Chapter 5
Practical Review of Robotics in the Treatment of Chronic Impairment After Acquired Brain Injury

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Why Robots? Basic Principles and Benefits of Robotic Interventions

In 1996, Nudo, Wise, SiFuentes, and Miliken published a pivotal preclinical neurological recovery study, which demonstrated that activity-dependent plasticity underlies motor recovery following brain injury. Two separate groups of primates underwent intracortical microstimulation (ICMS) to confirm the region of the motor cortex that was responsible for fine motor control. Both groups were then subjected to cortical injury, causing specific unilateral hemiparesis of the wrist and the hand. Following the neurological insult, the first group was allowed to recover without any further intervention. They exhibited minimal recovery of function, and repeat ICMS mapping revealed an extension of the brain lesion into previously undamaged, adjacent motor areas. The second group was provided intensive fine motor training involving retrieval of food pellets from small wells. Not only did the trained group exhibit recovery of function, but repeat ICMS mapping revealed that they had no further loss of neural tissue and, in some cases, had increased representations for hand movements expanding into regions of the motor cortex, which were originally responsible for shoulder/elbow control (Nudo et al., 1996). This study provided important evidence for activity-dependent neuroplasticity: the idea that intensive motor training can improve motor function and correspondingly reorganize cortical motor representations following ABI.

Results from early motor learning research highlighted key tenets of successful motor rehabilitation and drove the development of interactive robotic therapy devices. Effective robotic devices share several important characteristics; they are

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impairment focused, and they deliver ***reproducible***, ***objective***, and most importantly ***intensive*** and ***adaptive*** motor training (Krebs et al., 2004, 2007). Robotic therapy devices typically operate through a series of *interactive* motors with low impedance, which are ***adaptive***: the robot moves a patient's limb when the patient cannot move and progressively intervenes less as the patient improves and regains more voluntary movement. The assistance provided is no different from active-assistive range of motion exercises performed in physical or occupational therapy (Volpe et al., 2008). However, a robot can typically provide more ***intensive*** active-assistive intervention than a therapist, as the robot does not get tired or need a rest or break, it becomes a durable tool for therapists in any restorative clinic. For example, a single robotic therapy session will deliver over a thousand movement repetitions in an hour. In comparison, a recent study of 312 inpatient and outpatient sessions across seven rehabilitation sites demonstrated that a standard OT and PT treatment for individuals with stroke averaged only 32 repetitions of a given movement per session (Lang et al., 2009). Intensity of repetitions both within and across sessions has been shown to improve overall motor outcomes following acute and chronic brain injuries (Cramer, 2018).

Another key element of robotic therapy is that it is ***impairment focused***: each device trains a specific limb segment or segments in isolation, and allows the patient to focus on regaining motor control for a singular area of weakness such as the wrist, hand, shoulder/elbow, or ankle. The advantage of isolated joint(s) training is that it is safe, because a patient can typically sit during the intervention, and it is also easily ***reproducible***, allowing for quick setup, reliable dosing, and more ***objective*** measurement of improvements. Subjective clinical scales tend capture broad functional changes, whereas objective robotic measures are consistently precise and sensitive to small improvements. Nearly all commercially available devices today incorporate an online or intermittent "report card," which automatically tracks patient progress, providing the clinician efficient and unbiased data for justification of services, and providing the patient motivation to "beat" his or her previous score.

Overall, the most significant benefit of robotic intervention is its efficiency. A robot can efficiently deliver intensive repetitions of motor training at patient-specific areas of impairment, enabling the PT or OT to then incorporate those motor improvements into functional training for ADLs.

Efficacy: A Current Evidence Base for Robotic Intervention

The critical multicenter study providing an evidence base for upper limb robotic rehabilitation was executed by Lo and Colleagues (2010). A total of 127 individuals with chronic moderate-to-severe upper limb hemiparesis following stroke were randomized to three treatment groups: intensive robot-assisted therapy ($n = 49$), intensive comparison therapy ($n = 50$), and usual care ($n = 28$). Both the robot-assisted and intensive comparison therapy group received thirty-six 1-h sessions (3×/week for 12 weeks) of intensity-matched intervention, with the latter group performing all movements with the active assistance of a clinician instead of the robot. This active,

intensive therapist delivered treatment was verified as nearly comparable to the number of movements executed by the robot in a previous study (Volpe et al., 2008). The usual care group received standard medical and/or outpatient rehabilitation services, which were not intensity-matched. At 6-month follow-up (week 36 of study), the robot group and intensive comparison therapy group both improved significantly compared with usual care (average of ~3 points on the Fugl Meyer Upper Extremity Scale). Moreover, younger participants (<55 years) and participants who were a shorter time post-stroke (<12 months) exhibited the greatest improvements (average of 7–16 points on the Fugl Meyer) (Wu, Guarino, Lo, Peduzzi, & Wininger, 2016). Again, this study demonstrated that robotic devices do not inherently provide an intervention that a clinician cannot, but the robot exceeds at delivering intensive motor repetitions at a level that is impractical for a clinician to perform regularly. Overall, the take-home message was clear: intensive active-assistive motor intervention significantly boosts long-term functional recovery.

Subsequent cost–benefit analysis following this multicenter VA study found that at 36 weeks (6 month follow up appointment), individuals who received robotic intervention had actually cost the VA health system significantly less (over $1000 per patient) than usual care or intensive comparison therapy (Wagner et al., 2011). Even though robotic therapy had added costs to administer, the patients who received it ultimately used less resources throughout the health system following the intervention, thereby reducing the overall financial burden. Following the Lo et al. study, the American Heart Association recommended in favor of robotic therapy (level IIa) as a "reasonable" form of upper extremity stroke rehabilitation (Winstein et al., 2016).

There has been less rigorous investigation of robotics for the lower extremity, though a recent meta-analysis across 36 studies of electromechanical gait rehabilitation found that patients who received physical therapy in combination with these devices were more likely to walk independently, with the most benefit for clients who were nonambulatory and in the acute phase after stroke (Mehrholz et al., 2017). Comparatively, the LEAPS multicenter study employed locomotor training exercise and exoskeletal body-weight-supported treadmill training and found this intervention was comparable but not superior to progressive exercise at home managed by an expert therapist (Duncan et al., 2011). At present, the American Heart Association has assigned lower extremity robotic therapy with the slightly lower level IIB designation (Winstein et al., 2016). This means lower extremity robotics can be considered as an intervention, though patient candidacy and careful documentation of improvement should be tracked.

Rehabilitation Devices on the Marketplace

Over the past 20 years, there has been an explosion of commercially available rehabilitation devices in the marketplace for the treatment of hemiparesis following ABI. While this is an exciting time in rehabilitation medicine where technology is integrated to improve clinical care, it is critical to remember that not all

interventions are created equally. It is important that the clinician trial any new device in order to understand the type and level of assistance it provides, carefully review its evidence base, and develop an impairment-focused treatment rationale.

For the upper extremity, there are a multitude of rehabilitation devices, which vary widely based upon the types and levels of assistance they offer. The four main categories of interventions provided by rehabilitation devices are robotic, mechanical, electrical stimulation (e-stim), and biofeedback. While the primary focus of this chapter is on *robotic* rehabilitation devices and their evidence base, it is also important to briefly review mechanical, electrical stimulation, and biofeedback devices, as these are many of the commercially available interventional solutions in the market at present. Robotic devices such as the InMotion Arm™ provide motorized assistance to the limb as it engages in a movement, whereas mechanical devices such as the Saeboflex™ provide spring-loaded support. E-stim devices such as the Bioness™ deliver an electrical current to engage the muscle during the movement. In contrast, biofeedback devices such as MusicGlove™ provide only visual feedback to engage the patient to increase his or her own movement without direct assistance (Table 5.1). These devices also vary based on the level of assistance they offer from total passive ROM where the limb is taken through the movement without any required engagement of the patient, to active-assistive, which requires the patient to attempt to move and the device provides assistance-as-needed, to fully active ROM, where the patient is provided visual feedback of performance and encouraged to move independently. Many devices can provide a range of assistance, which is adjusted by the clinician or the patient with some training.

Generally, active-assistive devices employing either robotic support or electrical stimulation are superior for motor training, because they require continued attention from the patient to attempt to execute the motor task, while delivering interventional support as needed to complete the movement with the targeted muscle complex. Active attention and task-engagement are two components that are critical to motor learning (Antelis, Montesano, Giralt, Casals, & Minguez, 2012). In contrast, passive range of motion settings are beneficial to initially stretch a targeted muscle group or promote overall joint health, but do not directly assist in motor training (Hogan et al., 2006). The InMotion Arm™ and InMotion Wrist™ robots were some of the earliest robotic active-assistive devices to the marketplace and have the largest published evidence base across all upper extremity devices (Table 5.1). One of the important features that differentiates these devices from others is that they are "backdrivable": the device allows the patient to make an attempt *before* it provides any assistance (Hogan et al., 2006). Many other active-assistive range of motion devices provide a programmable percentage of assistance throughout the movement, which must be adjusted by the clinician, and they do not pause for the patient to attempt to move totally independently before providing support. At this time, there is not definitive clinical evidence in favor of one or the other approach. Nonetheless, there are many new and promising upper extremity device companies with emerging efficacy evidence.

One important gap in rehabilitation technology is the development of a consistent solution for the recovery of hand function, which is one of the most coveted

Table 5.1 Summary table of commercially available upper extremity rehabilitation devices (Lo, Stephenson, & Lockwood, 2017; Maciejasz, Eschweiler, Gerlach-Hahn, Jansen-Troy, & Leonhardt, 2014; McConnell et al., 2017; Poli, Morone, Rosati, & Masiero, 2013; Yue, Zhang, & Wang, 2017)

Device	Assistive technology	Mechanical design	Training modalities	Treatment target	Task description	Manufacturer
InMotion Arm	Robotic	End-effector	Passive/ active-assistive/ active/resistive	Shoulder and elbow	Desk-mounted, seated shoulder/elbow training device with back-drivable active-assistance integrated into a video game; for clinical use only	Bionik
InMotion Hand	Robotic	End-effector	Passive/ active-assistive/ active/resistive	Hand	Desk-mounted, seated, shoulder/elbow/grip training device with back-drivable active assistance integrated into a video game; for clinical use only	Bionik
InMotion Wrist	Robotic	End-effector	Passive/ active-assistive/ active/resistive	Wrist	Seated wrist training device with back-drivable active-assistance integrated into a video game; for clinical use only	Bionik
Hand of Hope	Robotic + biofeedback	Exoskeleton	Passive/ active-assistive/ active	Hand and fingers	Wearable surface EMG-driven robotic hand therapy device for isolated training or integrated with video games; for clinical use	Rehab-Robotics
Amadeo	Robotic	End-effector	Passive/ active-assistive/ active	Hand and fingers	Desk-mounted, seated finger movement and dexterity training device with active-assistance integrated into a video game; for clinical use only with higher functioning patients	Tyromotion
Diego	Robotic	End-effector	Passive/ active-assistive/ active	Arm and shoulder	Seated shoulder/elbow gravity compensation training device integrated into video game; for clinical use only	Tyromotion
Pablo	Biofeedback	End-effector	Active	Hand and arm	Wrist/hand/arm therapy and assessment device that facilitates independent movement with biofeedback; for clinical and home use	Tyromotion
Hand Mentor Pro	Robotic	Exoskeleton	Active-assistive	Hand	Wearable robotic hand device with guided and controlled interactive game based-training; for clinical use	Motus Nova

(continued)

Table 5.1 (continued)

Device	Assistive technology	Mechanical design	Training modalities	Treatment target	Task description	Manufacturer
Saebo Glove	Mechanical	Exoskeleton	Active-assistive/ active	Hand and fingers	Wearable, bungee-loaded hand device promoting active finger extension and training functional grasp; for clinical and home use	Saebo
Hand Tutor	Biofeedback	Exoskeleton	Active	Hand and wrist	Wearable hand device with integrated video display, facilitating independent hand function with biofeedback; for clinical and home use	MediTouch
SaeboFlex	Mechanical	Exoskeleton	Active-assistive/ active/resistive	Hand and fingers	Wearable, spring-loaded hand device promoting active finger extension and training functional grasp; for clinical and home use	Saebo
ExoHand	Robotic	Exoskeleton	Active-assistive/ active	Hand and fingers	Wearable hand device used to perform computer-based tasks and training of gross motor ADL; for clinical and home use	Festo
H200 Wireless Hand	Electrical stimulation	Exoskeleton	Passive/ active-assisted	Hand and wrist	Wearable hand orthosis providing Functional Electrical Stimulation to activate muscles of wrist and hand to facilitate hand function and prevent contractures; for clinical and home use	Bioness
Music Glove	Biofeedback	Exoskeleton	Active	Hand and fingers	Wearable hand device for independent movement with biofeedback during interactive music guided task; for clinical and home use	Flint Rehab
Armeo	Robotic	End-effector	Passive/ active-assistive/ active	Upper extremity	Seated shoulder/elbow training device with range of assistance during video game tasks; for clinical use only	Hocoma
MyoPro Orthosis	Electrical stimulation + robotic	Exoskeleton	Active-assistive/ active	Elbow, wrist and hand	Myoelectric elbow/wrist/hand orthosis that supports and enables controlled function of impaired hand and arm; for clinical and home use during ADLs	Myomo

Rapael Smart Glove	Biofeedback	Exoskeleton	Active	Hand and fingers	Wearable glove with biofeedback via integrated video display for customized hand rehabilitation; for clinical and home use	Neofact
Neomanus	Robotic	Exoskeleton	Active-assistive/ active	Hand and fingers	Wearable hand robot designed to assist with ADL training and integration of function; for clinical and home use	Neofact
Gloreha Sinfonia	Robotic	Exoskeleton	Passive/ active-assistive/ active	Hand, fingers and wrist	Robotic glove enriched by a multisensory stimulation and 3D animation that supports finger joints motion, while detecting voluntary active motion. Allows ADL training; for clinical use	REHA Technology
Armotion	Robotic	End-effector	Passive/ active-assistive/ active	Upper extremity	Portable Arm therapy device with computer-based gaming with visual feedback; for clinical and home use	REHA Technology

goals for patients after ABI. Part of the challenge is that the hand is made up of an inherently complex set of muscles with many degrees of freedom, allowing for the execution of specified, dexterous movements. The other challenge is that following a stroke, the hand typically presents with the most severe muscle spasticity. Consequently, it is difficult to create an interventional device with enough structure to prevent the hand from assuming a flexed posture, and enough fluidity to allow the degrees of movement freedom required for the articulation of the digits or apposition of the thumb during functional tasks.

Shoulder and elbow improvements from robotic training are mostly achieved by active-assistive and resistance-based tasks, but weakness and high tone of the hand impose challenges to the selection of patients that could benefit from any one product currently available in the market. Presently, clinicians should carefully review all available hand rehabilitation devices and select a device that fits with the impairment level of the patient. Generally, hand rehabilitation devices should not be introduced until the patient has enough proximal control of the shoulder and elbow for reaching tasks. At that time, patients with more severe difficulties might try a device that focuses on gross finger extension with a more fixed, structured spine to keep the hand in place during movement, such as Saeboflex™. For higher functioning patients with mild residual spasticity and partial finger extension, consider a device that focuses on finer finger movements with a less restrictive orthosis such as the RAPAEL Smart Glove™, Gloreha Sinfonia™, or the AMADEO™ (Table 5.1). Research and premarket testing of newer, improved hand devices remains ongoing, promising better solutions for functional hand use across the continuum of recovery.

For the lower extremity, the majority of the technology-based rehab interventions are known as electromechanical gait devices. These large, body weight-supported gait training devices can be divided into two categories: exoskeletal and end-effector. Exoskeletal devices, such as the EKSO™, ReWalk™, and Lokomat™, look like wearable robotic legs and function through programmable drives that move the knees and hips during gait phases. In contrast, end-effector devices, such as the G-EO System™ and the LokoHelp™, provide harness support while holding the feet on foot-plates that move in trajectories mimicking the stance and swing of gait (Table 5.2). Nearly all electromechanical gait devices can be programmed to provide more or less device assistance as needed in order to tailor therapy to the level of impairment. Other lower extremity devices in the market include the InMotion ANKLE™, which is an active-assistive robotic ankle therapy device used in a seated position, and programmable electrical stimulation gait devices such as the WalkAide™ and the Bioness™ L300™, which are worn in place of an orthosis to remediate foot drop during everyday gait function (Table 5.2). There is less overall data on lower extremity devices as a whole, and the largest single study of an exoskeletal device involving comparison of the Lokomat™ training to a home exercise program managed by a physical therapist found no additional benefit from device use (Duncan et al., 2011). However, as mentioned previously, a recent meta-analyses of electromechanical gait intervention across 36 trials with a total of 1472

Table 5.2 Summary table of commercially available lower extremity rehabilitation devices (Lo et al., 2017; Poli et al., 2013)

Device	Assistive technology	Mechanical design	Training modalities	Treatment target	Task description	Manufacturer
GEO System	Robotic	End-effector	Passive/ active-assistive/ active	Lower extremity	Body weight-supported gait trainer for simulated overground walking and step climbing prompted by video display	REHA Technology
NexStep	Robotic	End-effector	Passive/ active-assistive/ active	Lower extremity	Body weight-supported gait trainer for simulated overground walking	REHA Technology
Lokomat	Robotic	Exoskeleton	Passive/ active-assist/ active	Lower extremity	Treadmill-based body weight support gait trainer with assist-as-needed properties	Hocoma
LOPES	Robotic	Exoskeleton	Active-assistive/active	Lower extremity	Treadmill-based body weight support gait trainer with assist-as-needed properties	University of Twente
InMotion Ankle	Robotic	Exoskeleton	Active-assistive/active	Ankle	Seated isolated ankle-training device prompted by video display	Bionik
Gait Trainer GT 1	Robotic	End-effector	Active-assistive	Lower extremity	Body weight-supported robotic gait trainer system. Allows FES integration	Reha-stim
LokoHelp	Robotic	End-effector	Active-assistive/active	Lower extremity	Body weight-supported gait trainer and postural control device	Woodway
WalkAide	Electrical stimulation	Wearable	Active-assistive	Ankle	FES-triggered device targeting muscles involved in gait as an alternative to an AFO	Innovative Neurotronics
L300 Go	Electrical stimulation	Wearable	Active-assistive	Ankle, ankle + knee	FES-triggered device targeting muscles involved in gait as an alternative to an AFO	Bioness
Ekso GT	Robotic	Exoskeleton	Active-assistive/active	Lower extremity	Overground wearable dynamic robotic gait trainer for use in the clinic	Bionic
ReWalk	Robotic	Exoskeleton	Active-assistive/active	Lower extremity	Overground wearable dynamic robotic gait trainer for use in the clinic and out in the community	ReWalk Robotics

patients found that these devices in combination with physical therapy significantly improved functional ambulation status for individuals in the acute phase after stroke who were nonambulatory (Winstein et al., 2016).

Client Selection: Tips for Treating Clinicians and the Interdisciplinary Team

As a whole, robotic therapy is suitable for most patients seeking motor rehabilitation following ABI. As with all rehabilitation interventions, the client should be medically cleared for exercise, and may be excluded for complications such as cardiac failure, severe pain management issues, or recent orthopedic injury/surgery to the targeted joint. Additionally, clients who are unable to remain engaged in a robotic task for at least 45 min to 1 h or who present with total flaccid paralysis, often accompanied by near-complete sensory loss, or fixed contractures of the affected muscle complex should be excluded. More specific candidacy requirements are device dependent.

If there is a question of client candidacy and the intervention is relatively safe, such as a device used in a seated position, it is often worthwhile to trial the treatment, but with vigilant monitoring by the clinician. For example, we have noticed anecdotally that clients who present with receptive language deficits, neglect, and/or inattention (such as global aphasia and hemiparesis) may excel with seated, active-assistive robotic intervention involving a video game/visual display, because it provides a repetitive, goal-directed, nonverbal task, which can be intuited by the patient over time. It may require 2–3 sessions for the patient to initially engage in the task, but generally after this period, the patient becomes increasingly alert, more oriented to field of neglect, and actively participates using the hemiparetic limb. Similarly, for patients with significant shoulder dislocation, the OT may opt to trial a proximal upper extremity robotic device in a seated position, but should cautiously monitor shoulder positioning, provide adequate support for glenohumeral stability during exercise, and carefully assess the patient for report of pain or increasing edema. When carefully controlled, such shoulder intervention can successfully reduce shoulder subluxation, a problem which is often persistent, painful, and challenging for the clinician to address. In one such study with a robotic device, clients with chronic shoulder subluxation underwent 18 robotic sessions of targeted active-assistive training of the shoulder complex, and demonstrated an average reduction of glenohumeral instability of 36.4 mm, or about two finger breadths, at study follow-up (Dohle, Rykman, Chang, & Volpe, 2013).

Another important consideration when weighing the particular costs and benefits of a robotic intervention is setup time. Ideally, setup should not take more than 5–10 min to allow for a rigorous training session for the patient within what is often a tight clinical schedule for the therapist. In general, seated upper extremity robotic devices require limited setup and are well-suited for a fast-moving clinical context.

Some devices such as the MyoPro™ and the EKSO™ require a longer initial fitting/training, but save and retrieve individualized patient settings to be used for future treatments (Tables 5.1 and 5.2). Electromechanical devices involving bodyweight supported harnesses require longer setup and, based upon the severity level of the client, may necessitate the assistance of two clinicians to operate. Consequently, when a treatment team is testing these devices, there is a need to demonstrate improved efficiency of motor recovery to account for the time commitment and clinical resources. Since these devices have the most evidence for use in nonambulatory patients in the acute phase, the PT may consider trialing electromechanical gait intervention with this population, and plan for the commitment of at least two therapists and for lengthier treatment sessions initially (Mehrholz, Pohl, Platz, Kugler, & Elsner, 2015). If used with higher functioning clients that can ambulate, the PT should use his or her clinical judgment to select potential candidates and carefully track progress with repeated gait measures, as there is presently less clinical evidence for treatment with this group as a whole.

The great potential for robotics is to use them as a clinical tool, which augments the benefits of traditional rehabilitation and increases the efficiency of functional recovery. Training with rehabilitation devices can reduce pain and improve active range of motion at specific joints, which accordingly allows the clinician to reduce assistive devices/braces, train the patient/caregiver on correspondingly progressive stretch protocols for home, and, most importantly, integrate motor improvements to increasingly functional tasks. For chronic ABI populations where progress in standard OT/PT programs may plateau, there are evidence-based studies that robotic therapy may still provide additional functional benefits (Lo et al., 2010; Volpe et al., 2009). There is thus tremendous potential for the development of robotic outpatient gyms to be used in restorative care with some clinical oversight. Additionally, a recent uptick in lighter, more affordable home-use devices in the marketplace offers the opportunity to better integrate clinical goals into a home-exercise program both during rehabilitation and after discharge. Training intensity drives motor recovery, but insurance-covered rehabilitation sessions can be limited. Home use devices such as the HandTutor™, Bioness™, and RAPAEL Smart Glove™ enable the therapist to provide the patient with increased opportunities for intensive motor training beyond the clinical schedule at home, and also provide virtual report cards to track patient adherence and progress (Table 5.1). However, it is critical with such devices that the OT train the client and, ideally, the caregiver to monitor for correct device use, as it can be easy to cheat to complete the task, by, for example, hiking in the elbow to move a hand device downward instead of pronating at the wrist.

Overall, the integration of robotic therapy works best as an interdisciplinary team approach. Insights regarding patient medical history, cognitive and communication status, visual perception, sensation, balance, affect, recovery goals, and caregiver support, all contribute to selecting the best interventions for motor recovery. Moreover, input from across the rehabilitation team is needed to monitor functional carryover and best characterize real-world outcomes. The following case report illustrates this point.

Clinical Case Example

CT is a 62 year old woman who sustained a right subcortical CVA resulting in left hemiparesis and dysarthria. Her hospital course included 4 days at a medical center followed by 3 weeks of acute rehabilitation, with subsequent discharge home with 3 additional months of outpatient PT, OT, and ST services. Therapy was complicated by the development of upper extremity neuropathic pain, which reduced her tolerance and engagement in OT.

She enrolled in an upper limb robotic therapy research trial approximately 15 months after her stroke, and nearly a year after discharge from rehabilitation services. At the time of enrollment, her dysarthria had resolved and she walked with a quad cane and an ankle foot orthosis (AFO). She had glenohumeral stability and demonstrated normal shoulder range of motion (ROM), but only partial active ROM at the elbow, wrist, and hand, which was limited by weakness and spasticity. She was able to dress herself, but required assistance with buttons and zippers. She also required minimal assistance with bathing her unaffected side due to pain and weakness in her affected wrist and hand. She complained that her hand movement was not functional, and displayed only partial finger extension/flexion and limited pincer grasp.

After 3 months in the study, consisting of 36 sessions of intensive active-assistive shoulder/elbow and wrist training, she demonstrated a 4-point improvement on the Upper Extremity Fugl Meyer scale, moving from a score of 34 to 38 points. At her 3-month study follow-up, she had another 2-point improvement to a score of 40, for total increase of 6 points. Her improvements were characterized by an increase from partial to full active elbow and finger flexion and increased wrist/finger extension, such that she was able to perform a cylinder grasp for the first time. She reported that she could eat with her affected hand more easily and bathe more independently as she was now able to extend her fingers around a long handled sponge or built-up fork, hold with improved grasp, and flex her elbow enough to bring the fork to her mouth. She also reported that her upper extremity pain was improving with exercise, though still present. Following study discharge, she was referred back to outpatient OT for integration of more functional hand use with the Saeboflex or Bioness. She was also referred to Physiatry for pain management where she received a low dose of gabapentin and reported improving symptoms.

Challenges with Integration of Robotics in Rehab Settings

Despite continued emerging evidence confirming the benefits of robotic rehabilitation interventions, there remain several challenges with the integration of these devices as a standard of care. One challenge is that robotic interventions generally lack specialized billing codes. Nonetheless, many of the top rehabilitation hospitals in the United States do offer robotic therapy, and typically bill for those services under alternative

codes related to the rehabilitation approach rather than the specific device, such as neuromuscular reeducation, attention, and therapeutic activities. Another significant challenge is that many of the most successful clinical trials provide therapy at a higher intensity than is typically covered by insurance. For example, in our own outpatient stroke rehabilitation studies, a typical robotic therapy dosage is eighteen 1-h sessions, 3×/week for 6 weeks (Chang et al., 2017; Dohle et al., 2013). This intensity of intervention is usually only offered in either a research or fee-for-service outpatient setting, as reimbursement does not generally comply. In a standard inpatient or outpatient setting, it is difficult to provide anywhere near this intensity of intervention while still addressing patient's other recovery needs. In practice, when robotic interventions are used as a billable service, they are typically used with less intensity (e.g., fewer repetitions, less visits), and with diminished positive outcome.

It may be that intensity is as important as timing (acute versus chronic) of the intervention. To investigate this hypothesis, we treated 248 functionally diverse inpatients and outpatients who had a Fugl Meyer Upper Extremity Scale score that ranged from 0 to 54 points (out of 66) and who were time post stroke = 5 days–11.3 years from their acute event. Each patient received at least 18 sessions of robotic training for the treatment of upper extremity hemiparesis poststroke. All clients on average had significant changes in upper extremity Fugl Meyer scores; however, we found that baseline severity level bore a strong relationship to predicted dosage of intervention required to achieve maximal response. Clients with moderate-to-severe hemiparesis (average admission FM = 24) generally plateaued after nine treatment sessions, while clients with more mild-to-moderate hemiparesis (average admission FM = 35) improved across eighteen treatment sessions and, in some cases, continued to spontaneously recover hand function during the 3-month follow-up window (Volpe et al., 2009).

As a broad rule of thumb, these data suggest the clinician might expect clinically significant functional improvements (MCID for UE FM = 4 points) after nine sessions of intensive upper extremity robotic therapy, but may continue to document recovery beyond nine sessions, based upon patient severity level and treatment targets (Lundquist & Maribo, 2017). However, if there is no demonstrable benefit by the ninth session, the device may not be beneficial for the client.

Perhaps the greatest challenge for the integration of robotic interventions into rehabilitation medicine is that the efficacy evidence for robotic rehabilitation is based upon a body of clinical research with varied patient characteristics, types of intervention, and intensity/duration information across trials, rendering it difficult to determine which candidate, device, and dosage is needed for best results (Mehrholz et al., 2015). Further motor recovery research is needed to continue to provide more specified device recommendations to clinicians and better service justification evidence to insurers. Rehabilitation research of acquired brain injury is inherently difficult due to the varied nature of the illness. Moreover, many of the accepted measures for capturing improvement are derived from subjective clinical scales that can be unreliable, unless the therapists are formally and rigorously trained. The overwhelming challenge in clinical research is to design a study with a subject pool, which is narrow enough to capture reliable functional improvements,

but diverse enough to be able to generalize the results to the treatment population as a whole.

We attempted to address these challenges in a recent gait study involving 18 sessions of active-assistive ankle training in a seated position to improve functional ambulation status (Chang et al., 2017). Twenty-nine clients with gait speed impairments following stroke were categorized into three functional groups based upon admission comfortable gait speed on the 10-meter walk test, using established gait speed impairment levels with the low function group walking at speed of <0.4 m/s, the moderate function group at 0.4–0.8 m/s, and the high function group at >0.8 m/s (Fritz & Lusardi, 2009). The results indicated three distinct and significant between-group patterns of gait speed recovery. Clients who were at the ceiling for balance measures experienced an impairment level shift in gait speed moving from "community ambulators" (0.8–1.2 m/s) to "normal walking speed" (>1.2 m/s). They also exhibited gait speed improvements that approached significance ($p = 0.051$) from discharge to follow-up on the 10-meter walk fast-paced condition, indicating generalization of functional gains and the development of a fast-paced breakaway speed without further intervention. This suggests that for high functioning patients, isolated ankle training may open a new therapeutic window for further PT intervention to focus on more aggressive functional goals such as running. Clients with moderate-to-severe impairments also had improvements in gait speed and balance, but did not experience an impairment level shift. Comparatively, these patients (e.g., home or limited community ambulators) routinely demonstrate flexor synergy control patterns of the entire lower extremity (hip hike, knee flexion, and foot drop), and may benefit from isolated training of the ankle to target foot drop along with treadmill training of the entire lower limb.

Thus, by using well-established gait speed parameters, we were able to examine patient performance more specifically as a function of baseline severity, and isolate an important subgroup of patients who are able to make an impairment level shift in gait speed from 18 sessions of seated robotic ankle training alone. As demonstrated in this study, intensive robotic interventions may more effectively focus on individualized medicine, which tailors dosage and type of intervention to severity level of the patient. Real-world outcomes are important. By separating patients by severity of impairment, a study will avoid overall failure and specify real-world outcomes that are attainable. Additionally, given the current financial strictures in rehabilitation medicine, future research should also investigate the integration of home-use devices into clinical care in an attempt to increase the intensity of the intervention beyond the limited number of approved treatment sessions.

A typical case history from one of the clients in the study above follows:

Clinical Case Example

KM is a 46-year-old male who sustained a right frontotemporal intracerebral hemorrhage for which he underwent a decompressive craniotomy and subsequent cranioplasty. His hospital course included 2 weeks at an acute medical center;

followed by a month of acute rehabilitation, another 5 weeks in subacute rehabilitation; and finally discharge to home with outpatient PT, OT, and ST services for approximately 3 months. Prior to his stroke, he was a manager at a company and an active tennis player and musician. As per the client and caregiver report, he was initially wheelchair-bound after the stroke, but had progressed to walking with a single-point cane. He had limited recovery of his upper extremity function characterized by persistent weakness and pattern of flexor synergy. He had received ST services to address impairments of planning/judgment and short-term recall. Though these deficits had improved, he had been unable to return to work, but maintained a busy social and family life.

Approximately 4 years after his stroke, he enrolled in a research study involving 6 weeks (18 sessions) of intensive seated anklebot training. At that time, he walked with a single point cane and no AFO, but exhibited mild residual foot drop. Following anklebot training, he had a 4-point improvement on the Berg Balance Scale (moving from a score of 47 to 51 points). He also had an impairment level shift in his gait speed on the 10-meter walk test, moving from a limited to full community ambulator, 0.75–1.0 m/s. He had mild residual foot drop while walking, though he reported improved confidence and gait stability. He consequently gave up the use of his cane and began walking a half mile on his local track several times per week.

Innovation: Noninvasive Electrical Stimulation Techniques

In the past 20 years, there has been a growing interest across the scientific community to explore noninvasive electrical stimulation techniques for the treatment of different neurological conditions. While none of these interventions are currently approved for clinical use in ABI rehabilitation, it is important for the clinician to be aware of these interventions as they are being extensively tested in clinical trials worldwide and have shown some promising efficacy in the treatment of certain conditions. Moreover, there has been a breadth of recent rehabilitation researches in ABI combining noninvasive electrical stimulation with robotic devices and other rehabilitation interventions with the goal of augmenting motor learning/function during a therapy task to improve outcome.

Noninvasive brain stimulation (NIBS) has been shown to modulate brain activity and promote transient improvements in learning and motor function through inhibition or excitation of brain pathways (Ahmed, 2014; Dayan, Censor, Buch, Sandrini, & Cohen, 2013; Hays, 2016; Rossi et al., 2009). Presently, the most investigated noninvasive stimulation devices include Transcranial Magnetic Stimulation (TMS), Transcranial Direct Current Stimulation (tDCS), Transspinal Direct Current Stimulation (tsDCS), and Vagus Nerve Stimulation (VNS). Safety and feasibility studies have demonstrated that NIBS are largely low risk (Hays, 2016; Rossi et al., 2009). TMS has established efficacy data and received FDA approval for the treatment of refractory depression and migraines. However, to date, clinical trials pairing robotics and NIBS have shown mixed and inconsistent results, and comprehensive efficacy reviews of these studies have thus far not established superior

motor recovery benefit (Di Pino et al., 2014). In our experience, we have investigated noninvasive stimulation techniques for use in motor rehabilitation and demonstrated some significant individual treatment responses as referenced in the case example below. Despite this, more research is needed to specify treatment (e.g., target population, timing, dosage) and establish efficacy prior to the introduction of these interventions into clinical practice.

Clinical Case Example: AR

AR was a healthy and thriving 26-year-old college graduate starting his professional life in IT and keeping an important role as a brother and son to a close-knit family. In the spring of 2017, AR awoke with acute-onset right hemiparesis and expressive aphasia. He was taken to an emergency room where an acute cerebrovascular event was diagnosed. After being considered clinically stable, AR was admitted for 3 weeks of acute rehab care where he received ST, OT, and PT services. His lower hemiparesis subsequently resolved, and he was discharged home with outpatient OT and ST services, which targeted improved upper extremity function and verbal expression. Still aiming for an alternative to reduce stiffness and improve hand function, AR consented to participate in a clinical trial involving transspinal direct current stimulation (tsDCS), an experimental device being investigated to reduce the spasticity of the wrist and hand.

After completing the study, AR was encouraged to keep a home-based exercise regimen and integrate bimanual activities into his activities of daily living. He was also enrolled in a 6-week intensive wrist robot program to take advantage of an apparent treatment window opened by the decrease of spasticity achieved post study discharge. Following the study and subsequent robotic intervention, he underwent the same clinical and objective assessments with an exciting outcome: AR had maintained a significant reduction in spasticity below his baseline study scores and showed improvements in active range of motion during the robotic wrist evaluation. Most importantly, he demonstrated increased functional use of hand his hand in everyday activities, including self-feeding, opening doors, and carrying dishes with the affected hand.

Conclusion

Restorative treatments for those with ABI require a multidisciplinary effort, and now, with the addition of bioengineering tools, outcomes over the long term are likely to improve. The goal of restoring the optimum sensorimotor recovery after ABI should be a challenge picked up by the medical community at large, not just the therapists. This will likely require rule changes so that the payment structure can support treatment during the chronic phase of the recovery. Clearly, the evidence basis for these

treatments 6 months or more after the injury supports the rationale for treatment. There is a wealth of information appearing with the use of several of the NIBS devices, and there is great interest and enthusiasm for testing combinations of devices in a new push to help the client express an optimum motor outcome.

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