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Safety and risk management in designing for the lifecycle of an exoskeleton: A novel process developed in the Robo-Mate project

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Abstract

Even in our modern and high-tech manufacturing industry, it is often difficult to automate industrial processes which necessities the involvement of human workers. Subsequently, workers are exposed to factors that increase their risk of injury, particular experiencing Musculoskeletal Disorders (MSDs). In addition to contributing to workplace absenteeism and disability rates, injured workers have a negative impact on job productivity and quality.While earlier research and development of exoskeletons is targeted at military and rehabilitation, there is a shifting of interest to target industrial settings. Targeting industrial environments, the Robo-Mate consortium aims to develop a lightweight, flexible, easy-to-wear, easy-to-maneuver, and intelligent exoskeleton that augments the user's personal capabilities while accommodating their physical limitations. The safety of industrial worker exoskeletons is an emerging topic in legislation and standardization. Guidance from standards is only partially possible since no standard exists for industrial exoskeleton technology. This presents a challenging task since an exoskeleton combines technological characteristics of robots (collaborative), machines and appliances, and is used in proximity to and has close contact with the human body. The innovative character of the Robo-Mate technology requires a multidisciplinary approach to the identification of risk and usability while addressing both product safety and workplace safety. This requires a novel safety management approach that governs the life cycle of this new kind of product. This paper will discuss the risk management approach the Robo-Mate project developed and the resulting leading scenarios.

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Keywords: Robo-Mate;Industrial exoskeleton; Innovation; Risk-management; Design; Workplace; Emerging risk; Safety*experiencing*

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1. Industrial exoskeleton challenges risk managementof designers and employers

Even in modern and high-tech manufacturing industry, many operations necessary in industrial manufacturing processes are difficult to automate. 64% of highly skilled manual workers perform lifting and carry loads for at least a quarter of their normal work time[1]. Consequently, workers frequently perform manual handling activities that are an intrinsic requirement in the manufacturing and auxiliary operations. Such activities expose workers to risk factors that increase the likelihood of injury, particularly the development of MSDs. MSDs remain the most common occupational disease in the European Union, and workers in all sectors and occupations can be affected [2].The increasing prevalence of the disorders has a significant impact on both short and long-term sickness absences [3].About 44 million EU workers are affected by MSDs at a total annual cost in excess of €240 billion to the European economy [4].

The objective of the Robo-Mate project, founded under the 7th Research Framework Programme of the European Commission, is to provide a solution for these difficult-to-automate situations by developing an ‘exoskeleton’, to support the human worker while doing their job.The consortium is comprised of twelve partners from seven countries, which includes end-users from automotive and dismantling industries, industrial robotics/technology developers, a robotics integrator, and ergonomics research groups.

While earlier research and development of exoskeletons is targeted at military and rehabilitation, there is a shifting of interest to target exoskeletons at workers partaking in manual handling activities in an industrial setting. The earlier exoskeletons are now, or are almost, commercially available to research and rehabilitation facilities and on a smaller scale to individual users. However, due to excessive weight, severe restriction of human movement and further inadequate functionality, military and rehabilitation exoskeletons are ill suited for industrial work environments.

In order to meet industrial needs and to minimize workers exposure to MSD risk factors, the Robo-Mate project was initiated to create the industrial worker’s lightweight, flexible, easy-to-wear, easy-to-maneuver, and intelligent exoskeleton in accordance with ergonomics principles. Developing concepts and solutions for the Robo-Mate exoskeleton requires new ways for safety and risk management in its design, production, and operation lifecycle. However, safety of industrial worker exoskeletons is an emerging topic in legislation and standardization. It represents a typical example of the changing world of robotisation to accommodate a wearable robot for workers in an industrial workplace setting. In this case, the exoskeleton is being designed as a job aid that augments the user’s personal capabilities while accommodating their physical limitations. The robot is no longer separated in time and space from the operator. Additionally the exoskeleton will be classified as a machine when actuators become part of the exoskeleton concept.For the purpose of the Robo-Mate project, an industrial exoskeleton is defined as:

“*A user guided robot that is worn by or fits closely to his/her body with the purpose of aiding actions or performing actions that contribute directly towards improving the quality of the user’s work by augmenting the functions of their musculoskeletal system when performing physical work*” .

Anticipating the introduction of exoskeletons in both the private and industrial domain, further elaboration of risk analysis techniques and safety criteria is needed. This paper will elaborate on how the Robo-Mate project coped with the lack of applicable standards and legislation, and illustrates an approach for finding a solution for risk analysis. The paper gives an overview of safety issues considered, particularly leading scenarios to be taken into consideration.

2. Safety in industrial exoskeleton lifecycle

To assist in manual handling activities, technological evolution has progressed from mechanised tools, to automated systems, to collaborative interactive robots, and of late, to wearable exoskeleton devices. While modern research and development of exoskeletons primarily focuses on military and rehabilitation environments, the devices have potential for development as a work aid that augments the workers’ capacity.Using ergonomically designed exoskeletons will reduce the incidence and severity of manual handling related injuries for EU citizens and subsequently reduce associated financial burdens experienced by workers and society. Additionally, employers should have an overall positive financial return on their investment with reductions in MSD related absenteeism and improvements in the quantity and quality of productivity [5].

Besides Ergonomics and Human Factors, a diverse array of health and safety issues rise as a consequence of the introduction of an exoskeleton in the work place. Safety is only part of the total array of risk to be considered, see Fig.1.

The Robo-Mate exoskeleton, and its use, can be considered as a man-machine system that functions in specific use environments. A future Robo-Mate exoskeleton may be designed with exchangeable/detachable extensions such as specific clickable tools or cables connected for energy supply and communication. The overview presented in Fig. 2 outlines specific use environments for exoskeleton operation.

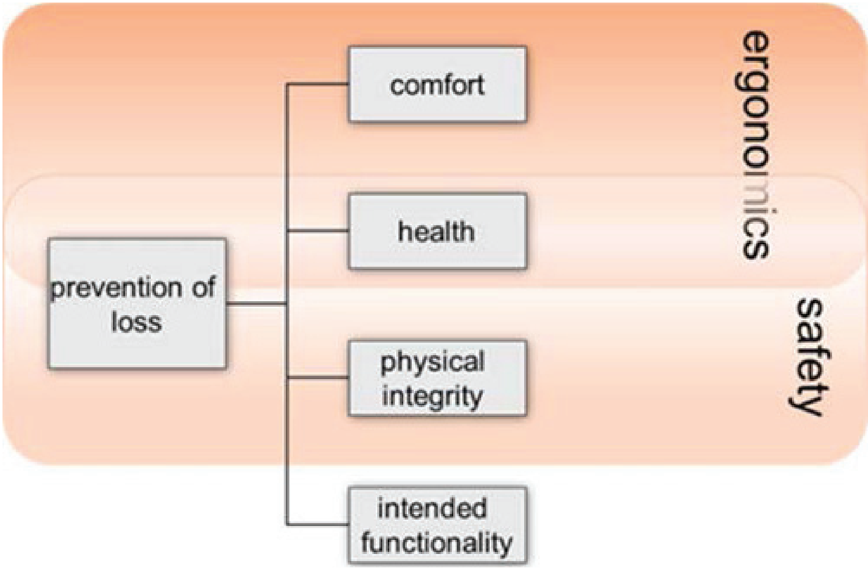

Fig. 1. Risks domains to be considered in exoskeleton design and use.

Fig. 2. Overview of use cases considered in Robo-Mate risk management.

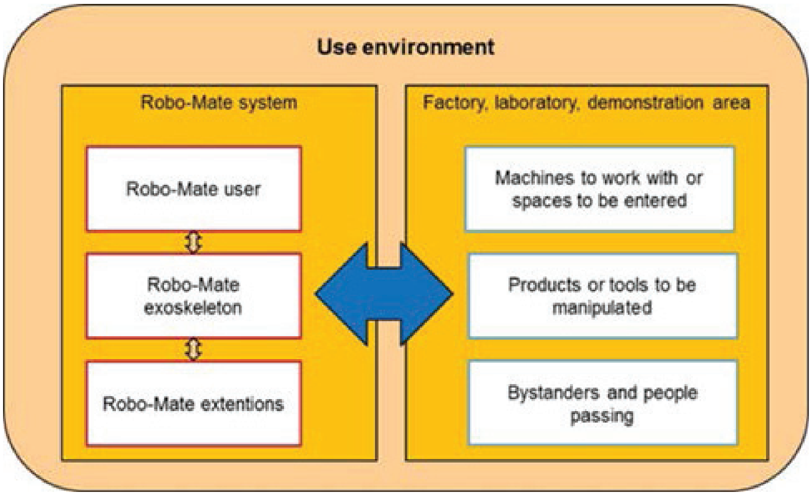

Fig. 3.Context of industrial exoskeleton use.

Studies of the use cases, observation of the activities, and expert opinion from thethe Robo-Mate project Safety Expert panel identified several interactions to be considered between the Robo-Mate exoskeleton and its user and their workplace context (see Fig 3).

- Comparabletools to be connected to the exoskeleton,
- Machines being worked with, conveyors in the vicinity of work activity, workspaces and access requirements,
- Products and tools being used,
- Others working in the vicinity or passing through the work place.

To identify hazards and relevant risk scenarios, the following phases in the life cycle were given priority: design, prototyping, testing, production, commissioning, service and maintenance. The following phases in the life cycle; internal commisioning, transport, storage in the workplace, disassembling and disposal, while being relevant, were not prioritised at this time. People at risk during the life cycle are those who work on or work with the Robo-Mate exoskeleton, and those who work/move in the vicinity of the Robo-Mate exoskeleton. They may be involved in:

- Assembling the Robo-Mate exoskeleton in test laboratory or in the manufacturing factory;
- Testing the Robo-Mate exoskeleton in laboratory or after commission at customer site,
- Training the tester/user,
- Set up and fine tuning the Robo-Mate exoskeleton,
- Using and demonstrating the Robo-Mate exoskeleton,
- Servicing (including cleaning) and maintenance (including trouble shooting) of the Robo-Mate exoskeleton,
- Receiving and delivering emergency service.

Given the innovative character of the Robo-Mate project, no precedent for a risk analysis and listing of potential hazards exists. Additionnally, no literature source or dedicated standard deemed appropriate at the start of the Robo-Mate project was identified. After a comprehensivesearch of potential usable standards was conducted,it appeared that no safety standard exists for an industrial exoskeleton [6, 7], but two sets of standards were identified as being usefulas reference documents. It was concluded that both the service robotsstandard and the industrial robots standard provided a complementary basis for setting safety criteria.

These two sets of standards provide the basis for the risk management in theRobo-Mate project and include:
Risk management oriented standards:

- NEN-EN-ISO 12100:2010, IDT (en) Safety of machinery - General principles for design - Risk assessment and risk reduction.This standard provides a means of conforming to Essential Requirements of the New Approach Directive Machinery, 2006/42/EC which is considered the most important legislative frame work for the Robo-Mate,
- ISO/IEC Guide 51:2014,IDT (en) provides writers of standards with guidelines for the inclusion of safety aspects in standards. The guide adopts an approach aimed at reducing risk arising from the use of products, processes or services.

Product safety oriented standards:

- ISO 13482:2014, Robots and robotic devices – Safety requirements for non-industrial robots – Non-medical personal care robot,
- ISO 10218-1:2011, Robots and robotic devices – Safety requirements – Part 1: Industrial robots,
- ISO 10218-2:2011, Robots and robotic devices – Safety requirements – Part 2: Robot systems and integration.

The standards provided an initial frame of reference for risk identification. Based on these standards,safety was analyzed by identifying hazards and developing leading risk scenarios for the Robo-Mate prototype and the final design and use of the Robo-Mate exoskeleton. The following key issues were deemed to be important:

- Define inherently safe design measures,
- Apply safeguarding and complementary measures to mitigate risks, and
- Provider of usage information or by the user through the implementation of:
  - Organizational measures (procedures, supervision, permits-to-work, etc.),
  - Measures based on the usage information provided by the designer,
  - Additional safeguarding due to specific process(es) in the context of the workplace,
  - Personal protective devices and appropriate clothing, and
  - Training.

By following a “crossover” from the indicated standards to the domain of industrial exoskeletons risk management,the Robo-Mate project could follow proven practices as far as possible. By doing so, it was possible to use the current experience in the field of robot technology to anticipate compliance to the European Machine Directive and European national legislation.

3. Risksidentification

The design and use of an industrial exoskeleton requires a unique approach to manage risks identifiedin the design phase and to anticipate possibly emerging risks in the use phase. An industrial exoskeleton can be considered as a combination of collaborative and service robot functionalitiesthat is carried by the user and directly controlled by the users’ body movements.The use environment is assumed to be: a) the premises of the organization producing and testing the Robo-Mate exoskeleton or parts of it, and b) factories and workstations being identified as use cases.

In order to provide a benchmark for further analysis, three existing cases of current work tasks in the factories of the projects industry partners were selected as representatives of future environments and task demands (Fig 2). The Robo-Mate project aimed to establisha list of applicable hazards by:

- Using lists from selected standards as a benchmark, hazards were identified and summarized,
- Organizing brainstorming sessions to assist in identifying specific hazards and risk scenario’sfor the use cases.

This analysis, conducted by Human Factors and Safety Experts in the Robo-Mate project, resulted in a tentative list of 165 potentially hazards for the exoskeleton. After prioritization,these experts selected 75 unique hazardsas a basisfor the design and prototype developing process. These hazards were summarized in 15 leading scenario's comprising both health and safety risks, see Table 1 [6].Other typical points of attentions to be considered, but not prioritized at this stage, include hygiene of the exoskeleton, and contact points between the exoskeleton and the user in which the distributed forces result in localized pressure to muscles and veins [6, 7].

Table 1.Leading risk scenarios for Robo-Mate industrial exoskeleton.

Leading scenario	Examples
Unintended movement of Robo-Mate (parts)	Robo-Mate sensorsmis-interpret the user's unconscious intended movement to removetheir glasses as a command to move its upper and lower arm in another direction.
Unexpected movement of Robo-Mate (parts)	The sensor-actuator combination flexes the left arm quicker than the right arm resulting in unbalance of the load being carried by both hands.
Movement of Robo-Mate (parts) outside human range of motion.	The Robo-Mate actuates user's arm by rotating the lower-arm part several degrees beyond their natural hyperextension.At the end of day, the first user stores the Robo-Mate in a different operational mode, or fails to reset their personal settings; the next user fails to reset the settings resulting in poor physical or biomechanical fitthat can result in overexerting of movement or force during work.
Non-synchronised movement of Robo-Mate (parts)	The user wants to move the load faster than the Robo-Mate allows causing unbalance.
Unequal distribution of forces on Robo-Mate (parts)	Due to worn out joints, or imprecise adjustments of Robo-Mate, forces are not distributed according to design specs.
Loss of Robo-Mate (parts) load support	The load starts to shift due to imbalance or loss of grip.The body limbs are not properly aligned with Robo-Mate parts and/or sensors leading to wrong interpretation of a command.
Loss of Robo-Mate stability	Due to change of posture, the centre of gravity of the user plus Robo-Mate moves beyond the tipping point of user.Uneven floor leads to stumbling of user due to inertia of Robo-Mate weight.Due to emergency stop of Robo-Mate, the actual inertia/momentum of the user/Robo-Mate ensemble does not fit with the expected kinematics, posture and stability of the user.
Loss of Robo-Mate control	Due to an unknown failure in the software controlled safeguards,Robo-Mate stops working while carrying a load.Exposure to vibration or stresses on body parts leads to fatigue and loss of control.Disconnected feeder cable, communication cable, or damage of the power cable leads to power interruption or black-out of Robo-Mate.
Operator not escaping from dangerous situations	The user who falls ill cannot be rescued from the Robo-Mate to receive first aid.Robo-Mate inertia hampers rapid withdrawal or reflexive action to move from a danger zone.Removing Robo-Mate in the event of fire alarm will delay their emergency response.
Operator not protected from dangerous situations	Robo-Mate user works close to a work environment with dangerous machinery and their view to the area limited, thereby failing to notice danger zones. Work spaces or passageways with dangerous climate (dangerous substances, excessive heat, slippery surfaces etc.) should be avoided.
Robo-Mate unintentional operated outside use conditions	The user walks with his Robo-Mate into an area where he is exposed to falling water splashes when cleaning work is performed in the environment.Abuse or misuse of emergency controls leads to control state outside designed limits. The user grips the load in a way that greater forces are exerted than intended e.g. lifting a load in an expected/intended way.
Entanglement/drawn in with Robo-Mate (moving parts)	The user wants to take out a cable entangled at the elbow joint of the Robo-Mate while flexing the lower arm resulting in crushing of a finger.
Non-robustness of critical Robo-Mate parts	The user overloads (misuse) the Robo-Mate arm beyond the designed capacity of its motor actuator resulting in breakdown of the motor.The expected use of Robo-Mate in a climate it is designed to (e.g. with very humid air) causes corrosion which leads to loss of sensor sensitivity.
Safety warning of Robo-Mate not noticed by user due to incompatibility of display with user demands and "noise" in environment.	The display is not well positioned or reflects light hampering reading and interpreting safety messages by user.
Discomfort due to noise or other stressing factors leads to loss of acceptance of Robo-Mate use	Robo-Mate user feels uncomfortable when temperature changes and body temperature cannot be cooled, user sweats and Robo-Mate does not "breath" etc.

4. Exoskeleton risk management

Both the exoskeleton supplier and the employer, as key stakeholders, have a responsibility to provide a safe reliable exoskeleton and to consider the work environment and activities being carried out. For example, in a car manufacturing company or in a car disassembly company, the workers partake in activities that involve repetitive and frequent lifting and supporting car component as illustrated in the use cases (Fig 2). The risk management needs considered are:

- Product management: product development, production, sales, and risk and safety management,
- Product reliability: failure modes and effects, fault analysis, software and controls reliability performance/ integrity levels,
- Maintainability,
- Product health and safety: safety analysis, ergonomic analysis, risk perception and acceptance of exoskeleton (objective and subjective),
- Occupational health and safety: selection of products fit for purpose and for user, usability, training, injury prevention, stress prevention, and monitoring of health and safety.

The users' needs and vulnerabilities, their operational needs and threats must be considered (both from a pre-market and post-market perspective). These include:

- The users fitness levels and capacity to operate the exoskeleton,
- The interactions between the exoskeleton and user (dialogue, matching intentions between the user and exoskeleton response),
- The interaction of the exoskeleton and its use environment,
- The return to a safe and controllable state when user becomes ill or in the event of exoskeleton malfunction,
- The ability for safe exit from the exoskeleton in the case of an emergency event.

Since the industrial exoskeleton is a new technology, new risks may appear because of unforeseen or unknown user behavior or because of exoskeleton performance. Therefore, in addition to extensive testing in real-life situations, post-market monitoring, and customer/service feedback is required to ensure safe competent users, and a safe reliable exoskeleton. This can be organized by:

- The employer utilizing appropriate health monitoring of Robo-Mate users on a frequent basis and updating risk evaluations and appropriate health and safety management OHSAS 18001 [8] and the pending ISO 45001 standard [9],
- The supplier by utilizing post market surveillance and customer feedback,
- Both the employer and supplier considering complementary risk solutions to augment the workers capabilities and minimize the physical stress imposed on the users.

5. Conclusions

The hazards and risk scenarios identified in the Robo-Mate project may guide the risk management process. Given future standardization on workplace safety and health [9], this analysis needs to be updated with respect to a) stakeholders demands (including the workforce), b) legislation, and c) risk analysis and evaluation based on knowledge and experience with an industrial exoskeleton in a diversity of domains. This requires a resilient, anticipatory, and adaptive organization that is prepared and willing to update their knowledge, keep an eye on emerging risks and maintain contact with industries interested in or using an industrial exoskeleton in order to organize cross-domain learning.

The innovative character of industrial exoskeletons requiresa risk management process that is adapted to its unique technology, its man/machine interface, and to the experience gained from developing a “wearable” robot.

The risk reduction gained when using the exoskeleton (reduced physical loading) should not be nullifiedby the introduction of transferable health and safety hazards and risks. To identify hazards, and to guide the exoskeleton design process, the Robe-Mate project developed a new approach by using a combination of generic risk management approaches being proposed in the field of machine safety, and specifications and guidance from industrial and service robot standards. This was complemented by carrying out a project specific risk analysis based on interactions between safety management and the Robo-Mate design and prototyping processes.

Present standards to support risk analysis are incomplete. Generic risk management standards can assist in establishing the risk management process during the life cycle of the industrial exoskeleton. Standards combined with hazard and risk analysis provide a good basis for design but requires updating as the knowledge of risks will evolve during the design, testing, and use phases. Industrial exoskeletons are not yet fully understood in terms of operational experience and long-term effects to the users of the exoskeleton. This calls for further development of the risk management process, the willingness of organizationsto anticipate, adapt, and learn from emerging knowledge and experience, andfeedbackfrom the stakeholders involved.

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