)	1
Name of exoskeleton not mentioned	Back (passive)	1
Name of exoskeleton not mentioned	Back (active)	2
Name of exoskeleton not mentioned	Shoulder (passive)	5

Appendix E

Table 5
Overview of outcome measurements for side-effects and adverse events and the measurement tools

Measurement	
Ratings of Perceived Exertion (RPE)	Borg's 10-point scale
Muscle activity	Surface EMG
Discomfort	Borg's 10-point scale
	7-point Likert scale
	5-point Likert scale
	Questionnaire with Visual-Analog Scale (VAS)
	Adapted Corlett and Bishop Scale (0–5 point scale)
Energy expenditure	O2 and CO2 uptake rates
	Heart Rate Variability (HRV)
Usability	7-point Likert scale
	5-point Likert scale
	1-5 System Usability Scale (SUS)
Perceived task difficulty	Questionnaire with Visual-Analog Scale (VAS)
Perceived effort	Borg's 10-point scale
	−5 to + 5 scale
Perceived pressure	Local Perceived Pressure (LPP) scale (0–10)
Precision	Number of errors made
Task performance	Time to complete the task
	Maximal weight lifted
	Endurance time

(*continued on next page*)

Table 5 (*continued*)

Measurement	
Workload (mental and physical demand, perceived effort and frustration)	NASA-Task Load Index questionnaire (NASA-TLX)
Postural balance	Force plate
Mobility	TUG test

References

Alabdulkarim, S., Kim, S., Nussbaum, M.A., 2019. Effects of exoskeleton design and precision requirements on physical demands and quality in a simulated overhead drilling task. Appl. Ergon. 80, 136–145. https://doi.org/10.1016/j.apergo.2019.05.014.

Alemi, M.M., Geissinger, J., Simon, A.A., Chang, S.E., Asbeck, A.T., 2019. A passive exoskeleton reduces peak and mean EMG during symmetric and asymmetric lifting. J. Electromyogr. Kinesiol. 47, 25–34. https://doi.org/10.1016/j.jelekin.2019.05.003.

Alemi, M.M., Madinei, S., Kim, S., Srinivasan, D., Nussbaum, M.A., 2020. Effects of two passive back-support exoskeletons on muscle activity, energy expenditure, and subjective assessments during repetitive lifting. Hum. Factors 62 (3), 458–474. https://doi.org/10.1177/0018720819897669.

2021 Ali, A., Fontanari, V., Schmoelz, W., Agrawal, S.K., 2021. Systematic review of back-support exoskeletons and soft robotic suits, Nov 2 Front. Bioeng. Biotechnol. 9, 765257. https://doi.org/10.3389/fbioe.2021.765257. PMID: 34805118; PMCID: PMC8603112.

Antwi-Afari, M.F., Li, H., Anwer, S., Li, D., Yu, Y., Mi, H.Y., Wuni, I.Y., 2021. Assessment of a passive exoskeleton system on spinal biomechanics and subjective responses during manual repetitive handling tasks among construction workers. Saf. Sci. 142 https://doi.org/10.1016/j.ssci.2021.105382.

Baltrusch, S.J., van Dieën, J.H., van Bennekom, C.A.M., Houdijk, H., 2018. The effect of a passive trunk exoskeleton on functional performance in healthy individuals. Appl. Ergon. 72, 94–106. https://doi.org/10.1016/j.apergo.2018.04.007.

Bessler, J., Prange-Lasonder, G.B., Schulte, R.V., Schaake, L., Prinsen, E.C., Buurke, J.H., 2020. Occurrence and type of adverse events during the use of stationary gait robots-A systematic literature review. Front Robot AI 7, 557606. https://doi.org/10.3389/frobt.2020.557606.

Bessler, J., Prange-Lasonder, G.B., Schaake, L., Saenz, J.F., Bidard, C., Fassi, I., Valori, M., Lassen, A.B., Buurke, J.H., 2021. Safety assessment of rehabilitation robots: a review identifying safety skills and current knowledge gaps. Front Robot AI 22 (8), 602878. https://doi.org/10.3389/frobt.2021.602878.

Bionics, Ekso, 2021. https://eksobionics.com/ekso-evo/.

Bosch, T., van Eck, J., Knitel, K., de Looze, M., 2016. The effects of a passive exoskeleton on muscle activity, discomfort and endurance time in forward bending work. Appl. Ergon. 54, 212–217. https://doi.org/10.1016/j.apergo.2015.12.003.

Crea, S., Beckerle, P., De Looze, M., De Pauw, K., Grazi, L., Kermavnar, T., Veneman, J., 2021. Occupational exoskeletons: a roadmap toward large-scale adoption. Methodology and challenges of bringing exoskeletons to workplaces. Wearable Technol. 2, E11. https://doi.org/10.1017/wtc.2021.11.

de Bock, S., Ghillebert, J., Govaerts, R., Elprama, S.A., Marusic, U., Serrien, B., De Pauw, K., 2021. Passive shoulder exoskeletons: more effective in the lab than in the field? IEEE Trans. Neural Syst. Rehabil. Eng. 29, 173–183. https://doi.org/10.1109/TNSRE.2020.3041906.

de Kok, J., Vroonhog, P., Snijders, J., Roullis, G., Clarke, M., Peereboom, K., van Dorst, P., Isusi, I., 2020. Work-related Musculoskeletal Disorders: Prevalence, Costs and Demographics in the EU. European Agency for Safety and Health at Work. https://doi.org/10.2802/66947.

de Looze, M.P., Bosch, T., Krause, F., Stadler, K.S., O'Sullivan, L.W., 2016. Exoskeletons for industrial application and their potential effects on physical work load. Ergonomics 59 (5), 671–681. https://doi.org/10.1080/00140139.2015.1081988.

de Vries, A.W., Krause, F., de Looze, M.P., 2021. The effectivity of a passive arm support exoskeleton in reducing muscle activation and perceived exertion during plastering activities. Ergonomics 64 (6), 712–721. https://doi.org/10.1080/00140139.2020.1868581.

Desbrosses, K., Schwartz, M., Theurel, J., 2021. Evaluation of two upper-limb exoskeletons during overhead work: influence of exoskeleton design and load on muscular adaptations and balance regulation. Eur. J. Appl. Physiol. 121 (10), 2811–2823. https://doi.org/10.1007/s00421-021-04747-9.

Elprama, S.A., Vannieuwenhuyze, J.T.A., De Bock, S., Vanderborght, B., De Pauw, K., Meeusen, R., Jacobs, A., 2020. Social processes: what determines industrial workers' intention to use exoskeletons? Hum. Factors 62 (3), 337–350. https://doi.org/10.1177/0018720819889534.Epub2020Jan23. PMID: 31971838.

Elprama, S.A., Vanderborght, B., Jacobs, A., 2022. An industrial exoskeleton user acceptance framework based on a literature review of empirical studies. Appl. Ergon. 100, 103615 https://doi.org/10.1016/j.apergo.2021.103615.

European Medicines Agency, 2016. EMA/CHMP/ICH/135/1995 – guideline for good clinical practice E6(R2). September 2022. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf.

Exoskeleton Report LLC, 2022. Shoulder. https://exoskeletonreport.com/product/shoulderx/#:~:texttekst=The%20shoulderX%20is%20a%20passive,light%20to%20moderate%20weight%20tools.

Giustetto, A., Vieira Dos Anjos, F., Gallo, F., Monferino, R., Cerone, G.L., Di Pardo, M., Micheletti Cremasco, M., 2021. Investigating the effect of a passive trunk exoskeleton on local discomfort, perceived effort and spatial distribution of back muscles activity. Ergonomics 64 (11), 1379–1392. https://doi.org/10.1080/00140139.2021.1928297.

Goršič, M., Song, Y., Dai, B., Novak, D., 2021. Evaluation of the HeroWear Apex back-assist exosuit during multiple brief tasks. J. Biomech. 126 https://doi.org/10.1016/j.jbiomech.2021.110620.

Grazi, L., Trigili, E., Proface, G., Giovacchini, F., Crea, S., Vitiello, N., 2020. Design and experimental evaluation of a semi-passive upper-limb exoskeleton for workers with motorized tuning of assistance. IEEE Trans. Neural Syst. Rehabil. Eng. 28 (10), 2276–2285. https://doi.org/10.1109/TNSRE.2020.3014408.

Harith, H.H., Mohd, M.F., Nai Sowat, S., 2021. A preliminary investigation on upper limb exoskeleton assistance for simulated agricultural tasks. Appl. Ergon. 95 https://doi.org/10.1016/j.apergo.2021.103455.

Higgins, J.P., Altman, D.G., Gøtzsche, P.C., Jüni, P., Moher, D., Oxman, A.D., Savovic, J., Schulz, K.F., Weeks, L., Sterne, J.A., 2011. Cochrane bias methods group; Cochrane statistical methods group. The Cochrane collaboration's tool for assessing risk of bias in randomised trials. Br. Med. J. 343, d5928. https://doi.org/10.1136/bmj.d5928. PMID: 22008217; PMCID: PMC3196245.

Howard, J., Murashov, V.V., Lowe, B.D., Lu, M.L., 2020. Industrial exoskeletons: need for intervention effectiveness research. Am. J. Ind. Med. 63 (3), 201–208. https://doi.org/10.1002/ajim.23080.

Huysamen, K., de Looze, M., Bosch, T., Ortiz, J., Toxiri, S., O'Sullivan, L.W., 2018. Assessment of an active industrial exoskeleton to aid dynamic lifting and lowering manual handling tasks. Appl. Ergon. 68, 125–131. https://doi.org/10.1016/j.apergo.2017.11.004.

Kermavnar, T., de Vries, A.W., de Looze, M.P., O'Sullivan, L.W., 2021. Effects of industrial back-support exoskeletons on body loading and user experience: an updated systematic review. Ergonomics 64 (6), 685–711. https://doi.org/10.1080/00140139.2020.1870162.

Kim, S., Nussbaum, M.A., Mokhlespour Esfahani, M.I., Alemi, M.M., Alabdulkarim, S., Rashedi, E., 2018a. Assessing the influence of a passive, upper extremity exoskeletal vest for tasks requiring arm elevation: Part I – "Expected" effects on discomfort, shoulder muscle activity, and work task performance. Appl. Ergon. 70, 315–322. https://doi.org/10.1016/j.apergo.2018.02.025.

Kim, S., Nussbaum, M.A., Mokhlespour Esfahani, M.I., Alemi, M.M., Jia, B., Rashedi, E., 2018b. Assessing the influence of a passive, upper extremity exoskeletal vest for tasks requiring arm elevation: Part II – "Unexpected" effects on shoulder motion, balance, and spine loading. Appl. Ergon. 70, 323–330. https://doi.org/10.1016/j.apergo.2018.02.024.

Kim, S., Madinei, S., Alemi, M.M., Srinivasan, D., Nussbaum, M.A., 2020. Assessing the potential for "undesired" effects of passive back-support exoskeleton use during a simulated manual assembly task: muscle activity, posture, balance, discomfort, and usability. Appl. Ergon. 89 https://doi.org/10.1016/j.apergo.2020.103194.

Kim, H.K., Hussain, M., Park, J., Lee, J., Lee, J.W., 2021. Analysis of active back-support exoskeleton during manual load-lifting tasks. J. Med. Biol. Eng. 41 (5), 704–714. https://doi.org/10.1007/s40846-021-00644-w.

Kim, S., Nussbaum, M.A., Smets, M., Ranganathan, S., 2021. Effects of an arm-support exoskeleton on perceived work intensity and musculoskeletal discomfort: an 18-month field study in automotive assembly. Am. J. Ind. Med. 64 (11), 905–914. https://doi.org/10.1002/ajim.23282.

Leheny, S., 2017. 'Adverse Event,' Not the Same as 'Side Effect'. Pharmacy Times. https://www.pharmacytimes.com/view/adverse-event-not-the-same-as-side-effect.

Linnenberg, C., Weidner, R., 2022. Industrial exoskeletons for overhead work: circumferential pressures on the upper arm caused by the physical human-machine-interface. Appl. Ergon. 101 https://doi.org/10.1016/j.apergo.2022.103706.

Liu, Y., Li, X., Lai, J., Zhu, A., Zhang, X., Zheng, Z., Zhu, H., Shi, Y., Wang, L., Chen, Z., 2021. The effects of a passive exoskeleton on human thermal responses in temperate and cold environments. Int. J. Environ. Res. Publ. Health 18 (8), 3889. https://doi.org/10.3390/ijerph18083889.PMID:33917655. PMCID: PMC8067969.

Luger, T., Bär, M., Seibt, R., Rieger, M.A., Steinhilber, B., 2021. Using a Back Exoskeleton during Industrial and Functional Tasks-Effects on Muscle Activity, Posture, Performance, Usability, and Wearer Discomfort in a Laboratory Trial. Human Factors, vol. 187208211007267. https://doi.org/10.1177/00187208211007267.

Madinei, S., Alemi, M.M., Kim, S., Srinivasan, D., Nussbaum, M.A., 2020a. Biomechanical assessment of two back-support exoskeletons in symmetric and asymmetric repetitive lifting with moderate postural demands. Appl. Ergon. 88 https://doi.org/10.1016/j.apergo.2020.103156.

Madinei, S., Alemi, M.M., Kim, S., Srinivasan, D., Nussbaum, M.A., 2020b. Biomechanical evaluation of passive back-support exoskeletons in a precision manual assembly task: "expected effects on trunk muscle activity, perceived exertion, and task performance. Hum. Factors 62 (3), 441–457. https://doi.org/10.1177/0018720819890966.

Maurice, P., Ivaldi, S., Babic, J., Camernik, J., Gorjan, D., Schirrmeister, B., Fritzsche, L., 2020. Objective and subjective effects of a passive exoskeleton on overhead work. IEEE Trans. Neural Syst. Rehabil. Eng. 28 (1), 152–164. https://doi.org/10.1109/TNSRE.2019.2945368.

McFarland, T.C., McDonald, A.C., Whittaker, R.L., Callaghan, J.P., Dickerson, C.R., 2022. Level of exoskeleton support influences shoulder elevation, external rotation and forearm pronation during simulated work tasks in females. Appl. Ergon. 98 https://doi.org/10.1016/j.apergo.2021.103591.

McGuinness, L.A., Higgins, J.P.T., 2020. Risk-of-bias VISualization (robvis): an R package and Shiny web app for visualizing risk-of-bias assessments. Res. Synth. Methods 1–7. https://doi.org/10.1002/jrsm.1411.

Moher, D., Liberati, A., Tetzlaff, J., Altman, D.G., 2009. Preferred reporting Items for systematic reviews and meta-analyses: the PRISMA statement. BMJ 339 (1), b2535. https://doi.org/10.1136/bmj.b2535.

Omoniyi, A., Trask, C., Milosavljevic, S., Thamsuwan, O., 2020. Farmers' perceptions of exoskeleton use on farms: finding the right tool for the work(er). Int. J. Ind. Ergon. 80 https://doi.org/10.1016/j.ergon.2020.103036.

Ottobock, 2021. Exoskeleton – ergonomics at work. https://paexo.com/?lang=en.

Ouzzani, M., Hammady, H., Fedorowicz, Z., Elmagarmid, A., 2016. Rayyan—a web and mobile app for systematic reviews. Syst. Rev. 5, 210. https://doi.org/10.1186/s13643-016-0384-4.

Pacifico, I., Parri, A., Taglione, S., Sabatini, A.M., Violante, F.S., Molteni, F., Crea, S., 2022. Exoskeletons for workers: a case series study in an enclosures production line. Appl. Ergon. 101 https://doi.org/10.1016/j.apergo.2022.103679.

Park, J.H., Kim, S., Nussbaum, M.A., Srinivasan, D., 2022. Effects of back-support exoskeleton use on gait performance and stability during level walking. Gait Posture 92, 181–190. https://doi.org/10.1016/j.gaitpost.2021.11.028.

Pinho, J.P., Forner-Cordero, A., 2022. Shoulder muscle activity and perceived comfort of industry workers using a commercial upper limb exoskeleton for simulated tasks. Appl. Ergon. 101 https://doi.org/10.1016/j.apergo.2022.103718.

Qu, X., Qu, C., Ma, T., Yin, P., Zhao, N., Xia, Y., Qu, S., 2021. Effects of an industrial passive assistive exoskeleton on muscle activity, oxygen consumption and subjective responses during lifting tasks. PLoS One 16 (1 January). https://doi.org/10.1371/journal.pone.0245629.

Rashedi, E., Kim, S., Nussbaum, M.A., Agnew, M.J., 2014. Ergonomic evaluation of a wearable assistive device for overhead work. Ergonomics 57 (12), 1864–1874. https://doi.org/10.1080/00140139.2014.952682.

Theurel, J., Desbrosses, K., 2019. Occupational exoskeletons: overview of their benefits and limitations in preventing work-related musculoskeletal disorders. Ergon. Hum. Factors 7 (3–4), 264–280. Ff10.1080/24725838.2019.1638331.

Theurel, J., Desbrosses, K., Roux, T., Savescu, A., 2018. Physiological consequences of using an upper limb exoskeleton during manual handling tasks. Appl. Ergon. 67, 211–217. https://doi.org/10.1016/j.apergo.2017.10.008.

von Glinski, A., Yilmaz, E., Mrotzek, S., Marek, E., Jettkant, B., Brinkemper, A., Geßmann, J., 2019. Effectiveness of an on-body lifting aid (HAL® for care support) to reduce lower back muscle activity during repetitive lifting tasks [Article]. J. Clin. Neurosci. 63, 249–255. https://doi.org/10.1016/j.jocn.2019.01.038.

Weston, E.B., Alizadeh, M., Hani, H., Knapik, G.G., Souchereau, R.A., Marras, W.S., 2022. A physiological and biomechanical investigation of three passive upper-extremity exoskeletons during simulated overhead work. Ergonomics 65 (1), 105–117. https://doi.org/10.1080/00140139.2021.1963490.

Yin, P., Yang, L., Qu, S., Wang, C., 2020. Effects of a passive upper extremity exoskeleton for overhead tasks [Article]. J. Electromyogr. Kinesiol. 55 https://doi.org/10.1016/j.jelekin.2020.102478.

Ziaei, M., Choobineh, A., Ghaem, H., Abdoli-Eramaki, M., 2021. Evaluation of a passive low-back support exoskeleton (Ergo-Vest) for manual waste collection. Ergonomics 64 (10), 1255–1270. https://doi.org/10.1080/00140139.2021.1915502.