Integration of Robotic Rehabilitation in Clinical Practice

DAIANA POPA
REHABILITATION HOSPITAL FELIX SPA
ESPRM ROBOTIC COMMITTEE

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Challenge for global robotic development:

Fourth Industrial Revolution :

- Increase Productivity
- Resource Efficiency
- Replace individual aspects of human performance with robotic capability:
  - Precision (surgery)
  - Logistic and mechanial task (service robots)
  - Complex cognitive task (rehabilitation robots)

Cresswell K, Cunningham-Burley S, Sheikh A
Health Care Robotics: Qualitative Exploration of Key Challenges and Future Directions J Med Internet Res 2018;20(7)

Challenge for robotic rehabilitation:

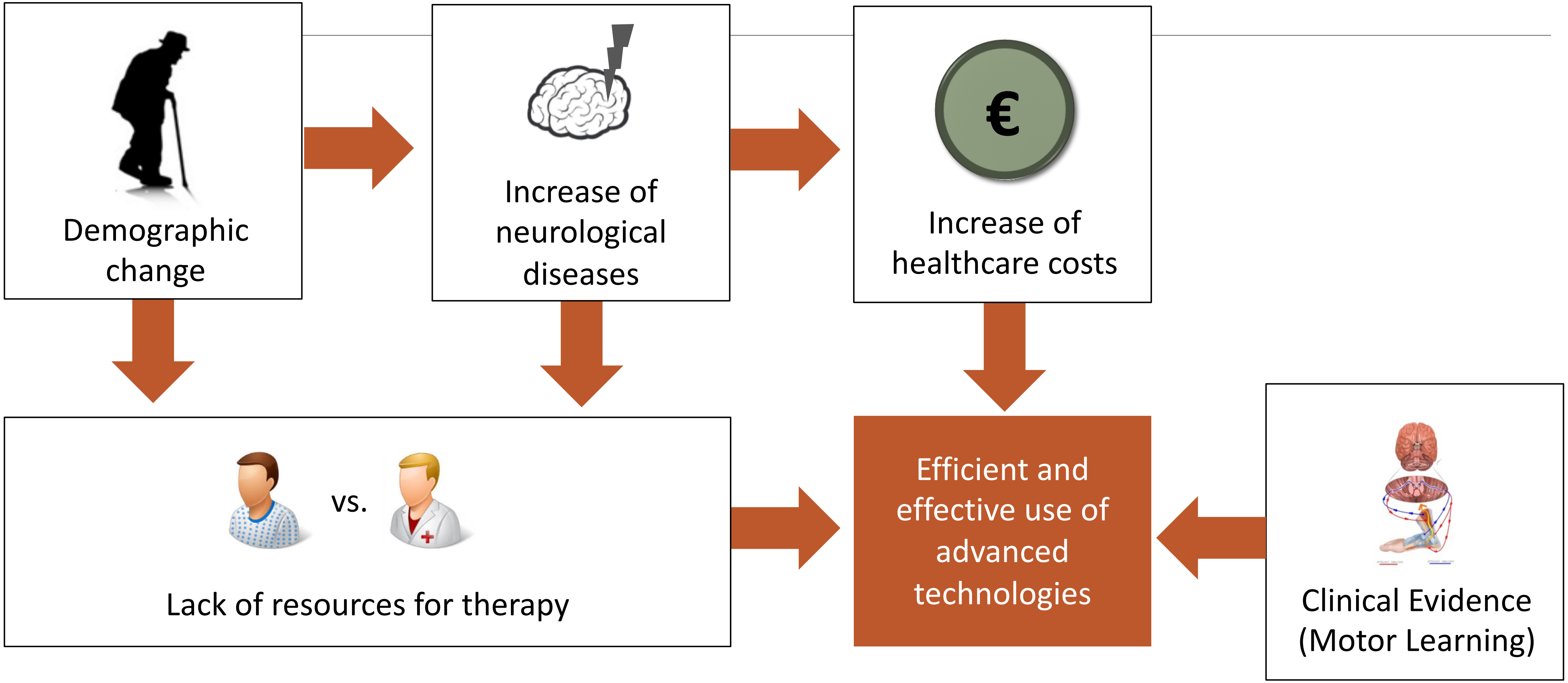
World Report on Disability: …Some **unmet** rehabilitation needs:

- can delay discharge,
- limit activities,
- increase dependency on others,
- decrease quality of life

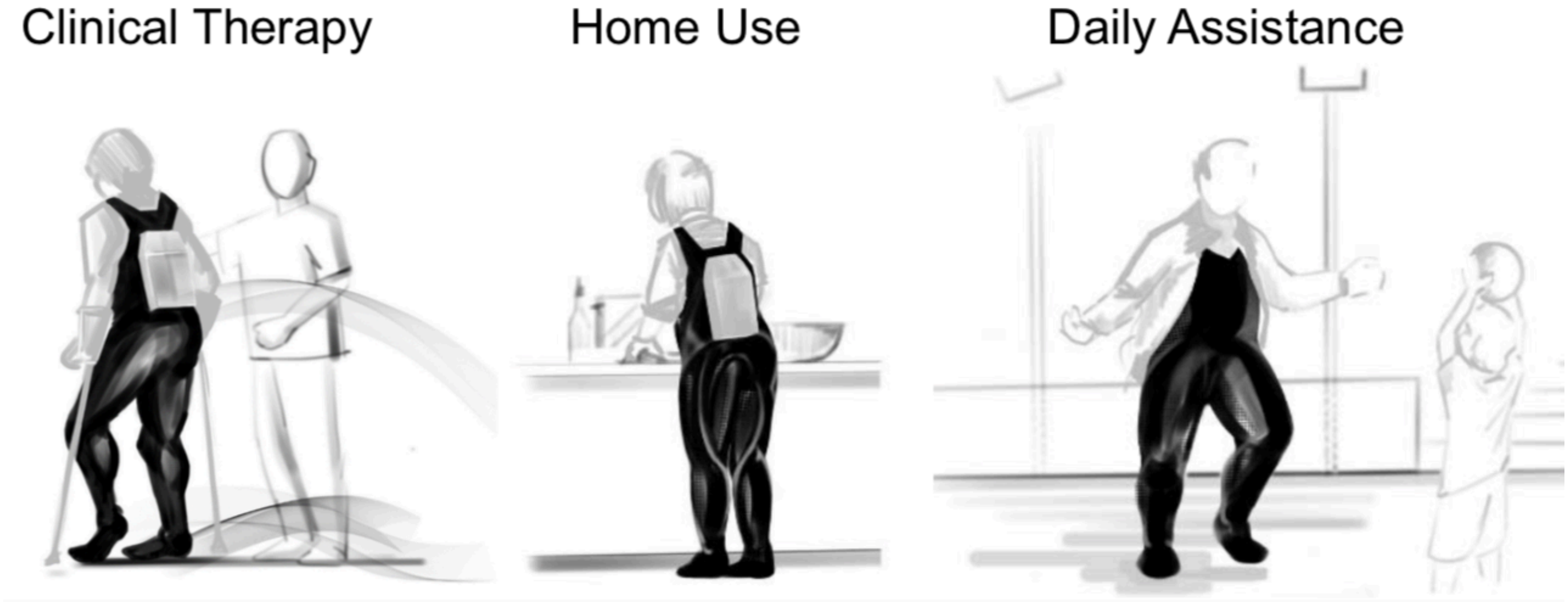
- Demografic and health profile changes - greater demands for cost-effective health care and rehabilitation
- Changing Paradigm in Health Policy
- Changing Paradigm in Neurorehabilitation (Use- Dependent- Plasticity)

World Report on Disability, World Health Organization 2011

Trend towards advanced technologies in Rehabilitation



Application of Robotics in Rehabilitation



Robots

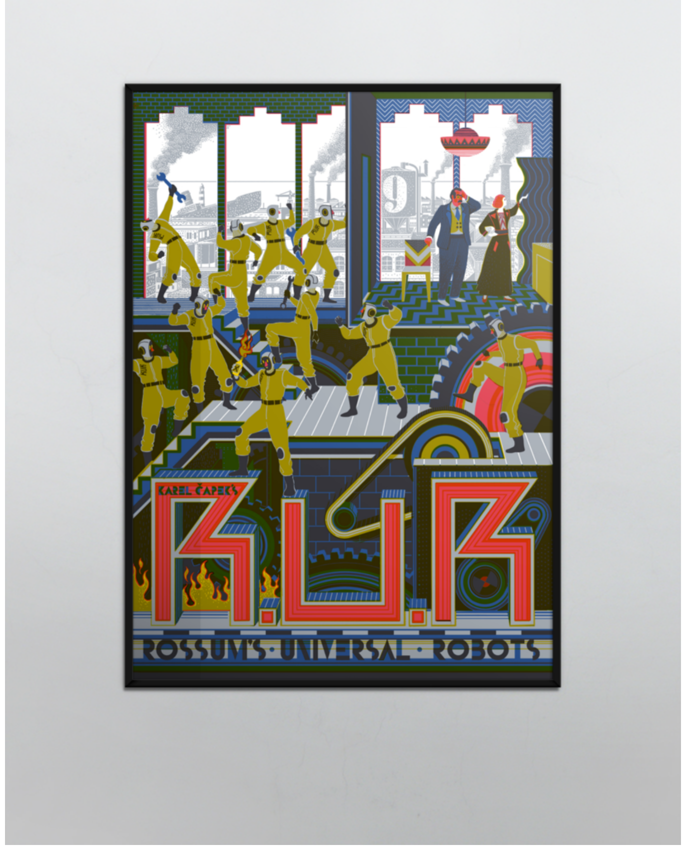
The word “robot” first appeared in **1921** in a science fiction play titled R.U.R. (Rossum’s Universal Robots) written by the Czech author **Karel Capek.**

- It derives from the Czech word “robota”, meaning hard workers.

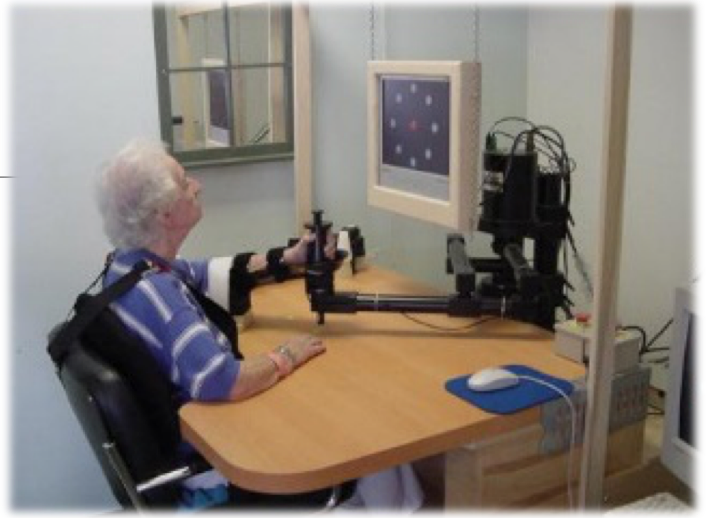
The term has since come to signify primarily **electromechanical devices:**

- often humanoid
- endowed with artificial intelligence
- able to perform a variety of functions (by programming and by their own ability to act autonomously).

The Robot Institute of America defined a robot as “a programmable, multi-functional manipulator designed to move material, parts or specialized devices through variable programmed motions to perform of a variety of tasks”.



Neurorobots



The first robots used for neurorehabilitation were developed in the 1980s

Their potential was claimed in the 1990s

Robotic exoskeletons started to spread in the 2000s

….However, their is still debate on the effectiveness of robots in neurorehabilitation !

Robots Advantage

Repetitions

Larger number of repetitions

- automated administration
- assistance for impaired patients

Earlier intervention

Even for severe disabilities

- Combining different technologies

Duration

Increased practice time

- high motivation
- lesser need for supervision
- home-based practice

Robots Advantage

Effort	Motivation	Difficulty

Increased effort

- adding resistance
- increased motivation

Increased motivation

- immersion through gamification
- encouraging feedback
- success through assistance

Adjustable difficulty

- added resistance
- reduced support
- adjusting feedback

Rehabilitation robots

Support in the physical rehabilitation of patients after **stroke, spinal cord** and **brain** injuries, by addressing various motor and functional impairments.

Alleviate **therapists' physical burdens**,

Increase limb practice, exercise **intensity,**

Increase **productivity,**

….Nevertheless several barriers have been identified, in implementation of the robotic rehabilitation:

- Lack of the evidence based protocols of treatment,
- Adherence of the user to therapy,
- Therapist's acceptance of technology,
- Financial constraints.

Implementing a new technology in clinical practice

Main areas of consideration in the systematic evaluation of new rehabilitation technologies:

(1) Clinical applicability, based on scientific evidence

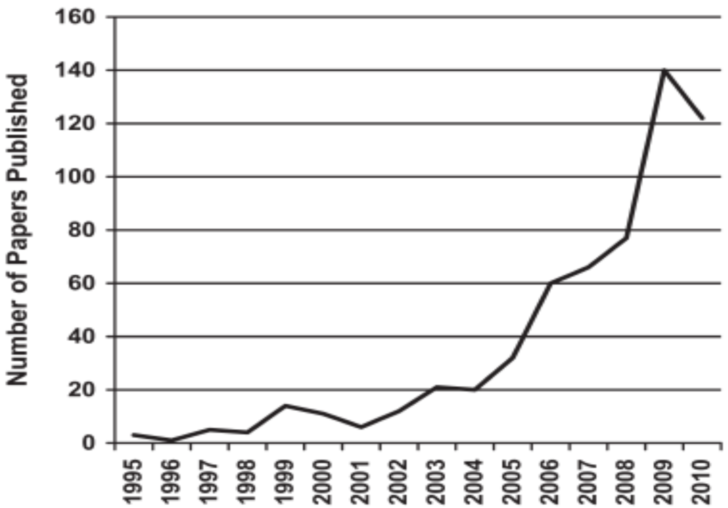
(2) Safety and ethics review of the device,

(3) Marketability of the devices,

(4) Financial and reimbursement issues.

Jones M, Mueller J, Morris J: Advanced technologies in stroke rehabilitation and recovery. Top Stroke Rehabil 2010;17:323–7

Clinical evidence of new technologies



THE COCHRANE COLLABORATION

- Increasing **clinical evidence-based literature**.

(1) Clinical applicability
Scientific Evidence

Contrasting results were obtained in different studies about neurorehabilitation robot efficacy,

Results of some randomized controlled trials performed on wide samples showed significant improvements in the outcome of robot-assisted therapy with respect to usual care

Meta-analyses have only partially helped in clarifying the objective effectiveness of robotic training, with most results being inconclusive.

The Cochrane Database of Systematic Reviews

Mehrholz, J., Platz, T., Kugler, J., Pohl, M. (2008). Electromechanical and robot-assisted arm training for improving arm function and activities of daily living after stroke. *The Cochrane Database of Systematic Reviews*, 8(4)

Mehrholz, J., Hädrich, A., Platz, T., Kugler, J., Pohl, M. (2012), updated 2018. Electromechanical and robot-assisted arm training for improving generic activities of daily living, arm function, and arm muscle strength after stroke. *The Cochrane Database of Systematic Reviews*, 6:CD006876.

Mehrholz, J., Werner, C., Kugler, J., Pohl, M. (2007). Electromechanical-assisted training for walking after stroke. *The Cochrane Database of Systematic Reviews*. 4:CD006185.

Mehrholz, J., Elsner, B., Werner, C., Kugler, J., Pohl, M. (2013). Electromechanical-assisted training for walking after stroke. *The Cochrane Database of Systematic Reviews*. 7:CD006185.

Mehrholz, J., Pohl, M., Elsner, B. (2014) updated 2017. Treadmill training and body weight support for walking after stroke. *The Cochrane Database of Systematic Reviews*. 1:CD002840.

Electromechanical and robot-assisted arm training after stroke

- A Cochrane review in 2008, on **post-stroke** arm training robots - analysis on 11 studies (**328** subjects) stating that: "patients who receive electromechanical and robot-assisted arm training after stroke are **not more likely to improve their ADL**, but arm motor function and strength of the paretic arm may improve".
  - ***Mehrholz, J***., *Platz, T., Kugler, J., Pohl, M. (2008). Electromechanical and robot-assisted arm training for improving arm function and activities of daily living after stroke. The Cochrane Database of Systematic Reviews.*

- A Cochrane review in 2018, including 45 trials (involving **1619** subjects), concluding: "Patients who receive electromechanical and robot-assisted arm training after stroke **are more likely to improve their generic ADL, arm function and arm muscle strength".**
  - ***Mehrholz, J.,*** *Hädrich, A., Platz, T., Kugler, J., Pohl, M. (2012). Electromechanical and robot-assisted arm training for improving generic activities of daily living, arm function, and arm muscle strength after stroke. The Cochrane Database of Systematic Reviews.*

These results were in opposition!

Robotic Gait rehabilitation

- A Cochrane review (2007) and its update (2013) reported higher probability of recovery in patients who receive electromechanical-assisted gait training in combination with physiotherapy.
  - *Mehrholz, J., Werner, C., Kugler, J., Pohl, M. Electromechanical-assisted training for walking after stroke. The Cochrane Database of Systematic Reviews. 2007*
  - *Mehrholz, J., Elsner, B., Werner, C., Kugler, J., Pohl, M. Electromechanical-assisted training for walking after stroke. The Cochrane Database of Systematic Reviews. 2013*

- Cochrane review (2014) reported similar recovery probabilities for patients with and without treadmill training (with and without body weight support).
- Its update (2017) reported higher probability of recovery in patients who receive electromechanical-assisted gait training in combination with physiotherapy (ncluding 36 trials involving 1472 participants and 19 different devices)
  - *Mehrholz, J., Pohl, M., Elsner, B. Treadmill training and body weight support for walking after stroke. The Cochrane Database of Systematic Rev. 2014.*
  - *. Mehrholz J, Thomas S, Werner C, Kugler J, Pohl M, Elsner B. Electromechanical-assisted training for walking after stroke. Cochrane Database Syst Rev. 2017;*

Powered robotic exoskeletons (PRE)

In a systematic review and meta-analysis of 111 patients (14 studies):

- Positive outcomes in improving functional walking independence with 76% of spinal cord injury patients who were trained for a period of 1 to 24 wks, able to achieve ambulation without aid using elbow crutches at a gait speed of 0.27 m/sec,
- Improved sphincter control in 66%,
- Reduced incidence of falls and fractures was 4.4% and 3.4%, respectively.

Miller LE, Zimmermann AK, Herbert WG: Clinical effectiveness and safety of powered exoskeleton-assisted walking in patients with spinal cord injury: systematic review with meta-analysis. Med Devices (Auckl) 2016;9:455–66

Critical aspects of the research

These Cochrane reviews analysed electromechanical devices and robots as a single and homogeneous field, but…

- Electromechanical devices developed for neurorehabilitation (treadmill with body weight support or Gait Trainer) are not robots!
- Effectiveness should be referred also to:
  - The specific **patient groups** targeted by the therapy
  - The patient **psychological** profile
  - The **timing and protocol** adopted for that device
  - The **phase of recovery**:
    - patients with more severe impairments in the motor leg can benefit more from robotic-assisted therapy, in combination with conventional therapy, than from conventional therapy alone (increased intensity).
    - patients with greater voluntary motor function in the affected limb can perform intensive training also in conventional therapy.

Robots vs Electromechanical devices

Presence of acuators.

Adaptability of their operation

- based on its on-board sensors

Signals from sensors are processed by artificial intelligence to change the behaviour of the robot.

Control mode for applying an assistance-as-needed guidance force to the limbs.

Sensors use to provide biofeedback:

- increasing patient's motivation /participation in rehabilitation
- feedback to therapists and clinicians on patient progress.

Once the physiotherapist has fixed their parameters, they are not capable of autonomously adapting during operation.

- Treadmills with body weight support
- Gait Trainer

(2)Ethics and Safety
The Three Laws of Robotics

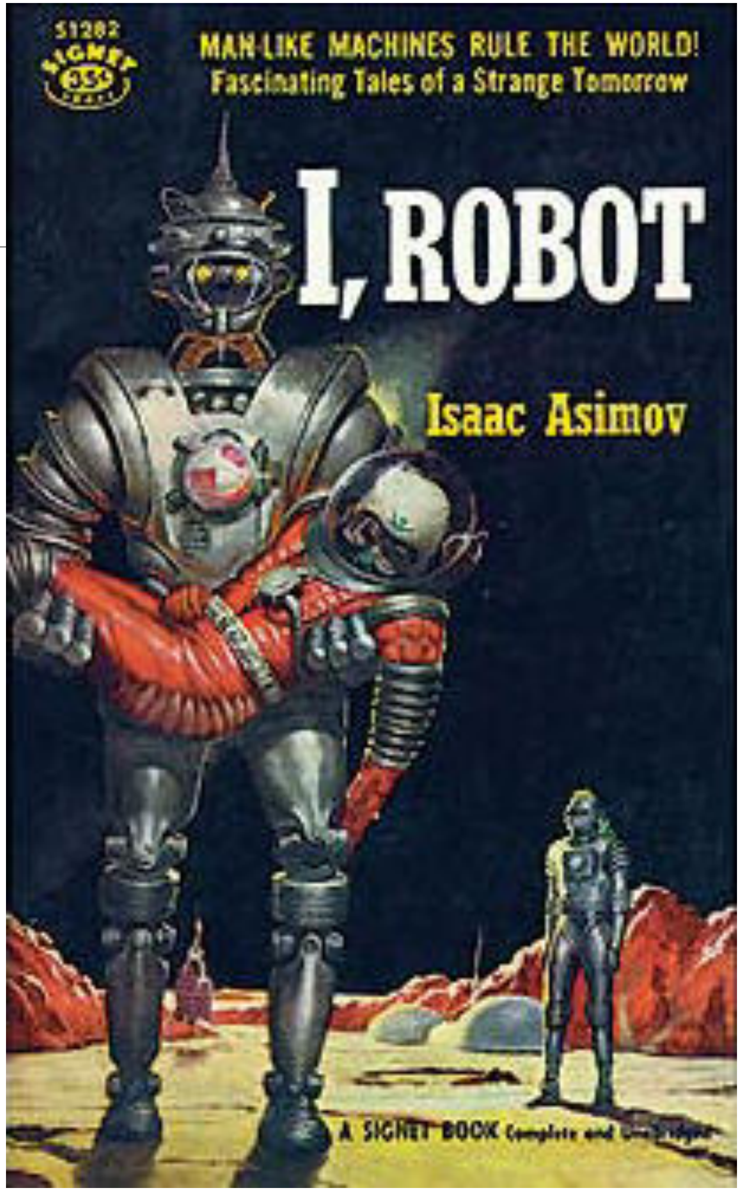
A robot may not injure a human being or, through inaction, allow a human being to come to harm.

A robot must obey the orders given it by human beings, except where such orders would conflict with the First Law.

A robot must protect its own existence, as long as such protection does not conflict with the First or Second Laws.

"Handbook of Robotics, 56th Edition, 2058".

- *Asimov I. I, Robot. New York, NY: Gnome Press; 1951*
- *Marco Iosa, Giovanni Morone, Andrea Cherubini, Stefano Paolucci [The Three Laws of Neurorobotics: A Review on What Neurorehabilitation Robots Should Do for Patients and Clinicians] Med Biol Eng. 2016; 36: 1–11.*



(2)Ethics and Safety
The Three Laws of Robotics

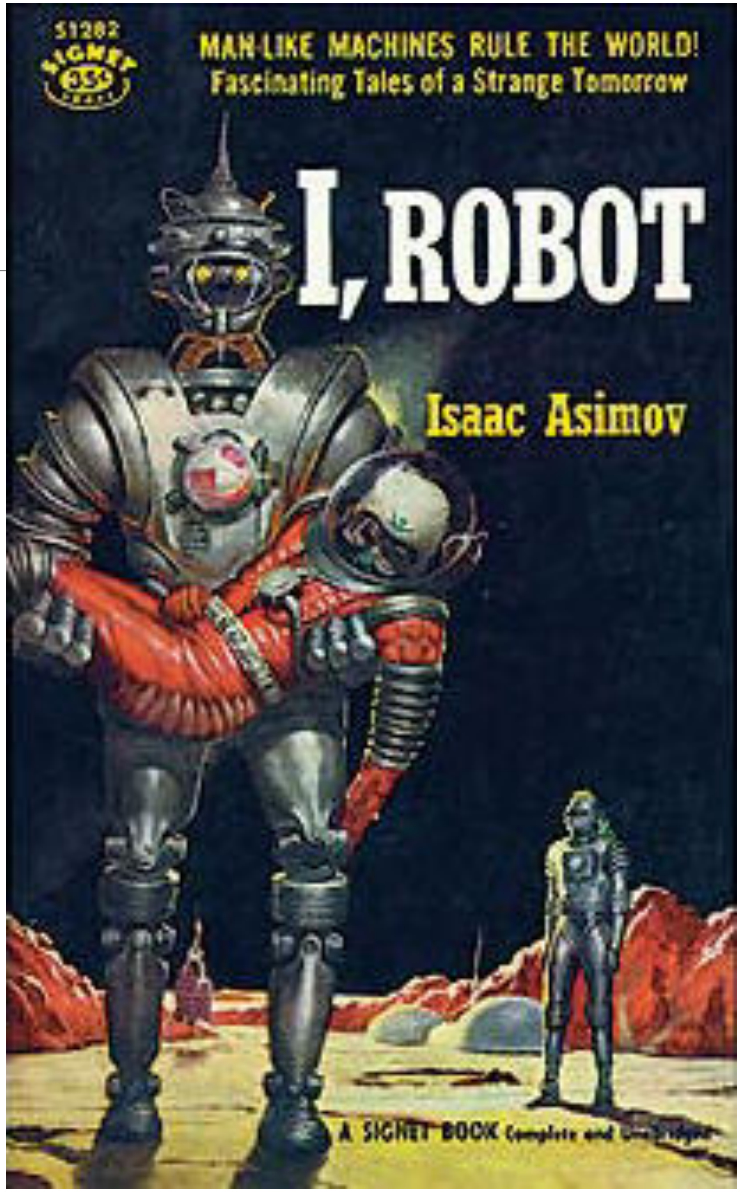
Define a set of ethic rules for robots;

The hierarchical structure of these laws places at the first level **human health**, followed by **human will**, and finally **robot self-preservation;**

Robots operate in **close proximity or direct physical contact** with humans, directly moving user's impaired limbs;

They can contribute to improving the **precision** of medical treatments, **relieving therapists** of tasks that require considerable accuracy and physical effort, and improving the **quality of life** of patients.

Datteri E, Tamburrini G. Ethical reflections on health care robotics. In: Capurro R, Nagenborg M, editors. Ethics and robotics. Amsterdam: IOS Press/AKA; 2009. pp. 35–48.



Safety issues

Nevertheless, they also may threaten the physical integrity of patients,

- Through harmful events caused by anomalous behaviours (e.g., in surgery), but even through normal operation;
- This can typically occur for neurorehabilitation robots whose efficacy has not been proven.
  - Ex. Lokomat (Hocoma), use to reproduces non-physiological gait patterns due to the restriction of pelvis movement, altering lower limb joint kinematics and muscle activations.
  - This limitation has recently been overcome in Lokomat®Pro by the addition of an optional module that allows **lateral translation and transverse rotation of the pelvis**, aiming at a more physiological movement

Datteri E, Tamburrini G. Ethical reflections on health care robotics. In: Capurro R, Nagenborg M, editors. Ethics and robotics. Amsterdam: IOS Press/AKA; 2009. pp. 35–48.

Safety issues

Neurorobots should be safe not only in terms of movement, but also from other medical points of view:

- Robotic gait training performed with body weight support has only recently been proven safe for training intensive walking in non-autonomous ambulatory patients with subacute stroke.
  - Cardio-respiratory demand is lower than that in conventional walk training performed overground.
- The authors found the opposite result for healthy subjects: overground walking was less demanding than robotic walking.
  - The robot imposes non-natural trajectories, which force subjects to activate non-natural sensorimotor walking patterns.

Delussu AS, Morone G, Iosa M, Bragoni M, Traballesi M, Paolucci S. Physiological responses and energy cost of walking on the Gait Trainer with and without body weight support in subacute stroke patients. Journal of Neuroengineering & Rehabilitation. 2014;11:54.

Safety issues

“Harm” should be enlarged to all possible damage to patients:

- Time spent on an ineffective, or even detrimental robot should be considered as **damage,** because the patient could spend the same time in a more effective treatment.
- The first law implies that robot usage should be at least **as safe and effective as other treatments**, meaning that it should have a higher benefit-risk ratio than that of human-administered treatments.

Contra-indication/ Limitations/ Side effects

- Impaired cognition,
- Behavioural agitation,
- Spatial neglect,
- Hemodynamic, or orthostatic instability,
- Severe cardio-pulmonary conditions
- Uncontrolled Seizure
- Uncontrolled Diabetes
- Pressure sores
- Oedema / Thrombosis
- Stiffness/ High Spasticity
- Lack of controlling Head and Trunk
- Blindness/ Very low vision
- Loose of Sensibility
- Osteoporosis/ high risk of fracture

Fear of Robots

Could fear actually play a role in the scepticism towards neurorobots?

Some therapists see a robot as a possible substitute for their work.

- The goal of introducing robots into rehabilitation hospitals is **not to replace** therapists, but rather **to complement** existing treatment options;
- Nevertheless, Robots may reduce the cost of rehabilitation by reducing the number of required therapists,
- Burgar et al. reported their experience in developing robots for neurorehabilitation, concluding their work with “we do not view robots as replacements for therapists”.

Burgar CG et al. Development of robots for rehabilitation therapy: The Palo Alto VA/Stanford experience. Journal of Rehabilitation Research and Development. 2000;37

Morasso, et al. Desirable features of a “humanoid” robot-therapist. Conference proceedings: Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 2009:2418–2421

Hidler J, Nichols D, Pelliccio M, Brady K. Advances in the understanding and treatment of stroke impairment using robotic devices. Topics in Stroke Rehabilitation. 2005;12(2):22–35.

Datteri E. Predicting the long-term effects of human-robot interaction: A reflection on responsibility in medical robotics. Science and Engineering Ethics. 2013;19(1):139–160.

Fear of Robots

Could fear actually play a role in the scepticism towards neurorobots?

A robot for rehabilitation should not be considered as **a standing-alone rehabilitation device**, but:

- A tool in the hands of therapists,
- More *precise* movements, more *intensive, repeatable*, or *adaptable* patterns according to the therapists' expertise,
- Relieving from fatigue.

The therapist should be included in the loop:

- Balance between robot and patient,
- Communicating with the patient,
- Motivating patients,
- Getting verbal feedback on fatigue, pain, and emotional stress (parameters difficult to monitor with sensors)

Golem of Prague

Fear of Robots

Could fear actually play a role in the scepticism towards neurorobots?

The therapist should play a key role in robotic therapy administration;

- robot parameter adjustments,
- avoiding harmful patient compensation strategies,
- identification of the trade-off between challenging tasks that help rehabilitation and those that demoralize patients.

The reduction of costs for the healthcare system can be obtained not by reducing the number of therapists, but:

- increasing the efficacy of rehabilitation,
- reducing the length of stay in rehabilitative hospitals,
- releasing more autonomous patients with a consequent reduction of home care costs

Der Spiegel, Issue 16/1978

Fear of Robots

Artificial Intelligence as Support for Human Intelligence

Therapist allows **human control** of the device:

- parameters should be to calibrate, tune, and adapt;
- consider the effects of a parameter change on other parameters:
  - Ex: to increase speed during over-ground walking, a subject can reduce step duration, increase step length, or both;
  - In Lokomat-based training, when a therapist increases the patient’s walking speed, they are actually reducing the step duration without altering the step length by manual adjustment of hip rang of motion

In contrast with the robot, the therapist has a qualitative but natural access to the health status of the patient!

Therapist is providing quantitative information about a patient’s deficits, residual abilities, and functional recovery!

Der Spiegel, Issue 36/2016

(3) Efficacy

Lack of clear information about how to administer robotic therapy, proper use, treatment duration and frequency, precautions, possible side effects, etc.

The effectiveness of treatment depends on the patient characteristics:

- type and severity of disease,
- presence of specific deficits,
- duration and frequency of sessions to administer,
- correct phase of rehabilitation at which the therapy should be administered:
  - Patients with more severe impairments in the motor leg benefited more from robotic-assisted therapy than patients with greater voluntary motor function in the affected limb (who can perform intensive and less constrained training in conventional therapy).

Masiero S et al. The value of robotic systems in stroke rehabilitation. Expert Review of Medical Devices. 2014;11(2)

Morone G et al. Who may benefit from robotic-assisted gait training? A randomized clinical trial in patients with subacute stroke. Neurorehabilitation & Neural Repair. 2011;25(7):636–644.

Morone G, et al. Who may have durable benefit from robotic gait training?: A 2-year follow-up randomized controlled trial in patients with subacute stroke. Stroke. 2012;43(4):1140–1142.

Challenges to Adoption Robot-Assisted Rehabilitation

Patient must be willing to comply with the prescribed regimen of exercise:

Patient adherence to prescribed regimens is associated with:

- increased satisfaction
- Improved outcome of treatment

Lack of motivation = non-compliance with therapy

Supplementing with additional motivational elements improve the effectiveness through increased compliance

- gaming consoles has been shown to increase motivation and enjoyment during exercise
- interactive computer play increase engagement in children rehabilitation.

Laut J, Porfiri M, Raghavan P. The Present and Future of Robotic Technology in Rehabilitation. Curr Phys Med Rehabil Rep. 2016;4(4):312–319.

Challenges to Adoption Robot-Assisted Rehabilitation

Games for entertainment may be too fast-paced for sensorimotor-impaired individuals;

‘’Serious games’’ developed specifically for rehabilitation

Games should enable clinicians to tailor it as rehabilitation progresses to ensure that the appropriate level of difficulty is maintained throughout the recovery process;

An important consideration - if the games encourage / discourage unwanted compensatory strategies;

Laut J, Porfiri M, Raghavan P. The Present and Future of Robotic Technology in Rehabilitation. Curr Phys Med Rehabil Rep. 2016;4(4):312–319.

Challenges to Adoption Robot-Assisted Rehabilitation

The older population, may be more receptive to games that challenge their intellect in contrast to the typical action and reflex videogames:

- They enjoy helping new players, solving puzzles, and participating in the social aspects of gaming;
- Pairing participants in cooperative or competitive gameplay may enhance participation in robot-mediated therapy,
    - Ex: A pair of ARMin exoskeleton rehabilitation robots, where participants competed in a virtual air-hockey game.

Children with developmental disorders appear less motivated and more passive in their playing behavior (less complex and less challenging) despite equal curiosity and pleasure.

Jennings et al. J Am Acad Child Adolesc Psychiatry. 1988; 27: 312–7;

Messier et al. J Dev Phys Disabil 2008; 20: 193–207

Clinical applicability

Das the robotic device answer a real clinical need?

Important questions include the following:

- Is the **right patient pool** in terms of *diagnostic group, duration, level of dependency ?*
  - subacute stroke < 3 months able to benefit from RAGT
  - severely impaired stroke patients who are unable to walk when considering implementing RAGT?

- **Right rehabilitation professionals/staff** keen to embrace the technology, develop programs, and achieve workflow redesign?

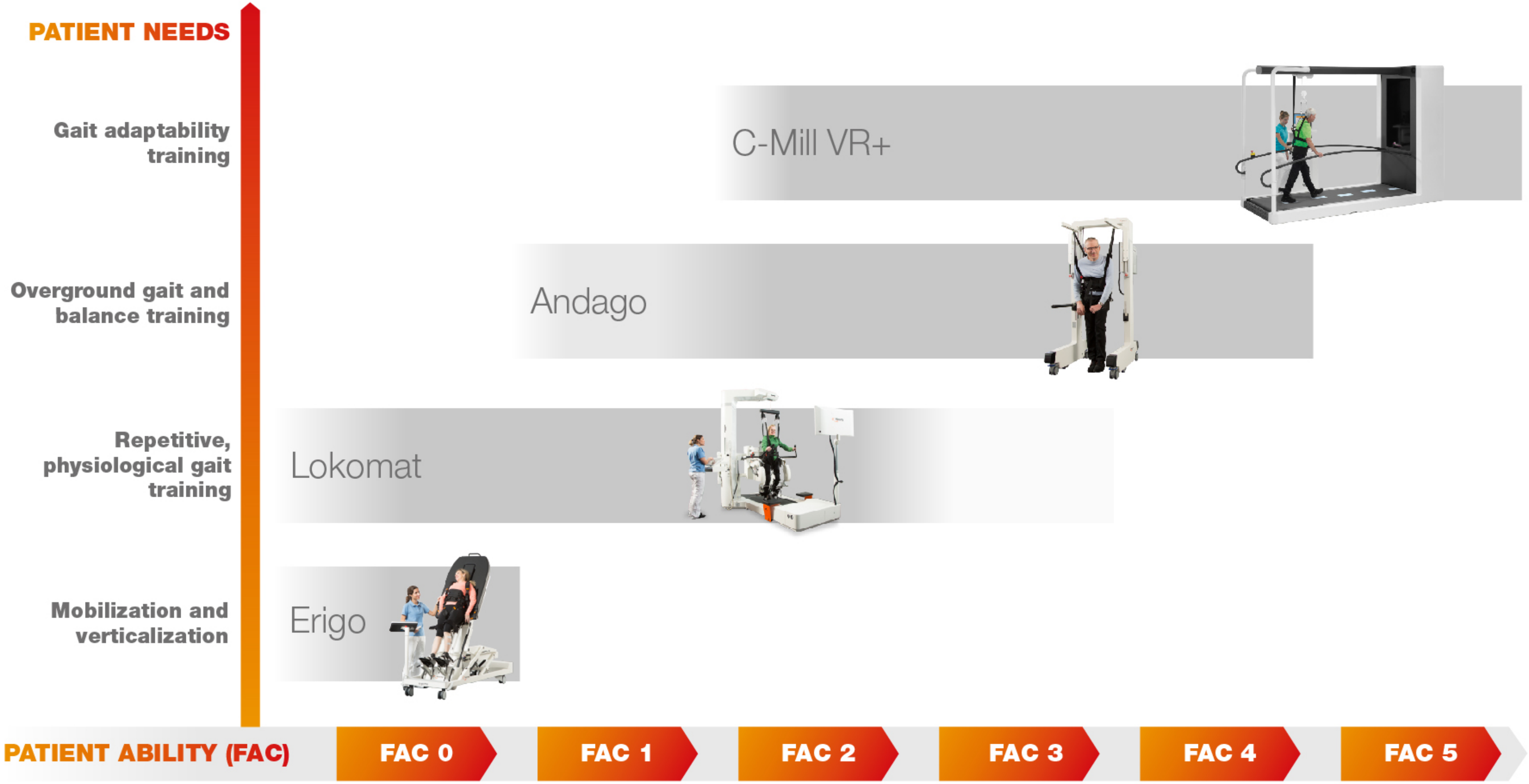
Underestimation of utilization may lead to under-exploitation of RAT in the rehabilitation clinic!

Initial barriers encountered with Lokomat

- **Practical barriers**
  - Skin irritations
  - Incontinence
  - Joint angles
  - Orthostatic Hypotension

- **Miscellaneous barriers**
  - Who should train on the Lokomat?
  - What do we want to improve?
  - Organisational issues

Continuum of Gait & Balance rehabilitation



FAC: Functional Ambulation Categories

Continuum of arm & hand rehabilitation

MMT: Manual Muscle Test for shoulder and/or elbow, *MMT 2 for ArmeoSenso = with arm weight support

Marketability

The acquisition of the robot will raise the local or regional profile of the centre?

Productivity will be enhanced by robotic therapy?

Free trial period (1 to 2 months):

- Allows the clinical team to objectively evaluate the suitability of the device in their environments,
- Enable to assess if RAT would enhance their current practices.

Economic burden

Potential limit for robot adoption in neurorehabilitation,

Uncertainty on the cost-effectiveness of robotic neurorehabilitation,

Rigorous studies in the economic sustainability of robots for neurorehabilitation are very sporadic

Few studies suggest that robotic therapy leads to a reduction of costs in terms of a reduction in the hospitalization and higher autonomy at discharge.

Although the long-term use of neuro-robots can decrease healthcare system costs.

- A single physiotherapist could manage up to four robots at the same time.
  - **Massiero et al.:** The cost of using a robot for the treatment of post-stroke upper limb impairment (NeReBot) is 37 % of the physiotherapy cost, with benefits that include a reduction in hospitalization time.
  - **Hesse et al**. found a similar percentage (41 %) under the assumption that the therapist is needed only at the beginning and end of therapy, and in particular situations where help is needed

Depends on the reimbursement regimen in each country/units.

Masiero S, Poli P, Armani M, Ferlini G, Rizzello R, Rosati G. Robotic upper limb rehabilitation after acute stroke by NeReBot: Evaluation of treatment costs. Biomed Research International. 2014;
Hesse S, Heß A, Werner C, Kabbert N, Buschfort R. Effect on arm function and cost of robot-assisted group therapy in subacute patients with stroke and a moderately to severely affected arm: A randomized controlled trial. Clinical Rehabilitation. 2014;28(7)

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Stroke. 2011 September ; 42(9): 2630–2632. doi:10.1161/STROKEAHA.110.606442.

An Economic Analysis of Robot-Assisted Therapy for Long-Term Upper-Limb Impairment After Stroke

Todd H. Wagner, PhD, Albert C. Lo, MD, PhD, Peter Peduzzi, PhD, Dawn M. Bravata, MD, Grant D. Huang, PhD, Hermano I. Krebs, PhD, Robert J. Ringer, PharmD, Daniel G. Federman, MD, Lorie G. Richards, PhD, Jodie K. Haselkorn, MD, MPH, George F. Wittenberg, MD, PhD, Bruce T. Volpe, MD, Christopher T. Bever, MD, Pamela W. Duncan, PhD, PT, FAPTA, FAHA, Andrew Siroka, BA, and Peter D. Guarino, MPH, PhD

Costs for VA Health Care System:

Average / patient additional costs: Robot Therapy = 5,152 US $

Intensive Conventional Therapy = 7,382 US$

Usual Care = 0 US$

Average total Cost over 36 weeks: Robot Therapy = 17,831 US $

(therapy + all heath care) Intensive Conventional Therapy = 19,746 US$

Usual Care = 19,098 US$

Sustainability and Beyond

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

- In passive diffusion, the robotic technology may be 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**.

Changes in organization balances:

- Time is taken for rehabilitation professionals to **learn, use, adopt,** and leverage on evidence-based practice using rehabilitation technology,
- Therapists are more likely to be <u>motivated to use and embrace rehabilitation technology</u> if performance expectancy or how the technology can help in therapists' work **was clearly defined**.

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) Including training for RAT for all therapists aides to improve productivity, thus alleviating workload for therapists to supervise during RAT.

(3) Workflow redesign to clinically integrate RAGT:

- allow patients to be examined to check for post-RAGT skin abrasions,
- Patients undergoing RAGT were assigned with individualized skin protection paddings,

(4) Emergency protocols were developed to address prompt evacuation of patients with syncope or seizure occurring during RAGT sessions.

CONCLUSION

Evaluate the «technological need» and develop a «strategy» for implementation.

Build-up strong collaborations (Healthcare-Technology-Business-Education).

Use high-tech and low-tech to create advanced care models.

Merge technological advances with good clinical practice in real-time.

Further developments of new technology is important.

Dissemination of both technology and knowledge are essential.

Thank you!