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Innovating With Rehabilitation Technology in the Real World

Promises, Potentials, and Perspectives

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Abstract: In this article, we discuss robotic-assisted therapy as an emerging and significant field of clinical rehabilitation and its value proposition for innovating rehabilitation clinical practice. Attempts to achieve integration among clinicians' practices and bioengineers' machines often generate new challenges and controversies. To date, the literature is indicative of a sizeable number and variety of robotic devices in the field of clinical rehabilitation, some are commercially available; however, large-scale clinical outcomes are less positive than expected. The following main themes related to integrating rehabilitation technology in real-world clinical practice will be discussed: the application of current evidence-based practice and knowledge in relation to treatment in the rehabilitation clinic, perspectives from rehabilitation professionals using robotic-aided therapy with regard to challenges, and strategies for problem solving. Lastly, we present innovation philosophies with regard to sustainability of clinical rehabilitation technologies.

Key Words: Robotic-Assisted Therapy, Neurotechnology, Stroke, Innovation, Gait Training (Am J Phys Med Rehabil 2017;96(Suppl):S150-S156)

ehabilitation robots have been developed to aid in the K physical rehabilitation of patients after stroke, spinal cord and brain injuries, in particular addressing various motor and functional impairments. Their other roles include the alleviation of therapists' physical burdens, increased limb practice, exercise intensity and enhanced productivity. After stroke, the brain can be influenced by intensive sensorimotor training through usedependent neuroplasticity operating in the subacute to chronic recovery phase.¹ The novel concept of using automatic devices or machines dates back to the early 1990s, where development of robotic haptic interfaces focusing on human interactions, showed that such devices can guide paretic limbs through passive- or active-assisted mobilization movements using fixed and simple trajectories that are aided by biofeedback systems and measurements of kinematics and forces. A confluence of various factors such as global population greying,

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a worldwide shortfall of rehabilitation professionals, increasing evidence, and proliferation of neurotechnology further fuels the growth of advanced rehabilitation ecosystems.²

Promises of Robotic-Assisted Therapy

The addition of a neurorobot during therapy imposes pivotal role changes on therapists because there are now multimodal feedback loops operating during robotic-assisted therapy (RAT), thus transforming the rehabilitation milieu and practice in a phenomenal way.³ Robots are currently viewed as advanced therapy tools under therapist's guidance.³ Inherent properties of any automated rehabilitation robot include highly repetitive, reproducible, and guided limb movements with intelligent control, continuous sensorimotor feedback, and monitoring of performance and behaviors with customization of settings by healthcare professionals. Hence, robots enhance traditional therapies by specifically providing therapy for long periods consistently and precisely, with less fatigue from the patient and therapist.² The labor-intensive aspects of physical rehabilitation are reduced, thus allowing therapists to focus on individual functional rehabilitation and supervision of simultaneous patients on RAT. Such measures may improve efficacy and efficiency of the rehabilitation program.⁴ Patients may also expect enhancement in training experience and faster recovery rates.

Except for conditions such as impaired cognition, behavioral agitation, spatial neglect, hemodynamic, or orthostatic instability, RAT is versatile and compatible with most patients, types, and severities of motor impairments resulting from poststroke hemiplegia, incomplete spinal cord injury, or cerebral palsy. Patients in the acute phase versus chronic phase are more likely to make larger gains after RAT.⁵ Patients with mild impairments benefit more from direct therapist inputs. Effects of RAT on functional gains are generally mixed.

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Few reports of serious adverse events or major complaints have surfaced.⁵

Applying Robotic-Assisted Therapy in the Rehabilitation Clinic

In a large meta-analysis of 999 patients, electromechanicalassisted walking using a variety of robotic devices after stroke resulted in a higher probability of achieving independent walking at the end of training and at follow-up (odds ratio = 2.39, P < 0.0001).⁶ The probability was higher if subjects were initially nonambulant or with less than 3-mo poststroke (odds ratio = 3.43 and 2.75, respectively). Functionally important parameters such as walking velocity or walking capacity were not positively impacted neither at the end of training nor at follow-up.⁶ Hence, robotic-aided gait training (RAGT) is often combined with overground training strategies or practice to translate initial motor gains achieved from RAGT into functional ambulation and independence in mobility.^{6,7}

In an earlier study involving subacute stroke patients with less than 6-mo poststroke with moderate to severe gait impairments and who were initially able to walk between 0.1 and 0.6 m/sec, participants who received a total of 24-hr-long sessions of conventional gait training derived significantly greater gains in walking speed, distance walked in 6 mins, and a 2-fold improvement in gait cadence, compared with a similar duration of RAGT using the Lokomat. Their gains were maintained at the 3-mo follow-up. Thus, the diversity of conventional gait training interventions seemed to be more effective than RAGT for facilitating returns in walking ability in those who had some initial locomotor ability.⁸ Similarly, in 48 ambulatory stroke survivors who were stratified by severity of locomotor deficits, greater improvements in gait speed, single-limb stance time on the impaired leg were observed in subjects who received a total of 12 thirty-min-long sessions of therapist-assisted manual locomotor training using an assist-as-needed paradigm, compared with those who received an equal amount of guided symmetrical locomotor assistance using a robotic orthosis.

Because not all patients placed on RAGT devices respond positively, individualized treatment approaches for gait training are needed. Advantages of overground practice not simultaneous with the use of body weight–supported treadmill training and robotic-assistive steppers include balance training, structured home-based practice, real-world problem solving in personal spaces and home-based environments, and overcoming disability.¹⁰ Therapist-facilitated exercises may have more cognitive challenge and motor learning, less error tolerance, and passivity as compared with robotic actuation and guidance.¹⁰ While demonstrated positive changes in cortical neural representation in the supplementary motor areas and cingulate motor areas in subjects after RAGT signify changes in neuroplasticity, this is neither a surrogate measure of efficacy of training nor a surrogate measure of positive effect.¹⁰

Since 2000, early randomized controlled trials on the efficacy of robotic-aided upper limb training (RAULT) provided the impetus to evaluate their clinical relevance and utility. One such early study demonstrated that training with the Massachusetts Institute of Technology-Manus shoulder-elbow planar robot within a multidisciplinary rehabilitation program, as early as 2-wk poststroke resulted in significant motor gains in the trained regions and an increase in Functional Independence Measure scores, as compared with those receiving robot exposure without training.¹¹ That only trained regions were associated with a significant increase in the contralateral lesioned sensorimotor cortex activation as opposed to nontrained areas was highlighted in a study using the Hand Wrist Assistive Rehabilitation Device to train grasp-and-release functions.¹²

For chronic poststroke upper limb impairment, a multisite randomized controlled trial demonstrated that motor gains resulting from 36 hrs of RAULT, using the suite of MIT-Manus robots targeting horizontal and vertical arm movements, wrist-forearm movements, and grasp-release, were not more effective than intensive comparison therapy at 12 wks.¹³ However, significant motor gains achieved in the RAULT group over usual care were sustained at more than 6 mos' posttraining.¹³ Furthermore, subjects in RAULT received only a quarter of therapist contact time as compared with the intensive comparison group and healthcare costs accrued per subject (therapy plus healthcare use) were comparable across the three groups at 36-wk follow-up.^{13,14} Hence, RAULT may positively impact the cost-effectiveness of delivering poststroke arm rehabilitation.

Using the ARMin robot, RAULT was found to accelerate stroke upper limb motor function gains as compared with conventional therapy after 24 sessions of training.¹⁵ However, these differences were no longer evident at 34-wk follow-up with the observation that greater gains in mean strength as assessed via the robot were achieved by the conventional therapy group instead and perhaps nullifying the impact of the initial gains achieved in the short term by the RAULT group.¹⁵ The RAT complements conventional therapy by impacting movement coordination more than strength, task performance speed, specifically for shoulder and elbow motor outcome, and activities of daily living performance with a high level of safety and compliance. Nonetheless, the role of RAULT is potentially valuable in a labor-intensive therapy milieu because a therapy assistantsupervised RAT group session of three to four participants can be 2.4 times cheaper than a standard arm individual therapy session conducted by a trained therapist, with comparable mo-tor function gains.¹⁶⁻¹⁸ In addition, latest stroke rehabilitation guidelines support the inclusion of RAT for poststroke upper limb treatment. $^{19-21}$

The translation of gains in motor impairment reduction through intensive RAT into function necessitates combinatory approaches of RAT with one-to-one therapist sessions. Hence, clinicians face challenges as to which of the multitude of variables or interactions may impact outcome and cost-benefit ratio in the current cost-containment environment.²²

The recent development of powered robotic exoskeletons (PRE) may possibly provide the initial steps to address the failures of conventional reciprocating gait orthoses combined with functional electrical stimulation. These include inefficient gait patterns, low walking speeds, high metabolic costs, and cumbersome braces.²³ Primary therapeutic goals of training with PRE include task-specific overground standing, walking, lower limb strengthening gait and balance restoration, and functional independence in the community. Secondary goals include reduction of spasticity, bladder and bowel functions, reduction of autonomic dysreflexia, possibly lowered incidences of osteoporosis, hyperglycemia, and obesity in the spinal cord injury population. To date, a handful of PREs are commercially available

and are classified as Food and Drug Administration class II devices to be used under medical supervision for central nervous system injuries. Their capabilities include limited community ambulation in those with motor-complete paraplegia from C7 to T12 levels with untethered walking, achieving gait speeds of 0.26 to 0.4 m/sec with supervision and the use of bilateral elbow crutches.^{23,24} Only the REX exoskeleton is suitable for use without elbow crutches.

Patient prerequisites include a height range of 1.6 to 1.9 m and maximum weight of 100 kg, intact upper limb function, cognition and motivation, adequate hip and knee range of motion, intact skin, and adequate bone mineral density for sustained weight bearing.

Medical contraindications include wounds in areas covered by the exoskeleton, orthostatic hypotension, autonomic dysreflexia, cognitve/behavioral disorders, severe spasticity, and severe osteoporosis.^{23,24} Common features of PREs include wrist pad controlled programmed actions of sit to stand, stand to sit, walking, stair climbing, and slope ambulation. Subtle forward and lateral trunk motions and center of gravity shift tilt sensors trigger independent hip and knee joint motors, which are embedded in orthotic joints. Their disadvantages include the time taken to don and doff the exoskeleton braces, weight of the exoskeleton (10–23 kg per exoskeleton), short lithium battery lifespan of 2.5 to 3 hrs, high intensity and duration of training needed to be able to use PREs safely and functionally, and the relatively high cost (US \$70,000–150,000).^{23,24}

In a systematic review and meta-analysis of 111 patients (14 studies), Miller et al²⁵ demonstrated positive outcomes in the use of PREs in improving functional walking independence with 76% of spinal cord injury patients who were trained for a period of 1 to 24 wks (range = 5.8-82 hrs), being able to achieve ambulation without aid using elbow crutches at a gait speed of 0.27 m/sec. Improved sphincter control was noted in 66%, and the incidence of falls and fractures was 4.4% and 3.4%, respectively.

The Hybrid Assistive Limb (HAL, Cyberdyne Laboratories) has modular upper and lower limb exoskeletal components and operates either under autonomous control or cybernic control by sensing of intact bioelectric or myoelectric signals. It is comparatively of lighter weight (8–10 kg) and lower cost (US \$20,000) than its counterparts and feasible outcomes have been reported in small studies of stroke, spinal cord injury, and traumatic brain injuries.²⁶

Description of Rehabilitation Facility and Clinic

At the 95-bedded inpatient rehabilitation facility where the authors practice, an ambulatory center for the clinical integration of rehabilitation technology, including robotic devices for adults and children aged >10 yrs, was set up in 2011 (Table 1, Figs. 1–3 for a brief description of devices). Individual programmatic robotic-aided protocols are available.²⁷

Data derived from standardized outcome measures measured at four specific time points (prerobotic therapy, postrobotic therapy, postfollow-up on conventional therapy, and 1 mo after completion of conventional therapy) are stored in two standing database registries (one adult and one pediatric) (Table 2). In addition, qualitative responses obtained via simple questionnaire at the postrobotic therapy phase included the following

TABLE 1.	Current rehabilitation technology systems available
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Upper Limb Devices	Lower Limb/Gait/ Balance Devices	General Devices
Armeo Spring	Lokomat	Jintronix
Inmotion II	Neurocom SMART	Meditutor: 3D tutor
ReJoyce	Balance Master	NeuroMove
MediTutor:	Bioness L300	Dynavision 2000
HandTutor		NintendoWii*
		Microsoft Xbox
		Kinect*
*Commercial-of	f-the-shelf video gaming systems	

questions: (1) What were your initial impressions of the RAT, which you received? (2) What were your perceived therapeutic benefits if any? (3) In your opinion, what constituted success factors for your progress if any? Mazzoleni et al²⁸ support the view that patients validate the functional benefits, acceptability, and tolerability of RAT and that they appreciate the synergies of a combinatory "high tech and high touch" approach with RAT and conventional therapy.

Setting up a Rehabilitation Technology Clinic

Three arbitrary nondistinct phases are described to guide conceptualization and practice:

- (1) Preacquisition of robotic technologies.
- (2) Real-world clinic challenges and strategies.
- (3) Sustainability and beyond.

Preacquisition Phase

This may commence 6 to 12 mos before clinic opening. Because the initial investment into robotic technologies is usually high, a systematic conceptual planning and justification process, which involves all stakeholders, is recommended to realize software and hardware potentials. This allows judging of technology potentials to be undertaken by all members of the rehabilitation multidisciplinary team, including administrative and operations staff. Jones et al²⁹ recommends four main areas of consideration in the systematic evaluation of new rehabilitation technologies. These include the following:

- (1) Clinical applicability,
- (2) Safety and ethics review of the device,
- (3) Marketability of the devices, and
- (4) Financial and reimbursement issues.

Under clinical applicability, the appraisal of the available evidence is important for clinical efficacy, effectiveness, strength (evidence-based vs. anecdotal), and whether the robotic device answers a real clinical need. Important questions include the following: is the right patient pool in terms of diagnostic group, duration, (e.g. subacute stroke < 3 mos able to benefit from RAGT) or level of dependency (e.g., severely impaired stroke patients who are unable to walk when considering implementing RAGT?); are the right rehabilitation professionals/ staff keen to embrace the technology, develop programs, and achieve workflow redesign?²⁹



FIGURE 1. Locomotor gym (left to right: multi-terrain walking surface, Neurocom SMART balance master, Lokomat).

With regard to safety and ethics review, initial checks into Food and Drug Administration and local health licensing or registration are needed. The history, track record, and local presence of the industry partner are important to provide efficient technical support to minimize service disruptions. Establishing a close professional collaboration with industry partners or vendors facilitates knowledge dissemination, specific training, skill transfer, and important technical support. Fulfillment of local minimum ethical requirements and approval by the facility's institutional review board are essential if the device is acquired for research purposes.²⁹

For marketability, questions pertaining to whether the acquisition of the robot will raise the local or regional profile of the center and if productivity will be enhanced by robotic therapy will arise. A no-obligations free trial period for 1 to 2 mos allows the clinical team to objectively evaluate the suitability of the device in their existing natural environments without duress and assess if RAT would enhance their current practices.²⁹

With regard to financial considerations, these include the need to include costs of extended warranties, preventive maintenance, insurance, or repairs in the initial evaluation. Pricing of a robotic therapy session is dependent on contextualized costing models and thus difficult to standardize. Such analysis could enable centers to objectively identify their unique areas of strength and weakness and develop strategies to aid clinical integration of neurotechnology.³⁰

Real-World Clinic Challenges and Strategies

The initial 3 to 4 mos after clinic implementation allows staff to familiarize and adapt to machines, machine-patient interactions, protocols, and environment. The implementation phase paradoxically requires increased energies, resources, time, and staff motivation rather than an abrupt reduction of manpower, in anticipation of productivity benefits accrued by acquiring robotic technology.³¹

Possible milestones at this stage could include optimal use of available rehabilitation technology, reduction of communication barriers within team, programmatic or protocol-based delivery of RAT integrated with conventional therapy, and collection of standardized clinical and robotic-related outcomes. A collaborative partnership with industry vendors helps bridge cultural gaps and fosters unique understanding of the real environment within which robotic practice is realized and facilitates the dissemination of new information and response time during technical failures.³¹

An underestimation of the realities of utilization may lead to underexploitation of RAT in the rehabilitation clinic. Evidence-based practice is not a good sole driver of successful use or market justifications. In some clinic settings, there are cost barriers to RAT, although recommendations exist for its inclusion as part of a stroke rehabilitation program.³² However, it is acknowledged that the costs of RAT may not be reimbursable in many centers worldwide. This is, in part, related to the paucity of research into the cost-effectiveness of rehabilitation robotics; thus, a strong case is not presented to third party payers nor presented to healthcare institutions.

The possible feared "deskilling" or skill replacement of a therapist by a robot should be superseded by "upskilling" of the therapist to cater for role modifications, for example, robotic prescription, refining of goal setting with a robotic interface, addressing expectations of patients exposed to RAT, innovative prescription of combinatory therapies, and clinical audit.³¹ The concept of individual members of the team as champions may further help disseminate the benefits of using RAT to drive optimal use. Longitudinal patient follow-up is also important to determine RAT suitability in the subacute



FIGURE 2. Upper limb robotic suite (left to right: inmotion II, Armeo Boom, Armeo Spring, Dynavision).



FIGURE 3. Technology-aided circuit training (left to right: Meditouch 3D Tutor wearable sensor for single-limb movement training, Jintronix Microsoft Kinect-based virtual reality platform to train full body movements, gait, balance and endurance capacities, ReJoyce to train upper limb functions focusing on prehension skills with proximal control [bilateral and unilateral training]).

to chronic phase, especially managing the rapid transitions from acute care institutions to rehabilitation facilities and discharge to outpatient clinics.

Sustainability and Beyond

Passive diffusion versus active adoption of rehabilitation technology needs to be clearly differentiated with regard to

Program	Armeo Spring (Adult)	Armeo Spring (Pediatrics)	Lokomat (Adult)	Lokomat (Pediatric)
Diagnosis/Outcome measure	Stroke/brain injury/ spinal cord injury	Cerebral palsy/stroke/brain injury/spinal cord injury	Stroke/brain injury/ spinal cord injury	Cerebral palsy/stroke/brain injury/spinal cord injury
Fugl Meyer Upper Limb	х	х		
Motor Assessment				
Motor power (Medical Research Council)		х		
Action Research Arm Test	х			
Grip Strength (KgF)	х	Х		
Modified Ashworth Scale	х	Х	х	Х
Shoulder Manual Muscle Test	х			
Trunk Control Measurement Scale				Х
ASIA Motor Score for Upper Limb	х	Х		
ASIA Motor Score for Lower Limb			х	Х
Jebson-Taylor Hand Function Test		Х		
Box and Block Test		Х		
Lower Limb Motricity Index			х	Х
Functional Independence Measure (Walk, Transfer)			Х	
Functional Ambulation Category			х	
10-meter Walk Test			х	Х
6-minute Walk Test			х	Х
Berg Balance Scale			х	
Walking Index for Spinal Cord Injury II			х	Х
Spinal Cord Independence Measure - Mobility Subscore			х	х
Gross Motor Function Classification System		Х		
Gross Motor Function Measure 66 - Domain D			Х	
Gross Motor Function Measure 66 - Domain E		Х		
Functional Mobility Scale	Х			

S, stroke; CP, cerebral palsy; BI, brain injury; SCI, spinal cord injury.

how machines are viewed in real-world practice. In passive diffusion, the robotic technology may be in existence and operational in the clinic in a "use-as-needed" paradigm with no efforts to ensure that it is maximally used or integrated into clinical practice. Adoption means to choose or take as one's own. Adopters include all who intend to use RAT and those who will need to live with the change and not just key decision makers.³¹ Such a mindset may promote sustainable practice for RAT in clinical practice. Efforts to drive the latter within each rehabilitation ecosystem may be the key to avoid the dreaded "white elephant" phenomenon for rehabilitation robots. An adoptive team mindset accepts challenges and drives active workflow changes to increase efficacy and efficiency of working with the robot.³¹

It is also acknowledged that with the inclusion of robotic technologies, changes in organization balances of units may occur because of the need to monitor the deployment of the robotic technologies. As time is taken for rehabilitation professionals to learn, adapt, use, adopt, and leverage on evidence-based practice using rehabilitation technology, "market failures" rather than "efficacy failures" may ensue early on.³¹ However, previous studies have pointed out that therapists are more likely to be motivated to use and embrace rehabilitation technology if performance expectancy or how the technology can help in therapists' work was clearly defined. Therapists were not influenced by the degree of difficulty or social pressures to use technologies where use of technology is nonmandatory.³³

The following are some practical examples illustrating adoptive practices in response to challenges:

- (1) Additional time (10–15 mins) is needed for setting up and down of RAT. Solution included an overall change of therapy duration times from usual 45 mins to 1 hr per session to accommodate this.
- (2) Manpower shortfalls: including training for RAT for all therapists and therapy aides to improve productivity, thus alleviating workload for therapists to assume supervisory or coverage roles where needed and where suitable patients could be minimally supervised during RAT.
- (3) Workflow redesign to clinically integrate RAGT: Lokomat was situated near a gym plinth to allow patients to be examined in a supine position after RAGT to check for post-RAGT skin abrasions, a known minor adverse effect. Patients undergoing RAGT were assigned with individualized skin protection paddings and onsite storage systems to reduce consumable wastage from misplaced paddings when these were brought home.
- (4) Emergency protocols/drills were developed to address prompt evacuation of patients with syncope or seizure occurring during RAGT sessions.
- (5) Functional database results were used to guide program modification.^{34,35}

The Next Frontier of Rehabilitation Technology: Home

Postinpatient rehabilitation discharge represents a significant milestone for patients as they test effectiveness and durability of skills learned during inpatient rehabilitation and adapt to a new body, function, and image. Major concerns at this phase are maintaining gains in mobility and function, reduction of care burden, compliance with home exercise, and prevention of falls.

At this stage, local therapy supports and intensity often drop drastically with resultant fears of early functional decline or failure to achieve further gains. Rehabilitation technologies need to address the longer burden of care in the chronic rehabilitation continuum. These include portable, less complex, cost-effective robots, telerehabilitation systems and maintaining function at home with gaming for health.

Virtual reality and interactive video gaming device such as Nintendo Wii and Microsoft Xbox Kinect 360 systems are easily accepted, incorporated, and deployed in conventional therapy. The advantage of video gaming over traditional stroke upper limb therapy is the significant increase in the amount of arm movements elicited. This increase is more than five and a half times in observed purposeful movements and more than two and a half times in accelerometer-recorded activity of the paretic arm for patients with chronic stroke.³⁶ The application of Wii gaming dose matched to constraint-induced movement therapy for persons with stroke after 2 to 46 mos showed significantly improved arm motor function and use.³⁷ This approach was also favorable for improving arm function, activities of daily living, balance, walking speed, and ability to negotiate community ambulation challenges.³⁸ Furthermore, portable and affordable interactive video gaming systems (e.g. Kinect-based virtual reality systems) can potentially enhance the home-based exercise experience through usability, gamification, and automated feedback features, at a fraction of the cost compared with complex robotic systems. Real-time performance feedback and telerehabilitation capabilities have the potential to transform home rehabilitation. Poststroke virtual reality interventions with custom-built and commercial gaming systems have demonstrated significant gains in upper limb function, activities of daily living performance, and balance, as compared with other interventions. It has positive impact on gait parameters suggesting its relevance for training of community ambulation.³

Innovating Rehabilitation Technology in Clinical Practice

"The art of progress is to preserve order amid change and change amid order." "Alfred North Whitehead"

Amid the science of machine-based rehabilitation and its challenges, the root of innovative practice lies in allowing humans (patients, families, and healthcare professionals) to understand technology, to change and adapt their practices, as well as to adopt and finally sustain. Passionate teams are driven from internal forces. Such leadership forms the cornerstone for success.⁴⁰ Future proofing rehabilitation technology lies in the philosophies of innovation, which are borne out of empathy to improve training experiences for patients.

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