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Overview of approaches and clinical outcomes

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INTRODUCTION AND IMPETUS FOR TELEREHABILITATION ROBOTICS

Best practice for successful rehabilitation often involves intensive, repetitive practice that actively engages the participant in goal-oriented and task-specific activities to regain functional capacities in upper and lower extremities [1]. As other chapters in this volume have discussed, recent advances in robot-assisted therapy have greatly increased the capacity for improving voluntary UE movement and LE strength and locomotor function. Several studies have observed that robot-assisted therapy demonstrates equivalent outcomes compared with one-on-one therapy, even when delivered in the home environment [2,3]. The results of these studies indicate that robot-assisted therapy provides reliable, reproducible treatment while measuring performance without the need for real-time human oversight [4]. Although there is ample evidence for the effectiveness of robot-assisted therapy and there is great potential to improve access and reduce cost, unfortunately, these technologies are underutilized in the home environment.

The US Department of Veterans Affairs pioneered telemedicine deployment to overcome geographic barriers that emerged as veterans returned home. Since the initial usage, demand for high-quality health care at an affordable price provides pressure for further development, which now includes provisions for rehabilitation services at a distance or telerehabilitation (TR) [5,6].

Telerehabilitation robotics (TRR) is a relatively new subdiscipline of health care and clinical science that bridges established features of robot-assisted rehabilitation and telehealthcare to provide efficacious services at a distance using information and communication technologies. Rehabilitation at home, most often by a spouse or child, was the standard for many people recovering from injury prior to the twentieth century. With the advent of the World War II and a nationwide polio epidemic during the early 1900s, demand for hospital-based rehabilitation rose. However, providing therapy in one's own residence has been revitalized in recent years due to several factors including advances in technology, shortage of licensed therapists, and patient preference all in an environment of ever increasing cost containment. Technological advancement and adoption of

new health-care models will change the way we practice rehabilitation medicine and facilitate the effective transition to home rehabilitation in select populations. The purpose of this chapter is to provide an overview of the current approaches and detail the available data on clinical outcomes and improved access to services.

SURVEY OF TECHNOLOGY

Changes in the health-care environment have led to the emergence of robotic devices that are aimed at improving the quality, reproducibility, and cost-effectiveness of rehabilitation. Additionally, research teams are working to weave the principles of motor learning and neuroplasticity into device construction to improve clinical outcomes [7]. Comprehensive reviews of currently available devices for upper [8] and lower extremities [9] have recently appeared in the literature.

Many devices are aimed at rehabilitation delivery. However, a limited number have demonstrated clinical efficacy and few are currently used for patient care in clinical settings. Due to the recent creation of the TRR field, only a handful of robotic devices have been investigated. Most devices tied to TRR are in the feasibility stage of development. Only two TRR devices (e.g., Hand and Foot Mentor [10,11] and SCRIPT [12]) have been fully deployed in the home environment. Several devices have shown promise for application to TRR delivery but have either focused on remote monitoring [13–15] or home deployment [16,17] but not both simultaneously. Both features are necessary to progress to a fully integrated TRR deployment; however, a distinction must be made to differentiate devices that have encountered the unique set of challenges associated with full TRR delivery including home deployment, connectivity, and remote monitoring.

Notwithstanding the relatively small numbers of TRR devices, substantial heterogeneity in robotic device construction, control protocol, and user interface exists. Despite these differences, all devices share the common capability to sense and record movement (e.g., position, velocity, torque, and various performance metrics). Additionally, devices share the capability to aid with user movement, typically through electric, pneumatic, or passive actuation. For a detailed discussion of design, control architecture, or general robotic devices, please refer to previous chapters. In this section, we will discuss the level of user involvement, remote assessment, treatment targets, and construction of various devices utilized in TRR application.

LEVEL OF USER INVOLVEMENT/ASSISTANCE

Rehabilitation robots can act as passive modalities (e.g., moving the extremity without active contraction); however, providing too much or a predictable amount of assistance may have negative consequences for learning, that is, encourage lassitude. This can occur when someone learns to provide only the amount of force needed to trigger the assistance. To avoid this, controls for rehabilitation robotic devices have primarily drawn concepts from rehabilitation, neuroscience, and motor learning that determine the level of initiation, user involvement, and control of actuation. With this

information, many devices provide active-assist interaction. Active-assist provides help to the user as needed to accomplish the task. This takes advantage of the device's ability to decrease task difficulty and encourage participation while capitalizing on active initiation of movements, which have been shown to increase cortical activity compared with passive motion [18].

The Hand Mentor and Foot Mentor devices (Motus Nova LLC, Atlanta, Georgia) (Fig. 1A and B) were designed for use by individuals with residual upper and lower extremity impairments with the goal of improving active range of motion (AROM) and strength in the distal musculature. Participants use their affected wrist or ankle to complete gamelike training programs to challenge motor control. A software algorithm constantly monitored patient performance and modifies the level of difficulty. Initially, performance required only a small degree of wrist or ankle voluntary motion. As user's motor control improves (8 successes in 10 attempts), the robotic device progressively increases the difficulty level, requiring greater AROM to achieve the goal. Conversely, if the user experiences difficulty (2 or fewer successful attempts out of 10), the device decreases the difficulty level. The Mentor systems provide visual and auditory feedback of the target location and summaries of trial-by-trial performances. Remote monitoring is available via a clinician dashboard.

Much like the Mentor systems, the home-based Computer-Assisted Arm Rehabilitation (hCAAR) [17] provides active assistance. In one study, the hCAAR was deployed in the home for 8 weeks and provided 17 stroke survivors with active assistance in the completion of task-specific goals. The hCAAR has a feature that allows the unaffected limb to signal the device to provide assistance. Although the hCAAR system was deployed in stroke survivor's homes, the authors did not report remote monitoring of patient performance. Instead, the hCAAR consistently monitors performance and adjusts the level of assistance according to the performance and baseline assessment.

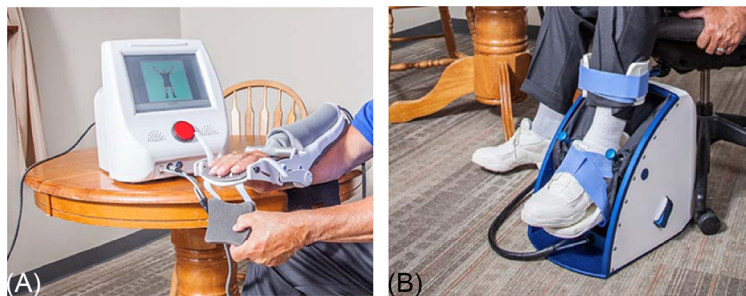


FIG. 1

Shown in (A) and (B) are the Hand and Foot Mentor air muscle assemblies utilized for telerehabilitation robotics. The setups shown display the typical usage of the devices when deployed in patient's homes. Both devices are compatible for right- and left-sided use and are designed for easy donning and doffing with elastic and Velcro attachments. The control unit (A) is compatible with both the Foot and Hand Mentor and displays the visual exercise interface for the patient.

Unlike the devices described above, the SCRIPT project evaluated both a passive and active control devices, ultimately using a passive dynamic assistance mechanism called SPO (SCRIPT passive orthosis) to aid with wrist and finger extension. A passive assistance mechanism simplifies the construction of software algorithms required to control the SPO and likely decreases the cost of deployment. Although the SPO provides passive actuation, the device provides an interactive environment much like that seen in the hCAAR and Mentor systems.

TREATMENT TARGET

The unique challenges that face TRR device deployment in the home environment have provided uncommon pressures not seen by general rehabilitation devices such as space, size, cost, and ease of use limitations. Due to these constraints, all the TRR devices have focused on rehabilitation of either the upper or lower extremity.

Contemporary robot-assisted rehabilitation focuses primarily on the proximal upper extremity [19]. As a result, initial research into whether the focus of treatment should target proximal and/or distal segments suggested that early involvement of distal arm movements is favorable over proximal training. The authors cite an increase in the transfer of treatment effects to the untrained arm segments [20]. The observed transfer effects can be partially explained by the inherent complexity of training distal motor control (e.g., grasping and manipulating objects) that automatically involved coordinating proximal segments. This great potential for distal targeted devices to improve clinical and kinematic performance in combination with generally smaller constructions makes these types of devices uniquely suited for TRR deployment. Both the SPO and the HM devices target the distal upper extremity. Unlike the Hand Mentor, which focuses intervention to the wrist, the SPO afforded individual extension assistance to individual digits and the wrist. Much like the HM™, the upper extremity portion of the assisted movement with enhanced sensation (AMES) was directed at assisting wrist motor control during its preliminary home deployment without remote monitoring.

TRR devices that do not focus on distal extremity control generally operate on an end-effector construction, resulting in targeting the proximal muscles. The hCAAR [21], Java Therapy [22], Jerusalem TeleRehabilitation System [14], MEMOS [15], and others [13,23] all share common lineage with the MIT-MANUS. Although these devices utilize the entire upper extremity to interact with the user interface and complete the interventions, the joystick design often constrained the distal upper extremity to grasp an end effector, thus driving the focus of the intervention to the proximal musculature.

IMPLEMENTATIONS

DEPLOYMENT

Telerehabilitation robotic interventions present challenges to researchers and clinicians needing to deploy robotic devices in the home. To date, there are two primary deployment strategies that have been utilized: home delivery and remote deployment. Many TRR interventions in the literature have utilized some version of home

delivery, where a clinician, trained in robot-assisted therapy, arranges an in-home delivery, setup, and training for the user and caregivers. The home delivery methods afforded treating clinicians the additional benefit of information regarding the user's home environment and allow tailoring of future interventions to the user's specific needs. Additionally, baseline functional assessments can be completed in the home reducing travel time for users that have transportation difficulties. Although this strategy provides the users with geographic or travel restrictions the most tailored care, this deployment strategy shifts the cost of travel onto the clinician. The significant drawback to the home delivery model was initially deemed obligatory due to the complexity of device setup and training. However, as devices become more commercialized and user friendly (Fig. 1A and B), the remote deployment strategy is becoming more feasible. With remote deployment, the device is shipped to the user's home, and training is handled through video modules, which are produced in advance or with direct web-based interaction with support staff trained in setting up the intervention.

While the home delivery method has not been directly assessed, a second method has been utilized that circumvents a portion of the travel demand for both parties, thus bridging the gap to remote delivery. The so-called clinic-based deployment adds TRR device setup and training to a previously scheduled clinic visit. While the patient is seen in the clinic for traditional rehabilitation, the TRR device is introduced, and a clinician trained in robot-assisted rehabilitation provides the preliminary training, so the user and caregiver can independently set up the device when they return home. Once the user and caregivers have demonstrated proper and safe use, devices are dispensed in the clinic. Trained staff can monitor the device setup remotely and provide support over the phone or through a web-based interface.

INTERVENTION PROTOCOLS, STRATEGIES, AND DOSING

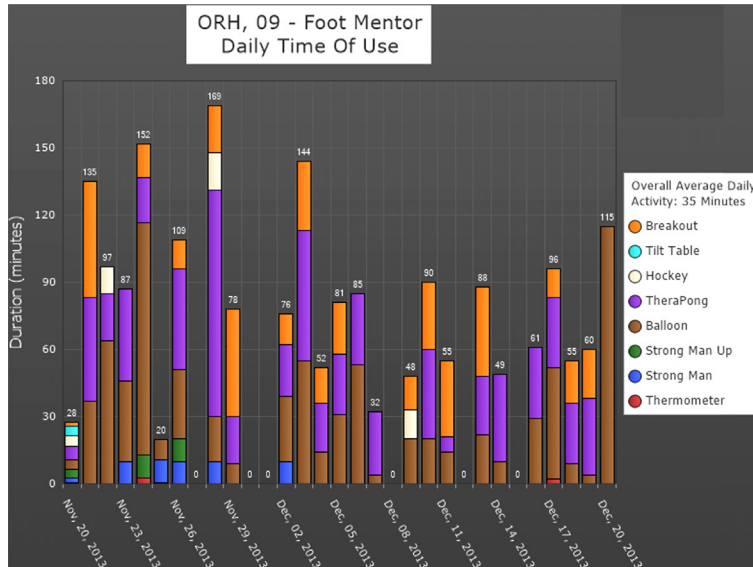
The innovative development of Java Therapy in 2001 prescribed TRR dosing of approximately 1 h per day over the course of a 4-week study [22]. Java Therapy involved a simple, force-feedback joystick that physically assisted or resisted upper extremity movement, while quantitative feedback of performance informed caregivers of progress through an Internet connection. While the intervention showed efficacy in improving kinematic motor performance, no clinical outcomes were assessed. Many TRR intervention strategies have been derived from validated studies investigating clinically successful neurorehabilitation dosing and intensity for the patient population of interest. Although there is little consensus on the ceiling effects of dosing and intensity for traditional rehabilitation, there does appear to be a dosing threshold (60 min per day) that must be surpassed in order to have meaningful improvements in functional outcomes [24]. However, the majority of TRR interventions derive daily dosing as a fraction of the study length, meaning the shorter the experimental protocol the higher the daily dosing parameters and vice versa for longer studies. Preliminary studies from Wolf et al. anchor their TRR interventions on previous evidence from 2-week constraint-induced therapy

studies that showed clinical efficacy with dosing up to 6 h per day [25]. For their longer-term TRR interventions, dosing was often prescribed for 5 days a week 3 h per day totaling to 120 h. More recently, our laboratory introduced an incremental approach to dosing. We progressively increased the volume and intensity of exercise to reduce fatigue [10]. The TRR interactive interface has been shown to improve exercise compliance. For our 3-month intervention, users were encouraged to start at lower daily activity levels and slowly progressed to the prescribed 2 h therapy dosage within 2 weeks.

MONITORING/OVERSIGHT

Monitoring and oversight are essential components of any successful rehabilitation paradigm, and that is especially true when the remote nature of TRR precludes physical interaction with a clinician. Several strategies have been used to monitor patient usage and performance during a study and can be categorized as “store and forward” and “real-time monitoring.” In 2001, Reinkensmeyer et al. published an early report on real-time monitoring and interaction with hemiparetic patients using a TRR interface [22]. Testing began with real-time oversight, while patients performed TRR interventions in a local outpatient clinic and progressed to home deployment. Further advancements were made when real-time monitoring began to include “remote control” of the TRR device by study clinicians. In the event difficulties occurred or modifications of the rehabilitation paradigm were required, the clinician was able to remotely take control of the device and provide assistance [15]. Carignan and Krebs described this innovation as “cooperative telerehabilitation” in which the clinician and user interacted directly with each other [26]. Cooperative telerehabilitation affords the advantage of remote, direct physical evaluation and assessment, while the user and clinician interacted in a graphical interface.

While these advancements in TRR devices and systems addressed concerns over remote rehabilitation, they do not address staffing challenges that are facing health-care systems. More recent clinical studies investigating TRR applications have sought to address the staffing concerns by eliminating active remote monitoring in favor of a “store-and-forward” model that does not require real-time oversight by clinicians [3,10,11,27]. The store-and-forward model affords significant advantages of scheduling flexibility to both clients and clinicians. The advantage of scheduling flexibility is amplified when dosing is taken into consideration. Many protocols prescribed two or more hours of rehabilitation per day, which would present a significant scheduling constraint to clinic-based therapy. For in-home users, the scheduling flexibility of TRR allows them to complete their prescribed robotic rehabilitation in any permutation that suits their lifestyle. This autonomy is not without complete oversight and required monitoring. The HM and FM devices record and store the following variables: overall active time, time in each training module, percent success for each training module, minimum and maximum wrist angle, and a measure of force (pneumatic pressure). These data are encrypted, stored, aggregated, and forwarded (telephone,

**FIG. 2**

Example of clinician interface presents graphic usage data in minutes of therapy provided by the FM for each type of game played over the course of study.

internet, and cellular connection), so the clinician can access all relevant user data, such as total time performing therapy (Fig. 2).

Users of the HM and FM devices are provided real-time feedback through a graphical user interface of their extremity position, force, and success rate. Each time a participant completes a training module, a summary for that session is displayed on-screen. Although real-time oversight is not required for the store-and-forward delivery model, highly individualized training programs are achieved by computer algorithms that continually monitor user performance and adjust difficulty based on performance. In short, changes in difficulty are based on success rate; above 80% the difficulty level is automatically increased. Progression requires an increase in the ROM to achieve the target. Conversely, if user success falls below 20% success rate, the difficulty level decreases [10].

One concept that unifies both active, remote monitoring and the store-and-forward model is the ability to monitor multiple patients at a time and effectively equate to TRR acting as a work-force multiplier of clinician hours. Although not directly practical for cooperative TRR applications described above, both general paradigms can take advantage of clinicians monitoring multiple users at a time. As demand for rehabilitation increases and evidence accumulates on the efficacy of life-long care following neurological damage, the importance of increasing clinician efficiency is paramount.

OUTCOMES

CLINICAL

The proposition that TRR can contribute to superior clinical outcomes is based on evidence that augmented exercise, particularly that of a minimum of 16h in the first 6 months after stroke [28], improves functional recovery. Additionally, utilization of TRR through distributed practice is associated with better retention of performance [7]. These key benefits of TRR serve to rebalance the current mismatch with conventional therapy services that typically utilize massed practice due to limited clinic schedules and staff. Research has shown that during intensive rehabilitation stays, patients spend only 13% of their time with activities that could improve mobility [29]. As such, TRR can play an important role in the recovery of distal hand and finger function, which is often the last to show signs of improvement.

To date, two TRR systems for stroke have been investigated for home deployment. The SCRIPT project deployed a passive dynamic wrist and hand orthosis (SPO) [30] that provides extension forces via passive metal springs that are used in combination with a Saebomas for proximal support. The gaming exercises are displayed on a touch screen computer and controlled by arm/hand movements including wrist and finger flexion/extension, pronation and supination, and reaching in all directions [30]. The SCRIPT intervention consists of 6 weeks of self-administered distal arm training in the home with custom-designed games. Participants are monitored remotely and have weekly in-home follow-up visits to adjust the SPO so that the participant can actively open the hand to grab a 2.5-cm cube [30].

In 2014, investigators studied the use of the SPO with chronic stroke participants with limited arm/hand function (having at least 15 degrees active elbow flexion and quarter range of active finger flexion, but not full active ROM). They reported significant changes in both the Fugl-Meyer (FM) and the Action Research Arm Test (ARAT) after 6 weeks of a home-based training. Positive correlations in usage time and improvement on the ARAT were shown across the group. Although participants were encouraged to use the device for an hour each day, the investigators found that participants averaged 15 min of self-selected usage of the device daily [31].

Our lab has investigated the Hand Mentor (HM) and Foot Mentor (FM). These devices are composed of a hand or foot peripheral component controlled by a pneumatic pump (i.e., McKibben muscle) to assist with wrist extension or ankle dorsiflexion. Training programs are designed to increase active wrist and finger flexion and extension and improve accuracy and motor control through variations in speed and graded movements to on-screen targets [10,11,27]. Participants with chronic stroke must demonstrate at least a trace of volitional wrist or finger extension in the extremity to use the device. The current protocol for the HM/FM studies provides the device in the home for 12 weeks with a custom exercise prescription/game selection for strengthening and/or motor control improvement. All participants are remotely monitored via a clinical dashboard. Clinicians also make weekly calls with participants to ensure continued compliance and progression of therapeutic activities.

Participants enrolled in Mentor™ system studies were instructed to complete up to two 1 h sessions daily over the course of a 12-week protocol. In 2014, our lab

documented statistically significant improvements of 7.7 points ($p=0.01$) on ARAT scores compared with baseline. Further, the improvements observed following the TRR intervention surpassed the previously validated minimally clinical important difference (MCID), indicating that participants achieved clinically relevant improvements [10]. In a follow-up study in 2016, we confirmed our 2014 findings in a larger population [11]. We observed significant improvement in ARAT scores (30%, $p=0.046$) among users with the average improvement again surpassing MCID of 5.7 points, indicating a clinically meaningful change in upper extremity function. The protocol when used with FM demonstrated a 29.03% increase in gait speed, from 0.31 to 0.40 m/s, correlating to a change from home ambulation status to limited community ambulation status per validated stratification of gait speed [32].

An evaluation of three studies that used different robotic systems showed no significant difference with respect to improvement in ADL measures (i.e., FIM score). Comparisons at the level of abnormal structure and function have not been made, nor between training in one or two planes of joint motion. To date, no studies have directly compared the SPO and HM/FM robotic system, but differences can be expected based on motor control principles.

One limitation of the HM, FM, and SPO devices is the requirement that users have some degree of volitional movement, often excluding those clients who are categorized as being severely impaired. Future research into the design and instrumentation of robotic devices is needed for the inclusion of severely impaired distal segments. To date, robotic devices and orthosis, such as the Java Therapy and AMES used in feasibility studies, have been too large and burdensome for deployment to homes or add to caregiver burden in terms of donning and setting up the therapy device.

SATISFACTION AND QUALITY OF LIFE

Patient satisfaction is an important and commonly used indicator for measuring the quality of health care. Patient satisfaction affects clinical outcomes and patient retention and is an effective indicator to measure the success of a rehabilitation intervention.

Satisfaction of the HM/FM devices was studied using a 14-question survey to assess user satisfaction, progress, ease of use, and appropriateness of the intervention for their needs. Based on 12 stroke participant responses, overall satisfaction with the Mentor intervention was high [10]. In a follow-up study published in 2016, survey responses from 19 stroke participants again showed high overall satisfaction with the Mentor intervention [11]. When asked what they would change about the device, participants requested adding games of greater difficulty, making the computer component smaller and easier to handle, and improving ease of donning/doffing the peripheral device. Overall satisfaction was consistently expressed in terms of an appropriate therapy for their condition from both participants and a survey of clinicians.

In a qualitative design study, 10 chronic stroke participants who used the HM device reported overall positive benefits in the following areas: increased mobility, a sense of control over their therapy and scheduling, increased independence, and an outlet for physical and mental tension and anxiety [33]. TRR therapy allowed users to feel “in control of their therapy” and supported the idea of patient-centered delivery of care [34].

Incident rates for depressive symptoms in persons post stroke have been reported to be as high as 41%–52% [35]. Additionally, stroke patients with depression have a higher utilization of health-care services [35] and higher health-care costs [36]. Depression is a predictor of poor functional outcomes [37] leading to an additional cascade of health-care service utilization and increased costs. In the comparison of home-based TRR with the Mentor device with traditional therapy services in an 8-week intervention at 6 months post stroke, Linder et al. found that participants in robot plus home exercise program (HEP) group demonstrated comparable significant gains (a decrease in reported depressive symptoms) on the Center for Epidemiologic Studies Depression Scale (CES-D) and Stroke Impact Scale (SIS) domain scores. Similar studies found a decrease in reported depressive symptoms on the CES-D after a 12-week HM/FM intervention [10,11].

INCREASE UTILIZATION

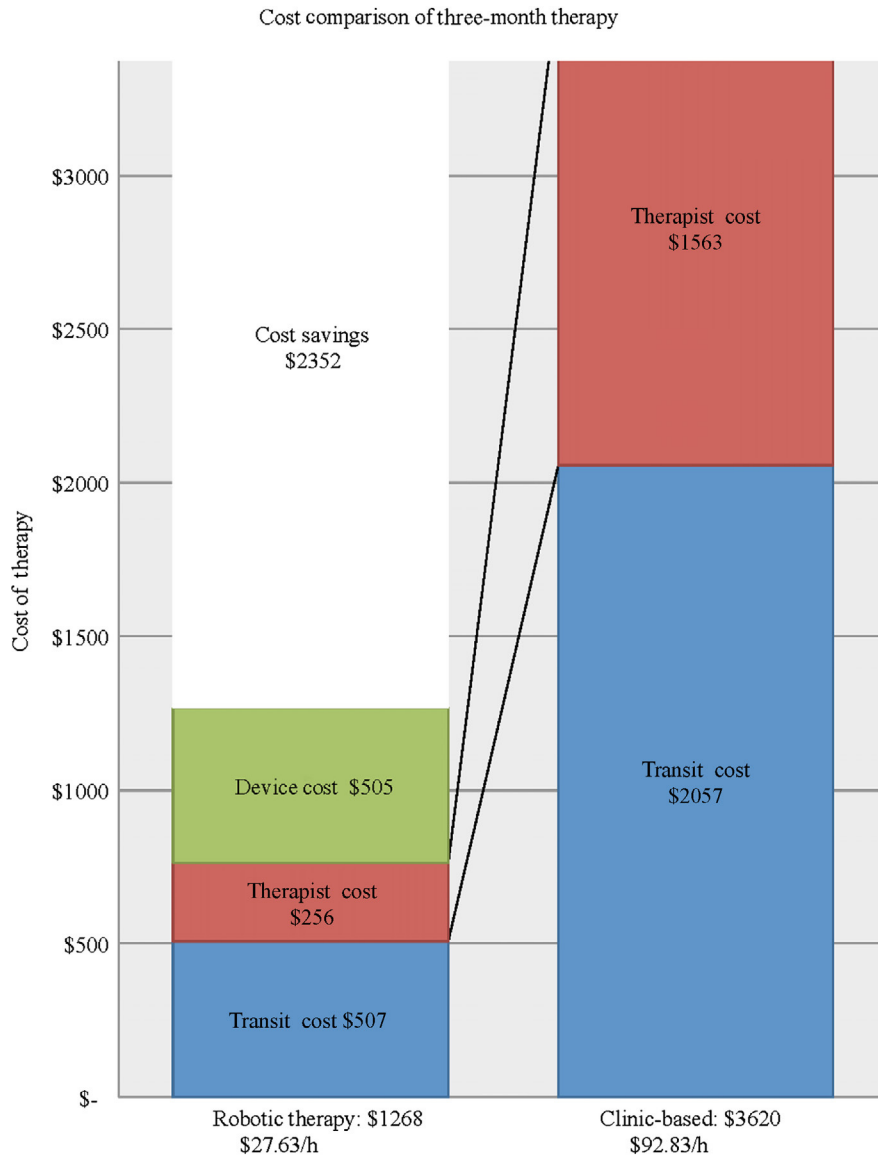
Protocol recommendations for at-home use of the TRR devices have wide variability in the literature ranging from 30 to 120 min. Chronic stroke survivors in the SCRIPT project were asked to use the SPO device for 30 min a day, 6 days a week and were otherwise left free in their choice of when and how long to use the device. Participants were monitored remotely and visited weekly by a supervising clinician to progress exercises on a case-by-case basis. Ten patients used the system on an average of 94.4 (± 43.6) min/week, averaging 14 min of self-administered training each day [34].

Recommendations for use of the Mentor system were significantly higher than those of the SPO. The Mentor devices were issued with the instruction to complete exercise for up to two 1 h sessions daily. Our analysis of usage determined that participants averaged 90.6 min of daily usage, over 30.6 therapy sessions, across the 106-day episode of care [11].

COST

One of the major drivers behind the proliferation of TRR practices is the potential to positively impact resource allocation while reducing health-care expenditures. Under certain conditions, robotic rehabilitation can provide even larger doses of therapy than would otherwise be completed in one-on-one therapy, especially in a labor-strapped health-care field. Unfortunately, high-quality evidence regarding the impact on resource allocation and health-care expenditures is still needed.

Despite the current limitations, promising findings have emerged. Tousignant et al. estimated 17% savings per patient during a 12-session intervention, compared with the estimated cost of home visits [38]. Larger cost savings (58%) were reported by Kortke et al. for 3 months of home-based cardiac rehabilitation, compared with the 3-week inpatient rehabilitation [39]. In agreement with the magnitude of savings Kortke et al. reported, a more comprehensive cost analysis comparing TRR with clinic-based rehabilitation in the VA health-care system [11] documented an average of \$2352 (64.97%) less costs than equivalent clinic-based stroke therapy (Fig. 3).

**FIG. 3**

Three-month cost of home-based, robotic telerehabilitation compared with clinic-based outpatient therapy, based on three, 1 h weekly physical therapy sessions in the outpatient clinic. Hourly costs are based on robotic therapy receiving an average of 30.6 sessions for 90 min compared with clinic-based therapy receiving an estimated three, hour-long sessions per week during the study.

Figure reproduced with permission from Housley S, Garlow A, Ducote K, Howard A, Thomas T, Wu D, et al. Increasing access to cost effective home-based rehabilitation for rural veteran stroke survivors. *Austin J Cerebrovasc Dis Stroke* 2016;3(2):1.

TRR costs included device, deployment costs (home delivery, support, connection, and pickup based on average round-trip distance), monthly maintenance, server connection costs, therapist monitoring of patient progress, and telephone-based follow-up calls. These elements were totaled across the treatment period and compared with projected clinic-based physical therapy of three 1 h sessions held weekly at the closest VA medical center.

In summary, future trials including TRR should incorporate cost analyses (cost per dosage), associated with clinical findings (cost per effect size). The main advantage of TRR is the possibility to reliably increase dosing and intensity of rehabilitation while providing interactive user interfaces that consequently motivates users. Although the evidence is gradually emerging regarding the positive impact of TRR on health-care costs, the lack of studies evaluating costs from similar perspectives and accounting for similar elements deters any definitive conclusions.

CONCLUSION AND FUTURE DIRECTIONS

This chapter has reviewed a large body of work with the aim of introducing the historical context and impetus for the development of TRR, provides an overview of the current approaches, and presents the data on clinical outcomes and improved access to services. It is reasonable to expect that a fuller understanding of TRR will enhance our understanding and increase our ability to design better approaches to neurological rehabilitation, especially for those affected by motor loss.

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