

Human-Centered Design of Wearable Neuroprostheses and Exoskeletons

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■ *Human-centered design of wearable robots involves the development of innovative science and technologies that minimize the mismatch between humans' and machines' capabilities, leading to their intuitive integration and confluent interaction. Here, we summarize our human-centered approach to the design of closed-loop brain-machine interfaces powered prostheses and exoskeletons that allow people to act beyond their impaired or diminished physical or sensorimotor capabilities. The goal is to develop multifunctional human-machine interfaces with integrated diagnostic, assistive, and therapeutic functions. Moreover, these complex human-machine systems should be effective, reliable, safe, and engaging and support the patient in performing intended actions with minimal effort and errors with adequate interaction time. To illustrate our approach, we review an example of a user-in-the-loop, patient-centered, noninvasive BMI system to a powered exoskeleton for persons with paraplegia. We conclude with a summary of challenges to the translation of these complex human-machine systems to the end user.*

Recent advances in smart human-machine systems, including wearable robotic technologies and neural interfaces, which are able to detect conscious choice, decision, and intent from the patient, now allow the design of wearable robots and powered prostheses and exoskeletons that assist and work cooperatively with people with disabilities (figure 1). Recently, the U.S. Food and Drug Administration (FDA) defined a powered exoskeleton as “a prescription device that is composed of an external, powered, motorized orthosis used for medical purposes that is placed over a person’s paralyzed or weakened limbs for the purpose of providing ambulation.” Moreover, the FDA determined that powered exoskeletons are class II devices with special controls that provide reasonable assurance of the safety and effectiveness of the device.



Figure 1. Two Examples of Exoskeletons with Bilateral Powered Ankle, Knee, and Hip Joints.

On the left is the Exo-H2 device (CSIC, Madrid, Spain) and on the right is the Rehab REX (Rex Bionics, Auckland, New Zealand).

Future generations of these human-machine systems will be designed with integrated diagnosis, assistive, and therapeutic capabilities, and will include brain-machine interface (BMI) subsystems that detect and interpret the patient's intent, make context-based decisions, and allow people to act on dynamical environments beyond their impaired or diminished physical, cognitive, or sensorimotor capabilities.

The design of effective wearable human-machine systems is a multifaceted effort that requires close collaboration among academia, clinical centers, industry, regulatory agencies, and end users to address the entire regulatory, engineering, and clinical life cycle for these devices, leading to fast translation to the end user. To accelerate the development and deployment of such complex human-machine systems, acting in direct support of individuals and groups, the multiagency U.S. National Robotics Initiative (NRI) was launched in 2011 by President Barack Obama. The most recent program solicitation can be found in National Science Foundation (NSF) (2015).

Indeed, consensus at the NRI workshop on Clinical Brain–Neural Machine Interface Systems held at the Houston Methodist Research Institute in Spring 2013¹ showed that although neuroprostheses, neurally controlled exoskeletons, and other types of BMI systems have achieved success in a handful of investigative studies, translation of closed-loop neuroprosthetic devices from the laboratory to the market is challenged by gaps in the scientific data regarding long-term device reliability and safety, uncertainty in the regulatory market and reimbursement pathways, as well as patient-acceptance challenges that impede their fast and effective translation to the end user (Liew et al. 2013).

In the past, wearable robotic prostheses and exoskeletons have been designed primarily to restore the mechanical function of impaired limbs in humans with physical disabilities — although powered exoskeletons have also been specifically designed to augment strength, endurance, and mobility of humans. However, by deploying a human-centered approach, BMI-enabled human-machine systems can be designed and specifically prescribed to provide direct health benefits across multiple physiological systems in health and disease (Contreras-Vidal and Grossman 2013). For instance, BMI systems could be specifically designed to trigger, facilitate, or enhance cortical plasticity leading to faster and more complete functional recovery of the patient. Moreover, health benefits through enhanced structured physical activity with exoskeleton-assisted mobility could serve as a stimulus to improve skeletal muscle structure and metabolism, skin and vasculature including vasomotor reactivity in legs and brain, bone health, and cardiorespiratory fitness of patients with paralysis and other forms of paraplegia (Evans et al. 2015). Importantly, intelligent human-

machine systems based on human-centered design principles could also serve to empower patients to engage in their own health care and wellness while allowing clinicians to harness diverse (multimodality) data to improve health outcomes through big data analytics, improving health-status predictions, and medical support decision making.

In this article, we summarize human-centered design principles for the development of BMI systems to multifunctional wearable robots. To illustrate our approach we discuss engineering and clinical challenges in the development and validation of a powered lower-body exoskeleton augmented with a non-invasive scalp EEG-based BMI capabilities to assist or restore independent walking to a mobility-impaired person. This approach has been extended recently to rehabilitation robotics for stroke patients by developing noninvasive neural interfaces to the NASA X1 exoskeleton (He et al. 2014) and the European H2 robotic exoskeleton (H2 2014; Bortole et al. 2015).

Human-Centered Design Principles

Figure 2 depicts a systems-level schematic of subsystems regulating context-dependent human-machine interactions between a mobility-impaired user or patient and an assistive powered exoskeleton while providing real-time monitoring of neurological, physiological, biomechanical, behavioral, location, and environmental signals with diagnostic value. The design of such human-machine systems operating in dynamic environments requires a human-centered approach to ensure that they are effective, reliable, safe, and engaging. To accomplish these aims, our laboratory employs several human-centered design principles for human-machine systems (HMSs) reviewed next.

Design Principle I.

Closed-loop human-machine systems require real-time coordination and management of power transfer between the user, robot, and their working environment.

Close physical contact between the wearable exoskeleton and the patient and the surrounding dynamic environment leads to power transfer (for example, interaction and gravitational torques, and possible forces due to collisions with movement agents or the built environment) that cannot be avoided. Seamless and comfortable physical interfaces between the patient and robot, and optimized mechanical design (weight, active power provided, materials, and others) of wearable robots are essential to enable efficient power transfer among three entities in HMS. Additionally, the human-machine interface needs to gather information from the patient's intent, the exoskeleton's states, and the environment ("context") to coordinate power transfer to achieve optimal performance, stability, and safety during locomotion and nonlocomotion tasks. Thus,

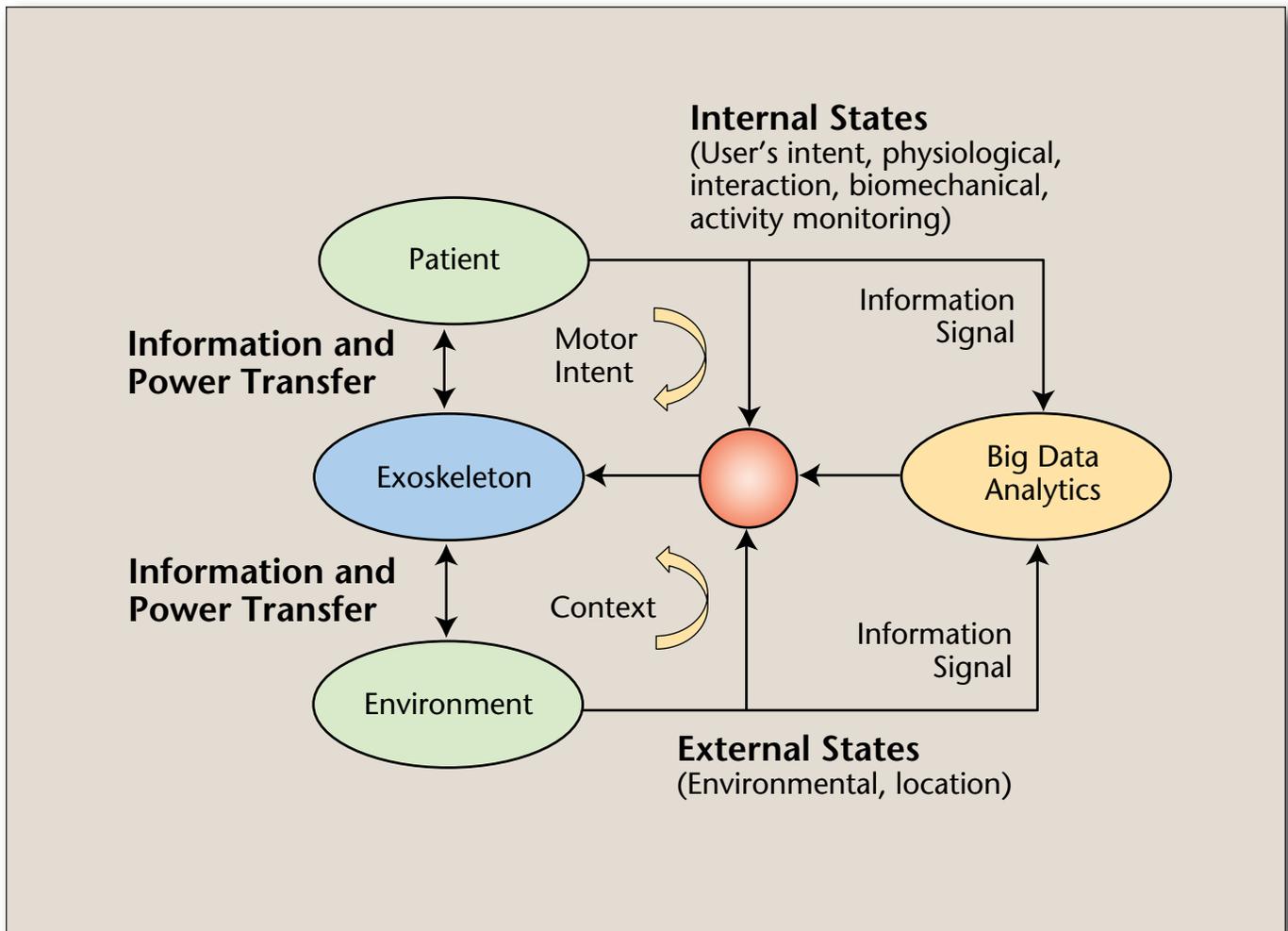


Figure 2. Closed-Loop Human-Machine System with Diagnostic, Assistive, and Therapeutic Functions.

the first human-centered design principle involves the adequate real-time coordination and management of power transfer in the human-machine-environment system.

Design Principle II.

Closed-loop human-machine systems require a direct and intuitive communication interface to allow adequate information transfer about the user's intent to the machine (for example, wearable prosthesis or exoskeleton), which is essential in determining function and usability of the powered device.

A wide range of assistive devices, from canes, walkers, and wheelchairs to electric scooters, power chairs, and lifters, and more recently powered exoskeletons, have been designed to assist, augment, restore, or enhance the functional capabilities of their users. Typically, these systems are either passive (that is, walking cane), and their functionality and stability are left to the user's strength and adequate managing of power transfer; or the systems are powered (that is, wheelchair or first-generation exoskele-

ton) and able to receive simple electronic command signals from the user or caregiver through a joystick, pushbutton, or other available input — an example of this type of system is the Ekso powered exoskeleton from Ekso Bionics (Ekso 2012, 2014). These assistive systems unfortunately are limited in their capability to interact with the user and the environment and they provide limited information about the users' internal states or the environment with which they interact.

Current control of lower-extremity powered prostheses is based on intrinsic (autonomous) control without involving the user's intent. For example, they use intrinsic feedback (that is, feedback measured by mechanical sensors in the prosthetic system) to adjust the knee and/or ankle joint impedance or position based on gait phase (that is, stance and swing; Martinez-Villalpando and Herr [2009]; Sup, Bohara, and Goldfarb [2008]; Hogan [1985]) and locomotion mode (that is, level-ground walking and stair ascent) (Martinez-Villalpando and Herr 2009;

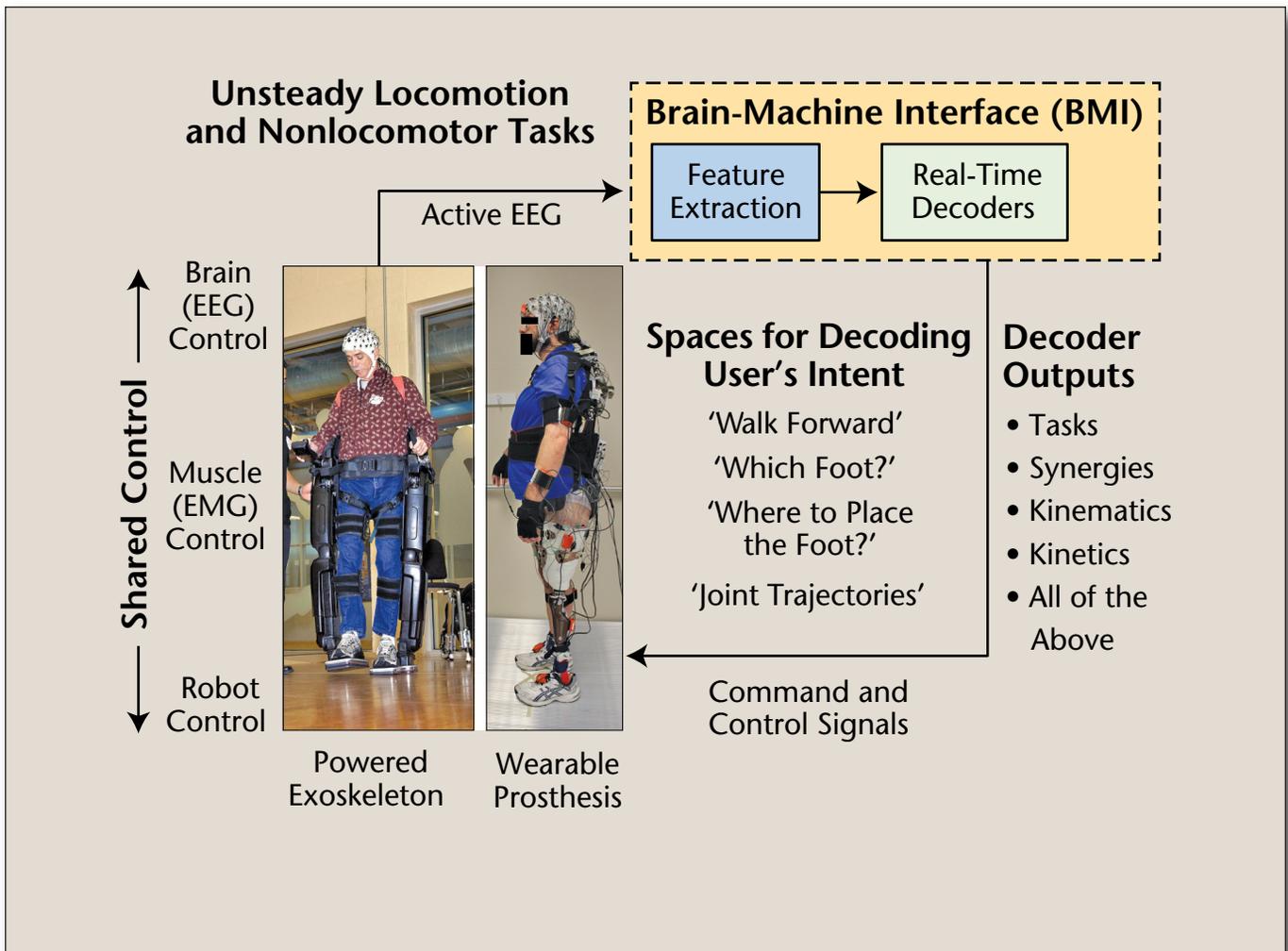


Figure 3. Neural Interfacing Systems Decode Neural Signals.

Neural interface system extracts information about user's intent through a brain-machine interface that translates brain activity (scalp EEG) into command and control signals for control of powered exoskeletons or prosthetic legs. Peripheral signals such as surface EMG signals that also reflect the user's intent can be combined with brain signals and autonomous robot control to increase accuracy and reliability. Examples of decoded actions spaces, from a continuum of high-level, discrete tasks (for example, *walk forward*) to low-level continuous decoding of movement kinematics (for example, *joint trajectories*) are shown.

Sup, Bohara, and Goldfarb 2008; Hogan 1985), which significantly limits the function of these devices in the presence of changing environments (for example, transitioning from level-ground walking to stair ascent, or from sitting to standing). In such cases, manual or ad hoc approaches such as body motions (for example, the ReWalk exoskeleton senses that the user's body shifts to command the robot [ReWalk 2011]) may be inadequate when the number of commands required from the user increases due to highly dynamic environments or conditions). Therefore, the second human-centered design principle involves creating a direct and intuitive communication interface (that is, information transfer links depicted in figure 2) between the user and the wearable prosthesis, which is essential in deter-

mining function and usability of the powered device.

Neural interfacing systems decode neural signals from the brain, peripheral nerves, or muscles and enable users to intuitively operate such assistive robotic devices (figure 3). For example, electromyographic (EMG) signals represent the neuromuscular control and have been explored to build intuitive voluntary connection between the amputees and robotic lower-extremity prostheses (Huang, Kuiken, and Lipschutz 2009; Huang, et al. 2011, Hargrove et al 2013; Zhang et al. 2014) and to extract intent from chronic spinal cord injury (SCI) patients to command powered exoskeletons using a shared control framework (Aach et al. 2014). These approaches are, however, challenged by the patient populations who have a limited number of muscles (for example, amputees)

or diminished or abnormal muscle activities (for example, SCI patients).

Noninvasive BMI systems enable various clinical populations intuitively to operate assistive robotic devices based on their voluntary control signals generated in their brains and acquired through scalp electroencephalography (EEG). BMI systems also allow the development of adaptive shared control strategies to control wearable robotic devices with multiple degrees of freedom by allowing modulation of the level of interaction and attention required by the user to command the prosthetic or orthotic device. For example, in a task-oriented human-machine system, the neural decoding algorithms may allow shared control modulation between a high-level neural controller that extracts the user's intentions from his/her patterns of brain, maybe fused with peripheral nerve/muscle activities, and the intrinsic low-level controller of the prosthetics (Au, Berniker, and Herr 2008; Hargrove et al 2013; Zhang et al. 2014) and exoskeleton. The distribution of the controller's loads based on the information extracted from the EEG signals and the exoskeleton controller can therefore be modified according to task performance (Kilicarslan et al. 2013). Such approach requires the user's mental effort only in task transitions and can operate multiple powered joints with coordinated motions based on the predefined autonomous control that implements each task or action (for example, *turn left*, *sit down*, or *walk forward*) in the robot operating system.

In some human-machine applications such as in rehabilitation robotics, it may be important for the user or patient to deploy "assist-as-needed" (for example, undesirable gait motion is resisted and assistance is provided toward desired motion) or full volitional control of the prosthetic/exoskeleton. In this scenario, the neural interface translates scalp EEG signals into kinematic and/or kinetic gait variables such as joint angles or surface EMG patterns associated with the various phases of walking (Presacco et al. 2011; Presacco, Forrester, and Contreras-Vidal 2012). These signals are in turn used to control powered exoskeletons or virtual walking avatars in rehabilitation applications.

Neuroprostheses and exoskeletons that provide real-time feedback to the user, engage their user by harnessing the user's intent from his or her own neural signals, and provide assist-as-needed functionality may also enhance motor learning and therefore neurological rehabilitation (Venkatakrisnan, Francisco, and Contreras-Vidal 2014). The availability of safe and reliable robotic therapy can also facilitate intense practice — at a reasonable cost — as well as continuous challenge during rehabilitation, which may accelerate neural plasticity and recovery and improve rehabilitation outcomes. In summary, BMI-enabled human-machine systems could offer personalized therapy, greater levels of patient engagement,

increased efficiency of training at a lower cost, and new sensing capabilities to the user, trainer, or physical therapist to quantify the user's or patient's progress.

Design Principle III.

Human-centered design involves empowering patients to engage in their own health care and wellness, while harnessing diverse data to improve health outcomes.

The user's internal state signals, acquired through the neural interface and the powered robot, as well as location and environmental sensors embedded in the exoskeleton and the built environment, provide useful information signals that can be used not only to compensate for unwanted interaction forces between the patient, exoskeleton, and environment, but also to provide diagnostic functions leading to individualized therapy (figure 4). Thus, big data streams carrying multimodal signals about the patient can be harnessed using big data analytics (for example, machine learning) for diagnostic purposes and to adapt exoskeleton control algorithms based on the user's current health and cognitive-motor capabilities while ensuring safety.

Specifically, human-centered design of wearable exoskeletons requires systematic safety and tolerability assessment of key cardiometabolic, musculoskeletal, skin, and biomechanical factors along with assessment of neurological and cognitive-behavioral deficit profiles that may define the user profile. For example, cardiopulmonary safety is paramount as individuals with stroke and spinal cord injury (SCI) may have autonomic instability that can alter blood pressure, and their heart rates may not reflect or respond correctly to increased cardiopulmonary demands, depending on the lesion level and completeness (Ivey et al. 2010, Roth 1994). The cardiopulmonary demands of steady state and sustained exoskeleton usage must be initially assessed and carefully monitored for two further reasons: (1) mean peak cardiovascular fitness levels after spinal cord injury vary considerably depending on the lesion characteristics, but are generally much lower than normal; (2) skeletal muscle after SCI or stroke shifts in a deficit-severity-dependent manner from slow twitch to a fast twitch molecular phenotype, which predisposes to anaerobic metabolism, reduced insulin sensitivity, and oxidative injury. Patients with abnormal gait biomechanics, anaerobic muscle metabolism, and fitness levels similar to those in heart failure patients must show adequate cardiopulmonary tolerance based on the subject's own perceived exertion scales, and objective monitoring of cardiopulmonary and metabolic profiles. These metabolic measures, careful clinical surveillance, and blood markers to assess for muscle injury are key to validating cardiopulmonary, metabolic, and muscle safety of exoskeleton use.

Rehabilitation clinician scientists are also highly aware that robotics may impose unusual joint kinet-

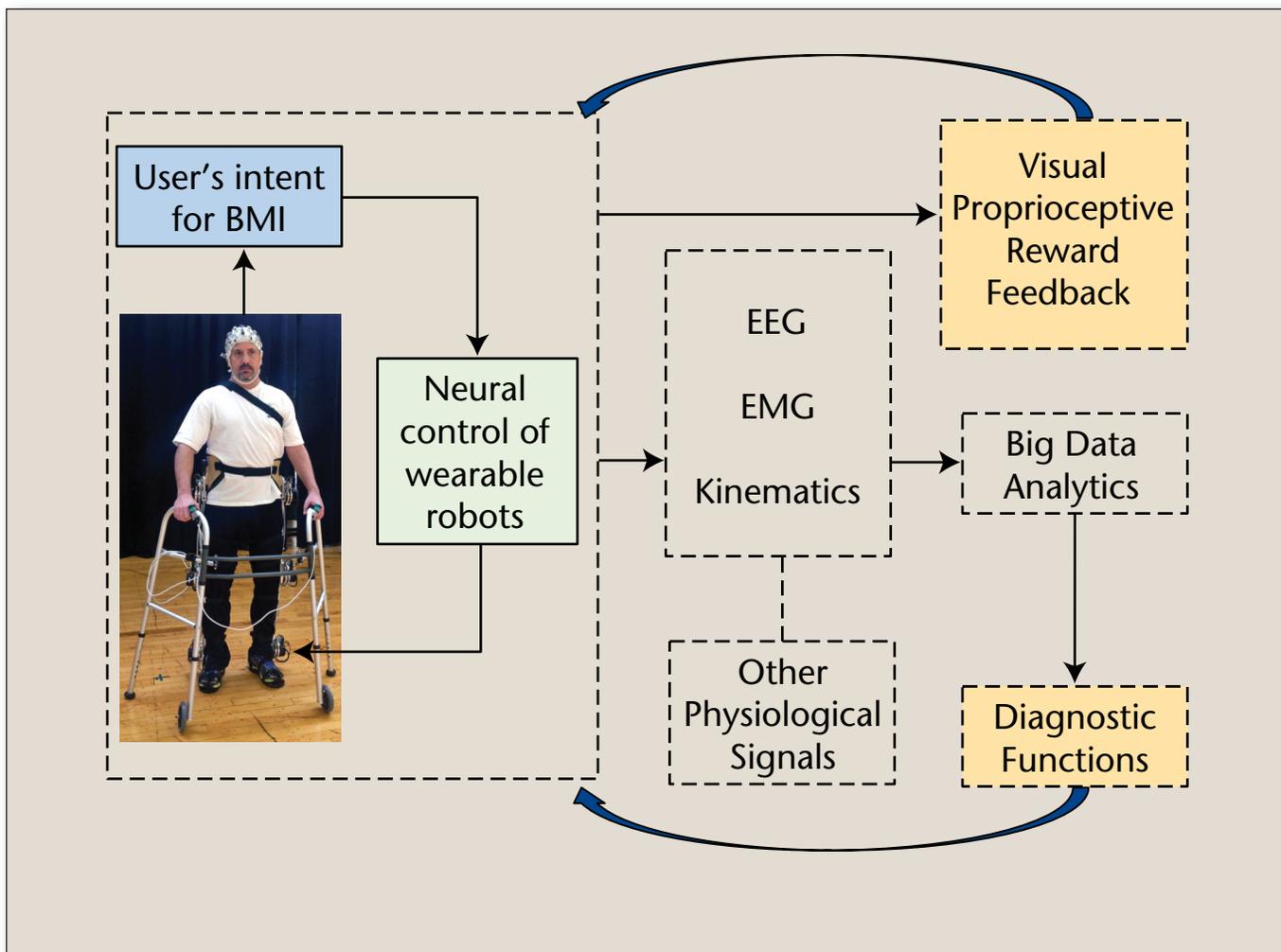


Figure 4. Diagnostic Functions of Closed-Loop Human-Machine Systems

Diagnostic functions of closed-loop human-machine systems harness the patient's information across multiple physiological systems through big data analytics allowing the patient to engage in his/her own health care while improving health outcomes. Adapted, with permission, from Venkatakrishnan, Francisco, and Contreras-Vidal (2014).

ics and kinematics that could potentially injure bone or skin, particularly in SCI or stroke populations that characteristically have accelerated osteopenia or osteoporosis, unusual spasticity patterns, abnormal movement synergy patterns, or contractures. Systematic screening for bone health and assessment ahead of time for hot spots of abnormal torque or impulses that could predispose to injury are key to safe utilization. While impedance control and torque cutoffs successfully assure safety in upper extremity robotics, cumulative experience is limited for mobility devices, warranting caution and careful consideration between engineers, clinicians, and individuals with neurological disability to appropriately apply this exciting new technology.

Design Principle IV.

Validation of human-machine systems requires a careful balance of engineering, clinical, and end-user metrics.

Due to the diversity of potential users and the spectrum of human-machine systems that have been emerging in the past few years, it is clear that users may differently prioritize their needs, and also their assessment of the benefits to risk ratio may vary when selecting a powered exoskeleton (for example, in terms of accepting a lower operating speed in exchange for a system with a higher margin of stability or less cost).

Users may also differently evaluate human-machine systems in regard to usability (for example, form factor, cosmesis, setup time, and others), functional gains, and other factors that may influence the user's acceptance of the neurobotic system. Moreover, clinical outcome measures by themselves may not reflect the overall benefit that robotic exoskeletons bring to the patient nor do they accurately capture the functional gains as interpreted by the patient

in a real-world context outside the clinic. Thus, validation of such systems requires careful selection of engineering, clinical, and end-user metrics that make sense to the developer, the physician or prescriber of the technology, and ultimately the end user. This area is unfortunately still in development (Contreras-Vidal 2014) and thus we are only able to review here a compact set of metrics that we believe are critical for the assessment of powered exoskeleton technology:

The International Classification of Functioning, Disability, and Health (ICF): The ICF is the international standard to describe and measure health and disability. It includes a list of environmental factors to address functioning and disability of an individual that occurs in an environmental context.²

The System Usability Scale (SUS): The SUS provides a simple, user-friendly, reliable tool for measuring the usability of a wide variety of products and services, including hardware and software. It consists of a 10-item questionnaire with five response options for respondents, from strongly agree to strongly disagree. The SUS has become an industry standard, and it can be used on small sample sizes with valid and reliable results.³

The Technology Readiness Levels (TRL): The TRL is a type of measurement system used to assess the maturity level of a particular technology. Each technology project is evaluated against the parameters for each technology level and is then assigned a TRL rating based on the project's progress. There are nine technology readiness levels. TRL 1 is the lowest and TRL 9 is the highest.⁴

Reliability Metric: The operational system availability of the human-machine system addresses the continued dependence of the patient or end user on the system for the execution of desired tasks, including activities of daily living. Reliability metrics should include physics-of-failure analysis with respect to expected life-cycle stresses and lifetime of the robotic exoskeleton, syndromic monitoring studies, and the design of sensor canaries (for example, redundant subsystem components that fail earlier than primary subsystems and thus provide an opportunity for maintenance and added safety) for self-diagnosis of signal quality may be required for characterizing the reliability and robustness of complex human-machine systems. In addition, methods for real-time anomaly detection and error correction, as well as novel methodologies for estimating model uncertainty using model performance data, are needed. Unfortunately, these reliability analyses methods have not yet fully reached the wearable robots industry yet.

Availability Metric: It reflects the probability that the system will operate satisfactorily at time t when called upon for use. It is expressed as the total system up time divided by the total operating hours.

In the last section of this review, we present a case study with a neurally controlled powered exoskele-

ton to illustrate the human-centered design principles reviewed.

A Self-Balancing Neuroexoskeleton for Users with Lower Body Paralysis

At the University of Houston, we have been conducting longitudinal testing with a BMI system to a powered exoskeleton (Rehab REX, Rex Bionics, Auckland, New Zealand) for restoration of walking after spinal cord injury (Kilicarslan et al. [2013]; Contreras-Vidal and Grossman [2013]; see figures 1 and 3 for illustrations of this system).

The REX exoskeleton provides a set of preprogrammed motions including sitting down, standing up, walking, right and left turns, and standing still, which are naturally the immediate focus of a real-time BMI application of restoration of gait function for users with lower body paralysis. The REX system is designed to keep its state kinematically balanced for combination motion types, which eliminates the requirement of crutches or any other external support system. Combined with a wireless EEG acquisition and real-time gait intent decoding interface, the NeuroREX system provides on-site model training and real-time application scheme for individuals with paraplegia. We use the advantage of the closed-loop joint position control (that is, the leg joint angles to provide a safe and balanced walk) that is embedded into the exoskeleton design, and decode the user's intention of different types motions, to be passed to the exoskeleton controller, thus forming a shared control design. Inclusion of a BMI control provides a paradigm shift on the use of such devices; as one of our subjects stated,

It provides the perception of being in control of the exoskeleton, as opposed to the exoskeleton moving my body around.

There are however several engineering challenges regarding the use of such systems while providing a more human-centered experience. Elimination of the usage of external support mechanism for balancing is indeed a significant step forward in the design of such lower-body exoskeleton systems. Despite the advantages, the design of the exoskeleton structure, selection of the actuators, and the overall motion speed has to evolve around this self-balancing design specification.

Real-time decoding of the user's intention of motion should also revolve around the capabilities of the exoskeleton. For example, the exoskeleton system should complete a predefined motion cycle for safe execution for each decoded neural command, thus bringing in inherent time delays for motion-to-motion transitions. Depending on the configuration (that is, instantaneous joint configuration while moving) of the robot, once a new motion command has been received, the BMI system should be able to hold the correct command until the execution of the

previous command has been safely completed. One approach is to model this variable time delay and build an adaptive BMI, which requires access to the low-level exoskeleton measurement/control algorithms. Another solution is to provide the users informative feedback on the current decoding result, and help them focus on their intended motion until it is correctly executed. Moreover, daily practice with the NeuroREX system is expected to lead not only to changes in human-machine interaction performance due to sensorimotor learning but also changes across multiple physiological systems, including brain activity.

Human-Centered Validation of Powered Exoskeletons

A clinical BMI roadmap for validation of lower-body wearable neuroprosthetics and orthotic devices is clearly needed. Several clinical trials are currently in progress to assess safety and usability (for example, Contreras-Vidal and Grossman [2013]; Ekso [2012, 2014]; Kilicaslan et al. [2013]; ReWalk [2011]; H2 [2014]). Here we summarize general clinical and patient-centered metrics for system validation.

First, it is necessary to determine the sensorimotor profile of individuals whose locomotion can be enhanced by the use of specific exoskeleton capabilities. This will elucidate the severity and neurological segmental levels of motor and sensory deficits that an individual must have to benefit from the use of a given human-machine system (for example, whether repetitive training and use of the exoskeleton leads to gains in mobility, health, and quality of life). Of particular importance is knowledge of the strength required for maintaining an erect posture in the exoskeleton, the strength required in muscles of the trunk, shoulders, arms, hands, and neck.

Second, specifications of primary and secondary outcomes are required for both system validation and regulatory approval (Contreras-Vidal and Grossman 2013). Among some of the relevant metrics, it is important to determine the incidence of adverse events associated with use of the system, including instability and falls; injury to skin, joints, and muscles; pain and fatigue; hypo- or hypertension; and arrhythmias. It is also necessary to determine the degree of mobility that can be achieved with such systems. Some clinical rating may include the time to completion for tasks such as (1) standing from a sitting position, (2) walking in a straight line, (3) turning right and left, and navigating obstacles.

The health and quality of life due to training with exoskeletons also needs to be quantified, including muscle strength and sensory function; cardiovascular function; pulmonary function; spinal cord independence measures with attention to bowel, bladder, and autonomic functions; and quality of life (Ware and Sherbourne 1992). Other relevant metrics in

exoskeleton systems augmented with brain-machine interfaces include quantification of (1) changes in patterns of brain activity (for example, EEG); (2) neural adaptation assessed with spatial, temporal, and frequency-based measures of signal stability and information content; (3) EEG source analysis to understand the origin of changes in the brain signals; (4) effects of artifactual components on EEG, including contribution of physiological (for example, eye blinks and eye movements, muscle activity, and so on) and nonphysiological sources (for example, power line noise, motion artifacts, and so on) that degrade signal quality and decoding of user's intent. As described earlier, measures of usability, user's acceptance of the device, reliability, task performance, and body image (for example, sense of ownership of the prosthetic or orthotic device) are also important for validation of the system.

Conclusions

Although significant advances in the design of brain-machine interfaces for the control of wearable prostheses and exoskeletons have been achieved in the recent past, current closed-loop human-machine systems have not yet reached the level of performance required to function in complex dynamic environments, have limited bandwidth for human-machine information exchange, usually require extensive training and/or a trained staff to set up or operate, put insufficient emphasis on understanding long-term system-level plasticity, and suffer from cognitive overload or from the changing effects of the patient's neurological status, biomechanical condition, attention, stress, medication, and fatigue (Courtine et al. 2013; Venkatakrishnan, Francisco, and Contreras-Vidal 2014).

Moreover, the long-term reliability of these complex systems is currently unknown, and the lack of standard metrics to quantify their effectiveness and reliability impede fast translation to the end user. In addition, we still do not know the potential adaptive and maladaptive emergent properties of neuroplastic changes that may arise from long-term dynamic interaction of complex human-machine systems with BMI systems (Hochberg et al. 2006). Systems engineering approaches complemented with big data analytics could be deployed to inform about these emergent properties across multiple neurobiological and physiological systems (Figure 2). Thus, these challenges also present significant multidisciplinary opportunities for researchers interested in human-machine systems for restoration, rehabilitation, or augmentation of motor function in humans.

Acknowledgments

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Note

1. bmiconference.org.
2. International Classification of Functioning, Disability, and Health (ICF). World Health Organization. Available at www.who.int/classifications/icf/en.
3. SUS. Digital Equipment Corporation, Reading, United Kingdom. Available at www.usability.gov/how-to-and-tools/methods/system-usability-scale.html.
4. Technology Readiness Level NASA. Available at www.nasa.gov/content/technology-readiness-level/#.UO_oza1dUcw.

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