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The progressive intertwinement between design, human needs and the regulation of care technology: the case of lower-limb exoskeletons

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Abstract.— The adoption of robot technology is accelerating in healthcare settings. Care robots can support and extend the work of caregivers in assisting patients, elderly or children. Typical examples of such systems are ‘cognitive therapeutic robots,’ ‘physical rehabilitation robots,’ ‘assistive and lifting robots.’ Although these robots might reduce the workload of care workers, and be a cost-efficient solution against healthcare system cuts, the insertion of such technologies may also raise ethical, legal and societal concerns concerning users. In this article, we describe some of these concerns, including cognitive safety, prospective liability, and privacy. We argue that the current regulatory framework for care robot technology is ill-prepared to address such multidisciplinary concerns because it only focuses on physical safety requirements, whereas it disregards other issues arising from the human-robot interaction. We support the idea that design plays a significant role in shaping the technology to meet the needs of the users and the goals set by the regulation. To illustrate practical challenges, in this article we consider as an example the case of lower-limb exoskeletons. This example helps illuminate the overarching idea of the article, that is, that regulation, design, and human needs need to intertwine and mutually shape each other to serve the solutions these technologies proclaim.

Keywords.— Human-Robot Interaction, Care Robots, Regulation, Design, User-Centered Approach, Law, Safety, Privacy, Cognitive, Technology.

1. INTRODUCTION

The adoption of robot technology in healthcare settings is accelerating. Typically named ‘healthcare robots,’ ‘care robots’ or ‘carebots,’ these robots are service robots that perform useful tasks for humans by processing of information acquired through sensors, in the context of healthcare. Care robots support impaired individuals, extend the work of doctors in medical interventions, help in patient care and rehabilitation activities, and also support individuals in prevention programs [1]. Those robots that assist users through social interaction are often called socially assistive robots (SAR) [2].

In a recent resolution, the European Parliament (EP) highlighted that in this context, robots might ease the work of care assistants by performing automated tasks [3]. In the EP’s understanding, this technology

may free caregivers from tedious work, and allow them to devote more time to diagnosis and better-planned treatment options. Notwithstanding the benefits of this technology, the latest research on care robot and artificial intelligence (AI) technologies shows that their implementation is not straightforward and that their interaction with the users raises many ethical, legal, and societal concerns [4-5]. Moreover, the EP’s statement is challenged by recent findings that show that AI systems can outperform doctors at diagnosing probabilities of diseases and the conditional dependencies between disorders [6].

Technology responds to human needs, creates new needs and behaves together with humans as a whole, even if not always in syntonio to human evolution. In this sense, technology can shape how we perceive reality [7]. For instance, technology has the power to drive us away, from who we are and from what surrounds us; and at the same time, to capacity to get closer to each other. In words of Bauman, due to technology ‘proximity no longer requires physical closeness; but physical closeness no longer determines proximity’ [8]. It is not surprising, therefore, that the insertion of technology in the health context may have undesirable consequences, at many levels, dimensions and concerning different people.

Technological innovation goes hand in hand with regulatory development. If the law establishes general rules of power and conduct of the society; in the context of research, development, and innovation, the law balances the potential benefits of innovation typically, with the negative impacts this may cause to society. However, the regulation does not advance at the same pace or direction of that of innovation [9]. Technological advances bring uncertainties on both the application of established legal and regulatory mechanisms and regulatory development. In light of new technology, applying an existing framework might not be straightforward, and the creation of a new framework might not respond adequately to the arisen issues [10].

In this article, we describe some of the concerns arising from the insertion of care robots in healthcare settings, including cognitive safety, prospective liability, and privacy. To illustrate practical challenges, we consider lower-limb exoskeletons as an example of care technologies. Lower-limb exoskeletons are physical assistant robotic devices that can be fastened to the human body to provide augmentation or supplementation of personal capabilities [11]. These

devices represent a great example of the intertwining between humans and technology and help illuminate the overarching idea of the article, that is, that regulation, design, and human needs need to intertwine and mutually shape each other to serve the solutions these technologies proclaim. We address only lower-limb exoskeletons because to tailor different forms of assessment to specific problems and situations is more constructive [12]. Moreover, although commonalities can derive from a particular analysis, every robot is different and will require different appraisals [10]. We do not consider other types of personal care robots such as person carriers or assistive robots in this article [13-14].

Building on the analysis of the legal and regulatory implications of personal care robot technology in previous related work [5], in this article we argue that the current regulatory framework for care robot technology is ill-prepared to address such multidisciplinary concerns because it only focuses on physical safety requirements, whereas it disregards other issues arising from the human-robot interaction.

We support the idea that design plays a significant role in steering the technology in the appropriate direction to meet the needs of the users and the goals set by the regulation. With the technological advancements, new user needs will arise. Designers should be aware of the current and future use and societal needs and think about how to incorporate them into the design process to achieve a better integration within the current technological and social milieu.

We divided this paper into different sections. Section 1 describes lower-limb exoskeletons, and section 2 introduces the regulatory framework for care technologies and its related problems. We also explicate concrete legal issues about cognitive safety and privacy. Section 3 lies at the intersection between design and human needs. Section 4 compiles some proposals for future multidisciplinary regulatory initiatives. The article concludes with the statement that regulatory actions that fail to address the interdependence of design, regulation, and human needs elements risk being ineffective.

2. CASE STUDY: LOWER LIMB EXOSKELETONS

a. Concept and characteristics

Exoskeletons are the opposite of endoskeletons, that is, a rigid external skeleton that covers the body in some invertebrate animals. From the Greek ἔξω - outer/external - and σκελετός - dried body - alias skeleton, when relating to robotic technology an exoskeleton is basically 'wearable robot attached to the wearer's limbs to replace or enhance their movements.' Also, called, Physical Assistant Robots (PAR), exoskeletons are assistive technologies and a sub-type of personal care robots [11]. They assist users to perform some tasks by providing augmentation of individual capabilities. They have been used for lower

and upper limb rehabilitation [16-17], including stroke patients gait and grasping rehabilitation [18-19]. In other domains, people use them in factories and the military field [20-21].

In this article, we focus on lower-limb exoskeletons. The majority of these exoskeletons are fastened directly to the user's body and work together 'in seamless integration with the user's residual musculoskeletal system and sensory-motor control loops' to assist him/her 'with minimal cognitive disruption and required compensatory motion' [22].

Table 1 compiles different examples of lower-limb exoskeletons such as HAL, Exo-Legs, HiBSO [23], ExoLite and HULC, and their characteristics including model, target users, size, the context of application, weight, battery life, speed, stair-climbing function, autonomy, body weight limit or whether it incorporates any accessories. The majority of the examples have a standard size, i.e., not adaptable to the user's physical characteristics; they cannot support more than 80 kg, and they tend to be over 12 kg. We also notice that exoskeleton technologies remain focused more on rehabilitation applications and military purposes [24]. Exoskeletons have potential applications in a wide variety of environments aside from healthcare too [25].

These robotic devices share some of the characteristics of what has been called wearable technology. Although exoskeletons are not in miniature, they are body-borne computational and sensory devices that can collect a wide range of information from the user's body and the user's environment. Wearable computers can be worn under, over or in clothing or may also be themselves clothes. Exoskeletons are typically worn over clothing and 'contextualize the computer in such a way that the human and computer are inextricably intertwined' [26].

Parameter	Lower limb exoskeletons				
Model	HAL	Exo-Legs	HiBSO	Exolite	Exokool
Academic project	No	Yes	Yes	Yes	N/A
Market Product	Yes	No	No	Yes	N/A
Certification	ISO 13482:2014	N/A	N/A	N/A	N/A
Users	Elderly, non-medical	Elderly, non-medical	Elderly, non-medical	Rehabilitation and home users	Elderly, non-medical
Size	S/M/L	N/A	Unique Size	Height range 160-190 cm	Height range 160-190 cm
Model	Medical/non-medical	Basic-Standard-Deluxe	N/A	N/A	Basic-Standard-Deluxe
Supported weight	Lower than 80 kg	N/A	N/A	Lower than 80 kg	Lower than 80 kg
Device weight	Double leg 12 kg, single leg 7 kg (excluding battery)	N/A	14 kg	N/A	14 kg
Battery life	60-90 min	Wear time: 60-90 min (battery doesn't say)	90 min	480 min	300 min
Speed	N/A	Doesn't say	4 km/h	5 km/h	4.5 km/h
Stair-climbing function	N/A	Yes	Yes	Yes	Yes
Robot autonomy	Yes	Yes	Yes	Yes	Yes
Assistance	N/A	30% max.	Not much	N/A	60% max.
Accessories	Belt, hip supporter, pad, sensor cable, electrode cable, leg cuff, custom shoe, leg module, custom PC, cover for battery connector, maintenance tool.	N/A	N/A	N/A	N/A

Table 1 Comparison table between different exoskeletons.

The human-robot interaction (HRI) of lower-limb exoskeletons is advanced, although it mainly differs from the interaction between social robots and humans. Exoskeletons work symbiotically with the user's movement, creating a perfect harmonious flow between the user and the robot, and do not typically interact with the human socially. Exoskeletons detect the intention of action and execute a movement according to the pre-set parameters, or adapting to the user's movement in real-time. This makes exoskeletons physically sensitive and empathetic to the user's movement. In exchange, the user needs to trust the robot and rely on it to perform his/her desired movement. Although this trust is not mutual, it is unidirectional [27]; it plays a vital role in the correct functioning of the robot.

b. Covered and provoked needs

At the same time that user needs give rise to technological solutions, the application of such solutions brings about other needs that, paradoxically, humans believe new technologies will solve. This is the case of lower-limb exoskeletons. These robotic devices have been designed to fulfill the needs the insertion of wheelchairs cause. Wheelchairs provide greater mobility to those who cannot walk, but they do not help users in the process of sitting, they cannot travel in uneven terrain, cannot usually climb stairs with few exceptions,¹ and they force the user to be sat all the time. One of the basic needs that lower-limb

exoskeletons covers are the need for walking. Exoskeletons are robotic devices that help users to walk, which is one of the conditions for the proper functioning of the internal systems and organs of the human: it stabilizes blood pressure, improves pulmonary ventilation, prevents the degeneration of muscle and bone tissue and increases joint mobility [28]. Robotic exoskeletons provide better patient training, quantitative feedback, improved functional outcomes for patients than manual therapy [29]. At a social level exoskeletons can offer the possibility to its users be in an upright position, which is helpful not only to make eye contact but also to give autonomy and independence to the user. Being in an upright position has been found to improve depression or social isolation reduction [30]. Other capabilities of exoskeletons may include stepping over objects, walking on the soft and uneven ground and walking up and downstairs. With the extended use of exoskeletons, new needs will arise. This is because there is pressure to deliver new products that focus more on economic profit than on human values and needs, resulting in rapid technological advancements designed to satisfy most of the times only desires, while real human needs are often disregarded [31]. This translates in this case study of lower limb exoskeletons in the fact that:

- Available lower-limb exoskeletons tend to be bulky and heavy, and made from hard materials. This not only hinders the correct adaptation to the user's body as shown in table 1, but it also may result in the user spending more energy than the energy the exoskeleton supposedly had to provide [32].
- The user of the robotic device is the object of the safety requirements, not the subject of them. This means that devices are designed to be safe in general, e.g., not to electrocute users or not to fall when functioning. An example of this general safety is the inclusion of general gait patterns to help the device make faster decisions [33]. However, individual users will have particular conditions and personal needs that may need more attention than minor general requirements.

3. THE CURRENT REGULATORY FRAMEWORK FOR CARE ROBOTS AND ITS LIMITATIONS

Usually, four constraints that regulate a thing: the law, social norms, the market and the architecture [34]. As with other personal care robots, there is no specific legal framework for lower-limb exoskeletons. Still, a partial regulatory framework can be pieced together based on existing European measures.² For instance, many existing laws and regulatory requirements may apply to exoskeletons such as the Directive 2001/95/EC on general product safety and Directive 85/374/EEC on liability for defective products, the

¹ Cfr.: scalevo.ch.

² For other countries, please consult what are the legislations that would be the framework for lower-limb exoskeletons.

Directive 2014/35/EU on low voltage; the electromagnetic compatibility Directive 2014/30/EU; or even the General Data Protection Regulation because of lower-limb exoskeletons process lots of personal data.

Until last year, there was the discussion on whether the Regulation 2017/745 on medical devices, would apply to all exoskeletons or only those that had a medical intended purpose. The article 1.3. of this regulation states that ‘devices with both a medical and a non-medical intended purpose shall fulfill the requirements applicable to devices cumulatively with an intended medical purpose and those applicable to devices without an intended medical purpose.’ This seems to suggest that exoskeletons robot technology has to comply with the medical device regulation independently of whether it has a medical or non-medical intended purpose. However, the lack of specific regulation brings about uncertainties concerning the application of the current framework to care robot technologies [5].

Leaving aside binding rules and legislation that could apply to care robots, a thing it is usually regulated by social norms, offer-demand market rules and technical norms [35]. Technical norms are industry-driven standards that are considered soft-law, that is, they are not binding but provide a framework that could be considered by the judiciary. ISO 13482:2014 ‘Robots and Robotics Devices - Safety Requirements for Personal Care Robots is the only technical norm that governs personal care robots, including physical assistant robots for non-medical device applications. This standard includes person carrier, physical assistant and mobile servant robots on its scope. Lower-limb exoskeleton designers will have to apply these safeguards to avoid compounding risks:

- Care robot **general risks** relate to the robot shape, robot motion, energy supply, and storage. ISO 13482:2014 identifies some hazards due to incorrect autonomous decisions when the device is in autonomous mode, hazards when the robotic device enters in contact with moving components, and navigation errors.
- **Specific risks** for a restraint-type physical assistant robot (lower-limb exoskeletons would be in this category) relate to instability - provoked by the attachment or removal of the device. According to the standard, producers should design the robotic device in a way that it can be fastened and put on when the user is in a stable position, and very lowly-powered so that it cannot harm the user. For further protective measures, the standard suggests the robotic device to incorporate a warning sound to indicate that its position is not correct, and to reduce (in case of moving in this phase) the speed to a safety-related speed/force control. As an additional protective measure, the standard mentions that the removal of the exoskeleton will lead this device to be in a *safe state*.

The technical norm ISO 13482:2014, however, falls short in providing more concrete guidance and in defining what constitutes safety for particular robots, e.g., lower-limb exoskeletons, or what practical protective measures could apply. For lower-limb exoskeletons, we could argue that safety lies on the motion of the device, in both the estimation and the execution of the movement - not only when the user puts on the device. The estimation of the movement should be reliable [36], although internal and external factors, e.g., when the user tremors or sneezes, condition the estimation of movement, posing at risk the correct performance of the device [37]. The time between transitions and between the motor commands and the generation of force should be as fast as possible, to avoid instability, especially in lower-limb orthosis [38].

Other risks challenging safety refer to the execution of the movement; in essence, to the risk of falling, either due to a slippery terrain or obstacle collision. While environmental-related accidents are the primary cause for falls in the elderly, balance is the second cause [39]. In the use of exoskeletons, balance is also a safety hazard, although travel instability is not considered for physical assistance robots in the standard ISO 13482:2014 [11].

Nevertheless, standards do not, in themselves, set legally binding rules. Besides, technical standards tend to be single-impact based. ISO 13482:2014 for instance merely establishes physical safety requirements for personal care robots. Care robots typical have a cyber-physical dual nature, that is, they may have part of their computation power in the cloud (via using cloud services), and they have a physical interface that interacts in the world directly with users. As these robots exert forces that can overpower humans, physical safety has received all the attention from regulators, at least from standard setting. However, the deployment of robot technologies may imply broader ethical, legal, and societal implications that a comprehensive framework should foresee. Indeed, other legal principles and values such as privacy, dignity, data protection, and personal autonomy, are often disregarded in standard setting [40]. This may respond to the idea that private actors tend to protect their interests more than promoting public objectives.

Whatever it is, the greater intertwinement between users and robotic devices will call for a much more comprehensive regulatory framework [5]. The latest robot public and private regulatory initiatives – Resolution 2015/2103 (INL) 2017 - and the most recent standards such as BS 8611:2016 Guide to the ethical design and application of robots and robotic systems, and IEEE Ethically Aligned Design 2017 from the IEEE Global Initiative and Standard Association seem to point to this direction. Still, these initiatives are at their infancy.

The following sections provide an overview of some of the issues that our current legal framework cannot easily accommodate, including cognitive safety, prospective liability, autonomy and data protection [41].

a. *Cognitive human-robot interaction: perceived safety*

Exoskeletons are an extension of our bodies both in physical and in cognitive terms. In physical terms, an exoskeleton needs to integrate the mobility requirements from the end users (human gait analysis, conditions, and characteristics) into the mechanical design, control system and the user interface [33]. In cognitive terms, the user needs to trust that the device is safe enough to walk with it (especially in lower-limb exoskeletons). From a legal viewpoint, the respect for the physical and the psychical integrity of the person are fundamental rights in relevant legal documents (e.g., the European Charter of Fundamental Rights) and deserve the utmost respect.

This physical-cognitive dual nature plays a significant role in determining whether a robot is safe to use. There are some differences between certified safety and perceived safety: perceived safety is described as ‘the user’s perception of the level of danger when interacting with a robot, and the user’s level of comfort during the interaction’ [42]. Indeed, ‘a certified robot might be considered safe objectively, but a (non-expert) user may still perceive it as unsafe or scary’ [43]. Being afraid of the device, for instance, not only affects the adequate performance of the device, but it may also affect the user: heartbeat may accelerate, hands may sweat. Depending on the condition of the user, these consequences may impact their perception of the overall safety of the device. As the European Parliament mentioned: ‘you (referring to users) are permitted to make use of a robot without risk or fear of physical or psychological harm’ [3]. Because physical assistant robots work symbiotically with the user’s movements - sometimes even having with the capacity to overpower human intentions - and those are indissociably physical and cognitive, special attention will have to be drawn progressively to both sides to ensure the safety with these devices too.

Although the literature has understudied ‘perceived safety,’ major studies acknowledge its importance [3, 44]. On its latest resolution, the EP encourages designers to ‘draw up design and evaluation protocols and join with potential users and stakeholders when evaluating the benefits and risks of robotics, including cognitive, psychological and environmental ones’ [3]. This suggests that such instruments identifying and mitigating hazards linked to the perception of the user are currently missing, although they seem to be crucial to ensure safety to the whole extension of the meaning of the word.

b. *Prospective liability*

Unintended harm can occur in the course of operation of a robot: a robot grasper can hit a person, or a user can fall when using a lower-limb exoskeleton. However, harm can also appear after a while, after using the robot continuously for a while. In the case of lower-limb exoskeletons, for instance, it could well be that the users’ muscles activate, but user’s do not detect

whether it is part of the normal robot usage, or not. Some of the users of this technology might lack the capacity to feel the legs, or may not merely know how their muscles were activated before they had the injury. In a recent study, this is what happened. Moreover, the problem lied on the fact that they could not provide reliable feedback to physicians or therapists because they lacked the means on how to do so [45]. Retrospective liability should apply if there is a causal link between the robotic device and the future harm, Datteri argues.

More qualitative and quantitative data is needed to understand the likelihood of occurrence (and the extension of the damage) of harms after robot usage, and whether some extra safeguards should be implemented in this respect. As the same as what happens with the use of robots in highly unstructured environments and diverse scenarios including the example of prostheses and exoskeletons, ‘only the diffusion and real use of the device – and subsequent accidents caused – will provide more reliable data’ [46]. However, should the society allow the occurrence of these accidents to have the actual data? It does not seem to work the same way with other technologies. Airplanes have a clear regulation on simulator hours for pilot training and a clear protocol before take-off for security purposes. At the moment, however, physical assistant robots are fastened to the body of a person, and even if they apply forces that could be destructive, it is not clear what protocol should apply to them. This is what Datteri refers to with the concept of ‘prospective liability’: ‘whether it is ethically acceptable to deploy some robotic system or technology for tasks that involve (potentially harmful) human-robot interactions’ [45].

In light of little knowledge on the potential negative impacts of a specific technology, the precautionary principle should apply, or at least further measures should mediate to prevent users from any harm. Roboticists should be able to provide the user with enough information and techniques so that appropriate feedback can be provided in the case of supervised activities, for instance, when using Retiatech’s system. MovMe, the system offered by Retiatech consists of two inertial sensors that detect the amplitude of the movement, the speed at which this is done and its acceleration. These sensors capture joint motion according to all these parameters. This can provide permanent information on the relative position of each sensor to the other, allowing measurements of high precision, with negligible errors concerning other measurement systems; an effective way to provide reliable feedback without even having the patient’s need to know whether their muscles activate in a normal or an abnormal mode.

In this respect, the EP argued that ‘as regards non-contractual liability, Council Directive 85/374/EEC of 25 July 1985 can only cover damage caused by a robot’s manufacturing defects and on condition that the injured person can prove the actual damage, the defect in the product and the causal relationship between damage and defect (strict liability or liability without

fault’ [3]. The problem is that the article 7 (e) of this European directive 85/374/CE on liability for defective products, establishes an exemption: ‘the producer shall not be liable as a result of this Directive if he proves (...) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.’ The big problem will be, then, how to justify what includes the available knowledge that the product liability directive mentions.

For instance, if there are possible push recovery and stabilization algorithms for exoskeletons [47], should they be included in the design for lower limb exoskeletons? At this moment, there is no obligation to cover these kinds of algorithms. It is also not very clear what role cognitive aspects play either. Moreover, although the EP suggested strict liability for those cases when it would be impossible to justify the device’s fault, it is not clear how the industry will respond to these pressures. Another approach is the creation of an insurance scheme, also proposed by the EP, which would cover the actions of autonomous robots. In this respect, it is not very clear which robots would have an obligation to have insurance, if it is more related for autonomous cars, or if in general for robots with a degree of autonomy [48].

c. Reversibility and user’s safety

Algorithms can learn very complex behavioral skills, but the application of such methods in the physical world involves much training, learning, and experience from a robot. In the course of education, a robot may attempt to carry out a task. The robot is gradually introduced to carefully selected scenarios to support learning, aka scaffolding [49], and bad policies bring the system to an unrecoverable state from which learning is no longer possible [50]. After each attempt, the environment needs to be reset to start the process again, and improve. However, not all the tasks are easily or automatically reversible. For instance, if a robot falls down the stairs, human intervention is needed to reset the environment between attempts [51].

In a similar line, the EP proposed the concept of reversibility as a ‘necessary condition of controllability, a fundamental concept when programming robots to behave safely and reliably’ [3]. For the EP the ability to undo the last (sequence of) action performed by the robot would empower the users ‘to undo undesired actions get back to the ‘good’ stage of their work.’ The problem with this concept is failing to acknowledge that there are and there will always be irreversible actions, states that might not be quickly restored after clicking the command Ctrl+z [14]. Indeed, catastrophic consequences such a lower-limb exoskeleton falling are irreversible.

Eysenbach et al. have recently proposed a framework to automate the reversibility process of reversible actions, and also have ideated the integration of early aborts to avoid unrecoverable states (see image below) [50]:

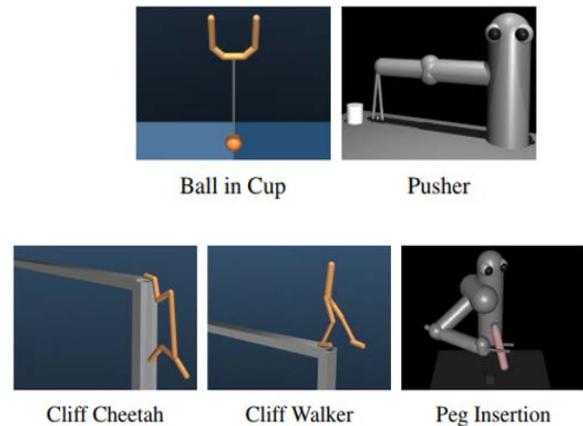


Fig. 1 Continuous control experiments used to answer the questions of the early abort approach. Extracted from [50]

From these scenarios, the pusher may push the block outside its workspace, and the cheetah and walker may fall off the cliff. These are considered irreversible situations. A designer may want to define an impact regularize to abort the performance of a task from which the robot cannot recover [50, 52]. Indeed, the inclusion of unsafe states in the learning process of a robot may help the system avoid adverse side effects and, thus, learn more safely [52].

Early aborts may not always work, especially in balance-of-interest scenarios. Imagine a trolley-problem inspired scenario: a robot has to choose between saving the granddaughter or the grandfather after the house sets on fire. Having to choose the lesser of two evils in a balance of interest may imply irreversible consequences for the unpicked interest. In the reasoning of Eysenbach et al., then the robot should have avoided being in that situation in the very first place, but setting the house on fire might not be on its decision power.

In connection to prospective liabilities, another question may arise: will these advances in reversibility work for long-term effects too? The uncertain and unknown nature of these consequences may challenge the correct categorization of unsafe states. More research is needed to understand what can be cataloged as risky so that these can be included in the system.

d. Kill switches, design and data protection

The same may happen the other way around, that is, a reversible action in the physical world might not prevent action in the cyber world. System failure leads the device to a protective stop mode. This very well known in the area of safety, and it refers to the avoidance of the continuation of a task if the system has failed [11]. This can be done automatically, or with human intervention, i.e., with a big red button that stops robot task performance. In this line, the EP mentioned that robot engineers ‘should integrate obvious opt-out mechanisms (kill switches) that should be consistent with reasonable design objectives’ [3].

The machinery directive states that protective stops need to be quickly accessible.



Figure 2 Extracted from [23]

The figure above shows an example of a kill switch. Although the inclusion of such red button makes the project comply with the regulation, it is hard to imagine a user with a particular health condition pushing it to stop the performance of the device. This is an example of how design plays a role in meeting regulation objectives. However, the mere compliance with the requirement without any reflection further may not serve the purpose of the law.

The cyber-physical nature of robots, however, raises other concerns about these kill switches: no matter how quickly accessible they are, part of the processing and functioning of the robot still occurs even if it is in protective stop mode. Although there exist hardware kill switches, there do not necessarily exist software kill switches. Having a hardware protective stop may protect the physical safety of the user but may not protect the user from interferences with other rights, like data protection for example [53]. While the art. 32 of the GDPR refers to the security of the data processing there could be created a virtual protective stop where the whole processing of the robot stops. Although this relates to the opt-out mechanism, we are referring not only at the possibility that the users have to opt out from giving specific personal data, but to the whole ensemble of the data processing, i.e., when the system is hacked, and the robot needs to stop performing the tasks.

4. DESIGN APPROACHES USER NEEDS

It is a hard task to decide the correct features for an exoskeleton design combining users, technology and medicine perspectives. Each of them considers specific requirements and constraints, for instance, aesthetics and comfort are essential for the user perspective; functionality and battery life are priorities for technological perspective; accuracy and availability are mandatory for medical perspective [54].

Lower-limb exoskeleton technologies are complex wearable systems that aim at being integrated into daily living activities. In this sense, they should design the systems in a way that they serve their first purpose. Wolff et al. identified some important design-related

aspects to consider in the development of lower-limb exoskeletons, including the comfort in use, the minimization of the risk of falls, their cost, and also the easiness of putting on and taking off. According to their survey, the specific needs for exoskeleton design can focus on robust control, safety and dependability, ease of wearability/portability, usability/acceptance [55].

According to Motti et al., there are other strong principles to be considered into the design process, including affordance, intuitiveness, and user-friendliness [54]. They support the idea that an intuitive interface tends to be easier to use and consequently more user-friendly, which leads to more adaptation. They also believe that the accuracy, availability, and security principles are complementary to the design process. These principles commonly relate to the degree of usability of the designed product by people with the broadest range of security capabilities.

However, user-friendliness does not have to imply oversimplification. Indeed, incorporating principles of customization and simplicity is beneficial, but may need to be carefully managed by designers to ensure that overall design objectives are not comprised.

a. *Human-centered and ability-based design approaches*

Designers need to focus their solutions in meeting users' needs, interests and requirements via current functional design approaches. In the assistive technologies field, there are different approaches to design interactive products, including the activity-centered design, systems design, genius design or user-centered design. It is better to apply more than only one design approach to achieve more efficient and suitable outcomes through the design process [56].

Some of these approaches have received regulatory attention, at least from the private setting viewpoint. ISO 9241-210:2010 Ergonomics of human-system interaction - Part 210: Human-centered design for interactive systems refers to user-centered approaches. These approaches are useful in design processes because they alternate iterations and evaluations, such as focus groups, interviews, and surveys with the end users of the technologies. Human-centered design is the 'approach to systems design and development that aims to make interactive systems more usable by focusing on the use of the system and applying human factors/ergonomics and usability knowledge and techniques' [57]. It normally refers to human because it emphasizes the fact that the design approach includes other types of stakeholders, not only users, but it has also been named 'user-centered design' (UCD). This approach considers human participation in all stages of the process [58]. Since it takes into account users' needs and interests from the first stage, this approach increases the effectiveness of the process, the quality, and usability of the final product, and improves the accessibility of interactive systems using integrating theoretical models with practical user performance feedback [56]. According to the ISO 9241-210:2010 it

also ‘counteracts possible adverse effects of use on human health, safety and performance.’

The human-centered design aims at increasing the acceptance and productivity of interactive systems, reducing errors and hours of support and training, as well as providing the best possible user experience. User experience refers to the perception the user has about a product, and it includes affections, emotions, beliefs, and expectations that occur before, during and after use of the product and is directly and closely related to the user experience when interpreted from the perspective of the range of user goals. It also has some connections with universal design, which refers to the design for diversity, including people with different ages, people with sensory, physical or cognitive impairment and people with different background and cultures [59]. In short, the universal design focuses on designing systems to be used equally for all.

For lower-limb exoskeletons, Ability-Based Design (ABD) may also be an exciting approach to meet the user needs. ABD attempts to shift the focus of accessible design from disability to ability throughout the design process to create systems that leverage the full range of human potential. Although prior approaches to available computing may consider the user’s capabilities to some extent, ABD makes ability its central focus [60].

For instance, a user with limited dexterity can have difficulty to use a mouse, which was designed for users with standard ability. The user may additionally have to use accessibility-based software or get a particular device designed precisely for people with disabilities. The ABD approach would instead provide a system that is aware of the abilities of the user and would provide an interface better suited to those abilities. The SUPPLE system is an example of a system that measures the user’s pointing abilities and automatically redesigns, rearranges, and resizes the interface to maximize performance [60-61].

ABD is a useful refinement to existing open computing approaches such as rehabilitation engineering, universal design, and inclusive design because prior approaches consider users’ abilities to some extent, ABD tends to centralize the disability rather than the ability. When designing lower-limb exoskeletons, the appropriate question will be ‘what can a person do?’ rather than ‘what disability does a person have?’ Such as UCD focuses interactive systems development to users, ABD refocuses accessible computing from disabilities to abilities. Designing lower-limb exoskeleton with the ABD approach requires developing systems that can fit the skills of the users.

b. Regulatory needs of human-centered approach

Although UCD is the most common approach, it has some regulatory needs. According to Marti and Bannon, UCD approach lacks methods that adequately integrate user requirements and needs in situations

where the user involvement is challenging, e.g., because the user has special health conditions, or has different mental abilities [62]. The authors argue that in psychological experiments, users should be observed, studied and questioned and have performance on tasks measured.

Activities involving users with different abilities can trigger potentially incorrect interpretations of the real needs of users. It may be awkward or even inappropriate in some cases. To circumvent the limited expressiveness of this profile, Marti and Bannon suggest allowing therapists and caregivers to have a voice in the process and take the place of other stakeholders mentioned in ISO 9241-210: 2010 [62].

Other regulatory needs on a UCD approach focus on the cognitive requirements of the users, such as acceptability of the device, abandonment, or social isolation. Already acknowledged in the previous sections, cognitive aspects are only acknowledged but not part of current legislation. In our case study, to provide a consistently positive experience to people with disabilities via the use of lower-limb exoskeletons it is necessary not only to focus on their physical safety but also onto the user’s cognitive needs and requirements.

Another weak point of today’s exoskeletons design is the direct information exchange between the user’s nervous system and the device. Advancements in neural technology will have meaningful importance to the field of robotic devices. Neural implants might provide sensory feedback to the nerves or brain, thus allowing the exoskeletal wearer to have some form of kinetic and kinematic sensory information from the wearable device [63].

Although robotic exoskeleton technologies advanced rapidly, there are also some mechanical design challenges that impede meeting completely the goals set by the regulation. For instance, current lower-limb exoskeletons are heavy, unnatural, noisy, have limited power and difficulty to augment the user’s movements. All these influences negatively the user’s experience [64]. It is worth mentioning that current mechanical interface designs also cause discomfort to the wearer, and are not suitable to be worn for long periods. It will be an essential development to achieve comfortable and effective mechanical interfaces with the human body.

Latest advancements promise lighter, smarter, and stronger exoskeletons [65]. Current lower-limb exoskeletons are bulky, expensive and not personalized. Moreover, users still need, in most of the cases, the help of a human caregiver to put these devices on and make them work. If rehabilitation therapists charge by the hour, these time spent in setting the devices on has an impact on the overall cost of the sessions. Soon the need for new designs that can address these scarcities will become evident. Future design of lower-limb exoskeletons will follow bio-inspired materials and bio-inspired design patterns, similar to the ones used by Soft-Exosuits in Harvard

Bio-Design Institute, which can be worn under the clothes of the user.³ Perhaps in the future exoskeletons will also be created with other materials for instance with non-Newtonian liquid. This material can solidify, at the command of the wearer through a magnetic or electric current and it has been already used in some exoskeletons at MIT.⁴ The more the exoskeletons will be softer, lighter and more comfortable to wear, the more human needs will be covered and, thus, the more usability will increase.

Last but not least, upcoming binding privacy-by-design principles suggest that technical measures to preserve the privacy of users will have to be implemented in the very design process of the device. Available literature fails to address the translation problem between general principles and concrete technical requirements, as it is uncertain how to enforce transparency, right to be forgotten and data portability requirements among others in technical terms.

5. PROPOSALS FOR A BETTER INTERTWINEMENT BETWEEN DESIGN AND REGULATION

a. Personalized, dynamic and reactive legislation

Regulation typically happens in a reactionary fashion: because there were many road accidents, the government implemented seat belts as mandatory. Accidents, thus, tend to lead to regulatory change. This cannot happen in rapid-changing fields like robotics, primarily because of the growing numbers of applications where robots work with senior adults, disabled or children.

One of the possibilities to avoid unfortunate scenarios provoked by robotic technology is to have legislation that covers all these aspects. In February 2017, the EP approved a report with several recommendations to the European Commission on Civil Law Rules on Robotics. While the EP expects the European Commission to make a regulation foreseeable in 10-15 years, it is not clear what legislation is applicable in the transition time, nor what is expected from roboticists.

It can be that future regulations include the obligation of conducting ex-ante impact assessments to anticipate and mitigate legal risks involving particular interests or technologies. According to the Article 29 Working Party's opinion (A29WP), the 'risk-based approach goes beyond a narrow harm-based-approach that concentrates only on damage and should take into consideration every potential as well as actual adverse effect, assessed on a vast scale ranging from an impact on the person concerned.' Impact assessments are an excellent instrument to deal with the problems that new technologies pose in a bottom-up approach. There are currently many impact assessments, including data

protection impact assessment, surveillance impact assessment or environmental impact assessment [66-67]. Since a robot can challenge many of these impacts, maybe a technology-specific multi-impact assessment could make more sense to collect all the impacts (and mitigations to those impacts) in a single document.

A multi-impact assessment for robot technology may be called merely 'robot impact assessment.' This methodology was applied to care robots in 2015 and was called 'care robot impact assessment' [35]. Even if this can improve accountability, trust, and transparency, however, the fulfillment of an accountability requirement does not feedback the regulation per se, i.e., the regulation is not easily updated thanks to the compliance of this requirement [10].

The problem with classical static regulations, even if they include the obligation to conduct impact assessments, is that they do not foresee the renovation of the rules to meet the regulatory needs of new technical innovations. As new technologies grow exponentially, the need for a system that can cope with this rapid path and vast state of the art will become evident very soon [10].

Products are unique, and each product needs to comply with different regulations. Robots are the same: their characteristics and their context of use make each robot unique. Although personalized, dynamic, and proactive regulations might seem unrealistic at the moment, current legislative trends suggest that there will be, in the future, systems, and programs to allow cross-compliance systems. In 2016, the Consumer Product Safety Commission (CPSC) launched 'Regulatory Robot' (RR), a portal that tries to facilitate the identification of the American federal product safety requirements for those who want to manufacture a product (for children or other consumers).

This system does not retrieve information for updating the regulatory system back. However, the program could be used to identify gaps into the regulatory system, for instance, when the users running the software do not find a legal solution within the system [10]. Recognizing these gaps could help the process of ex-post legislative evaluations [68]. These impact assessments are used to assess the administration, compliance or outcomes of legislation to learn and inform enforcement. The nature of this process is, therefore, cyclic.

The sophistication of legislative tools – making compliance easier – and the current trend of ex-post checking systems – for improvement purposes on the legislative side – envisages a communication between both creators of technology and regulators. This will soon translate in a faster updatable legal framework that will be able to help solve the translation problem current rules have – providing more meaningful and realistic rules.

b. Future exoskeleton design

Our technological creations are grand extrapolations of the bodies that our genes build. In this

³ Cfr.: biodesign.seas.harvard.edu/soft-exosuits

⁴ See <http://web.media.mit.edu/~neri/site/projects/talos/talos.html>

way, we can think of technology as our extended body. Technology as body extensions will become more enjoyable, will last longer, perform better, without susceptibility to breakdown. We are already in the early stages of augmenting and replacing each of our organs, even portions of our brains with neural implants, where the most recent versions of which allow patients to download new software to their neural implants from outside their bodies [69].

This extension does not need to be ingested or to be prosthetic. These advanced technologies do not need to be invasive. They can be more natural and closer to us – a jacket or a watch for example. Indeed, we can think of clothes as an extension of our body, that protect us; cars as a faster way of locomotion than walking; powerful telescopes to observe outside our planet as an extension of our eyes; hearing aids to hear better. Wearable devices such as exoskeletons have the potential to transform our daily lives. The forthcoming years will show how integrated technology can impact our lives for the better.

The new human-machine nature will come gradually because of the presence of new products designed to share knowledge, emotions, and experiences through socially oriented platforms (e.g., open source design, hackerspaces) supporting social co-operation and social augmentation, engaging people in this way at perceptual, emotional, social and intellectual levels. This will lead us to wonder whether these devices can be considered part of the human body and be treated as equal as human parts, e.g., for indemnification reasons in case of harm. As there are already taxonomies that give value to human body parts (e.g., for insurance or the worker's disability compensation act) would then new types of exoskeleton be valued the same amount of money? Would there be a provision on compensation terms for this? Are they going to be considered part of the human body even if they are for activities of the daily living, for instance, to work in an industry where the owner of the company decides to provide that to the workers? Should there even be a discussion on this? The more these robotic devices will be mixed with the human body, the bigger room for these discussions in the legal domain.

Advancements in brain-computer interface (BCI) exoskeletons will make them more adaptive to user needs. Improvements in material research will allow developing 4D printed soft wearable skin-like exoskeletons, which can also be ultra-light and breathable at the same time and that can be powered by a continuous power source, e.g., movement or temperature.

Most humans see the advantages of a technological, diverse civilization since they see more possibilities for the improvement of themselves and their lives. Likewise, this technical diversity brings choice through wearable, portable, ubiquitous devices, augmented abilities or technologies such as artificial intelligence, synthetic biology, transformability and emotional feedback (through physiological or neurological data). With more products becoming connected, and with the

growth of Artificial Intelligence, these new products can work together to fulfill our needs, or ideally, even their own needs. These products could be self-aware, self-sustainable, and self-organizing.

Considering the facts mentioned above, we propose an innovative design approach including some additional features towards a better exoskeleton design for today and also for the near future. As an innovative approach, the design process should include not only the user in the center but also the changing user needs coupled with technology advancements. For instance, technology can provide advantages to augment the people abilities to adapt to today's living conditions better and also, help to reduce the difficulties of people with physical and mental disabilities. A better solution might be an inclusive and universal approach to integrate with both neurotypical people and people with physical or cognitive disadvantages into society giving equal living standards.

Designers should carefully analyze the costs and benefits of each solution before developing the design process. To be efficient enough to offset the user's need during the process, technical and ergonomic requirements, available features, device, size, or computational power, also need to be analyzed [54]. A clear understanding of target users and their contexts are also advantages.

c. Emotions as part of the design process

The co-evolution between design, human needs, and technology determine a dynamic, timeless, interrelated way to design exoskeletons. One of the most critical social needs is the user's cognitive and emotional well-being. However, little exists on the meaning that it has under the user's point of view, especially concerning which emotions it evokes [70]. What's more, little is said on how this applies to those physical-empathic relationship created between users and devices.

Emotions are in the way of significant innovation, require the endowment of positive experiences consistently, and should be considered as a substantial component in the design process [70-71]. In the case of lower-limb exoskeletons, the user's emotional answers during exoskeleton usage could be analyzed to understand the perceptions of the user over safety, and other aspects. For Desmet, there are no general rules or a manual of conduct to evaluate the relationship between the product and the users' emotional answers [72]. However, these play a significant role in the usability and adaptability of new technological advances. Indeed, the interpretations of the characteristics of the product evoke emotions that can inform and feedback the design process [73].

Desmet and Dijkhuis' study shows that a wheelchair can entertain its users and positive emotions can be resulted [72]. Using the user's characteristics with exoskeleton interaction could provide better technology and human-robot interaction in acceptability terms. Desmet agrees that positive emotions stimulate the acceptance of objects and

negative emotions stimulate their rejection. Pleasure and emotion, thus, support interaction and rehabilitation [74]. As Mallin et al. state, ‘it is not a matter of giving the projects a false impression of beauty but, to provide them of aesthetic-formal quality and significance while considering in all cases the user's final experience. Safety, functionality, usability, pleasure, and individualization configure some of the instruments with which the product's personality is obtained leading to the perfect synergy between the aesthetic, symbolic, practical and semantic functions’ [70]. Also, safety, functionality, usability should be subordinated to the user's satisfaction [75].

To decrease the abandonment and increase the acceptability of exoskeletons, a multi-disciplinary, universal, inclusive user-centered approach to better understand user needs with the development of person-environment-technology interaction should be addressed into the design process [76]. Additionally, research providing user insights may be useful to help understand and optimize the acceptance and adoption of such devices especially by older adults [25].

6. CONCLUSION

In this article, we described a human-robot interaction that has scarcely been covered in the HRI literature, that is, the interaction of lower-limb exoskeletons and its users. We have considered design, human needs, and regulation. The overarching idea of the article is that regulatory initiatives that fail to adequately integrate design, human needs, and regulatory aspects into each of these categories will compromise the future of healthcare robot technology.

Although not part of the safety requirements yet, there is a growing part of the literature that believes that cognitive aspects like the perception of safety from the user are crucially important. The fear of falling, for instance, constraints the appropriate performance of a lower-limb exoskeleton. This dissociates physical/cognitive nature of exoskeletons, initiates a debate on whether current safety requirements fall short in addressing the whole extension of the word safety, and whether these will progressively include cognitive aspects into the design process to make a safe human-robot interaction or not.

In the article, we proposed the inclusion of the cognitive dimension in the user-centered design process by understanding the user needs and helping to have better interaction with his exoskeleton device. The role of a user with a disability should be placed in the center of the design's innovation. During the design process, questioning, test, and reflection about the project and to evaluate the prototypes in a real context should be included to improve the final product design quality. Designers need to understand that current creations can impact how we conceive this world and that it is in our hands whether we want to create products to preserve our nature, our humanity or to destroy what it means to be human.

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CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest.

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