Chapter 6
Prototypes for Assistive Innovation

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Acronymns

ADA	Americans with Disabilities Act
ADL	Activity of daily living
ANSI	American National Standards Institute
CE	Conformité Européene
EMG	Electromyographic (impulse)
FDA	US Food and Drug Administration
FES	Functional electrical stimulation
FNS	Functional neuromuscular stimulation
HCI	Human-computer interaction (or interface)
iBOT	Powered wheelchair that uses gyroscopes to balance and climb steps/terrain
IADL	Instrumental activity of daily living
ICF	International Classification of Functioning, Disability and Health
IMS	Inertial measurement system
ISO	International Organization for Standardization
LDS	Local dynamic stability
MOD	Mechatronic Orthotic Design
NCHPAD	National Center for Health, Physical Activity, and Disability
NIDILRR	National Institute on Disability, Independent Living, and Rehabilitation Research
RERC	Rehabilitation Engineering Research Center
RESNA	Rehabilitation Engineering Society of North America
RRTC	Rehabilitation Research and Training Center
RSP	Running-specific prosthesis
SCI	Spinal cord injury
TBI	Traumatic brain injury

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6.1 Introduction: The Concept of Universal Exercise Access

The major advances in the development of assistive technology for people with disabilities have included rehabilitation research and engineering programs that are located at universities across the United States. Many of these programs receive federal funding from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). NIDILRR, a division of the US Department of Health and Human Services, periodically offers peer-reviewed grant competitions for 5-year Rehabilitation Engineering Research Centers (i.e., RERCs) and Rehabilitation Research and Training Centers (RRTCs) as well as annual competitions for research and development projects. All centers and projects have the twin goals of supporting the NIDILRR Long-Range Plan and the Rehabilitation Act of 1973 (Public Law 93–112, 87 Statute 344, 29 U.S.C. § 701) to promote research that advances the health, civil rights, community integration, and independent living for people with disabilities. NIDILRR-funded research projects at universities and rehabilitation hospitals across the United States are working to advance the technologies to support people living with mobility limitations and other disabilities.

The major areas of technological development for assistive devices include the following foci:

1. Wheelchairs that are specifically tailored to each user's unique needs, specific terrains and surfaces, and motion functions (e.g., specific sports)
2. Prostheses of varying capacities that replace upper or lower limbs
3. Advanced gait mechanisms and orthotics for people who can walk but face difficulties due to physiological barriers, anatomical anomalies, and/or terrain
4. Battery-operated exoskeleton devices for people living with spinal cord injury so that they can walk and experience mobility for performing daily tasks beyond the limitations of wheelchairs
5. Sensory-assisted technologies with eye motion and voice computer applications to perform tasks that may be limited by combinations of upper limb disabilities and/or vocal limitations brought about by traumatic brain injury (TBI), spinal cord injury (SCI), birth defects, or other events

These areas represent the foci of this chapter and the major research areas for rehabilitation assistive device technologies, although other areas exist as well. The principle of universal access derives from the well-developed and advocated architectural principles of universal design for buildings, transportation, and other structure access for people with disabilities (see Chap. 1 and https://www.cdc.gov/ncbddd/disabilityandhealth/disability-strategies.html). These principles promote independent living and community integration for people with disabilities in accordance with the Americans with Disabilities Act (ADA) and the Rehabilitation Act of 1973 and its amendments.

6.2 Advances in Technology

Technological developments have been driven by advances in the understanding of human performance, human factors, the mechanics of moving bodies, computer advances and miniaturization, human-computer interaction, and energy source (i.e., battery) maximization. Besides important issues involved in assessing the best, most appropriate, and economical assistive device, providers must work with consumers to plan the appropriate human factors and ergonomics mapping that best evaluates the consumers' environment, which also promotes product research and continuous process improvement (Fuhrer et al. 2003; Lenker and Paquet 2003). One of the most influential tools is the International Classification of Functioning, Disability and Health (ICF; World Health Organization 2000).

With all of these efforts, the objective is to maximize functioning in a variety of environments. Just as a biker will switch from a racing bicycle to a trail/mountain bike for off-road use or as an astronaut uses a highly complicated spacesuit that can withstand the near vacuum of outer space plus certain levels of cosmic radiation, we modify devices and machines to improve our access and functioning in diverse environments. The individual who lives with mobility limitations needs exercise and desires to participate in the environment. The environment extends beyond the workplace and city to natural environments that are even less accessible. Nevertheless, people have a natural affinity for the outdoors, for recreation, and for the living world (Wilson 1988). While often neglected, there is growing research that demonstrates the positive benefits of nature and the outdoors on human health (Hartig et al. 2014). Thus, we focus on devices to maximize functioning for people living with mobility limitations.

6.3 Wheelchairs

The standard tool for many people who live with mobility limitations is the wheelchair, a machine based upon the simple principle of placing a chair on wheels, with the wheels appropriately engineered for balance around the user/machine center of mass, smooth movement over relatively smooth surfaces, and the dual capacities for independent operation by the user or by a caregiver. There is historical evidence of at least some variation of the wheelchair being used by ancient cultures, including China, although the first specific development of wheelchairs to address mobility disabilities did not occur until a few 100 years ago (Woods and Watson 2004). Herbert Everest and Harry Jennings patented the first practical wheelchair during the 1930s, a model that has remained mostly intact for wheelchair design to the present day. The Everest/Jennings model was widely adopted by hospitals and ultimately for individual use at home and in public. Individual use models that are lower cost and lightweight structurally meet durability standards (e.g., Rehabilitation Engineering Society of North America – RESNA) that are comparable to heavy duty hospital wheelchairs (Gebrosky et al. 2013). Individual use wheelchairs are widely available from major retail and pharmaceutical stores.

Cooper et al. (2008) reported that wheelchairs represent approximately 1% of Medicare spending and are a $1.3 billion dollar industry in the United States with 170 wheelchair manufacturing companies. Regardless, they argue the need for advancements in wheelchair technologies and reduced costs to provide greater access and options for different environments and unique, individual situations.

A variety of rehabilitation hospitals and research centers (e.g., Craig Hospital, Denver, Colorado; Shepherd Center, Atlanta, Georgia; National Center for Health, Physical Activity, and Disability – NCHPAD; Shriners Hospitals for Children) have developed and provide to users many different wheelchair styles that are adapted for specific environments. For example, there are wheelchair designs for different Paralympic sports, including basketball, softball, soccer/football, rugby, and hunting/fishing. For direct contact competition, wheelchairs often have angled wheels and accessories for appropriate ball handling. For outdoor environments with rough terrain, wheelchairs may have modified tread on the wheels or even caterpillar tracking treads for electric wheelchairs that can maneuver over extremely rough terrain. Hunting and fishing wheelchairs also can include mounts for fly-fishing or for bow/rifle firing. Handcycles represent a synthesis of bicycles and wheelchairs for effective exercise.

With these modifications, we move to electric wheelchairs and even more advanced robotic/smart wheelchairs (Woods and Watson 2010). Electric wheelchairs, including scooters, provide motorized motion without the requirement of hand propulsion of the wheels. The iBOT is a motorized power chair that uses balance and spatial orientation for motion over difficult terrain, most notably its capacity to climb stairs. With the addition of a user-interactive computer system, the iBOT and similar power wheelchairs can be transformed into even more effective smart wheelchairs (Woods and Watson 2003). Such smart power wheelchairs are under continuous development and receive considerable investment from federal grant agencies (e.g., National Institute on Disability, Independent Living, and Rehabilitation Research – NIDILRR) and major transportation technologies that invest considerable research and development funding for customer accommodation needs.

Among the major obstacles to widespread use of smart wheelchairs is cost. Current research is focused on these more advanced technology wheelchairs so that they are more economical and will be covered by Medicare, Medicaid, and other insurance providers. With advances in neuroscience and computer interface, some experimentation with brain implants and virtual reality applications may make wheelchairs more easily operable over even greater physical obstacles and terrain, although such efforts are in the early stages and also face cost issues for widespread distribution (Pazzaglia and Molinari 2016). However, some preliminary studies question the added benefit of these more advanced wheelchair modifications (Harrand and Bannigan 2014; Simpson et al. 2008). Regardless of this debate, people with disabilities and disability researchers will continue to innovate with new ideas to advance capabilities of wheelchairs and other mobility devices.

Given the long history of wheelchair development and use, substantial research continues to further advance this technology. Much of this work focuses on the biomechanics of wheelchair use to optimize performance, to reduce physical stress, and to promote the health of the individual wheelchair user. Goosey-Tolfrey (2010) examined Paralympic training methods in Great Britain for wheelchair basketball, racing, rugby, and tennis. The research found that wheelchair biomechanics needs to be assessed at the individual level to promote optimum performance.

Faupin et al. (2013) examined synchronous versus asynchronous propulsion of wheelchairs among wheelchair basketball players. They found that synchronous propulsion was more efficient in terms of velocity and wheelchair performance during sprints. Nevertheless, asynchronous propulsion was superior for user applications of hand-to-rim forcing during sprints. Bergamini et al. (2015) recommended biomechanic evaluations of wheelchair athletes to reduce injury risk and to maximize performance. Munaretto et al. (2013) collected kinematic data on a wheelchair user, finding through data-based simulations that upper extremity injuries can occur due to excess mechanical load based upon type of use, forcing, seating position during locomotion, and other individual factors.

The individualized approach to the analysis of assistive devices can be further augmented by how these devices work well or contribute to additional physical problems due to the altered biophysical environment. For people living with spinal cord injury and long-term standard wheelchair use, Asheghan et al. (2016) found heightened risk for carpel tunnel syndrome as a secondary condition due to wrist motions. Findings such as these illustrate the need for more comprehensive biophysical studies as well as the further development of smart, robotic wheelchairs. At the same time, standard wheelchairs enable physical activity and upper body exercise. The risk for carpel tunnel syndrome and other secondary conditions can be prevented by careful exercise physiological and human factors assessments of functional form in wheelchair and other assistive device usage. Jain et al. (2010) observed that people living with spinal cord injury (SCI) are prone to shoulder pain, even with standard, manually prepared wheelchairs and with motorized wheelchairs. Assistive technologies offer advantages to the user, but they can contribute to injury if improperly used. Biomechanical assessments are important to improve human performance with assistive devices while minimizing risks. Russell et al. (2015) demonstrated that modified wheelchair usage with considerations for body position, propulsion, and reaction forces can reduce shoulder and other upper extremity injuries.

An expert trainer can identify potential form/pattern problems and train the user on biomechanic adjustments to reduce risk. Similarly for wheelchairs and certain prosthetics, the issue of pressure ulcers can be prevented by proper supports and repositioning activities exercise to avoid these sedentary risks. Requejo et al. (2015) argued that these evaluations need to be applied to age-related disability, as older adults who use wheelchairs are at increased risk to experience pain and mobility limitations. They strongly recommended individually based ergonomic assessments to reduce these risks as wheelchair user's age.

6.4 Prostheses

Artificial limbs, or prostheses, represent a major type of assistive technology for people living with mobility limitations. Prosthetics include artificial hands, feet, digits for either hands or feet, forearms and complete arms, and lower legs and full legs. Obviously, the greater area affected, the more substantial difficulty in producing and providing a functional device with few barriers. Prosthetics often are used for aesthetic purposes to hide the limb loss. However, device innovation is improving the functionality of these devices so that there are prosthetics with increasing capabilities that offer the user improved functioning and the performance of many desired activities of daily living (ADLs) and instrumental activities of daily living (IADLS) independently, a major goal of our efforts to improve devices for functioning and exercise. Even novel prosthetics such as running blades utilize innovative designs that are based upon physical principles, not on appearance, in order to provide superior mobility to users. Thus, the opportunities for innovation should incorporate aesthetic comparability to the affected limb as much as possible and as needed by the individual while simultaneously aiming for high functioning and unique designs.

Prosthetic limbs are needed for a variety of conditions, ranging from congenital birth defects to diabetic foot/limb neuropathic limb loss to cancer to limb loss from accidents/warfare. Aging-related loss of functioning can represent an additional factor. Recent historical events and global health as well as aging demographic trends have increased the need for prosthetics. Wounded warriors and civilians affected by the worldwide use of land mines and other explosives numbered over 8600 (42% children of the 78% civilian victims) in 2016, a sharp increase over previous years and likely a conservative estimate (International Campaign to Ban Landmines 2017). Furthermore, they have documented approximately 110,000 victims (approximately 80,000 surviving) since 1999.

Currently in the United States, approximately 1.6 million people live with limb loss, with an expected increase to 3.6 million by the year 2050, albeit with projected trends of decreased loss related to diabetes and peripheral neuropathy and projected increased loss due to dysvascular amputations (Varma et al. 2014). The projected increase may be attributable to many factors, most notably the long-term effects of diabetic and nondiabetic health declines related to the obesity epidemic and lack of exercise as well as other health conditions (e.g., aging, drug use/abuse). Also in the United States, Barmparas et al. (2010) found that limb and digit losses occurred primarily from motor vehicle accidents (51%) and equipment/machinery accidents (19.4%), with pedestrians and motorcyclists experiencing a greater degree of lower limb amputations.

Transplantation of organs for limb loss has improved and remains one option for treatment, although the primary limitations are the lack of organ/limb donors and HLA tissue matching to reduce transplant immune rejections. As a result, the number of limb transplants has remained very low, especially so for allogeneic transplants compared to autologous (self) digit transplants. Weissenbacher et al.

(2014) estimated slightly over 100 single or double hand transplants since 1998. Weissenbacher et al. (2014) followed up five hand transplant recipients for 8–14 years, finding that all of them experienced at least one tissue rejection event, although every event was successfully treated. Hand transplant recipients demonstrated increased sensory and grip strength functionalities during the years following the transplant, although one patient showed a slight decline in grip strength. Ziegler-Graham et al. (2008, see also Flaubert et al. 2017) reported over 41,000 cases of above-the-wrist limb lost in the United States during 2005. Durban et al. (2015) reported a successful above-the-knee reimplantation of a severed leg for a child with few long-term complications at 24 years postsurgery. Despite these demonstrated successes, limb transplantation remains a complex, extremely limited procedure that requires regular monitoring and follow-up procedures. For the foreseeable future in the absence or limited (ethically) development of self-cloned tissues and organs, prosthetic devices remain the best assistive device for limb loss.

Flaubert et al. (2017) described four principal types of prosthetic devices:

1. Passive
2. Body-powered
3. Externally powered
4. Hybrid

These four prosthetic types have progressively increasing functionality for the user. All of them attach to a joint or remaining limb or partial limb. The passive prosthetic device provides only cosmetic/aesthetic replacement of the lost limb and has no functionality. The body-powered prosthetic device is moved along with another body part via some type of anchoring device, usually a strap and/or harness to position and manually operated cables to move the prosthesis in a limited fashion.

The externally powered prosthetic device receives an energy supply for motion from a battery connected to a small motor within the device that is coupled with neurological sensors linked to several of the user’s antagonistic muscles for the affected region of the body. For example, the two primary antagonistic muscles for lifting versus extending the forearm are the upper arm biceps brachii and the triceps brachii, respectively. A prosthetic forearm would contain a motor for movement with a battery supply and sensors driven by contraction of the appropriate upper arm muscle.

Lower limb prosthetic devices operate on similar principles. Windrich et al. (2016) described advantages and disadvantages of 21 lower limb prostheses, 3 of which were being marketed. Lower limb devices may be for the entire leg (above the knee), lower leg and/or ankle, or combined knee-lower leg-ankle units. Some models provide a prosthesis that enables passive motion that is consistent with the attached limb/limb portion. Overwhelmingly, the newer models utilize external power (motor and battery) and are driven by electromyographic (EMG) muscle sensors, as described with the upper limb prosthetics. A few models utilized either pneumatic (i.e., air pressure forcing) or hydraulic mechanisms, although these devices have been problematic compared to the EMG models. Experiments with the EMG stimulation have focused on echo or resonance control by matching the prosthetic limb motion with the corresponding gait of the healthy leg. Alternatively, gait modeling can be recorded into the small computer for EMG signaling of prosthetic leg motion. Both approaches require computer control within the device and have required considerable work given the greater parameters involved for walking upright compared to upper limb motions.

With respect to prosthetic devices, many individuals receive surgery with titanium rods and other implantable bone replacement or joint support devices. Such implantable structures are prosthetic in their own right, but they generally operate efficiently with an intact limb such that substantial ranges of motion and functionality are maintained, thereby reducing disability. Nevertheless, implantable devices may limit certain types of physical activity such as high-impact sports and walking or running over rough terrain. Additionally, secondary conditions such as obesity or other conditions can be limiting factors. With respect to lower leg rods, aging can be a factor, as the rods have a given length and can cause pain with weakened muscle and slightly reduced stature as part of the aging process.

Returning to true prosthetic devices and specifically lower limbs, running blades have been popular with Paralympic runners. Running blades, termed running-specific prostheses (RSPs), are carbon-fiber passive devices that attach to the unaffected portion of the limb and enable the user to run using the force of their thigh muscles and the elastic spring-mass physical properties of the RSP and its shape. Beck et al. (2016) evaluated 55 different RSP models for running performance by female and male transtibial amputees working on treadmills. They found that manufacturer RSP models significantly differed in product stiffness relative to muscle stiffness. Most interestingly, they found that athletes could increase or decrease the stiffness during running by changing the angle of their RSP. Overall, the RSPs provided running performance approaching that of a nondisabled athlete, although biological ankles return over twice the power of the RSPs (Beck et al. 2016). Further advances with RSP technology look promising for people living with lower limb amputations to engage in running for health and for competition.

Hybrid prosthetic systems involve a mixture of body- and externally powered movement. Such devices may have less range of motion compared to the purely external power prosthetics, although the hybrid devices can be less expensive. Many such devices are available from various manufacturers, and more are in testing and development. Both Flaubert et al. (2017) and Windrich et al. (2016) provide a strong discussion of major researchers and distributors for externally powered prosthetic limbs, both upper and lower body in nature. The Amputee Coalition (www.amputee-coalition.org) provides numerous resources to assist people who are living with limb loss.

Motion sensors typically involve electromyographic (EMG) impulse inputs to the motor that drives the externally powered prosthetic device. Resnik et al. (2017) tested the new DEKA arm with patients having brachial plexus injury and who wanted to shift from a passive upper limb device. The DEKA device provides transhumeral and shoulder configurations, plus it operates with an array of inertial measurement unit (IMU) commands for ERG sensory control of the unit's motions. Participants demonstrated significant improvement in writing, grasping, opening cans, and other ADLs/IADLs, and they reported high satisfaction with the device along with a desire to ultimately have such a device for personal use.

Caputo and Collins (2014) addressed one critical issue involved with lower limb prostheses: increased required energy exertion leading to overall physical fatigue and damage to the remaining limb, upper limb joints, and muscle tissue. This is particularly a problem for ankle-foot prostheses. They modified such a prosthesis with an emulator, a device that can vary joint torque and angle. They measured variations on these two parameters for non-amputee participants walking on a treadmill to effectively test and reduce the push-off work exerted by the ankle-foot prosthesis during each step. They discovered that these exertion/work reductions primarily helped lower metabolic rate involved with leg swing and that further biomechanics research needs to be conducted to better understand the dynamics of walking with prosthetic lower limbs (Caputo and Collins 2014).

These findings clearly show that a substantial body of work remains to be conducted to more completely understand the biomechanics of walking and the translation of this research into more precise, maneuverable prosthetic limbs that more realistically reproduce the movements of healthy limbs with minimal effort, fewer secondary effects on the body, and, hopefully, low cost for widespread distribution. Flaubert et al. (2017) and Caputo and Collins (2014) stressed this need as well as the synergy of robotics and human-computer interfaces (e.g., artificial intelligence applications) to continue device innovation. As described above, there are variations in the technologies such that the type of exercise to improve health will be different for each situation (e.g., wheelchairs for TBI, SCI, and lower limb loss versus lower limb prosthetics for lower limb loss alone). Quite succinctly, there is more work to be done!

6.5 Gait/Orthotics

Related to Caputo and Collins' (2014) gait work for walking with lower limb prosthetic devices, we move to the closely related orthotics, which also play an important role in the gait walking research that is so important for efficient walking with assistive devices. Many people experience foot, ankle, or lower leg injuries that require orthopedic shoes. Additionally, people who are overweight, diabetic, or aging are more likely to require additional foot support for walking, a basic task essential to health and wellness. The most critical feature of orthopedic shoe and foot orthotic design is individualized tailoring for the shoe to enable balance, comfort, and reduced energy expenditure for walking. Availability, access, and individual design represent some of the major barriers in this area, as too many providers of foot orthotics provide a "one size fits all" approach when an individualized, universal design approach is needed.

Terrier et al. (2013) examined gait and balance for study participants recovering from foot and ankle injuries at a rehabilitation clinic. Participant walking gait using orthopedic shoes or ankle boots was measured with piezoelectric skin sensors to evaluate local dynamic stability (LDS). The researchers found that the use of orthopedic shoes significantly stabilized walking gait and reduced walking−/injury-related pain. LDS is particularly important for prevention of falls with people recovering from ankle injuries, lower limb neuropathy, and older adults (Reynard et al. 2014).

Riskowski et al. (2011) reviewed studies of orthopedic shoe and orthotic interventions. Rigorous research studies are limited, but the researchers found that properly designed orthotics represent a preventative approach to foot health, walking, and exercise, especially for aging populations and the associated increased risk for mobility limitations. They cited 24% of adults who experience some type of foot ailment, often including arthritis, and these ailments increase with age. The expansion of orthotic foot supports can benefit from crossover exercise science and athletic training research so that a wider range of people with and without disabilities can benefit.

Orthotic insoles have been researched to maintain balance for people living with multiple sclerosis, lower limb neuropathy, and foot-ankle injuries. Dixon et al. (2014) found that insoles did not significantly benefit balance, but they do improve walking gait. For people living with diabetic foot neuropathy, Paton et al. (2016) found that memory fitting insoles maintained balance and improve pressure velocity, but they identified a need for the development of offloading insoles that offer both performance and balance while addressing the potential complications of diabetic foot ulcers. Shin et al. (2016) likewise found that full and partial insoles both improved anterior-posterior and medial-lateral balance while stabilizing the walking velocity of participants.

Few studies have addressed the individualized design of orthopedic shoes, ankle boots, and orthotic insoles. Infrared pressure contact assessments of foot support have become more widespread in the footwear industry. Furthermore, competitive athletic footwear involves the construction of each shoe that is specific to the athlete's feet. Advances in footwear technology should similarly move in this direction for people who face balance and walking stability issues. These issues indicate another strong opportunity area for further research and innovation for assistive footwear. One particular low-cost opportunity is the use of adaptive manufacturing, better known as 3D printing, for novice entrepreneurs and people with disabilities to design and produce functioning orthotics with a wide variety of 3D-printable resins that have become available, even with hobbyist 3D printers.

Effective walking gait assessments represent a central component for evaluating orthopedic shoes and foot orthotics. Kluge et al. (2017) described the validity of inertial measurement system (IMS) in the evaluation of gait movements. Sensors can be applied to study participants in order to measure posture, balance (e.g., LDS), specific motions, velocity, musculoskeletal exertion, and lower limb pressure per unit area of foot contact. Typically, participants walk or run over a flat surface, although treadmills or elliptical stepping devices usually are used to control for speed and ramp angle across participants. Kluge et al. (2017) found that IMS gait assessment systems are accurate and exhibit high test-retest reliability. Other exercise researchers combine such assessments with VO_2 max and other measures of biophysical stress and metabolism. Gait analysis has also played a central role in the analysis of lower limb prosthetic devices.

6.6 Exoskeletons

One of the most exciting, but still limited, types of advanced assistive device is the exoskeleton, a battery or corded electronic robot that fits around the torso and legs to physically support the body and uses muscular sensors to drive lower limb movements. The device is designed for people living with severe spinal cord injuries, including thoracic 4 vertebra (T4) injuries and below on the spinal column, although home use currently is limited for less severe spinal injuries. The marketed exoskeletons require extensive training for the user in order to operate independently. In the United States, FDA restrictions (US Code of Federal Regulations Title 21, Volume 8, Part 890 – Physical Medicine Devices) require the user to have a fully trained companion to assist the user with the robotic suit. In the European Union, no such restriction exists.

The primary exoskeleton robots on the market include the following products:

1. The Indego™ (www.indego.com), manufactured by Parker Hannifin, a technology company spin-off from device invention and development at Vanderbilt University's Center for Intelligent Mechatronics
2. The ReWalk™ (www.rewalk.com), invented by Amit Goffer in Israel and marketed by Argo Medical Technologies, Ltd.
3. The Ekso™ (www.eksobionics.com), invented and marketed by Ekso Bionics, a technology spin-off company of the University of California at Berkeley Robotics and Human Engineering Laboratory.
4. The Hybrid Assistive Limb (HAL 5™; www.cyberdyne.jp), invented and marketed by Professor Yoshiyuki Sankai of Japan's Tsukuba University and the company Cyberdyne
5. Fortis™ (www.lockheedmartin.com), invented and marketed by the aerospace corporation Lockheed Martin, initially for industrial workers but now available for people with disabilities

Other companies (e.g., U.S. Bionics, Panasonic) are developing exoskeleton models as well, but four of the above companies (ReWalk, Ekso, Cyberdyne, Lockheed Martin) have consolidated the majority of the exoskeleton market share, with 272 exoskeletons being sold during 2015, approximately 54% going to health-care rehabilitation, about half of all sales in the United States, and a 2015 global market value of US $25 million (Grand View Research 2016). Note that the majority of the roughly 140 exoskeletons that were sold in health care likely went to rehabilitation centers and hospitals for patient/user training. As of 2017, individual exoskeleton units cost around US $90,000, a cost that is prohibitive to most people living with disabilities but a cost that will decline as market demand increases and other companies market competitive exoskeleton alternatives. ReWalk and Indego were the first exoskeleton models to obtain FDA approval for personalized use beyond the rehabilitation clinic.

Grand View Research (2016) projects that the exoskeleton market will grow from the 2015 value of US $25 million to US $1.6 billion by 2025 with more products entering the market, growth of the global aging population to nearly two billion people, increasing spinal cord injuries, and substantial market growth/demand in Japan and China. All five of the above, highlighted exoskeleton companies have secured approval for product sales by the US Food and Drug Administration (FDA) and the European Union Conformité Européene (CE) product approval.

A typical exoskeleton consists of three measurable components for the lower abdomen, thigh, and lower leg. The parts are interchangeable and can be outfitted based upon the user's physical parameters up to certain limits, depending upon the manufacturer. Battery life is generally around 4 h, but batteries can be exchanged quickly and recharged within short time frames. Exoskeleton composition includes carbon fiber, plastic, and some metal, and the technology has advanced to lightweight models less than 30 pounds. The technology also is moving away from backpacks in order to remove weight. The exoskeleton moves via sensors located throughout the leg attachments that provide balance information to a small computer that sends signals to motors that usually are located in the unit hip and knee joints. The user can provide commands via a wireless remote.

Exoskeleton movement is slow for most users and often requires the use of canes for forward motion support. As stated earlier, the United States requires training for the user plus a companion individual to assist the user. With the rapid expansion of robotic exoskeleton use in rehabilitation settings and now even for personal use, various standards organizations such as the International Organization for Standardization (ISO) and ASTM International are developing guidelines for exoskeleton development, ergonomics, training, and use.

Fritz et al. (2017) evaluated the Ekso, Indego, ReWalk, and Rex Bionics exoskeleton models, finding that all of these models currently are inadequate for personalized use and independent living outside of rehabilitation training centers. They argued that the exoskeletons had balance and upper extremity support problems, plus they require substantial companion support. They recommended improved designs, the continued use of lightweight materials, and better collaboration between actual consumers/users of the devices, physicians, nurses, rehabilitation professionals, and design engineers.

Several manufacturers, including Ekso, are developing exoskeleton models that have differential left-right functioning for stroke victims (i.e., one body side affected). Exoskeleton research and development has been impressive, so the technology should steadily improve the maneuverability and independence of the user. Grand View Research (2016) cites the exoskeleton as one of the top technologies for development during the next 10 years. A search of the US Patent and Trademark Office (www.uspto.gov) for "full-body robotic exoskeleton" yielded approximately 250 matches, a number that likely will substantially increase during the next decade.

Onose et al. (2016) provide a thorough discussion of design issues for further technological development. As with other studies, balance for the exoskeleton itself is one of the major limitations. Of particular importance, Onose et al. (2016) emphasized several physiological features, including exoskeleton designs that reduce muscle spasticity and contractures, promote lower limb circulation for the avoidance of edema and more serious secondary conditions, and reduction of risks for lower limb fractures due to unit mechanical stress. They provided several Mechatronic Orthotic Design (MOD) illustrations to highlight specific engineering needs/opportunities.

The implications for full-body or other accessory robotic exoskeletons to health and exercise are considerable. Actual bipedal locomotion with robotic assistance might not necessarily promote widespread lower limb muscular contraction, but it can reduce atrophy, promote muscular activity with undamaged muscle tissue that otherwise might not receive necessary activity, promote neural activity, and promote circulation as well as cardiovascular functioning. Certainly, the exoskeletons likely will create unexpected side effects in conjunction with each person's particular injury such that regular physiological functioning will be necessary to prevent overexertion and the development of secondary conditions. Such scenarios plus substantial consumer input need to be considered during the development of these devices. Improvements on robotic exoskeletons potentially could open up this particular assistive device as an important contributor to improved physical activity for people living with SCI and stroke, providing them with renewed vigor, quality of life, command of environmental terrains, and neuromuscular activity that counteracts atrophy and related detrimental secondary events that severely impact this population.

Kolakowsky-Hayner et al. (2013) provided one of the early studies on the Ekso device. They studied motion and physiological characteristics of five male and two female participants, all of whom had an SCI of T1 or below. Over approximately 400 h in the device, about half of which was spent walking, the study participants tended to improve walking and speed with increased training time. Suit-up time ranged from 10 to 30 min. Kolakowsky-Hayner et al. (2013) recommended companion assistance during operation, including an overhead tether, and that the device should be used in rehabilitation settings. These findings are consistent with more recent studies described above on the limitations of current devices, particularly for personalized use.

Whereas current robotic exoskeletons use functional electrical stimulation (FES), Chang et al. (2017) experimented with an exoskeleton that uses functional neuromuscular stimulation (FNS). This latter approach would be a novel advance in the technology by involving the activity of nerves and muscles in the affected limbs, thereby promoting more natural driving of the exoskeleton with fewer manual, wireless commands. This FNS model does include battery-powered assistance to support limited muscle power in activities such as standing up, maintaining standing position with balance, and stepping with balance maintenance as well. The researchers tested the model with three people living with paraplegia, yielding positive results and yielding additional ideas for incorporation of foot plantar flexion and other capabilities.

Miller et al. (2016) performed a meta-analysis of 14 comprehensive research studies involving 111 people with SCI who used either the ReWalk, Ekso, or Indego exoskeletons in rehabilitation training. Strong positive results were consistent across all studies, including only 4.4% of participants experiencing falls during training, 76% being able to move in the unit without physical assistance, and 61% experiencing improved bowel regularity following training. The studies indicated only mild exertion requirements on participants during the training sessions. From this perspective, robotic exoskeletons seem to be highly beneficial to users when proper training methods and user needs are addressed. One curious note from the Miller et al. (2016) analysis was the high prevalence of males (over 80%) in these studies. As research progresses, differential male/female physiology with respect to bony density, musculature, and metabolism should be considered during the testing of robotic exoskeletons, particularly with respect to age and longitudinal use as well.

6.7 Other Robotics

Besides the "full-body," walking robotic exoskeletons, limb-specific robotic exoskeletons are more widely available on the market and are undergoing similar technological advancements for users. Powered upper limb robotic exoskeletons are being tested to assist people living with SCI and stroke to perform upper limb coordination and tasks such as grasping objects (Jarrassé et al. 2014). Pirondini et al. (2016) experimented with a lightweight robotic arm (ALEX™) on healthy subjects and demonstrated comparable EMG activity for various monitored upper limb muscles (as compared to sensors placed on nonusers) while performing a variety of tasks.

For all limb injuries, one of the major rehabilitation issues that confronts the development of robotic exoskeletons and other prosthetic devices is muscle spasticity in response to muscle and nerve damage as well as muscle atrophy. In a randomized control trial for upper arm strength activities among rehabilitation patients using robotic upper limb exoskeletons, Calabrò et al. (2017) demonstrated that applying muscle vibration antagonist action on the affected limbs significantly reduced spasticity during robotic motion activities. Consequently, combinations of physical principles and physical therapy should be incorporated with the most effective use of robotic exoskeletons and prosthetic assistive devices.

Beekhuis et al. (2013) described a self-aligning robotic arm accessory that uses sensors to monitor muscle forcing, torque, and other parameters as well as for adjusting direction of motion. The device is simple to place on the forearm and coordinates smoothly with the wrist and elbow joints, another issue with many limb prosthetic devices. Their proof of concept design is consistent with current state-of-the-art upper limb robotic exoskeletons.

Lower limb robotic orthoses are available for people who have greater leg movement but who have leg injuries or muscle deterioration due to aging or disease. Much of the research on these devices is focusing on gait mechanisms to improve walking, balance, and reproduction of natural gait patterns following injury. As with the full-body robotic exoskeletons, user training is important, but much research remains to be conducted to optimize the functionality of these orthoses (Hussain 2014; Maggioni et al. 2016). Computer simulations of gait patterns assist lower limb prosthetic design by matching natural patterns, and even animal models (e.g., horses), to improve user functionality and satisfaction with walking lower limb robotic prosthetic devices (Meyer et al. 2016).

6.8 Sensory Devices

While not directly pertinent to exercise and health at this time, a number of important sensory technologies exist that enable people with TBI or SCI-related speech, sight, hearing, or upper arm mobility to perform ADLs and IADLs that indirectly relate to activities and participation that are essential for good health and positive psychological well-being. Most of these devices are computer-based systems that enable simple commands to write, speak, and command household and office operations.

For writing on a computer, researchers have used virtual reality and human-computer interaction (HCI) technologies for the development of head-mounted laser and other electronic devices to link to a command screen on a computer. Pereira et al. (2009) described the use of a video camera and a hat/cap-mounted target that aligns so that the user can move and operate an on-screen cursor to manipulate a command screen. More recent developments have included cameras that detect and track eye movements, thereby moving the computer screen cursor to the appropriate commands (Lopez-Basterretxea et al. 2015). Such devices have been demonstrated to be highly reliable with error levels under 5% (Zhan et al. 2016). These devices work particularly well for people who cannot speak and/or use hands/arms for manipulating computers. However, the devices are expensive, but increased use and demand has reduced the costs to a certain degree. As with each of these technologies, our goals are not just to improve and provide them to people living with disabilities, but also to make the devices practical and affordable.

Voice-control technologies are widely advertised for the general population. For people with limited mobility, voice commands can be used with voice recognition software programs on computers for writing as well as for devices that activate/inactivate lights and other electronic appliances. One major issue with voice recognition is altered speech patterns due to speech disabilities or damage to cerebral vocalization centers from stroke, TBI, or SCI. Researchers have developed databases of altered speech patterns that can be accessed by special voice recognition programs and algorithms that utilize maximum likelihood regression analysis to match intended speech to appropriate computerized actions (Mustafa et al. 2014).

Therefore, continuing advances in technology and the interfacing of multiple technologies enable improved assistive devices that can address single or multiple sensory or motility disabilities. These developments illustrate a commitment by rehabilitation professionals, engineers, and other scientists to realistically troubleshoot basic functional problems and to yield efficient solutions to these barriers. As one example, the motor vehicle industry has provided people with limited hand, arm, and leg mobility alternative vehicle control technologies, now computer-driven, that enable them to demonstrate driving proficiency and to independently drive motor vehicles (Lane and Benoit 2011; Rapport et al. 2008). Major rehabilitation centers provide people with stroke, SCI, TBI, and other mobility limitations a variety of these many technologies to provide them with the best support mechanisms to optimally participate in society and to live independently, consistent with the objectives of the Rehabilitation Act of 1973 and its amendments plus other legislation and policy advocacy to enhance the lives of all people who live with disabilities.

6.9 Exercise Guides

The National Center for Health, Physical Activity, and Disability (NCHPAD; www.nchpad.org) is a NIDILRR-funded research and rehabilitation center that promotes physical activity for people living with mobility limitations. It provides a number of exercise guides for people with various conditions such as limb loss, paraplegia, tetraplegia (i.e., quadriplegia), spinal cord injury, cerebral palsy, and multiple sclerosis.

For limb loss, the NCHPAD guide recommends weighted cuffs that will match the prosthetic device. Strength exercises for the upper body include bicep curls, shoulder lateral and front raise, standing bent over shoulder fly, standing shoulder press, standing bent over row, and pectoral fly. The standing exercises can be seated for those individuals with lower limb loss or low functioning. For lower body workouts, weighted cuffs can be used with seated leg extensions, hip flexion, hip abduction, torso lateral bends, and lying abdominal crunches. Other exercise guidelines, including recommended consultations with rehabilitation fitness trainers, are provided.

For spinal cord injuries, exercises are coordinated with the level of injury, an important issue to consider with trained exercise physiologists to guide proper exercise regimens that minimize the risk of further injuries or secondary conditions. For T1-T6 thoracic spinal injuries, possible exercises recommended by NCHPAD include seated elastic resistance exercises such as rhomboid rowing, reverse fly, chest press, internal rotations, rotator cuff, deltoid shoulder presses, lateral and front raise, biceps curls, and triceps flexion. Again, the emphasis for T1-T6 injuries is elastic resistance exercises. For lower thoracic into lumbar spinal area injuries, seated and lying abdominal crunch, leg lifts, curls, and thigh adduction/abduction exercises can be performed.

For people living with tetraplegia, individual levels of functioning determine the appropriate level of physical exercise. As with all conditions, physician and rehabilitation exercise physiologist consultations are essential, and supervision/assistance should be available during exercise. NCHPAD recommends weighted wrist cuffs and elastic resistance training for upper body exercises that are similar to the exercises described for spinal cord injury. Similar training approaches are provided for people living with paraplegia.

People living with multiple sclerosis or other disabilities that enable more mobility can perform standing, lying, and seated stretching exercises, appropriate lifting of weights, and elastic resistance as recommended by their physician and exercise trainer. People living with cerebral palsy can perform controlled weights, elastic training, and seated stationary exercise bicycling.

Public health policymakers, providers, and exercise center operators need to realize the added importance of exercise for the health, independence, and positive outlook of people living with mobility limitations. The coordination of an individual's specific physical needs, assistance devices, accessibility to suitable exercise equipment, and social/community supports can easily promote everybody's health, with no exceptions.

6.10 Challenges and Opportunities

Across this wide span of accessory devices, the user has little or some degree of motion and functionality. If we incorporate the degrees of barriers for functioning in each instance, exercise physiologists can work with each person to identify appropriate exercise devices, activities, and venues to perform needed daily and weekly exercise regimens. Therefore, the assistive devices provide a support mechanism to assist each person with a given mobility disability. It is still up to health and exercise professionals, family, friends, and other peers to be there to help each person achieve their physical activity goals with independence and confidence. That means that we still remove the social and environmental barriers that might present a barrier to the individual living with a disability as well as the assistive device that they are using.

With any of these devices and advancing motion technologies, a critical emphasis must be placed upon the individual. Each person is unique and faces their own array of facilitators and barriers for movement and exercise. Therefore, the process of rehabilitation involves a variety of community and professional supports to evaluate and continuously monitor the technology user's needs. This is part of any persons's standard annual health and wellness checkups plus follow-up evaluations for specific conditions. However, for everyone, unique personal, environmental, social, and condition-specific considerations must be weighed together over the life course of development to maximize health, wellness, and opportunities. Continued research on novel technologies, human factors, and ergonomic analysis of how these advances best work with individual needs, and, most importantly, consumer input, are needed to drive improved health and exercise opportunities for people with disabilities.

6.11 Summary

Advances in assistive technologies for people living with mobility limitations and other disabilities have been dramatic. Nevertheless, we remain in the early stages of this movement as scientists and rehabilitation engineers try to better model and understand the varied physical conditions that are unique to each individual, design of appropriate devices, and matching these devices for optimal use without generating secondary conditions, many of which could be as serious as the primary disability. Furthermore, the expense involved in many innovative technologies poses another dimension to the problem of access, including whether or not insurance companies, Medicaid, and/or disability insurance cover the devices. The last point on insurance is particularly problematic with new experimental devices.

Most of the more advanced technologies (e.g., robotic prostheses and exoskeletons) remain limited to rehabilitation centers due to costs, the complexity of operating the experimental devices, lengthy training times, and extensive need for support mechanisms. For people with disabilities to achieve independent living with these technologies, considerably more innovation, experiment, support, and distribution channels need to be developed to provide efficient, safe products at reasonable cost and that can be widely distributed. Policy experts, legislators, and business leaders can play an important role in driving public and private supports for these much needed efforts. We have only just started getting these assistive innovations to a small percentage of the population of 57 million Americans living with disabilities, and the availability is even lower for people with disabilities in much of the rest of the world.

The prospect for exercise and health looks promising, particularly with advanced wheelchairs and robotic devices that can promote movement and neuromuscular/skeletal actions that stimulate these organs and reduce their risks for atrophy. The kinematic aspects of these innovations cannot be understated. While nerves and muscles may be severely limited, any stimulation is beneficial and translatable across organ systems. Visionaries discuss the enhancement and even tissue cloning replacement of damaged organs, but these potential advances remain even further away. We currently need to provide artificial sources that can manipulate and enhance physical functioning for exercise and independent living.

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