Supplementary material to: "Using exoskeletons to assist medical staff during prone positioning of mechanically ventilated COVID-19 patients: a pilot study"

Serena Ivaldi, Pauline Maurice, Waldez Gomes, Jean Theurel, Liên Wioland, Jean-Jacques Atain-Kouadio, Laurent Claudon, Hind Hani, Antoine Kimmoun, Jean-Marc Sellal, et al.

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I. Questionnaires

In this supplementary material, we report the entire set of questionnaires that we used during our study, to facilitate reproducibility and replication of our results by other teams.

A. Human factors related to prone positioning

This questionnaire must be filled by **any participants** to the prone positioning (PP) study before doing any PP maneuver in simulation or in the ICU. It is necessary to retrieve relevant information such as experience with the PP in the hospital before and during the COVID-19 pandemic, history of back pain that is medically relevant for the study, attitude towards the exoskeleton technology. A semi-directed interview to gain a deeper knowledge of the expectations of the participants is complementary: the experimenter can ask, for example, if the participants have already seen or used an exoskeleton, a robot or a prosthetic device, and get insights into their past experience.

Questionnaire on human factors	
Instructions: This questionnaire is to be completed once, before the start of any experiment.	
Question	Answer
Participant ID	
Gender (M/F)	

Age	
Occupation (nurse, doctor…)	
Number of months/years of hospital experience	
Number of days/months/years of experience performing the PP maneuver	
In the past, have you had back problems (recurring pain that requires medical attention or sick leave)?	
Do you currently have back problems?	
Have you ever used a back-support system? If yes, which one(s)	
Have you ever interacted with robotic systems or physical assistance devices such as exoskeletons? If yes, which one(s)	
What is your overall attitude towards physical assistive devices such as exoskeletons?	❑ Very negative ❑ Rather negative ❑ No opinion ❑ Rather positive ❑ Very positive
How many times have you performed this maneuver in the field since the beginning of your activity as a caregiver?	❑ 1-10 ❑ 10-50 ❑ 50-100 ❑ 100+
Do you consider yourself an expert in this maneuver?	❑ Expert ❑ Medium ❑ Beginner
Before COVID-19	
On a scale of 1 (not stressful at all) to 10 (very stressful), if you performed the PP maneuver in the past, before the COVID-19 outbreak, how stressful was it …?	
… physically	❑_____
… cognitively	❑_____
How often did you execute the PP maneuver before the crisis situation COVID-19?	
… times per day	❑_____
… times per month	❑_____
During COVID-19	
On a scale of 1 (not stressful at all) to 10 (very stressful), if you performed the PP maneuver during the COVID-19 outbreak, how stressful was it …?	
… physically	❑_____
… cognitively	❑_____
How often do you execute the PP maneuver every day during the COVID-19 outbreak?	
… times per day	❑_____
… times per month	❑_____

B. Acceptance evaluation of an exoskeleton for prone positioning

This questionnaire is an extract from a larger questionnaire[1] that was developed by INRS to investigate the acceptance of exoskeletons introduced in an industrial context. Some questions have been adapted to our specific use case.

This questionnaire must be filled by the **physicians** equipped with the exoskeleton to receive physical assistance during the prone positioning maneuver. It is used to evaluate the exoskeletons in the simulated study and in the real-life conditions. Questions marked with an asterisk are to be filled only after using the exoskeleton in real-life condition, i.e., in the ICU. Reverse questions are marked with R.

Questionnaire for exoskeleton evaluation	
Question	Answer
Participant ID	
Exoskeleton type	❑ Laevo

[1] Wioland L., L. Debay, J.-J. Atain-Kouadio (2019) Processus d'acceptabilité et d'acceptation des exosquelettes: évaluation par questionnaires. Références en santé au travail, TF 274, n. 160, pp. 49 - 76. Available at: http://www.inrs.fr/dms/inrs/CataloguePapier/DMT/TI-TF-274/tf274.pdf

	❑ Corfor ❑ CrayX ❑ BackX

Instructions: In the questionnaire you will find a series of statements about your experience with the exoskeleton. For each statement that follows, please give your opinion by checking the corresponding box on a five-point Likert scale.

Scale A:
1. Strongly disagree
2. Disagree
3. Neither Agree nor Disagree
4. Agree
5. Strongly agree

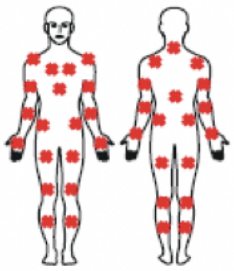
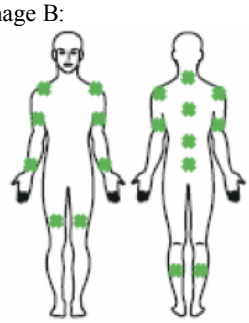
Scale B:
1. Much lower
2. Lower
3. Identical
4. Higher
5. Much higher

N.	Reverse & ICU	Question	Scale
Exoskeleton setup and calibration			
1		I find the exoskeleton is easy to set up	A
The use of the exoskeleton			
2		Overall, I find the exoskeleton easy to use	A
3		I find that I can easily perform my movements with the exoskeleton	A
4		I find that I can easily move and walk with the exoskeleton	A
5		I find that I control my gestures as I wish with the exoskeleton	A
6	R	I find that the exoskeleton prevents me from working the way I want	A
7		I find that I easily got used to working with the exoskeleton	A
8	R	I find that using the exoskeleton requires an extra effort of concentration	A
My performance with the exoskeleton			
9		I find that the speed of my work with the exoskeleton is …	B
10	*	I find that the quality of my work with the exoskeleton is …	B
11		I find that my effectiveness with the exoskeleton is …	B
12		I find that the productivity of the team with the exoskeleton is …	B
My health and safety			
13	R	Overall, I find that my physical efforts with the exoskeleton are …	B
14	R	Overall, I find that with the exoskeleton, my fatigue is ...	B
15		I feel safe working with the exoskeleton.	A
My feeling with the exoskeleton			
16	R	I feel nervous when I use the exoskeleton.	A
17	R	I feel worried when I use the exoskeleton.	A

18		I feel confident when I use the exoskeleton.	A
19	R	I find I annoy my colleagues when I use the exoskeleton.	A
Future use			
20		If I have a choice, I am thinking of using or continuing to use the exoskeleton in the next months	A
21	*	I find that over the course of the day I have adapted to the exoskeleton	A
22	*	I find that using the exoskeleton during the day has been beneficial	A

C. Evaluating the overall effort of a prone positioning maneuver with/without an exoskeleton

This questionnaire must be filled after realizing a prone positioning (PP) maneuver with or without an exoskeleton. It provides a subjective evaluation of the amount of physical effort and discomfort perceived while executing the PP. It provides a surrogate measure of standardized quantitative measures of efforts, such as surface EMGs placed over muscles of interests, whenever obtaining such measures is not possible. For example, using surface EMGs in the ICU was not possible for sanitary reasons.

Questionnaire for evaluation of the overall effort	
Question	Answer
Participant ID	
Exoskeleton type	❑ Laevo ❑ Corfor ❑ CrayX ❑ BackX ❑ none
Instructions: This questionnaire is to be completed after a PP maneuver with or without an exoskeleton. Put a circle on the relevant areas in the double-sided images, as well as a number, as per instructions. Image A:  Image B: 	
Question	Image

Put a circle on this image on the areas where you felt physical effort during PP maneuvers [with the exoskeleton].	A
Put a circle on this image on the areas where you felt physical effort becoming annoying during the PP maneuver [with the use of the exoskeleton], and a number next to each circle (1-10) to indicate the severity (1= no effort, 10= a lot of effort).	A
Only if you used the exoskeleton	
Could you indicate on this image the areas where you feel a new redistribution of physical effort, which you do not feel without the exoskeleton? Put a circle on the areas where you feel new efforts, and a number next to each circle (1-10) to indicate how much (1= no effort, 10= a lot of effort).	B
Could you indicate on this image the areas where you feel discomfort caused by the exoskeleton? Put a circle over the areas of discomfort, and a number next to each circle (1-10) to indicate how much (1= no discomfort, 10= a lot of discomfort).	A

D. Questionnaire for physicians using the exoskeleton in the ICU

This questionnaire must be filled by the **physicians** equipped with the exoskeleton and using them in the ICU for PP maneuvers. The first part must be filled at the end of each PP maneuver (i.e., if the physician performs 20 maneuvers, he/she will fill the sheet 20 times, one after each PP). The second part must be filled at the end of the work-shift, for example in the changing room of the medical staff to avoid contamination. It must be noted that since the first batch of questionnaires are filled in the ICU following each PP, the paper sheets are considered "potentially contaminated" and therefore should rest untouched in a safe place for 3-4 days before manually processing them by the experimenters, in order to reduce any risk of contamination by direct skin contact.

Questionnaire to evaluate the exoskeleton in the ICU	
Instructions: This questionnaire is to be completed by volunteers equipped with exoskeletons throughout their working hours. The first part must be filled after each PP maneuver. The second part must be filled at the end of their working hours.	
1st PART : TO FILL AFTER EVERY PP	
Question	Answer
Participant ID	
n. PP of the day	
With exoskeleton?	Yes / No
Position?	Head / Side
Your perception during the PP maneuver	
Please note for each anatomical zone your perceived effort during your last PP maneuver according to Borg's Perceived Effort Rating Scale (Borg CR10). 0 nothing at all 0.5 extremely weak / very, very slight 1 very weak / very slight 2 weak / slight 3 moderate 4 5 strong / severe 6 7 very strong / very severe 8 9 10 extremely strong / very, very severe	

Neck	▢_____
Lower back	▢_____
Legs	▢_____
Left shoulder / arm	▢_____
Left forearm / hand	▢_____
Right shoulder / arm	▢_____
Right forearm / hand	▢_____
2nd PART: FILL WHEN YOUR WORK WITH THE EXOSKELETON IS FINISHED	
Question	Answer
Participant ID	
Exoskeleton type	❑ LAEVO
Between when you started to work and now, how many times have you practiced the PP maneuver today?	
Have you systematically used the exoskeleton to perform the PP maneuver?	Yes / No
If not, why did you remove it?	
In how many of the total PP maneuvers out of the total PP maneuvers did you use the exoskeleton?	_____ *(number)* out of _____ *(total)*
In total, how long did you keep it?	
Did you change any settings during use? If yes, specify when and why.	
Did you change any settings after removing the system (for example, after using the restroom)? If so, specify when and why.	
Did you unhook the thighs pads to walk? If yes, how many times?	
Did the exoskeleton prevent you from making one or more movements? If yes, can you list them.	
Did something unexpected happen? If so, can you describe it?	
Do you have any comments about your experience today as a physician equipped with an exoskeleton? Are there things you noticed while using and working with the exoskeleton?	*(free comment)*

E. Questionnaire for colleagues in the ICU

This questionnaire must be **filled by colleagues of the physicians equipped with the exoskeleton**. The first part is filled before the normal work-shift. The second part is filled at the end of the work-shift, when they have had the experience of working with colleagues wearing the exoskeleton. The questionnaire can be filled outside the ICU, for example in the medical staff changing rooms, thus avoiding any risk of contamination by paper.

Questionnaire for colleagues in the ICU

Instructions: you are going to work alongside people equipped with exoskeletons. We need to get some information about your perceptions. This is important for our research to evaluate the impact of introducing such a tool in a hospital setting during COVID-19. The questionnaire consists of two parts: the first, to be completed just before you start working with your colleagues equipped with exoskeletons in the ICU; the second, at the end of your working day. Please fill the two parts outside the ICU.	
1st PART: TO BE FILLED BEFORE ANY WORK WITH PEOPLE USING EXOSKELETONS	
Question	Answer
Participant ID	
Gender (M/F)	
Age	
Occupation (nurse, doctor...)	
Number of months/years of hospital experience	
Number of days/months/years of experience performing the PP maneuver	
In the past, have you had back problems (recurring pain that requires medical attention or sick leave)?	
Do you currently have back problems?	
Have you ever used a back-support system? If yes, which one(s)	
Have you ever interacted with robotic systems or physical assistance devices such as exoskeletons? If yes, which one(s)	
What is your overall attitude towards physical assistive devices such as exoskeletons?	❑ Very negative ❑ Rather negative ❑ No opinion ❑ Rather positive ❑ Very positive
2nd PART: TO BE FILLED AFTER YOU WORKED WITH PEOPLE USING EXOSKELETONS	
You have worked with people wearing an exoskeleton.	
Did working next to a colleague with an exoskeleton make you nervous?	❑ 1 = not at all ❑ .. ❑ 10 = very nervous Answer: _____
Have you been annoyed by working next to people with exoskeletons?	❑ 1 = not at all ❑ .. ❑ 10 = very annoyed Answer: _____
Compared to the "normal" situation (no exoskeleton), did you find the new situation more physically demanding?	❑ 1 = much less ❑ … ❑ 5 = identical ❑ … ❑ 10 = much more Answer: _____
Compared to the "normal" situation (no exoskeleton), did you find the new situation more cognitively demanding (for example, you had to pay more attention...)?	❑ 1 = much less ❑ … ❑ 5 = identical ❑ … ❑ 10 = much more ❑ Answer: _____
If you had the choice, would you use an exoskeleton yourself in the next few months if the current sanitary situation continued?	❑ Strongly disagree ❑ Disagree ❑ Neither agree nor disagree ❑ Agree ❑ Strongly agree

Your perception about the PP maneuver during COVID-19	
On a scale of 1 (not stressful at all) to 10 (very stressful), if you performed the PP maneuver during the COVID-19 outbreak, how much "stressful" was it …?	
… physically	☐_____
… cognitively (pay attention)	☐_____
How often do you practice the PP maneuver every day during the COVID-19 outbreak?	
… times per day	☐_____
… times per month	☐_____
How many times have you practiced the PP maneuver today?	
Do you have any comments on your experience today working alongside people equipped with exoskeletons? Are there things you noticed about the use of and the work with the exoskeleton?	*(free comment)*
Please note for each anatomical zone your perceived effort during your last PP maneuver according to Borg's Perceived Effort Rating Scale (Borg CR10). 0 nothing at all 0.5 extremely weak / very, very slight 1 very weak / very slight 2 weak / slight 3 moderate 4 5 strong / severe 6 7 very strong / very severe 8 9 10 extremely strong / very, very severe	
Neck	☐_____
Lower back	☐_____
Legs	☐_____
Left shoulder / arm	☐_____
Left forearm / hand	☐_____
Right shoulder / arm	☐_____
Right forearm / hand	☐_____

II. EXOSKELETONS USED IN THE EXPLORATORY STUDY

Four commercial exoskeletons were used in the exploratory study at the Hospital Simulation Center: Corfor (Corfor, France), Laevo v1 (Laevo, Netherlands), BackX (SuitX, USA), and CrayX (German Bionics, Germany). It must be noted that in this study we are not claiming a comprehensive comparison of the different exoskeletons that could have been helpful. At the time of the study (which was during the 1st wave of the COVID-19 pandemic) it was not possible for us to rapidly purchase more exoskeletons to evaluate, and it is possible that other passive or active exoskeletons for low-back support which exist on the market could have been helpful for our task. Rather, we have an empirical proof of feasibility at least for one exoskeleton: it can be used in the ICU to assist in Prone Positioning, it is well perceived and possibly beneficial.

Figure 1: the four commercial exoskeletons used in the exploratory study

Figure 2 - evaluation of the Corfor exosuit by the PP team. We assigned a Corfor system to each participant, choosing the size according to their height and the recommendations of the manufacturer. Two participants are also equipped with the Xsens MVN suit to record their motion. The device was reported as not helpful for the specific PP maneuver.

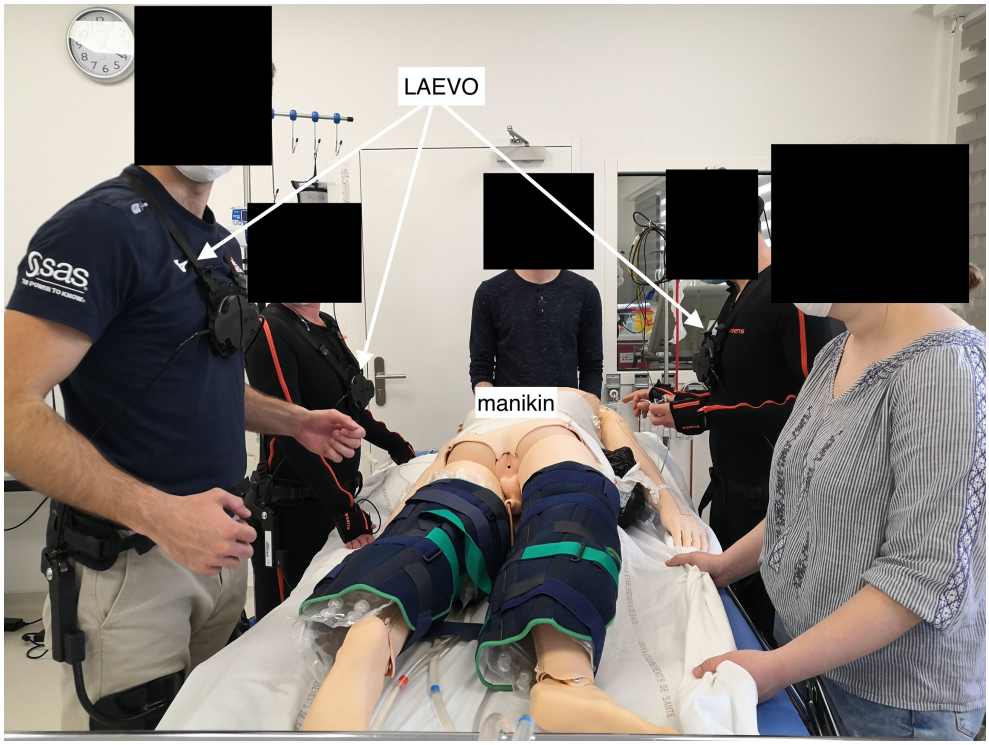


Figure 3 - evaluation of the Laevo exoskeleton by the PP team. We only had three Laevo v1, one for each size (small, medium, large). Each exoskeleton was attributed to the participants according to their height and following the recommendations of the manufacturer. The Laevo exoskeleton was immediately perceived helpful and intuitive. One participant reported a slight discomfort on the sternum during back flexion and on the thighs during walking, noticing it would be better to unlock it to walk normally. This issue was solved in later versions of the Laevo exoskeleton, such as the v2.5 that was purchased and used in the 2nd wave of the pandemic in the ICU (since October 2020).

Figure 4 - BackX worn by one participant. The arrows point to the metallic arcs that are constraining the arms during the PP gestures: the participants pointed out that this was one of the main reasons for not choosing to use this exoskeleton for this particular gesture. The BackX was perceived similar to the LAEVO in terms of assistance, but both participants reported that the metallic curved bars from the sternum to the hip were preventing several arm movements necessary to complete the PP maneuver, and as such they felt they could not execute the entire maneuver with this equipment in real conditions.

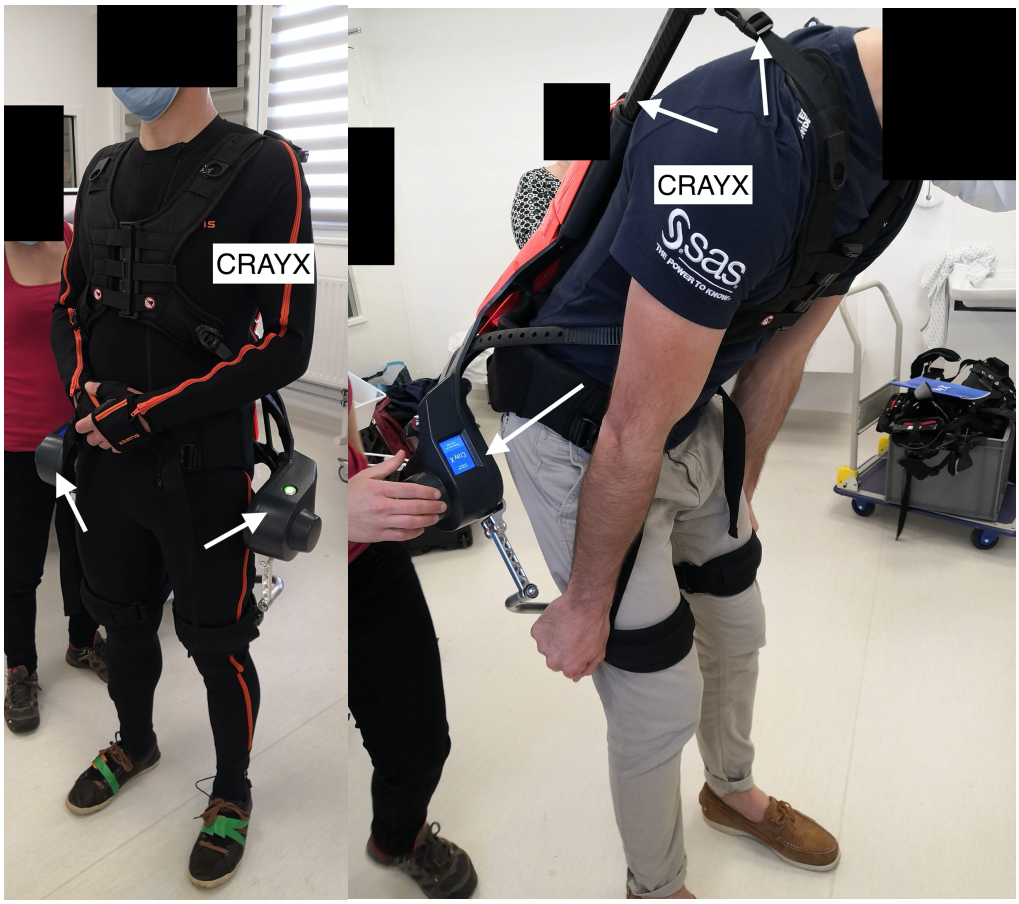


Figure 5 - CrayX worn by two participants. The arrows highlight the external parts of the exoskeleton that add constraints to the workspace. The CrayX was considered too cumbersome to be used around patients, and very difficult to tune. Both participants perceived it required additional concentration effort during back flexion to enable the active support, which they couldn't improve even after changing the sensitivity parameter. Furthermore, one participant reported a critical discomfort due to a part of the CrayX applying a force on the dorsum.

III. Analysis of Motion and Lumbar Effort with Digital Human Model

We replayed the participant's whole-body motion recorded with the Xsens motion capture system with a 43 DoFs Digital Human Model (DHM) using the Dart physics engine. The DHM consists of 19 rigid bodies linked together by 18 compound joints, for a total of 43 DoFs (11 for the back and neck, 9 for each arm including the sternoclavicular joint, and 7 for each leg), plus 6 DoFs for the free-floating base. Each DoF is a revolute joint controlled by a single actuator. The length of each segment of the DHM was scaled to match the participant's body segment length, while the DHM inertial parameters were scaled based on the participant's height and mass using average anthropometric coefficients.

To retarget the participant's upper-body motion in the Cartesian space, we used a hierarchical quadratic programming (QP) controller based on the OpenSoT library, which computes velocity commands to animate the DHM. The QP objective function consisted of the following tasks and priorities:

- level 1 (top priority tasks): balance (center of mass) position task, feet position task (fixed);
- level 2: Cartesian trajectory tracking of the pelvis and thoracic spine segments (position and orientation), of the right and left shoulder, elbow and wrist (position only), and of the head orientation;

where the reference trajectories for the tracking tasks were the 3D positions and orientations of the Xsens avatar's body segments.

After retargeting the participant's upper-body motion, we used the DHM L5/S1 flexion/extension joint torques estimated with the dynamic simulation to compare the lumbar effort exerted by the participant with and without the exoskeleton. The pipeline for this processing is represented in the following Figure.

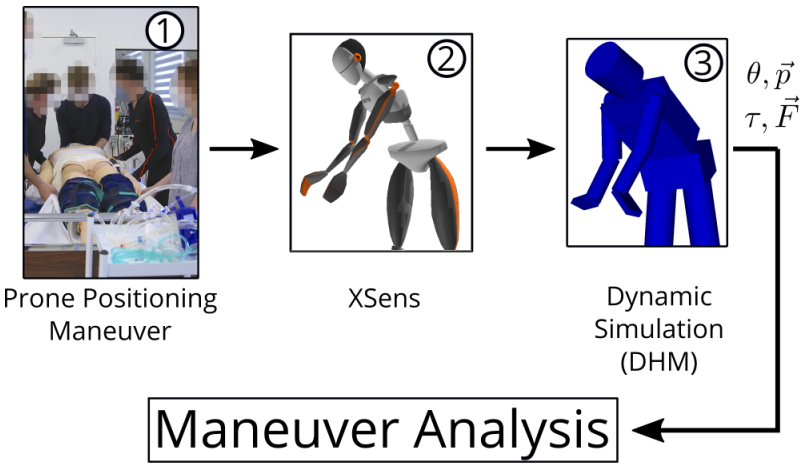


Figure 6- In the study conducted at the Hospital Simulation Center, the motion of one physician executing the PP maneuver was captured with the Xsens MVN suit (Step 1). We used the whole-body kinematic estimation of the Xsens MVN software (Step 2) as an input to our dynamic simulation with a Digital Human Model (Step 3). The analysis of motion and estimation of human lumbar effort are based on this dynamic simulation.

IV. KINEMATIC ANALYSIS

We analyzed the motion of the L5/S1 joint in the sagittal plane during the use of the four exoskeletons in the Prone to Supine (PS) and Supine to Prone (SP) positioning. The following figure displays typical profiles of low-back flexion angle of one participant, for the PS and SP, for all four exoskeletons and without exoskeleton. The joint angle profiles are overall similar for all conditions; variations from one condition to another can be explained by small differences in the manikin's position on the bed and intrinsic variability in the entire maneuver performed by the team.

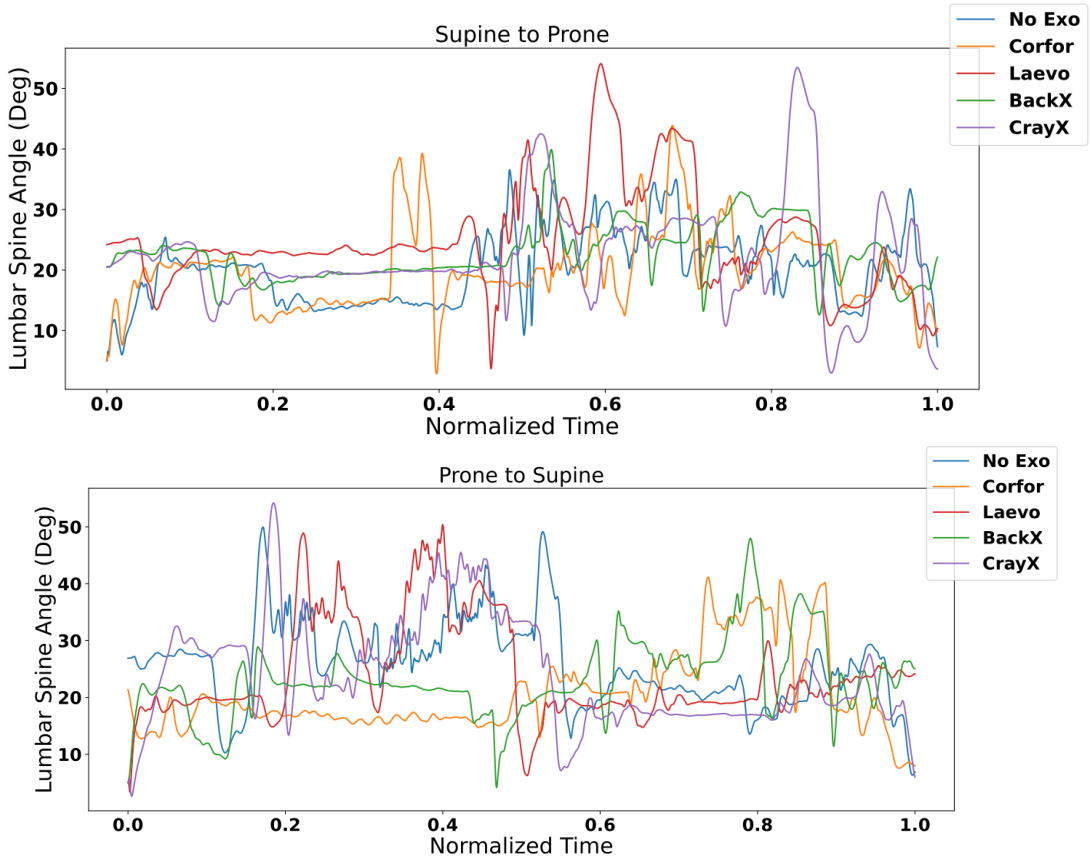


Figure 7- Lumbar spine flexion angle of one participant performing the PP maneuvers at the Hospital Simulation Center.

V. DYNAMIC ANALYSIS

We estimated the human L5/S1 joint torque during the Prone to Supine (PS) and Supine to Prone (SP) positioning, with and without the Laevo exoskeleton, using our DHM simulation.

When the participant is equipped with the exoskeleton, the net torque exerted at the L5/S1 joint to counter the dynamics and gravity effects on the upper-body is a sum of the human-generated torque and of the exoskeleton assistive torque: $\tau_{L5S1} = \tau_{human} + \tau_{exo}$. In order to estimate the human torque, the assistive torque τ_{exo} provided by each exoskeleton is needed. To compute this torque, one needs the details about the mechatronics design of the platform.

We performed this computation only for the Laevo exoskeleton, since it was the one unanimously perceived by the participants as the most suitable candidate for use during PP maneuvers. Based on the Laevo empirical calibration curve published by Koopman et al. and on the Laevo user manual which specifies that its set of springs provides a maximum torque of 40 Nm, we used the following model to estimate τ_{laevo}:

$$\tau_{laevo} = \begin{cases} k_0 + k_1\theta & \dot{\theta} > 0 \\ k_0 + k_1\theta - k_{loss}, & \dot{\theta} < 0 \end{cases}$$

where θ is the back flexion angle, $k_0 = -80/3Nm$ and $k_1 = 4/3\,\frac{Nm}{deg}$ are constants that encode the spring linearity in its range of operation from 20 to 50 degrees (with the maximum assistance of 40 Nm at 50 degrees), and $k_{loss} = 10Nm$ represents frictional losses which introduce hysteresis in the system (numerical values of the model's coefficients were set so that the model matches the calibration curve in [9] as closely as possible).

The following figure displays the estimated joint torque and lumbar flexion angle across time for one PP trial for one participant.

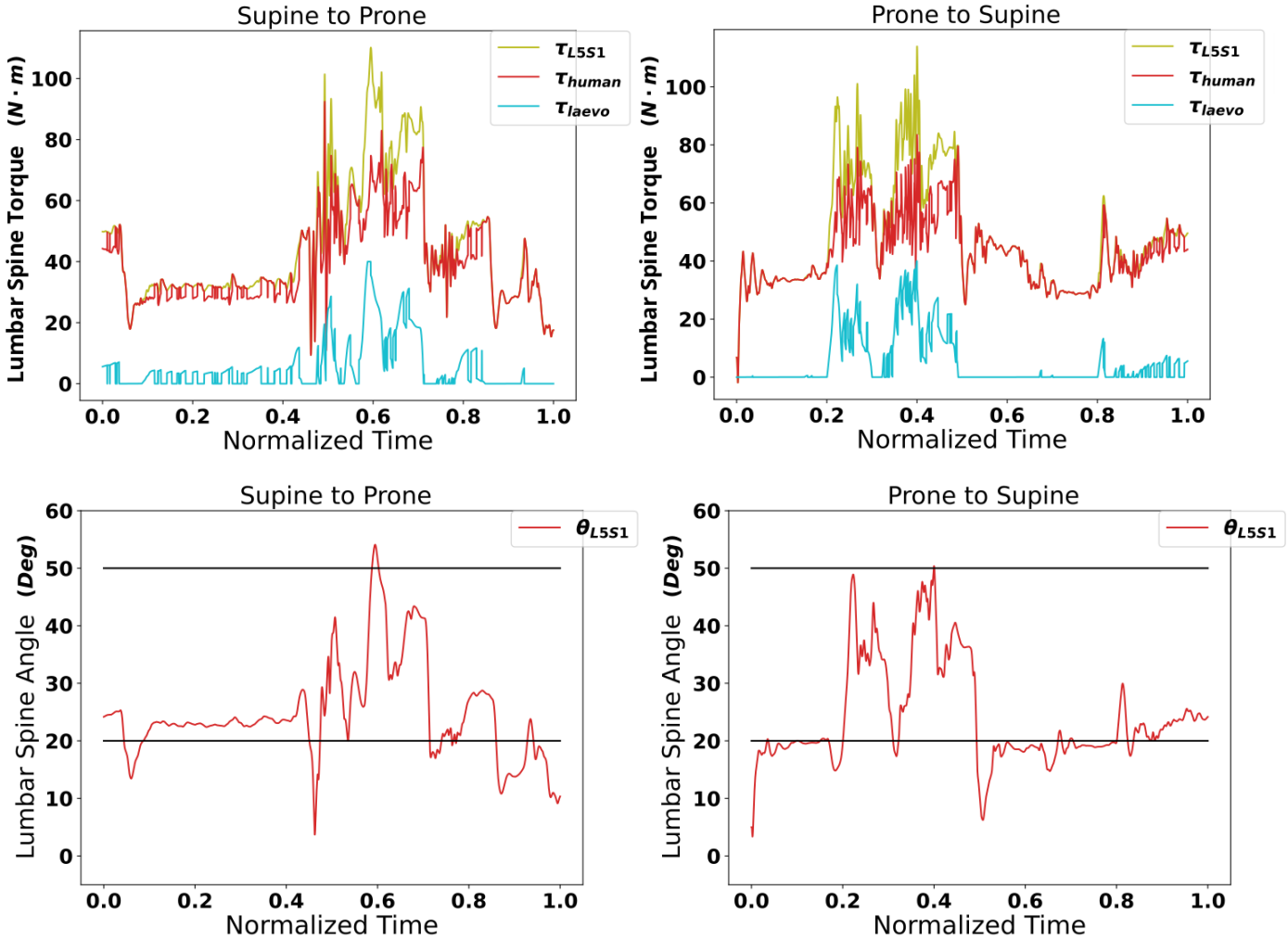


Figure 8 – Estimation of the human lumbar flexion torque and lumbar flexion angle of one participant performing the PP maneuvers at the Hospital Simulation Center. The torques are estimated with the DHM simulation. The plot reports one PP trial across time.

VI. EMG AND ECG PLACEMENT

To study the quantification of the Laevo's assistance, we recorded physiological measures on the participants executing PP maneuvers with and without the Laevo exoskeleton. The participants were equipped with an ECG sensor (Delsys Trigno ECG Biofeedback, 2 channels, bandwidth: 30Hz, ECG sampling rate 4370 sa/sec with onboard Butterworth bandpass filter 40/80 dB/Dec) and 12 surface EMG sensors (Delsys Trigno, EMG sampling rate 4370 sa/sec). The following figure shows the sensors placement on the participant's body, which was done according to Seniam protocol recommendations after abrasion and cleaning with alcohol.

Figure 9 - ECG and surface EMG placement for the quantification of Laevo's assistance during a PP maneuver. A: EMG sensors on ESL, ESI, TA, BF and GM. B: ECG sensor with 2 electrodes and EMG sensors on RA, RF and TA.

VII. DETAILED EMG RESULTS

In the following figure we report the distribution of the EMG signals for 8 right side muscles of one participant, with and without the Laevo exoskeleton.

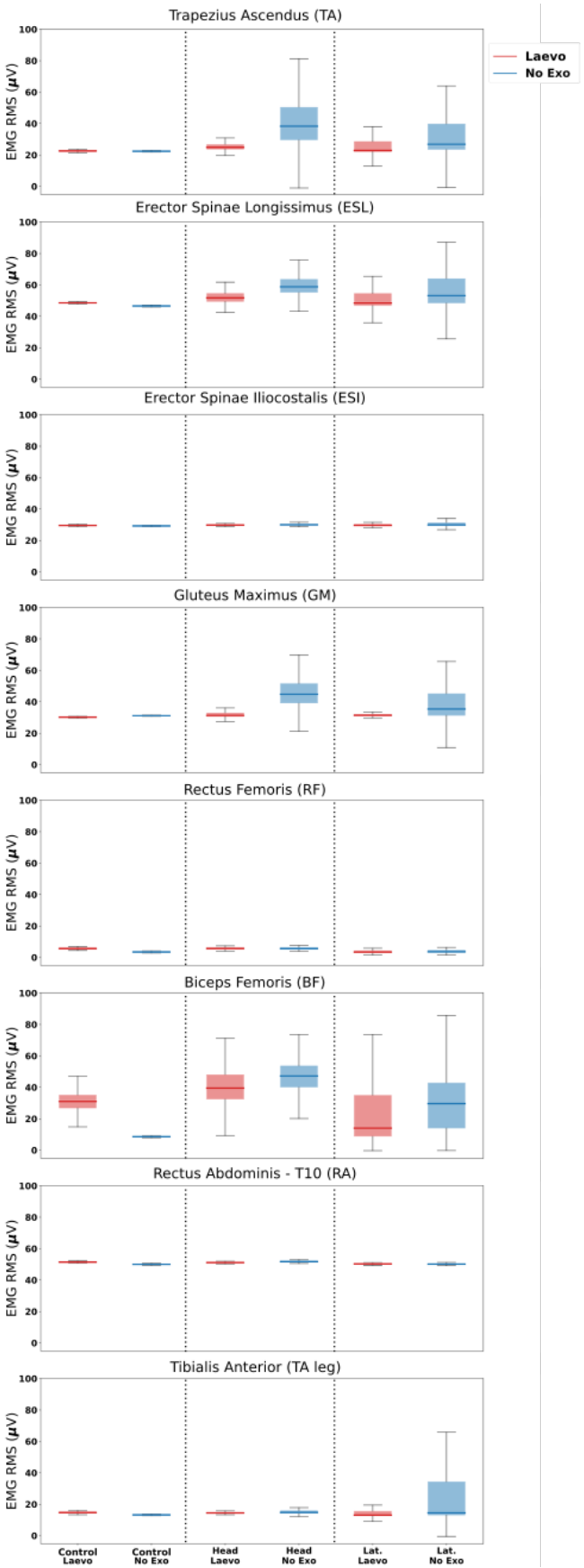


Figure 10 - Boxplots representing the distribution across time of the EMG signal for 8 right side muscles of one participant with and without the Laevo exoskeleton, during a control condition (i.e., resting) and executing the PP maneuver at the head and at the side of the patient simulator at the Hospital Simulation Center.

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