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REHABILITATION TECHNOLOGY

Robotics: A Rehabilitation Modality

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Abstract A novel rehabilitation technique must demonstrate certain attributes, namely demonstrate GAINS at the end of intervention, PERSIST beyond treatment, show evidence of GENERALIZATION, reduce COST, or demonstrate cost/benefit advantages. Upper extremity robotics is a novel post-stroke rehabilitative modality as it has already demonstrated these attributes. Lower extremity robotics has yet to demonstrate the same attributes. We are highly optimistic that with careful research basic on solid neuroscience principles, we can improve outcomes for lower extremity robotics as a rehabilitative modality.

Keywords Stroke · Rehabilitation robotics · Upper extremity · Lower extremity

Despite the seminal definition for a clinician to consider a novel rehabilitation technique that Krakauer and colleagues set nearly 10 years ago, their attributes have remained timely and appropriate [1]. They stated that the GAINS measured for the adoption of a novel rehabilitation technique must be as good or better than those resulting from other treatments. Further, the measured gains needed to PERSIST beyond treatment and then for an undefined but "significant" period; clearly, they were suggesting strongly that the improvements should be permanent. Also the measured gains needed to be demonstrated in untrained tasks; namely, there should be evidence of GENERALIZATION of the improvements to other tasks not involving direct training. Simply training for the test, an element central to many arguments in modern teaching politics, would not qualify a novel rehabilitation technique. To those clinically important parameters, we would add that the COST of the rehabilitation technique should improve the current cost/benefit ratio of the current treatment. Knowing that most rehabilitation units operate on a daily capped cost basis, there is a continuing drive to control costs even while delivering the most modern and effective treatment [1].

Taking advantage of Krakauer's crisp statement, we argue here that rehabilitation robotics has met the stringent requirements and should be adopted as a novel rehabilitation technique. Our data have demonstrated efficacy and effectiveness for the interactive-robot treatment of upper extremity (UE) weakness for patients who have experienced subacute stroke [2•, 3•] and also those who sustained chronic stroke (see VA—Veterans Affairs' ROBOTICS study and the employed robots in Fig. 1) [4••, 5••]. It revealed that, in an era of cost containment, introducing upper extremity robotics in a clinic did not increase the total healthcare utilization costs. Active interventions add cost; for example, the extra cost of the robotic equipment

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Fig. 1 A gym of upper extremity robots (Permission: Subject to MIT amendment to Publication Agreement)

plus an additional therapist cost the VA $5152 per patient. However, when we compared the total cost, which included the clinical care needed to take care of these Veterans, the robotic group cost less to the VA. The total healthcare utilization cost of the usual care group was $19,098 per patient, compared to $17,831 total healthcare cost for the robotic group (including the additional cost of equipment and delivering robotic therapy). To rule out any Hawthorne type effect, we requested the VA to continue collecting healthcare utilization costs after the completion of the study. The data collected demonstrated no placebo effect. In fact, the total healthcare cost for the robotic group went down further after the completion of the study, perhaps because patients continued to improve even without intervention [5••]. This suggests in the "real" therapy world away from the research environment that robotic therapy for the upper extremity offers better care for the same or lower total cost. This result led the UK National Health Service (NHS) and its Health Technology Assessment (HTA) Programme to embark in the largest ever RCT in robotic therapy; the RCT plans to enroll between 720 and 800 stroke patients to determine whether the same cost advantage can be observed in the British healthcare system (see https://research.ncl.ac.uk/ratuls/).

Furthermore, we have demonstrated that the gains measured by objective kinematic measures [6, 7•] reproducibly generalized to untrained tasks [8, 9]. These trials and a multi-center randomized trial [4••, 10] prompted the American Heart Association (AHA), the Veterans Administration (VA), and Department of Defense (DOD) to endorse the use of upper extremity robotics [11••, 12••].

Top row, left shows a person with chronic stroke working with the anti-gravity shoulder-and-elbow robot. The top row, middle panel shows a person working with the planar shoulder-and-elbow robot. The top row, right panel shows the wrist robot during therapy at the Burke Rehabilitation Hospital. The lower row, left panel shows the hand module for grasp and release. The lower row, middle panel shows reconfigurable robots. The robotic therapy shoulder-and-elbow and wrist modules can operate in standalone mode or be integrated into a coordinated functional unit. The *lower row*, right panel shows the shoulder-and-elbow and hand module integrated into a coordinated functional unit.

Although we predict that robotic training devices are destined to revolutionize standard restorative neurology and physical medicine practices, robotics are not a general panacea for stroke recovery; actually, for clinically effective training, there should be a mandatory number of movements per session and a number of sessions along the lines of the 10,000 h of practice required to attain "expert athlete" levels of physical performance. Interactive robots easily reach high levels of intensity, and it remains to be shown that therapists, replicating the high intensity of robotic training, could achieve the same motor outcome goals. In fact, we recently showed that intensity-matched manually delivered therapy could, in laboratory conditions, deliver 1000 to-and-from movements per 45-min of therapy session and achieve similar results (not practical in the clinical setting) [13]. It allowed us to directly test whether the robot-treated or therapist-treated group demonstrated comparable improvement in motor behavior. These results support the effectiveness of high intensity training for the impaired limb and should banish forever the therapy in standard care that averages 45 movement attempts per session [14]. Moreover, no clinician or patient should expect a superior outcome with a low number of attempts to move an affected limb delivered during robotic or usual care [15, 16]. Missing among these clinical trials is mention of the fact that for nearly all of the patients who were 6 months or more after their acute stroke and who then received intensive robotic training, the impairment was considered permanent and impervious to standard out-patient therapies, a fact belied by novel intensive training programs [4••].

That said, much remains to be done to improve outcomes further. To highlight the variability of outcomes, notice the changes from admission to discharge in the VA-ROBOTICS study [4••].

Figure 2 shows the results of the 3 groups of chronic stroke patients: black "o" = usual care (UC), blue "+" = robot training group (RT), and red "x" = intensive comparison training group (ICT). UC received 3 therapy sessions focused on the upper extremity, average of 45 movement attempts per session. RT and ICT received 3 therapy sessions per week focused on the upper extremity, average of 1024 movement attempts per session. The robot and intensive care therapy group demonstrated a significant reduction in impairment and disability and significant gains in quality of life scores as compared to usual care.

Of notice, a third of the patients improved over 5-points in the Fugl-Meyer assessment, which corresponds to the minimal clinically important difference (MCID), a third of the patients improved somewhat, and a third did not improve. Those studies raised new questions focused on those patients who were mildly or completely resistant and the quest to determine in short order who might be a responder, quasi-responder, and non-responder and perhaps how to combine robotics with another intervention such as neuromodulation to transform a non-responder into a responder.

The accumulated evidence for the effectiveness of robotic mediated rehabilitation led the American Heart Association (AHA) to include endorsements for upper extremity (UE) robotic therapy in their guidelines for the standard of post-stroke treatment. The recommendation does not extend for the lower extremity (LE), stating that "most trials of robot-assisted motor rehabilitation concern the UE, with robotics for the LE still in its infancy…" [11••]. The Veterans Administration similarly endorsed robotic therapy for UE but not for LE: "recommendation is made against routinely providing the [LE] intervention… At least fair evidence was found that the intervention is ineffective…" [12••]. The AHA and VA recommendations compared robotic outcomes with usual care as practiced in the US.

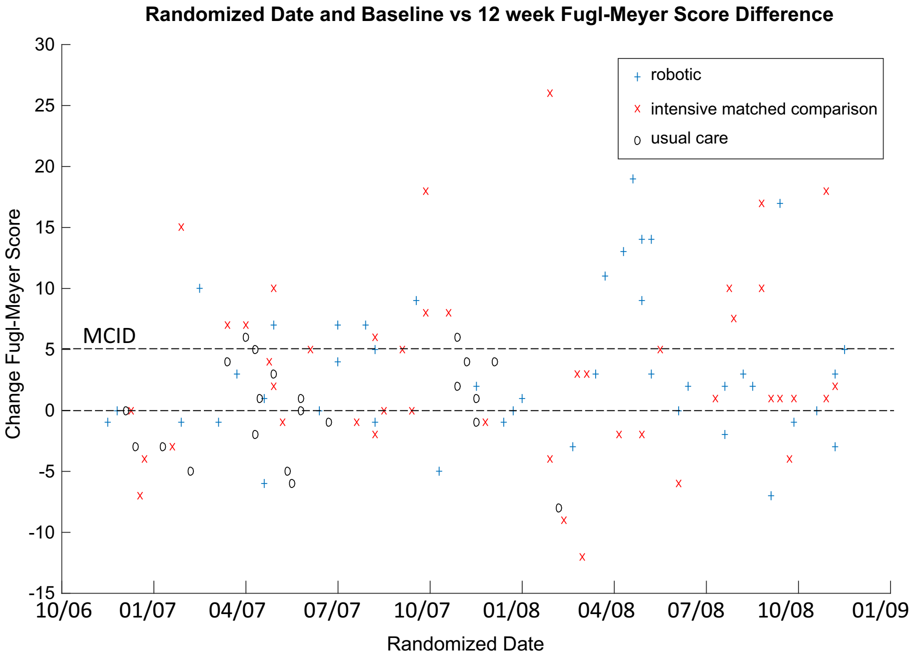

Fig. 2 VA-ROBOTICS Multi-Site Trial: individual patient's change in score and randomization date (Permission: Subject to MIT amendment to Publication Agreement)

One first step to remedy this situation is to distinguish between "best practices" and tested practices. Clinicians have operated on the assumption that body-weight-supported treadmill (BSWTT) training delivered by 2 or 3 therapists per stroke patient was "best practice" and superior to the usual care. Thus, automating BWSTT appeared to be logical. However, an NIH-sponsored clinical trial, locomotor experience applied post-stroke (LEAPS) demonstrated that BSWTT did not lead to results superior to those from a home program with only strength and balance training [17••]. This result was contrary to the hypothesis of its clinical proponents. The goal of rehabilitation robotics cannot be to simply automate current rehabilitation practices as, for the most part, they lack evidential basis: a scientific basis is needed for development of effective robotic therapy. In order words, existing robotic tools that represent a robotic embodiment of BWSTT train only a subset of the required aspects for normal gait and hence, a direct comparison robotic versus usual care as practiced in the US led to negative outcomes [18, 19].

The landmark LEAPS study must be seriously considered by both roboticists and clinicians: it did not demonstrate superiority of BWSTT for either severe or moderate stroke patients. While many studies of robotic embodiments of BWSTT compared to usual care as practiced outside the US (varied levels of usual care) were more positive [20], we continue to be highly optimistic that with careful research, we can improve outcomes for LE, possibly expanding the tools and training approaches to include other aspects of gait and balance.

Compliance with Ethics Guidelines

Conflict of Interest Bruce T. Volpe declares that he has no conflict of interest. Hermano Igo Krebs is a co-inventor of several Massachusetts Institute of Technology-held patents for the robotic technology. He holds equity positions in Interactive Motion Technologies, Watertown, MA, USA the company that manufactures this type of technology under license to MIT.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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