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Review article

Subjective assessment of a lumbar exoskeleton's impact on lower back pain in a real work situation

Mélissa Moulart [a,b,*], Nicolas Olivier [c], Yonnel Giovanelli [d,e], Frédéric Marin [a]

[a] Université de Technologie de Compiègne (UTC), UMR CNRS 7338 BioMécanique et BioIngénierie, Alliance Sorbonne Université, 60200 Compiègne, France
[b] Japet Medical Devices, 59120 Loos, France
[c] University of Littoral, University of Artois, University Littoral Côte d'Opale, ULR 7369—URePSSS—Unité de Recherche Pluridisciplinaire Sport Santé Société, F-59000, Lille, France
[d] SNCF, DSV Voyageurs, 1-7, Place Aux étoiles, 93212 Saint Denis Cedex, France
[e] Laboratoire PSMS, EA 7507, 51100 Reims, France

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ABSTRACT

This study evaluated the impact of a lumbar exoskeleton on low back pain perception, in a real work situation. For three weeks, 30 subjects with and without specific low back pain assessed daily their lumbar pain on their work activities at the beginning and end of the workday by a visual analogue scale. The first and the third week, participants worked normally. The second week, participants wore the exoskeleton to work. For subjects with specific low back pain, our results showed a significant decrease in low back pain perception at the end of the week two when wearing the exoskeleton Our result showed that the exoskeleton studied had a positive impact on the pain index perception of workers with mechanical lumbar pathology.

1. Introduction

Low back pain (LBP) is a growing concern in most industrialized countries. It is estimated that about 80% of the adult population suffered, suffers, or will suffer from low back pain, with an annual prevalence of 30%. Progression to chronicity (lasting more than three months) is observed in 6–8% of cases (HAS, 2019; Wippert et al., 2017). Many epidemiological studies reported a similar prevalence in the different industrialized countries (Andersson, 1999). The prevalence of the chronic low back pain has more than tripled between 1992 and 2006, with a predilection age being between 30 and 60 years (Zaina et al., 2020). Consequently, low back pain is a major public health problem as it generates significant costs, estimated at 900 million euros per year in France (Assurance Maladie, 2019). These costs can be divided into direct and indirect costs. Direct costs are related to the various treatments such as medication, physiotherapy, imaging and even surgery (Parker et al., 2014; Zgierska, MD, PhD et al., 2017). Furthermore, indirect costs represent the major part of the overall expenses, as back pain is responsible for 30% of the work interruptions which last more than 6 months, and 20% of occupational accidents with work stoppages lasting more than two months, all sectors combined (HAS, 2019).

The analyses carried out by ergonomists and occupational physicians have led to the development of workstations and the automation of companies (Pope et al., 2002; Vignais et al., 2013). However, not all workplaces can undergo environment modification, and it is in this context that companies are interested in exoskeletons (Theurel and Claudon, 2018). Exoskeletons are still the subject of many studies today (Steinhilber et al., 2020). Indeed, many exoskeletons which have joined the market, arrived in prototype form before being modified to better suited the needs, therefore making it possible to provide a solution adapted to an environment that otherwise could not have been improved (Theurel and Claudon, 2018). Meanwhile, after the proof-of-concept phase, exoskeletons require an evaluation phase. Exoskeletons with medical claims must additionally meet specific safety and performance standards related to medical devices (IEC 60601). Most of the studies performed are biomechanical studies analyzing the range of motion and the muscle activity (Hansen et al., 2018). Actually, ever since work exoskeletons have been developed for preventive use, only the ergonomic aspects based on physical measure are studied e.g., muscles activity, range of motion, joint moments, metabolic cost and heart rate, etc (Abdoli-E and Stevenson, 2008) without taking into account the user's perception.

* Corresponding author.
E-mail address: moulart.melissa@gmail.com (M. Moulart).

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The purpose of this study is to subjectively quantify the impact of a lumbar exoskeleton on low back pain, in a real work situation.

2. Materials and methods

2.1. Workplace

The study was carried out in 17 companies (railway, automotive, naval, heavy industry, retail, healthcare, energy, carrier, food and clothing industries) in France.

These tests in a real work situation allowed to subjectively assess the impact of the exoskeleton on fatigue and low back pain. These companies offered different types of workstations. Many different activities were present and were potentially representing a risk for the back (heavy loads, torsion, etc.).

2.2. Population

Thirty-four workers were enrolled in this study but only thirty participants correctly completed the follow-up questionnaire (five women and twenty-five men). All volunteers were identified by the occupational physician or the attending physician, for having previously experienced lumbar pain and not having any contraindications. All participants gave their informed consent.

Two groups were identified:

- A group of ten people without evidence of lumbar pathology, called "non-specific LBP subjects" (age 44.8 ± 9.9 years, mass 79.1 ± 15.0 kg and height 173.4 ± 13.3 cm),
- A group of twenty people with mechanical pathology confirmed by medical imaging, called "specific LBP subjects" (age 41.5 ± 10.1 years, mass 80.1 ± 11.6 kg and height 178.1 ± 8.3 cm).

For all the volunteers, the medical register of industrial medicine was used by the occupational physician of the company and helped to define the two groups. In case of missing information in this register, the occupational physicians ordered an additional medical investigation e.g., medical imaging. Most pathologies represented in the specific LBP were herniated discs, vertebral compression, ankylosing spondylitis and arthritis.

2.3. Apparatus and data collection

2.3.1. Low back exoskeleton

The exoskeleton worn was a dynamic trunk orthosis (Japet.W, Japet Medical Devices©, France) able to apply vertical traction forces to reduce pressure on the lumbar spine (Chung et al., 2015). The device is composed of two belts, one on the iliac crests and one on the lower ribs (Figure 1).

These two belts are connected by two sets of actuators positioned on both sides of the body. The four actuators perform a dual role: preserving the trunk mobility while applying the traction force. The actuators are series elastic actuators (SEA), which allows bringing a mechanical damping and dynamism to the movement. They act as "intelligent pistons", controlled by force. Schematically, a set point is sent to a motor which, through a mechanical transmission system, transmits an effort that is measured by a force sensor and adjusted to reach the force set point. Each actuator is connected to the belts by a ball joint and automatically adapts to different heights, allowing to follow the movement of the trunk (Figure 2). The exoskeleton has four levels of traction force, 4kg, 8kg, 12kg and 16kg.

This exoskeleton is used in various types of companies (food processing, aeronautics, automotive, heavy industry, logistics, crafts, personal care, etc.) in the context of the usual worker's activity. It is mainly used for standing up tasks, such as carrying loads, transferring loads, working on a workbench (with back tilt), repeated movements (such as working on an assembly line). The range of motion of the actuators (0 cm–8.5 cm) is managed by the microcontroller which gives the set point to the SEA. To avoid any intrusions which could affect productivity, worker's activities are unsupervised.

2.3.2. Data collection

The data were collected in an individual logbook split in two parts. Before the start of the training, the occupational health team (occupational physician or occupational nurse) checked the candidate's eligibility for the study. Once the eligibility was verified, a date was scheduled to train the candidate and explain to him the two parts of the logbook.

The first part of the logbook concerning data on operators (age, weight, stature, job and description of 5 daily tasks maximum) was completed during the training day with permanent technical support from Japet Medical Devices for the installation and adjustments of the device.

The second part was completed every day by the operator, indicating the task carried out during the day (among the five tasks described previously), and the assessment of lumbar pain at the beginning and the end of the day. For this evaluation, the subject put a line on a 100 mm gauge ranging from "no pain" to "severe pain", thus simulating the pain scale ruler, e.g. Visual Analogue Scale (VAS), conventionally used by physicians (Meyer, 2014). In addition, the participants were free to comment on their personal feelings on a daily basis. After the week of using the device, the volunteers had to answer additional questions about the perception of the device and give an overall satisfaction score between 0 (very bad) to 10 (very good).

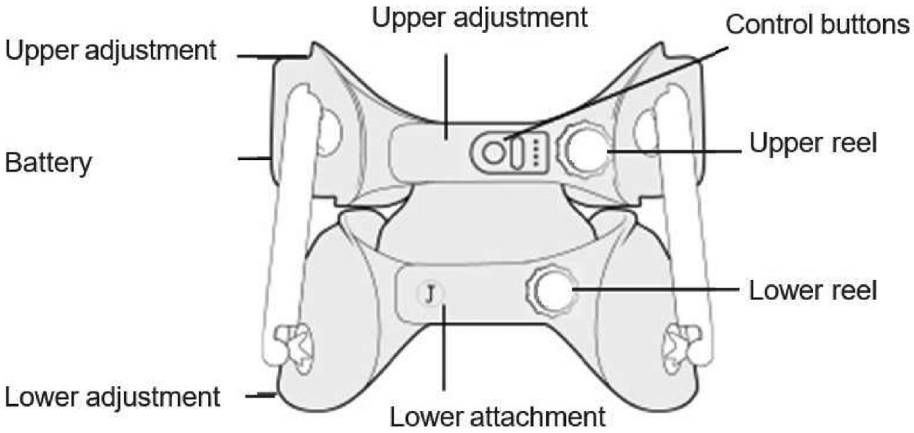

Figure 1. Schematic drawing of the Japet. W exoskeleton.

Figure 2. Japet. W following the inclination of the trunk.

During the study, the undesirable effects were carefully reported.

2.4. Experimental procedure

The experimental procedure included 2 information sessions and 3 weeks of effective pain report with and without the exoskeleton (Figure 3) detailed as follows:

- Time T0: The first information session is the meeting between the physician and the volunteer, to verify that the volunteer has no contraindications. The occupational physician offered the test to several operators affected by low back pain. During a first appointment, the occupational physician performed a clinical evaluation, and verified that the volunteer had no contraindications to participate in the study.
- Time T1 (often the day before the week 1): The second information session is the briefing, and the training of the volunteer by a member of the Japet team, and the signature of the consent. Each volunteer provided informed consent. The test could then begin.
- Week 1: This phase is named "No Exo 1". During this first week, participants did not wear the exoskeleton.
- Week 2: This phase is named "Exo 2". This second week, participants wore the exoskeleton.
- Week 3: This phase is named "No Exo 3". This last week, participants did not wear the device.

During the week 1–3, the participants had to document their VAS index at the start and end of the working day.

Moreover, to guarantee homogeneity of the experimental procedure, additional instructions were done as follows:

- Using the device during the identified task (among the five tasks described), not more than 2 h consecutively, with a maximum of 4 h per day.
- Fill in the logbook every day, even if the device was not used.
- The duration of the test was three working weeks, which corresponded to fifteen days.

At the end of the test, the volunteer's impressions (positive and negative points) were collected, and logbook data was sent to Japet Medical Devices to be analysed.

The whole protocol was validated by an ethics committee (Île-de-France III, ID-RCB, 2020-A02970-39).

2.5. Data analysis

The analysis consisted in comparing the VAS pain index between the first week (No Exo 1), the second week (Exo 2) and the third week (No Exo 3). It was carried out by taking into account the first and the last day of each week since the goal of the device was to reduce lumbar pain during the week. Two indicators were considered, the evolution of pain

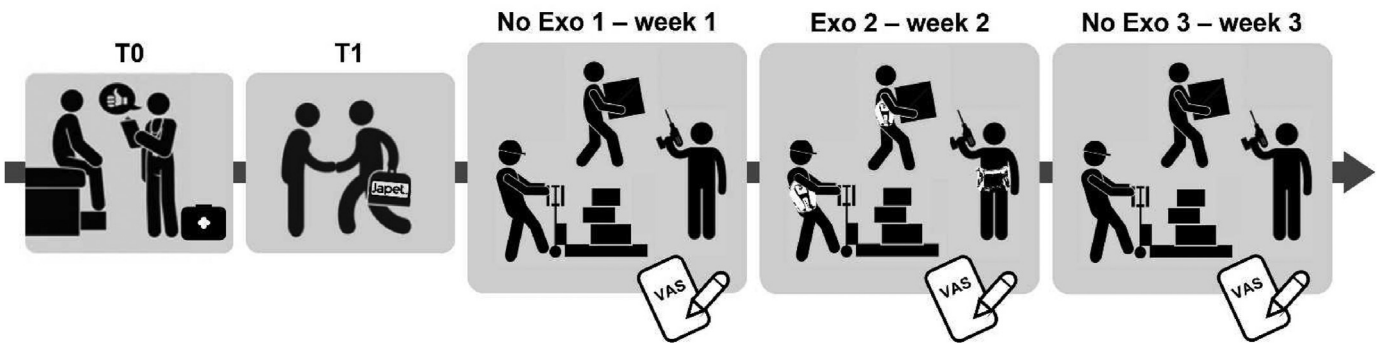

Figure 3. Workflow of the study.

at the start of the day during the week, and the evolution of the pain at the end of the week.

Data analyses were separated into two groups, the non-specific LBP subjects corresponding to the subjects having back pain but no proven lumbar pathology (nothing visible by medical imaging), and the specific LBP subjects.

The responses to the questionnaires were compiled into three categories:

- Benefits: which correspond to the relief of lumbar pain, the reduction of lumbar fatigue and the maintenance of good posture for the lower back;
- Adaptability in the workplace: corresponds to the ease and speed with which movements can be performed, the possibility of equipping oneself with PPE, and the ease of storage and transportation;
- Usability: which takes into account weight, size (bulky), fit, ease of use, etc.

For each question, four responses were possible, "++" (very positive opinion), "+" (positive opinion), "-" (negative opinion) and "- -" (very negative opinion). A tally was taken to define a percentage of the different opinions according to the three categories.

No comments were written in the logbook.

2.6. Statistical analysis

For both groups, statistical analysis was performed on the difference of the VAS index between the one reported at the ends of the week, and the one of the beginnings of the week for the week 1 (No exo1), 2 (Exo 2), and 3 (no Exo 3). Let's note Δi_{NS} the metric of difference of VAS index between the last and the first days of the week i for the non-specific LBP group represented by the arrow in Figure 4. Δi_{NS} quantify the magnitude of the arrow and its sign indicated the positive or negative evolution of the VAS index between the beginning and the end of the week. $\overline{\Delta i_{NS}}$ is the median value of all subjects of the non-specific LBP group. Let's use the same notation for the specific LBP group by Δi_{LBP} and $\overline{\Delta i_{LBP}}$.

First, two Friedman tests as non-parametric test similar to an ANOVA were performed with the two set $\{\Delta 1_{NS}; \Delta 2_{NS}; \Delta 3_{NS}\}$ and $\{\Delta 1_{LBP}; \Delta 2_{LBP}; \Delta 3_{LBP}\}$ separately. The null hypothesis was no significant difference between $\overline{\Delta 1_k}$, $\overline{\Delta 2_k}$ and $\overline{\Delta 3_k}$ with k $\in$ {NS,LBP}. The null hypothesis is rejected if the p-value (level of significance) of the Friedman test is less than 0.05 and the alternative hypothesis e.g. significant difference could be supported. If the alternative hypothesis can be considered, a post-hoc test can be performed. As post-hoc test, a Wilcoxon test with set $\{\Delta i_k; \Delta j_k\}$ with $i \in \{1,2,3\}, j \in \{1,2,3\}, i \neq j$, and k $\in$ {NS, LBP} were computed. Here the null hypothesis is no significant difference between $\overline{\Delta i_k}$ and $\overline{\Delta j_k}$. The null hypothesis is rejected if the p-value of the Wilcoxon test is less than 0.05.

All calculations were performed with MATLAB R2022a software (Mathwork, USA).

3. Results

Four of the thirty-four workers were excluded from the study since their data could not be analysed (lack of information in the follow-up). The VAS results were reported separately for the non-specific LBP and the specific LBP subjects. Each volunteer used the exoskeleton during standing up tasks, presenting high lumbar constraints such as carrying and transferring loads (with and without moving). Some of them performed bench work and assembly line work. In general, the work activities involved the trunk's forward and lateral bending, as well as axial rotation. The questionnaires were not analysed separately between the two groups of volunteers. Indeed, the objective is to have a global feeling for all the users of the device, and not by categories of users.

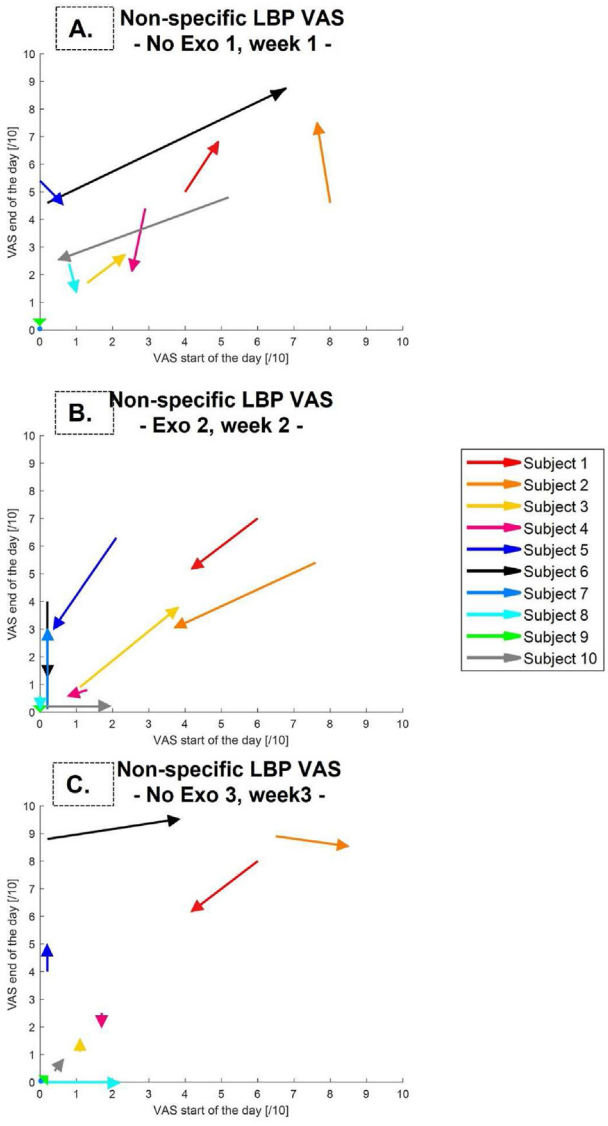

Figure 4. VAS between the first and the last day of the first week (A) the second (B) and the third week (C), on non-specific LBP subjects. The x-axe represents the VAS at the start of the day (index between 0: No pain and 10: extreme pain). The y-axe represents the VAS at the end of the day. Each arrow represents a subject. The initial endpoint of the arrow is the VAS index of the first day, while the head of the arrow (final endpoint) is the VAS index of the fifth day (last day of the week). An arrow pointing to the right, means that the pain at the start of the day increased between the day 1 and the day 5. An arrow pointing to the left means that the pain at the start of the day decreased between the day 1 and the day 5. An arrow that goes upwards, means that the pain at the end of the day increased between day 1 and day 5. An arrow that goes down, means that the pain at the end of the day decreased between day 1 and day 5.

3.1. First analysis: non-specific LBP subjects n = 10

The following figures (Figure 4) represent the evolution of the non-specific LBP VAS over the three weeks.

For the population of 10 non-specific LBP subjects, in the week 1 (Figure 4A), at the start of the day, 5 of them have an increased pain (50%), 3 of them have a decreased pain (30%) and 2 of them have the same pain between the day 1 and the day 5 (20%). At the end of the day, 4 of them have an increased pain (40%), 5 of them have a decreased pain (50%) and 1 of them has the same pain between the day 1 and the day 5 (10%). For the week 2 (Figure 4B), at the start of the day, 2 of them have an increased pain (20%), 3 of them have a decreased pain (30%) and 5 of

them have the same pain between the day 1 and the day 5 (50%). At the end of the day, 2 of them have an increased pain (20%), 7 of them have a decreased pain (70%) and 1 of them has the same pain the between day 1 and the day 5 (10%). For the week 3 (Figure 4C), at the start of the day, 5 of them have an increased pain (50%), 1 of them has a decreased pain (10%) and 4 of them have the same pain between the day 1 and the day 5 (40%). At the end of the week, 5 of them have an increased pain (50%), 3 of them have a decreased pain (30%) and 2 of them have the same pain between the day 1 and the day 5 (20%).

Our results showed that there are fewer subjects who have lumbar pain at the end of the day when they wear the exoskeleton. For the first week, 40% of non-specific LBP subjects have more pain at the end of the week than at the beginning. Then in the second week, 20% of non-specific LBP subjects have more pain, and at the third week 50% of them.

Taking the data from the first week as a reference data, there are 50% of non-specific LBP subjects who are relieved in the second week. In the third week, 25% more non-specific LBP subjects have lumbar pain compared to the first week.

For the non-specific LBP (NS) group, data used for the Friedman test are in the following table (Table 1):

Friedman test ($N = 10$, $dl = 2$, $Chi^2 = 1.51$, $p = 0.4692$) indicated the null hypothesis is supported. There is no significant difference between the median values of the difference of the VAS index between last and first days of each week. A post-hoc analysis is not required, and we can conclude that there is no week effect associated to the wear of the exoskeleton.

3.2. Second analysis: specific LBP subjects n = 20

The following figures (Figure 5) represent the evolution of the specific LBP VAS over the three weeks.

VAS of the specific LBP subjects during the first week (Figure 5A) are as follows: at the start of the day, 8 of them have an increased pain (40%), 6 of them have a decreased pain (30%) and 6 of them have the same pain between the day 1 and the day 5 (30%). At the end of the day, 14 of them have an increased pain (70%), 4 of them have a decreased pain (20%) and 2 of them have the same pain between the day 1 and the day 5 (10%). For the second week (Figure 5B), we noticed at the start of the day that 5 of them have an increased pain (25%), 12 of them have a decreased pain (60%) and 3 of them have the same pain between the day 1 and the day 5 (15%), and at the end of day 2 of them have an increased pain (10%), 15 of them have a decreased pain (75%) and 3 of them have the same pain between the day 1 and the day 5 (15%). For the third week (Figure 5C), we noticed, at the start of the day, that 8 of them have an increased pain (40%), 8 of them have a decreased pain (40%) and 4 of them have the same pain between the day 1 and the day 5 (20%). At the end of the day, we reported that 6 of them have an increased pain (30%), 9 of them have a decreased pain (45%) and 5 of them have the same pain between the day 1 and the day 5 (25%).

Our results showed that there are fewer subjects who have lumbar pain at the end of the day when they wear the exoskeleton during the second week. In fact, during the first week without the exoskeleton, 70% of specific LBP subjects have more pain at the end of the week than at the beginning, in the second week with exoskeleton 10% have more pain, and, in the third and last week without the exoskeleton 30%.

Taking the data from the first week as a reference data, there are 85% of specific LBP subjects who are relieved between the first week without the exoskeleton and the second week with the exoskeleton, and 57% between the first week and the third week without the exoskeleton.

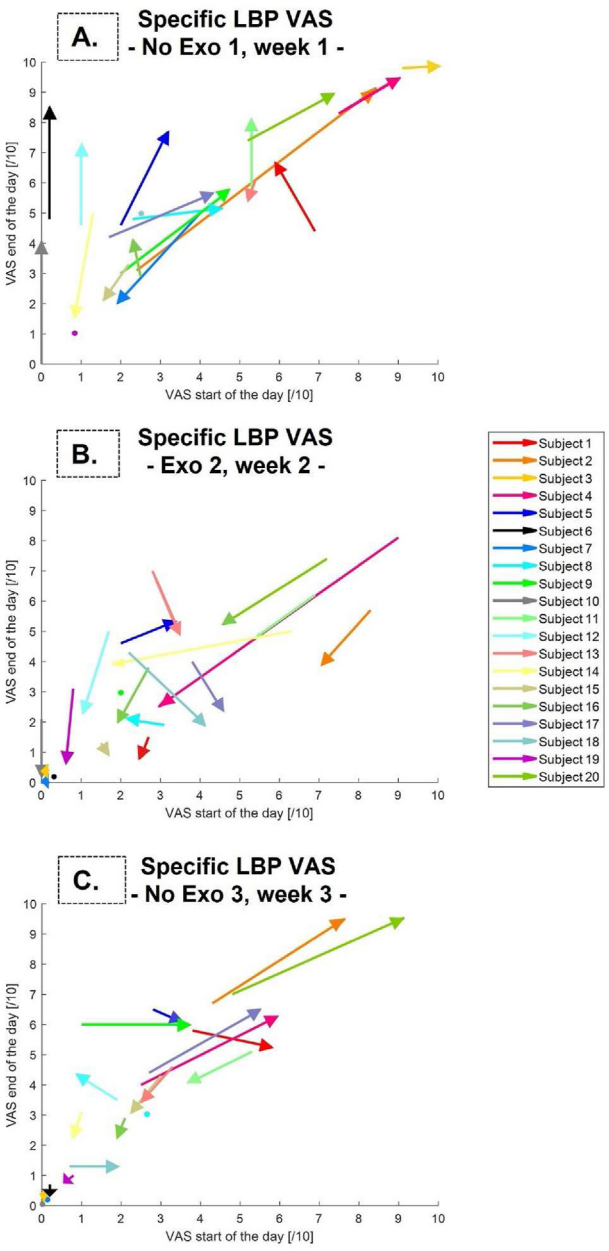

Figure 5. VAS between the first and the last day of the three weeks on specific LBP subjects. The same representation as Figure 4 is used.

For the LBP group, data used for the Friedman test are in the following table (Table 2):

Friedman test ($N = 20$, $dl = 2$, $Chi^2 = 15.77$, $p = 0.0004$) indicated that the null hypothesis is rejected. There is a significant difference between the media values of the difference of the VAS index between last and first working day of each week.

Table 1. Summary of the difference of the VAS score between the last and first days of each week for the non-specific LBP group by the metric $\Delta 1_{NS}$.

Variable	N	$\overline{\Delta i_{NS}}$	Minimum	Maximum
$\Delta 1_{NS}$	10	0.5094	-5.7773	8.6125
$\Delta 2_{NS}$	10	-0.8407	-5.0704	4.4606
$\Delta 3_{NS}$	10	0.1013	-2.8284	4.0451

Table 2. Summary of the difference of the VAS score between the last and first days of each week for the LBP group by the metric $\Delta 1_{LBP}$.

Variable	N	$\overline{\Delta i_{LBP}}$	Minimum	Maximum
$\Delta 1_{LBP}$	20	2.6006	-4.00451	9.4452
$\Delta 2_{LBP}$	20	-2.1526	-9.1382	1.7527
$\Delta 3_{LBP}$	20	0	-2.3754	5.5552

Results of the Wilcoxon tests as post-hoc tests are in the following table (Table 3):

The Wilcoxon tests indicated that there are significant differences between the week 2 (Exo2) and the week 1 (no Exo 1) and between the week 2 (Exo2) and the week 3 (no exo3), but no significant difference between the week 1 and week 3. This result suggested that the wear of the exoskeleton has an impact of the VAS perceptions. In addition, Table 2 shows that the median value of $\Delta 2_{LBP}$ is negative while $\Delta 1_{LBP}$ and $\Delta 3_{LBP}$ are positive suggesting that wearing the exoskeleton decreased VAS between the beginning and the end of the week.

3.3. Questionnaires analysis: subjects n = 30

The following figures (Figure 6) represent the percentage of different feelings about the benefits of the device, its adaptability in the workplace and its usability.

In the benefits part, 56% of users have a very positive opinion, 36% have a positive opinion, 3% have a negative opinion and 5% have a very negative opinion. By aggregating the very positive and positive opinions, and the negative and very negative opinions, we can consider that 92% of the users are rather positive about the benefits of the exoskeleton, and 8% are rather negative. The subjects with a rather negative opinion are those with initially low back pain (no more than 2.7/10 of the VAS score over the three weeks).

Regarding the adaptability in the workplace part, 38% of users have a very positive opinion, 42% have a positive opinion, 14% have a negative opinion and 6% have a very negative opinion. By aggregating the very positive and positive opinions, and the negative and very negative opinions, we can consider that 80% of the users are rather positive about the adaptability of the exoskeleton in the workplace, and 20% are rather negative. The main negative opinions reported in some subjects are the decrease in the lumbar range of motion and the storage of the exoskeleton.

Finally, for the usability part, 43% of users have a very positive opinion, 38% have a positive opinion, 13% have a negative opinion and 6% have a very negative opinion. By aggregating the very positive and positive opinions, and the negative and very negative opinions, we can consider that 81% of the users are rather positive about the usability of the exoskeleton, and 19% are rather negative. The negative points that emerge from this questionnaire are essentially the heat felt when wearing the exoskeleton, and its bulkiness.

4. Discussion

This comparative study, carried out in real working conditions, with and without the exoskeleton, claims to reduce pain in low back pain subjects. Based on the VAS report, we demonstrated that the exoskeleton has a positive instantaneous effect on the population with specific LBP. Moreover, the feeling of the exoskeleton is very positive in spite of the few points of improvement underlined.

Most of the commercialized exoskeletons are not validated as medical devices (De Bock et al., 2022), and therefore have no relief claims from specific LBP people, even if it was generally aiming to prevent musculoskeletal disorders (Godwin et al., 2009). In addition, the study of exoskeletons is almost exclusively focused on a biomechanical analysis considered as an objective validation, without considering that pain can be considered as subjective (Giordano et al., 2010). However, pain, long regarded as inevitable, is now considered a public health issue in industrialized countries (Assurance Maladie, 2019) due to its deleterious action not only physical but psychological (Kamper et al., 2015). In addition, the cost to care and manage people with pain is substantial, both in terms of direct costs linked to the consumption of care, and of indirect costs mainly linked to the interference of pain in professional life (Dagenais et al., 2008). However, the measurement of pain is complex since it is very subjective. There are several means for measuring pain (Shafshak and Elnemr, 2021). The assessment method used in this study is a visual analogue scale, commonly used by physicians. However, this version of VAS has been adapted as a paper version for easier monitoring and with no need for a third-party presence. This endpoint was chosen because it is easy to implement and is consistent with the measurement of lower back pain (Boonstra et al., 2008).

Our results demonstrated the instantaneous effect of the exoskeleton which is consistent with the literature (Elprama et al., 2022). Although the results of the literature have a low statistical power, some studies show a decrease in muscle activity (Abdoli-E et al., 2006) which involves a muscle relaxation, generally implying a decrease in pain (Alvarez and Rockwell, n.d.). In addition, the lumbar traction performed by the exoskeleton allows a slight decompression at the level of the intervertebral discs (Zaïri et al., 2021), thus being able to reduce the pain associated with a herniated disc (Karimi et al., 2017). Even if the direct biomechanical effect is often analyzed, it is also important to consider the psychological effect that the device can have. Indeed, several studies prove the therapeutic effect of the placebo effect (Reinhold et al., 2020), considered as a therapeutic process having no specific efficacy but acting positively on the patient thanks to psychological mechanisms (Požgain et al., 2014). Subjects' expectations have been shown to have an important role in the placebo effect, the more enthusiastic a subject is and has high expectations, the more the placebo effect is likely to work (Klinger et al., 2018). In this study, many subjects had high expectations about the exoskeleton, which may influence the results of pain experienced by subjects. It is therefore possible that the reduction in pain in some subjects is not a direct consequence of wearing exoskeleton but is a consequence of the placebo effect of wearing the exoskeleton.

However, our study presents limitations. The VAS index used is complicated to analyze since it is subjective. Furthermore, there is a high variability of low back pain between participants since the studied population is very heterogeneous in terms of lumbar musculoskeletal disorders, with various lumbar pathologies and at different stages of evolution. Pain assessment is a controversial thematic (Ramasamy et al., 2017). VAS are subjective indices, which consequently depend on the pain acceptance (Giordano et al., 2010) and pain history (Becker et al., 2021) of the subject. In addition, lower back pain is painful episodes that could vary from day to day (Hartvigsen et al., 2018). Consequently, a subject with pain rated at 9/10 one day, could experience pain rate of 4/10 the next day, without any treatment between the two days. In order to limit intersubjective perception, we analysed the difference in VAS between the first and the last day working day. Thus, it was the individual evolution of pain perception which was observed. This measurement tool does not allow homogeneity in the measurements. Long-term monitoring of the VAS index (several months) will provide more reliable data. Unfortunately, the duration of the trial was limited by the intrinsic structure of the study, which was intended to be conducted in a real-life situation, with the constraints and limits imposed by the companies. Further investigation could include that the protocol design could also have mixed conditions (e.g., case 1: No Exo, Exo, No Exo; case 2: No Exo, No Exo, Exo; case 3: Exo, No Exo, No Exo) to strengthen the reliability of the VAS data in order to better understand the relief effect of the exoskeleton. A future study could consider these measures in crossover. Finally, the population tested is based on voluntary subjects, which can positively influence the results. The results of the study are based on 30 subjects divided into two groups, non-specific LBP subjects with a high lumbar strain job, and subjects with specific LBP. This division of subjects into two groups decreases the statistical power of the study. In addition,

Table 3. Summary of the Wilcoxon tests on the difference in VAS score between the last and first day of each week for the LBP group.

	N	Z	p-value
$\Delta 1_{LBP}$ vs $\Delta 2_{LBP}$	20	3.8564	0.00015
$\Delta 1_{LBP}$ vs $\Delta 3_{LBP}$	20	1.6409	0.1008
$\Delta 2_{LBP}$ vs $\Delta 3_{LBP}$	20	-3.1435	0.0015

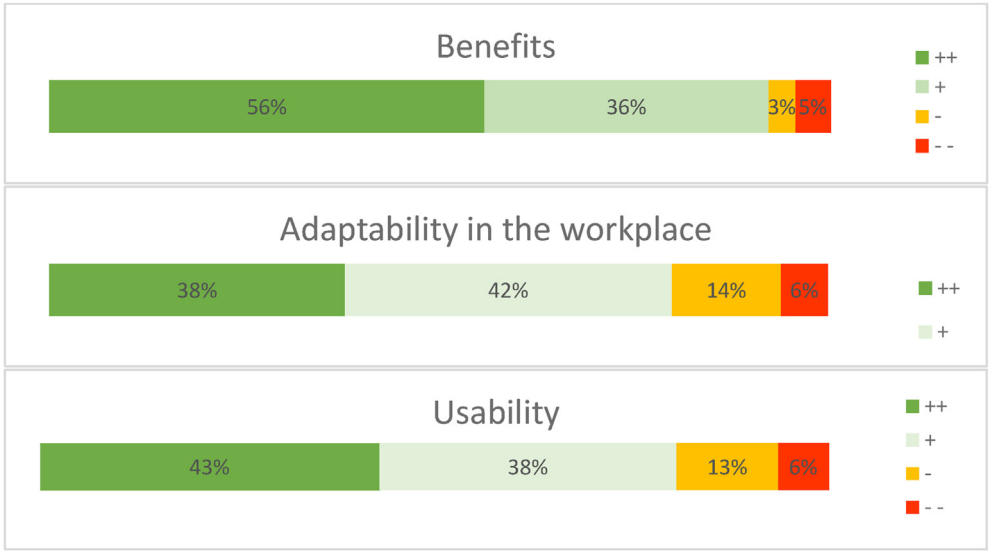

Figure 6. Responses to the questionnaires: percentage of different feelings about the device. The signs "++", "+", "-" and "- -" correspond respectively to a very positive opinion, positive opinion, negative opinion and very negative opinion.

we have a heterogenous population with various workload which could be categorized our protocol as unsupervised, consequently only tendency could be deduced, and further investigation need working activity monitoring to normalize the data. Finally, the fact that participants had accessed their previous scores could affect the following scores. Indeed, each participant had beliefs or expectations (positive or negative) related to the use of the exoskeleton. We cannot exclude a "confirmation bias" which is very difficult to remove (Talluri et al., 2018).

5. Conclusion

The studied exoskeleton allows a decrease in the VAS index in specific LBP subjects. Monitoring this index over several months would make it possible to standardize the values to draw more reliable conclusions.

Finally, the state of the art on exoskeletons mainly focuses on biomechanical and physiological aspects to assess the impact of these new technologies on the body. Our study therefore stands out significantly since it assesses the pain of subjects in their work environment, thus filling a gap between biomechanical studies carried out on preventive exoskeletons, and medical exoskeletons used in an occupational context. However, this work was focused on the subjective perception of the exoskeleton which is the first step of acceptation and impact of the use of such device. Based on this experience, further investigation will have to be completed by a biomechanical study with quantitative parameters e.g., kinematics, kinetics, etc. in order to evaluate the objective impact of the exoskeleton on the body.

Declarations

Author contribution statement

All authors listed have significantly contributed to the development and the writing of this article.

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Data availability statement

The data that has been used is confidential.

Declaration of interest's statement

The authors declare the following conflict of interests: Mélissa MOULART is an employee of the Japet Medical Devices© company which designed the Japet. W device. This study was carried out according to the rules of good practice and with full knowledge of the ethical rules under supervision of academic partner according to the agreement of the ethical committee (Île-de-France III, ID-RCB, 2020-A02970-39).

The others authors declare no competing interests.

Additional information

No additional information is available for this paper.

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